Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Whalen Optical Lab, Inc.,
(NPI: 0148350001)

Petitioner

v.

Centers for Medicare & Medicaid Services.

Docket No. C-10-555

Decision No. CR2196

Date: July 26, 2010

DECISION

Petitioner, Whalen Optical Lab, Inc., is an optician's office, which is considered a supplier of Medicare durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS supplier). The Centers for Medicare & Medicaid Services (CMS) determined that the facility was not in compliance with 42 C.F.R. § 424.57(c)(26) (supplier standard 26) and revoked Petitioner's Medicare supplier number on November 10, 2009. A reconsideration decision dated February 17, 2010 upheld the revocation.

Petitioner timely challenged CMS's determination. CMS sought summary disposition. After Petitioner failed to respond to CMS's motion and failed to submit its exchange in accordance with my pre-hearing order, I ordered the record closed.

For the reasons set forth below, I find that CMS is entitled to summary judgment, and I deny Petitioner's cross motion. The undisputed evidence establishes that Petitioner was not in compliance with Medicare program requirements, and, as a consequence, CMS has the authority to revoke Petitioner's Medicare supplier number.

I. Applicable Law and Regulations

Section 1834(a)(16)(B) of the Social Security Act (Act), 42 U.S.C. § 1395m(a)(16)(B), states that the Secretary of Health and Human Services (Secretary) "shall not provide for the issuance (or renewal) of a provider number for a supplier of durable medical equipment for purposes of payment . . . for durable medical equipment furnished by the supplier unless the supplier provides the Secretary on a continuing basis . . . with a surety bond in a form specified by the Secretary and in an amount that is not less than $50,000."

CMS implemented these requirements among the "supplier standards" at 42 C.F.R. § 424.57(c), which DMEPOS suppliers must meet to maintain Medicare billing privileges. 74 Fed. Reg. 166 (Jan. 2. 2009). As relevant here, section 424.57(c) provides:

> (c) *Application certification standards.* The supplier must meet and must certify in its application for billing privileges that it meets and will continue to meet the following standards. The supplier:
>
> * * * *
>
> (26) Must meet the surety bond requirements specified in paragraph (d) of this section.

The surety bond requirements at 42 C.F.R. § 424.57(d) referenced in supplier standard 26 state, as relevant here, that "beginning October 2, 2009, each Medicare-enrolled DMEPOS supplier must meet the requirements of paragraph (d)," which include "a bond that is continuous," which "meet[s] the minimum requirements of liability coverage ($50,000)," and provides that "[t]he surety is liable for unpaid claims, CMPs [civil money penalties], or assessments that occur during the term of the bond." 42 C.F.R. § 424.57(d)(1)(ii), (4), (5). "The term of the initial surety bond must be effective on the date that the application is submitted to the NSC [National Supplier Clearinghouse, a Medicare contractor]." 42 C.F.R. § 424.57(d)(2).

The regulations specify requirements for certain suppliers to be exempt from the surety bond requirements. 42 C.F.R. § 424.57(d)(15). The categories that may qualify for an exception are: (1) government-operated DMEPOS suppliers with comparable surety bonds under state law; (2) "state-licensed orthotic and prosthetic personnel in private practice making custom made orthotics and prosthetics," if the business is solely owned by such personnel and bills only for orthotics, prosthetics, and supplies; (3) physician and nonphysician practitioners who furnish items only to their own patients as part of their own practices; and (4) certain physical and occupational therapists. *Id*.

The regulations provide that failure to submit a surety bond as required is grounds for revocation of a supplier's billing privileges:

> CMS requires a supplier to submit a bond that on its face reflects the requirements of this section. CMS revokes or denies a DMEPOS supplier's billing privileges based upon the submission of a bond that does not reflect the requirements of paragraph (d) of this section [42 C.F.R. § 424.57].

See 42 C.F.R. § 424.57(d)(4)(ii)(B); *see also* 42 C.F.R. § 424.57(d)(11) ("CMS revokes the DMEPOS supplier's billing privileges if an enrolled supplier fails to obtain, file timely, or maintain a surety bond as specified in this subpart and CMS instructions."). CMS may at any time require a DMEPOS supplier to show compliance with the surety bond requirement. 42 C.F.R. § 424.57(d)(12). The regulations also provide more generally that CMS "will revoke a supplier's billing privileges if it is found not to meet" the supplier standards or other requirements in section 424.57(c). 42 C.F.R. § 424.57(e) (formerly § 424.57(d)).[1]

A supplier that has had its billing privileges revoked is "barred from participating in the Medicare program from the effective date of the revocation until the end of the re-enrollment bar. The re-enrollment bar is a minimum of 1 year, but not greater than 3 years depending on the severity of the basis for revocation." 42 C.F.R. § 424.535(c).

II. Background

By letter dated November 10, 2009, the NSC, a Medicare contractor, notified Petitioner that its Medicare supplier number would be revoked effective 30 days after the letter, because Petitioner failed to submit a surety bond by October 2, 2009 as NSC required. CMS Ex. 8, at 1. Petitioner timely requested reconsideration arguing that a Medicare representative had told them they were exempt from the surety bond requirement. CMS Ex. 9. On February 17, 2010, the hearing officer issued an unfavorable reconsideration decision. CMS Ex. 11. The hearing officer explained that "[o]pticians are exempt from accreditation requirements; however, a surety bond is not exempt for the business type of Optician." *Id*. at 2. She concluded that, due "to the supplier's business type, Whalen Optical Labs, Inc., is not exempted from surety bond requirements." *Id*. Since Petitioner had not submitted a surety bond by the required date, the hearing officer concluded that the revocation was proper. *Id*.

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[1] Paragraph (e) of section 424.57 was previously designated paragraph (d) and was redesignated by the rulemaking that imposed the surety bond requirements at paragraph (d); however, the redesignations have not yet been incorporated in the Code of Federal Regulations. *See* 42 C.F.R. Ch. IV § 424.57, Editorial Note (Oct. 1, 2009). References are to the regulation as redesignated.

By letter dated March 15, 2010, Petitioner requested an ALJ hearing (HR). Petitioner explained its position as follows:

> When CMS notified everyone of the surety bonding process, there was quite a discrepancy regarding opticians. We in turn called Surety Bonding, per the number supplied, and were informed by a three way call with a Medicare representative that we were exempt. Next, we're notified that we were no longer able to submit claims for Medicare patients. We appealed and stated we were ready to be surety bonded but never received a direct answer. Now we are bonded per the requirements and would appreciate being reinstated.

HR. Along with its hearing request, Petitioner submitted a surety bond dated March 11, 2010.

On March 25, 2010, I issued an acknowledgment and pre-hearing order (PHO) setting dates for CMS and Petitioner to exchange evidence, argument, and any motions for summary disposition. PHO at 2. I explained that time was of the essence in this case and that I might impose sanction for failure to comply with the order. PHO at 4.

CMS submitted its evidence, pre-hearing brief, and motion for summary judgment (MSJ) by the required date. Petitioner did not make any further submissions. On July 15, 2010, I issued an order closing the record. Petitioner did not request that the record be reopened or otherwise contact my office. I therefore proceed to decision on the record before me.

With its motion and brief, CMS filed 12 exhibits (CMS Exs. 1-12). Petitioner did not object to any of CMS's exhibits, and I admit them into the record. I address below CMS's objection to the surety bond attached to the hearing request as "new evidence" within the meaning of section 498.56(e).

III. Issues

The issues in this case are:

1. Whether Petitioner was exempt from the requirement to submit a valid surety bond by October 2, 2009; and

2. If not, whether CMS is entitled to summary disposition on the ground that the undisputed facts demonstrate that the revocation of Petitioner's Medicare billing privileges was legally authorized.

IV. Applicable Standard

The Departmental Appeals Board (Board) stated the standard for summary judgment as follows.

> Summary judgment is appropriate when the record shows that there is no genuine issue as to any material fact, and the moving party is entitled to judgment as a matter of law. . . . The party moving for summary judgment bears the initial burden of showing that there are no genuine issues of material fact for trial and that it is entitled to judgment as a matter of law . . . . To defeat an adequately supported summary judgment motion, the non-moving party may not rely on the denials in its pleadings or briefs, but must furnish evidence of a dispute concerning a material fact - - a fact that, if proven, would affect the outcome of the case under governing law. In determining whether there are genuine issues of material fact for trial, the reviewer must view the evidence in the light most favorable to the non-moving party, drawing all reasonable inferences in that party's favor.

Senior Rehab. & Skilled Nursing Ctr., DAB No. 2300, at 3 (2010) (citations omitted). The role of an ALJ in deciding a summary judgment motion differs from the ALJ's role in resolving a case after a hearing. The ALJ should not assess credibility or evaluate the weight of conflicting evidence when resolving a summary judgment motion. *Holy Cross Vill. at Notre Dame, Inc.*, DAB No. 2291, at 4-5 (2009).

V. Findings of Fact and Conclusions of Law

My findings and conclusions are set forth in the bold italicized headings and supported by the discussions in the sections below.

1. Petitioner was not exempt from the surety bond requirements.

The regulatory exceptions to the requirement that existing DMEPOS suppliers obtain a valid surety bond are limited and quite specific. 42 C.F.R. § 424.57(d)(15). Petitioner does not identify any of the exceptions under which it claims exemption or explain how it might qualify for any of them.

Petitioner does not claim to be government-owned or to consist of physical or occupational therapists. Petitioner does not claim to be a physician or other practitioner supplying only its own patients, and, indeed, its own application as a Medicare supplier identifies it as an "optician." CMS Ex. 1, at 2. Consistent with that identification, Petitioner described itself in its reconsideration request as "an independent Optical shop (without a Doctor)." CMS Ex. 9.

The only remaining exception is for "state-licensed orthotic and prosthetic personnel in private practice making custom made orthotics and prosthetics" if the business is solely owned by such personnel and bills only for orthotics, prosthetics, and supplies. 42 C.F.R. § 424.57(d)(15). Petitioner provides no evidence that it could qualify for this exception, and the record evidence indicates that it could not. Petitioner's enrollment application indicates that it is a corporation and that Ms. Catherine J. Whalen owns five per cent, or more, of the entity and is its managing employee and authorizing official. CMS Ex. 1, at 6. Ms. Whalen is not identified as either sole owner or as a state-licensed orthoticist or prosthetist.

I conclude that the record does not establish that Petitioner was qualified for any exception to the surety bond requirements.

2. CMS was authorized to revoke Petitioner's billing privileges based on undisputed evidence that Petitioner had not submitted a surety bond that met the requirements set forth in 42 C.F.R. § 424.57(c)(26) and (d).

Petitioner does not dispute, and affirmatively admits, that it did not obtain or submit a surety bond by the required date of October 2, 2009. HR; CMS Ex. 12 (Petitioner's January 26, 2010 letter to the hearing officer reiterating that a "Medicare representative" said they were exempt and that "is why we did not get bonded"). Petitioner does not assert that it voluntarily terminated its enrollment with Medicare prior to October 2, 2009. Nothing else in the record supports any reasonable inference that Petitioner was in compliance at the time of revocation. As I explain below, even if Petitioner achieved compliance some time after its revocation, I could not overturn the revocation on that basis if it was authorized at the time the contractor took the action. The undisputed facts thus suffice to establish that Petitioner was out of compliance with the surety bond requirement at the time that its supplier number was revoked.

Instead of arguing that it was in compliance at the time of its revocation, Petitioner asks to be reinstated, because it has now obtained a surety bond. Petitioner has identified no authority for me to reinstate Petitioner based on its later efforts to achieve compliance. [2] CMS objects to Petitioner's submission of a surety bond, dated March 11, 2010, with its hearing request. CMS Br. at 5-6. CMS argues that the "sole issue" before me is whether the revocation was in error, because Petitioner complied with the requirement to submit a surety bond by October 2, 2009. *Id.* at 5. Furthermore, CMS argues that, under section

[2] CMS or its contractor has discretion to accept a showing that a supplier has achieved compliance as demonstrated in a corrective action plan (CAP) submitted within 30 days of a revocation notice. 42 C.F.R. § 424.535(a)(1). Petitioner was advised of this option in its revocation notice. CMS Ex. 8, at 2. The record does not reflect whether Petitioner submitted a CAP; however, in any case, I have no authority to review any CMS decision not to accept a CAP. *See DMS Imaging, Inc.*, DAB No. 2313 (2010).

498.56(e), I may only consider newly submitted evidence if the provider or supplier can demonstrate good cause for submitting such evidence for the first time at the ALJ level instead of on reconsideration. *Id.* at 6, citing 73 Fed. Reg. 36,448, 36,452 (June 27, 2008).

Petitioner did not attempt to make any good cause showing. On the one hand, Petitioner obviously could not have submitted the new bond to the hearing officer on reconsideration, because it was not yet executed. On the other hand, for the same reason, the 2010 bond cannot be evidence of compliance at the time of the revocation. Even if the 2010 surety bond were admissible, it would be irrelevant. I thus agree with CMS that the 2010 bond is not admissible evidence and that NSC erred in revoking Petitioner's supplier number.

Petitioner complains that it never received a "direct answer" to its willingness to obtain a surety bond after its revocation. HR. The only answer that Petitioner could receive from either the hearing officer on reconsideration or on appeal to an ALJ (and which it has received) is that it is too late to avoid revocation. As an existing Medicare DMEPOS supplier, Petitioner had an obligation to become bonded by October 2, 2009. Once Petitioner became noncompliant, it was subject to revocation regardless of whether it later achieved compliance.[3]

Finally, Petitioner's failure to realize that it was subject to surety requirement is no ground for relief. As a Medicare supplier, Petitioner was charged with knowing the requirements for maintaining enrollment. *See Waterfront Terrace, Inc.*, DAB No. 2320, at 7 (2010), citing *Heckler v. Cmty. Health Servs. of Crawford County*, 467 U.S. 51, 63-64 (1984) ("As a participant in the Medicare program, respondent had a duty to familiarize itself with the legal requirements" of the program); *see also Manor of Wayne Skilled Nursing & Rehab.*, DAB No. 2249, at 10-11 (2009) and *Regency on the Lake*, DAB No. 2205, at 5-6 (2008) (noting facilities participating in Medicare had constructive notice of regulations). The law expressly holds Medicare suppliers responsible for knowing the regulatory requirements and the information in the accompanying preambles published in the *Federal Register* and treats such publication as constructive notice whether or not the supplier actually was aware of the requirements. 42 C.F.R. § 411.406(e)(2). Petitioner's vague allusion to a "discrepancy regarding opticians" does not present a triable issue of fact in the face of the express language of the regulations

[3] Regulations also provide that a supplier whose number has been revoked is barred from re-enrolling in Medicare for a period of one to three years. 42 C.F.R. § 424.535(c). NSC imposed the minimum one-year bar in the present case. CMS Ex. 8, at 1. Petitioner points to, and I am aware of, no authority that would empower me to grant relief from the re-enrollment bar. I therefore do not discuss it further.

requiring all DMEPOS suppliers to obtain surety bonds with limited exceptions that nowhere refer to opticians. HR.

The regulation requiring surety bonds and the explanations of it in the preamble should have put Petitioner on notice of its obligation to obtain a valid bond timely. CMS Ex. 2. CMS points out, however, that Petitioner was provided with multiple additional sources of actual notice (to which Petitioner has not denied having access). CMS Br. at 3-5; CMS Exs. 3-7. Those sources included a new section 21.7 in chapter 10 of CMS's Medicare Program Integrity Manual (CMS Ex. 4) and two articles published on the NSC website on January 7 and April 29, 2009, which set out the requirements, exceptions, and deadlines for DMEPOS suppliers to obtain surety bonds. CMS Ex. 3, at 1-2. In addition, CMS represents that NSC sent a letter on August 21, 2009 to all existing DMEPOS suppliers believed subject to surety bond requirements reminding them of the deadline. CMS Br. at 4, citing CMS Ex. 5. Petitioner not only does not deny receiving this letter, but referred to a time when "CMS notified everyone of the surety bonding process." HR. Petitioner thus does not raise a dispute of fact about whether she received actual notice of the surety bond requirements.

CMS notes that the NSC letter had a chart attached that clearly showed that opticians were not exempt from surety bond requirements (although they are exempt from the requirement to obtain accreditation). CMS Br. at 4, citing CMS Ex. 5, at 3. The same chart was posted on the NSC website on August 28, 2009, along with a list of frequently asked questions (FAQ) about DMEPOS surety bonds. CMS Br. at 4, citing CMS Ex. 6. The FAQ makes clear that exemption from accreditation does not equate to exemption from surety bond requirements, as these are "two completely separate mandates." CMS Ex. 6, at 11. The FAQ further addresses the specific situation of an optical center:

> An optometrist or ophthalmologist who dispenses eyeglasses can qualify for the physician exemption if the glasses are furnished only to his/her own patients as part of his/her own service. . . .
>
> The same general principle applies to an enrolled optical center owned by an optometrist or ophthalmologist. The center can only qualify for the physician exemption only if: (1) the shop and the physician's practice are under/within the same TIN and business structure (e.g., part of the same corporation), and (2) the glasses are furnished only to the optometrist/ophthalmologist's own patients as part of his/her own service. . . .

CMS Ex. 6, at 12. Since Petitioner expressly asserts, as noted above, the center is independent and not part of a physician's practice (HR; CMS Ex. 9), Petitioner should have been aware that it could not qualify for an exemption from the surety bond requirement.

I therefore conclude that CMS acted within its regulatory authority to revoke Petitioner's Medicare supplier number, because Petitioner was not compliant with the surety bond requirements of 42 C.F.R. § 424.57(c)(26) and (d) by October 2, 2009.

3. ***Petitioner's equitable arguments are unavailing in this forum.***

The essence of Petitioner's appeal is an argument that the impact of the legal consequences of its failure to obtain a valid surety bond before its revocation is excessively onerous. Petitioner thus explains that the office has been operating and filing Medicare claims for over 20 years and that its ability to file claims for its patients is a "necessity" especially "in these economic times." HR.

This argument asks me to relieve Petitioner of the legal consequences for equitable reasons. The Board has long held that applicable statutes and regulations are binding both on it and on ALJs. *See, e.g., Sentinel Med. Labs., Inc*., DAB No. 1762, at 9 (2001). I lack authority to deviate from the law, however sympathetic I may be to Petitioner's situation. *See Oklahoma Heart Hosp.*, DAB No. 2183, at 16 (2008).

Petitioner also suggests that it was misled by information provided by an unnamed "Medicare representative" into believing that it qualified as exempt. HR. The information that Petitioner provided is too vague as to: the date or time of the "three way call;" the identity of any of the participants; or the content of the discussion to discern what questions were asked or what information was provided. In any case, it is well-established that the government cannot be estopped from applying the law or forced to expend federal funds based on inaccurate representations by its agents absent, at the least, a showing of affirmative misconduct about which Petitioner makes no allegations. *Office of Personnel Mgmt. v. Richmond*, 496 U.S. 414 (1990); *Heckler v. Community Health Serv. of Crawford City, Inc*., 467 U.S. 51 (1984); *Schweiker v. Hansen*, 450 U.S. 785 (1981); *Shenandoah Prof'l Stds. Review Found*., DAB No. 652 (1985). I therefore need not reach CMS's further arguments that Petitioner could not make out the traditional elements of estoppel, including reasonable reliance. *See* CMS Br. at 11-12.

VI. Conclusion

For the reasons explained above, I grant summary judgment in favor of CMS.

/s/
Leslie A. Sussan
Board Member