Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

In the Case of:	DATE: March 2, 2010
A TO Z DME, LLC,	Civil Remedies CR1995 App. Div. Docket No. A-10-03
Petitioner,	Decision No. 2303
- v. -	
Centers for Medicare & Medicaid Services.	

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

A TO Z DME, LLC (Petitioner, A TO Z), a company in Grand Blanc, Michigan that was enrolled as a Medicare supplier, requests review of a decision by Administrative Law Judge (ALJ) Steven T. Kessel, dated August 24, 2009. A TO Z DME, LLC, DAB CR1995 (2009) (ALJ Decision). The ALJ Decision granted summary disposition sustaining the determination of the Centers for Medicare & Medicaid Services (CMS) and its contractor, National Supplier Clearinghouse (NSC), to revoke A TO Z's Medicare supplier number. The ALJ concluded that CMS was authorized to revoke A TO Z's Medicare enrollment because the undisputed facts established that A TO Z was not complying with two enrollment standards and was not operational when NSC attempted to conduct two on-site inspections of A TO Z's facility. Because each of these findings would provide a separate legal basis to revoke A TO Z's supplier number, the Board need only affirm one of the ALJ's three conclusions to sustain the revocation. Based on A TO Z's admission that it was in "start up mode" and was "not yet selling to patients" at the time of the attempted on-site inspections (Request for Review of the ALJ Decision (RR) at 8), which was consistent with the undisputed evidence, we affirm the

ALJ Decision on the sole ground that A TO Z was not "operational" to furnish Medicare items or services within the meaning of the regulations. Accordingly, we need not and do not consider the ALJ's conclusions that CMS was also authorized to revoke A TO Z's supplier number based on its noncompliance with two supplier enrollment standards.

Background

The following facts from the ALJ Decision and the record are undisputed. On August 1 and 4, 2008, at about 9:45 a.m. and 2:00 p.m., respectively, an NSC inspector working on behalf of CMS attempted to conduct on-site inspections of A TO Z's facility. However, the office was closed and a sign on the door read "By Appointment Only Please Call 1-810-606-0801[,]" and no other signs or notes were present on the office door. ALJ Decision at 3-4, citing CMS Exs. 2, at 2, 7; 3, at 1-3; 10, ¶¶ 2, 3, 5. When the NSC inspector later called the phone number listed on the door on August 1, and when another NSC inspector called the office "multiple times" on August 11, 2008, no one answered the phone and both inspectors were instead connected to a fax machine. Id., citing CMS Exs. 10, ¶ 2; 11, ¶ 3.

NSC notified A TO Z in correspondence dated October 31, 2008, that its supplier number was being revoked pursuant to 42 C.F.R. §§ 424.57(d) and 424.535(a)(5)(ii) because it was not in compliance with enrollment standards applicable to suppliers of "durable medical equipment, prosthetics, orthotics and supplies" (DMEPOS), and because it was not operational at the time of the two attempted on-site inspections and related phone calls by NSC inspectors in August 2008. See CMS Ex. 5. On November 20, 2008, A TO Z submitted a corrective action plan to NSC. In a letter dated December 18, 2008, NSC rejected A TO Z's corrective action plan because A TO Z did not provide "any evidence [its] business was operational during the attempted [on-site] inspections" in August 2008. CMS Ex. 5, at 4. A TO Z requested reconsideration of the revocation by NSC in a letter dated December 30, 2008 and submitted evidence to support its request on February 18, 2009. Id. at 1; 6. In a decision dated March 24, 2009, a Medicare hearing officer denied A TO Z's request for reconsideration, concluding that the documentation that A TO Z provided on February 18, 2009 did not establish that it was operational and in compliance with supplier enrollment standards "on the times and dates of the attempted [on-] site inspections." CMS Ex. 1, at 2. A TO Z subsequently requested a hearing before an ALJ.

The ALJ decided the case on summary disposition because the material facts were undisputed. ALJ Decision at 2. The ALJ concluded that the "undisputed facts establish three grounds for the revocation of Petitioner's Medicare enrollment." Id. at 4. First, the ALJ concluded that A TO Z was not accessible during reasonable business hours to Medicare beneficiaries and to CMS, as required by 42 C.F.R. § 424.57(c)(8) for suppliers of DMEPOS to maintain Medicare billing privileges.[1] Id.

Second, the ALJ concluded that A TO Z "was relying exclusively on the use of a facsimile machine during the period that ran from August 1 through August 11," in violation of 42 C.F.R. § 424.57(c)(9). Id. Section 424.57(c)(9) requires that a DMEPOS supplier maintain "a primary business telephone listed under the name of the business locally or toll-free for beneficiaries" and forbids "[t]he exclusive use of a beeper number, answering service, pager, facsimile machine, car phone, or an answering machine" as the primary business telephone. The ALJ concluded that "[o]n at least three occasions during this period[,] inspectors attempted to call Petitioner and each time they were connected to a facsimile machine." Id. As the ALJ observed, these two regulatory requirements are among the supplier standards listed at 42 C.F.R. §§ 424.57(c)(1)-(25) that a DMEPOS supplier must meet to obtain Medicare billing privileges, and CMS "will revoke the supplier's Medicare billing privileges if the supplier fails to meet any of these standards." Id. at 3, citing 42 C.F.R. § 424.57(d); see also 1866ICPayday.com, DAB No. 2289, at 13 (2009) ("failure to comply with even one supplier standard is a sufficient basis for revoking a supplier's billing privileges").

Third, the ALJ concluded that A TO Z was not "operational[,]" as required by 42 C.F.R. § 424.535(a)(5)(ii), which permits CMS to revoke a supplier's Medicare enrollment and billing privileges if CMS determines upon an on-site review that the supplier is "no longer operational." ALJ Decision at 4. "Operational" means that-

[1] "Enrollment" means the process that Medicare uses to establish a supplier's eligibility to submit claims for Medicare-covered services and supplies. 42 C.F.R. § 424.502. DMEPOS suppliers enrolled in Medicare receive a supplier number conveying Medicare billing privileges. Id.; § 424.57(a), (b)(2).

> the provider or supplier 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 (as applicable, based on the type of facility or organization, provider or supplier specialty, or the services or items being rendered), to furnish these items or services.

42 C.F.R. § 424.502. The ALJ cited A TO Z's statements that it had been in "'start up mode'" and "'did not start selling to patients until October, 2008'" when it hired a new employee. ALJ Decision at 5-6, citing P. Response to CMS's Motion for Summary Disposition and Pre-hearing Brief (Response) at 3, 6. The ALJ concluded that based on the supplier's own admission, A TO Z was not operational within the meaning of section 424.502 because it "plainly was not open to the public for the purpose of providing health care related services during the period when the inspectors attempted to perform [on-] site visits at Petitioner's facility." ALJ Decision at 4.

In addition, the ALJ concluded that he had "no authority to decide whether CMS properly exercised [its] discretion" to reject A TO Z's corrective action plan. Id. at 7.

The ALJ also declined to consider new evidence that A TO Z did not submit to NSC with its request for reconsideration, citing the appeal regulation requiring that there be "good cause" for submitting documentary evidence "for the first time at the ALJ level." 42 C.F.R. § 498.56(e). The ALJ concluded that A TO Z "made no attempt to demonstrate good cause for its failure to present such evidence to CMS previously." ALJ Decision at 2.

Standard of review

Summary disposition is akin to summary judgment; whether summary judgment is appropriate is a legal issue that we address de novo. 1866ICPayday.com, at 2, citing Lebanon Nursing and Rehabilitation Ctr., DAB No. 1918 (2004). Summary judgment is appropriate when the record shows that there is no genuine dispute of fact material to the result. See 1866ICPayday.com at 2, citing Celotex Corp. v. Catrett, 477 U.S. 317, 322-25 (1986). Our 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, www.hhs.gov/dab/divisions/appellate/guidelines/index.html.

Analysis

A TO Z does not dispute any of the facts the ALJ cited in his decision regarding the attempted on-site visits and phone calls by the inspectors. Instead, A TO Z offers explanations for those facts, challenges their legal significance, and asserts that corrective actions were taken after the attempted on-site inspections in August 2008. However, none of these efforts demonstrate that the ALJ erred in concluding that the undisputed facts establish A TO Z was not operational as determined by the attempted on-site inspections and A TO Z's own admissions. Our affirmance of the ALJ's conclusion that A TO Z was not operational provides a sufficient legal basis for CMS to revoke A To Z's supplier number pursuant to section 424.535(a)(5)(ii). Accordingly, we do not need to consider whether the ALJ erred in concluding that A TO Z was not in compliance with two supplier enrollment standards. However, nothing in this decision should be taken to mean that we would not uphold any of the ALJ's conclusions regarding other grounds that could provide additional authority to sustain the revocation decision.

1. The ALJ did not err in concluding that the undisputed facts established that A TO Z was not operational.

Although A TO Z asserts that it was in operation at the time of the inspector's attempted visits, it acknowledges, as it did before the ALJ, that it was not fulfilling the requirements a Medicare supplier must meet to be considered "operational" for the purpose of maintaining enrollment and billing privileges. 42 C.F.R. §§ 424.535(a)(5)(ii), 424.502. On appeal, A TO Z repeats its statements before the ALJ that it was "still in start up mode and not yet selling to patients . . . both before and after August 1 – August 4, 2008" and "did not start selling to beneficiaries until October, 2008 when it hired a new employee." RR at 5, 8; ALJ Decision at 6; see also P. Response at 1, 6. As the ALJ correctly observed, merely planning or preparing to do business with the public is not equivalent to being actually operational as required. ALJ Decision at 6. Because A TO Z admitted it was only in "start up mode" and was not selling products to patients until October, A TO Z could not have been "open to the public for the purpose of providing health care related services," able to "furnish [Medicare] items or services" and "prepared to submit valid Medicare claims" as

required by section 424.502 at the time of the attempted on-site inspections and phone calls in August.

There was also no error in the ALJ's rejection of A TO Z's assertion that it was operational because A TO Z began selling to beneficiaries in October 2008. Section 424.535(a)(5) authorizes CMS to revoke a supplier's billing privileges if CMS determines that the supplier is "no longer" operational "upon on-site review . . . ." A supplier disputing CMS's determination must thus demonstrate under this regulation that it in was fact operational during the time period relevant to the on-site review findings underlying the determination. An argument that the supplier became operational at some later point in time would not, by itself, demonstrate that CMS's revocation determination was erroneous.

Requiring ongoing compliance and focusing on the supplier's status as of the time of the on-site review is consistent with the following language in the preamble to the supplier (and provider) appeal regulations, in response to comments concerning the restrictions on a supplier's submission of new evidence during the ALJ and Board levels of appeal:

> Consistent with the provisions of our April 21, 2006 final rule titled "Requirements for Establishing and Maintaining Medicare Billing Privileges and Provider Enrollment Process"(71 FR 20754), we believe all providers and suppliers must meet and maintain all Federal and State requirements for their provider or supplier type to enroll or maintain their enrollment in the Medicare Program.
>
> When a Medicare contractor makes an adverse enrollment determination (for example, enrollment denial or revocation of billing privileges) . . . appeal rights are limited to provider or supplier eligibility at the time the Medicare contractor made the adverse determination. If a Medicare contractor determines that a provider or supplier does not meet State licensure requirements on June 1, 2007, it is the provider's responsibility to demonstrate during the appeals process that State licensure requirements were met on June 1, 2007. Conversely, if a provider only can demonstrate that State licensure requirements were met on a later date; such as, August 16, 2007, we believe that the contractor made the correct determination, and that the provider or supplier may reapply for Medicare billing privileges. Accordingly,

> a provider or supplier is required to furnish the evidence that demonstrates that the Medicare contractor made an error at the time an adverse determination was made, not that the provider or supplier is now in compliance.

73 Fed. Reg. 36,448, 36,452 (June 27, 2008) (emphasis added).

This preamble language demonstrates the intent of the regulations is that a supplier must maintain, and be able to demonstrate, continued compliance with the requirements for receiving Medicare billing privileges. To prevail on appeal, a supplier must show that the substantive factual findings underlying CMS's revocation determination are incorrect. In the case of a revocation under section 424.535(a)(5)(ii), those are the findings of the on-site review upon which CMS bases its determination that the supplier is no longer operational.

Under the facts of this case, the material time for determining whether A TO Z was operational was the dates of the attempted on-site inspections and phone calls in August 2008. Here, A TO Z does not dispute that the results of the attempted on-site inspections and related phone calls in August 2008 were factually correct. As in the preamble example, A TO Z's assertion of compliance in October does not demonstrate that it was operational as of the time of the attempted on-site inspections and phone calls some two months earlier, which formed the basis for CMS's revocation decision under section 424.535(a)(5)(ii).

In addition, A TO Z asserts it passed "numerous" inspections prior to the attempted inspections in August 2008 that resulted in the revocation. RR at 5. However, as the regulation authorizes revocation when a supplier is "no longer operational," it is irrelevant whether A TO Z had been operational at some point prior to the attempted on-site inspections in early August 2008.

A TO Z further asserts that its operational status was shown by its receipt of a Blue Cross/Blue Shield number on August 15, 2008, and by its receipt of loans from its owner in July 2008, as well as its purchase of insurance and maintenance of a bank account. The receipt of a Blue Cross/Blue Shield number is not evidence that A TO Z was "operational" as defined in the Medicare supplier regulations, especially given A TO Z's admissions that it "was waiting to receive" the Blue Cross/Blue Shield number "before it started selling to beneficiaries" and

did not in any event begin selling until October 2008. RR at 9. (Similarly, its receipt of a Medicare supplier number, apparently in February 2008, would not demonstrate that it was still operational in August 2008. CMS Ex. 11, ¶ 3.) A TO Z also does not explain how its receipt of loans, purchase of insurance and maintenance of a bank account demonstrate that it was "operational" within the meaning of section 424.502 discussed above. RR at 8.

Thus, the ALJ did not err in concluding, based on A To Z's admissions and the undisputed facts, that A TO Z was not "operational" within the meaning of section 424.502 of the regulations, at the time of the attempted on-site inspections and phone calls in August 2008 that correctly formed the factual basis for CMS's determination. That conclusion alone is sufficient to sustain the revocation of A TO Z's billing privileges under section 424.535(a)(5)(ii).

2. The ALJ's determination not to review CMS's rejection of A TO Z's plan of corrective action was not erroneous.

A TO Z challenges the ALJ's conclusion that he had no authority to decide whether CMS should have accepted A TO Z's plan of corrective action, which it asserts "would have corrected all of the problems perceived by CMS." RR at 12. In support of its challenge, A TO Z contends that "42 C.F.R. § 424.535(a)(1) allows for a supplier to submit a corrective action plan[,]" prior to revocation of a supplier number. RR at 12. Section 424.535(a)(1) provides as a ground for revocation that a supplier "is determined not to be in compliance with the enrollment requirements described in this section, or in the enrollment application applicable for its provider or supplier type, and has not submitted a plan of corrective action as outlined in part 488 of this chapter." RR at 12, citing 42 C.F.R. § 424.535(a)(1) (A TO Z's emphasis). Section 424.535(a)(1) further 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." A TO Z contends that the ALJ erred because if there is no appellate review as to whether CMS properly accepted or rejected the corrective action plan, it would "obviously" make the regulation "meaningless." RR at 12.

This argument is without merit. As CMS points out in its brief, A TO Z's supplier number was revoked pursuant to section 424.535(a)(5)(ii) based on its nonoperational status as determined by the attempted on-site inspections and phone calls,

not pursuant to section 424.535(a)(1). See CMS Br. at 18; see also CMS Exs. 1 at 3; 4 at 1. We agree with CMS that the opportunity to submit a plan of corrective action extended by section 424.535(a)(1) does not apply to the revocation of billing privileges under section 424.535(a)(5). CMS Br. at 18, citing Uzzie Medical Supply, LLC, DAB CR1984 (2009) ("However, the regulation that applies in this situation is 42 C.F.R. § 424.535(a)(5) . . ., which does not require CMS to grant providers or suppliers an opportunity to correct [before revocation]"). We see nothing in the language of section 424.535(a)(5)(ii) that requires CMS to permit a supplier to submit a plan of corrective action prior to revocation where CMS has found that the supplier is no longer operational. While section 424.535(a)(1) authorizes revocation for noncompliance with enrollment requirements generally, sections 424.535(a)(2) through (a)(8) delineate additional, specific grounds for revocation. See 71 Fed. Reg. 20,754, 20,761 (Apr. 21, 2006) (preamble describing paragraphs (a)(2)-(8) as "[a]dditional proposed reasons that may result in the revocation of billing privileges in § 424.535(a)"). Sections 424.35(a)(2) through (a)(8) make no mention of the opportunity for corrective action discussed in section 424.535(a)(1). Thus, CMS was not required to offer A TO Z the opportunity to submit a plan of corrective action prior to revoking its billing privileges pursuant to section 424.535(a)(5)(ii) based on its determination, upon on-site review, that A TO Z was no longer operational. See, e.g., Abdul Razzaque Ahmed, M.D., DAB No. 2261, at 17, n.10 (2009) (opportunity to correct noncompliance prior to revocation under section 424.535(a)(1) not applicable to revocation under section 424.535(a)(3) for felony conviction; "[W]hen the regulations confer pre-revocation due process rights, they clearly specify them").

Apparently assuming that the opportunity to submit a plan of corrective action prior to the revocation of billing privileges available under section 424.535(a)(1) could be applicable to a revocation based on section 424.535(a)(5)(ii), the ALJ stated that section 424.535(a)(1) "[a]t most" affords only the opportunity to submit a plan of corrective action prior to CMS's final determination on whether to revoke billing privileges. ALJ Decision at 7. The ALJ further concluded that CMS complied with the provisions of section 424.535(a)(1) because A TO Z was allowed to file a plan of corrective action before CMS finally determined to revoke its supplier number. See ALJ Decision at 7; see also CMS Exs. 1 and 6. However, we agree with CMS that it was not necessary for the ALJ to have determined whether CMS had complied with 424.535(a)(1) in this instance because CMS

revoked A TO Z’s supplier number pursuant to section 424.535(a)(5)(ii). CMS Br. at 18, n.5. Because section 424.535(a)(5)(ii) does not require CMS to permit a supplier to submit a plan of corrective action prior to revocation, the ALJ properly determined that he lacked the authority to consider A TO Z’s arguments regarding CMS’s rejection of A TO Z’s plan of corrective action.

3. The ALJ’s determination not to consider A TO Z’s new documentary evidence was not erroneous.

A TO Z also contends that the ALJ “erred in excluding evidence submitted by A TO Z” that A TO Z did not submit to NSC with its request for reconsideration.[2] RR at 13. A TO Z argues that “it would be reasonable to grant A TO Z some leeway [regarding the submission of new exhibits] due to the fact it was not represented by counsel” when it requested reconsideration by NSC and then an ALJ hearing. Id.

A TO Z’s arguments are without merit. First, A TO Z mischaracterizes what the ALJ ruled. The ALJ did not formally exclude any evidence as contended by A TO Z. Instead, the ALJ specifically stated that “I make no ruling at this time as to whether any of Petitioner’s exhibits should be excluded from evidence . . . because I issue summary disposition based on undisputed material facts.” ALJ Decision at 2.

Second, as the ALJ correctly observed, 42 C.F.R. § 498.56(e) precludes an ALJ from considering documentary evidence that had not been presented to CMS prior to requesting a hearing, absent a showing of good cause for submitting the new evidence for the first time at the ALJ level. ALJ Decision at 2. A TO Z does not challenge the ALJ’s conclusion that it “made no attempt to demonstrate good cause for its failure to present such evidence to CMS previously,” notwithstanding the ALJ’s specific warning in his prehearing order that he would exclude new documentary

[2] The ALJ did not identify which of A TO Z’s 16 exhibits were not submitted to NSC with the request for reconsideration. CMS reports, and A TO Z does not dispute, that A TO Z did not submit its exhibits 4 and 9 through 14 to the NSC hearing officer. CMS Br. at 19, and n.6. CMS also states that A TO Z’s other exhibits consist of materials contained in CMS’s exhibits, and affidavits from A TO Z’s owner and his wife, dated July 30, 2009; CMS does not argue that these other materials should be excluded. Id.

evidence absent a showing of good cause as the regulation requires. Id. Indeed, even on appeal, the only reason A TO Z gives for not submitting all of its documentary evidence to the Medicare hearing officer is the fact that it was not represented by counsel, which is insufficient by itself to show good cause. Moreover, the regulations do not contain any exception for the ALJ to consider evidence for the first time simply because a party chose not to be represented by counsel during the reconsideration process.

In any event, we agree with the ALJ's conclusion that A TO Z's factual assertions (in support of some of which A TO Z offered the new documentary evidence) "do not, as a matter of law, amount to viable defenses." Id. at 5. A TO Z's principal fact assertion purportedly supported by the new documentary evidence concerns the reason for its closure during the time of the attempted on-site inspections and phone calls. However, as the ALJ correctly concluded, A TO Z "does not address the fact that, as of August 2008, Petitioner was by its own admission not operational . . . [and] admits that it was not providing any services to the public as of August 2008, and did not begin to do so until October of that year." Id. at 6.

The new documentary evidence also relates to A TO Z's additional arguments that it received loans from its owner, maintained a bank account, had contracted for a telephone number and insurance, and received a Blue Cross/Blue Shield number. A TO Z also submitted, with its request for an ALJ hearing but not as proposed exhibits pursuant to the ALJ's prehearing order, documents relating to its claim that it began selling supplies to patients in October 2008. The facts A TO Z sought to establish before the ALJ do not undermine the NSC inspectors' reports of their inability to access A TO Z's office or to reach someone from A TO Z by phone. Nor would the new documentary evidence undercut A TO Z's own admissions that it was not operational during the time period relevant to the findings underlying CMS's determination, the period of early August 2008 encompassing the attempted on-site inspections and phone calls.[3] Accordingly, the ALJ did not err in declining to consider the new documentary evidence.

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[3] As CMS notes, bank records that A TO Z sought to introduce before the ALJ show only four transactions over a nine-month period, including a loan from its owner, and do not establish that A TO Z was operational during August 2008. CMS Br. at 11-12, citing P. Exs. 9, 14.

Conclusion

For the reasons stated above, we conclude that the ALJ did not err in granting summary disposition in favor of CMS, sustaining the revocation of A TO Z's supplier number pursuant to section 424.535(a)(5)(ii).

/s/
Judith A. Ballard

/s/
Sheila Ann Hegy

/s/
Stephen H. Godek
Presiding Board Member