Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

TC Foundation, Inc.,
(NPI: 1619246261),

Petitioner,

v.

Centers for Medicare and Medicaid Services.

Docket No. C-13-263

Decision No. CR2834

Date: June 18, 2013

DECISION

This matter is before me on the Motion for Summary Disposition filed by the Centers for Medicare and Medicaid Services (CMS). For the reasons set out below, I GRANT the CMS Motion and AFFIRM the revocation of Petitioner TC Foundation's enrollment and billing privileges as a supplier in the Medicare program.

I. Procedural History

Petitioner TC Foundation was enrolled in the Medicare program to provide laboratory services. On June 7, 2012, First Coast Service Options (First Coast), a Medicare contractor, revoked Petitioner's enrollment and billing privileges effective April 6, 2012 and barred Petitioner from reenrolling for a three-year period. CMS Exhibit (Ex.) 3. Petitioner appealed and First Coast affirmed its revocation. CMS Ex. 6.

Petitioner timely requested a hearing (RFH) before an Administrative Law Judge (ALJ). In accordance with my Acknowledgment and Prehearing Order, CMS submitted a Motion for Summary Disposition and a brief in support of its Motion (CMS Br.), along with seven exhibits identified as CMS Exs. 1-7. Petitioner filed its Response in

Opposition to Respondents' Motion for Summary Disposition (P. Br.), and no exhibits. In the absence of objection, I admit CMS Exs. 1-7 into the record.

II. Applicable Law

Section 1831 of the Social Security Act (the Act) (42 U.S.C. § 1395j) establishes the supplementary medical insurance benefits program for the aged and disabled known as Medicare Part B. Payment under the program for services rendered to Medicare-eligible beneficiaries may only be made to eligible providers of services and suppliers.[1] When applying for enrollment in the Medicare program, a supplier is required to provide complete accurate and truthful responses to all information requested within each section on the enrollment application applicable to the supplier type. 42 C.F.R. § 424.510 (d)(2)(i). Also, a supplier is obligated to report within 30 days any changes in the supplier's practice location and other changes to the supplier's enrollment must be reported within 90 days. 42 C.F.R. § 424.516(d). CMS may revoke a supplier's enrollment if the 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. . . ." 42 C.F.R. § 424.535(a)(1). CMS may also revoke supplier enrollment if it certified as "true" misleading or false information on the Medicare enrollment application. 42 C.F.R. § 424.535(a)(4).

A supplier "must be operational to furnish Medicare covered items or services before being granted Medicare billing privileges." 42 C.F.R. § 424.510(d)(6). A supplier is "operational" when 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 these items and services." 42 C.F.R. § 424.502. CMS has a right to perform on-site inspections to verify the accuracy of a supplier's enrollment information and to determine the provider's compliance with Medicare enrollment requirements. 42 C.F.R. § 424.510(d)(8); *see also* 42 C.F.R. § 424.517(a)(1). The on-site inspection permits the Secretary "to verify . . . that [she] is paying an entity that actually exists or that is providing a service that it represented it would provide in its enrollment application." 71 Fed. Reg. at 20,755.

CMS may revoke a supplier's enrollment if, upon on-site review, CMS determines that a "supplier is no longer operational to furnish Medicare covered items or services, or the

---

[1] A "supplier" furnishes services under Medicare and the term supplier applies to physicians and other non-physician practitioners and facilities that are not included within the definition of the phrase "provider of services." Act § 1861(d) (42 U.S.C. § 1395x(d)). An Independent Clinical Laboratory (CLIA), such as Petitioner, is considered a supplier under the regulations. *See* 42 C.F.R. § 400.202; 42 C.F.R. § 424.502.

supplier has failed to satisfy any or all of the Medicare enrollment requirements, or has failed to furnish Medicare covered items or services as required by the statute or regulations." 42 C.F.R. § 424.530(a)(5)(ii).

III. Issue

The issue in this case is whether CMS was authorized to revoke Petitioner's enrollment and billing privileges in the Medicare program.

IV. Analysis

My findings of fact and conclusions of law are set forth in italics and bold in the discussion captions of this decision.

A. *This case is appropriate for summary judgment*

CMS argues that it is entitled to summary judgment. The Departmental Appeals Board (Board) stated the standard for summary judgment:

> 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 Rehabilitation & Skilled Nursing Center, DAB No. 2300, at 3 (2010) (citations omitted).

The Board has further explained that the role of an Administrative Law Judge (ALJ) in deciding a summary judgment motion differs from its role in resolving a case after a hearing. The ALJ should not assess credibility or evaluate the weight of conflicting evidence. *Holy Cross Village at Notre Dame, Inc.*, DAB No. 2291, at 5 (2009). I find that Petitioner has not disputed any fact material to my resolution of the case. Accordingly, I conclude that summary judgment is appropriate in this case. Here, the material facts are not disputed, and I draw all reasonable inferences in favor of Petitioner.

B. *CMS was authorized to revoke Petitioner's enrollment as a supplier in the Medicare program because Petitioner was not "operational" because it was not furnishing laboratory services*

The facts in this case are not disputed. Petitioner, a nonprofit foundation, established a clinical laboratory and sought to enroll it as a Medicare supplier. Petitioner filed its application for Medicare enrollment on January 3, 2012, listing its effective date as December 13, 2011 (the date that the State of Florida issued Petitioner's CLIA license). P. Br. at 1-3; CMS Ex. 1 at 2; RFH.

On March 13, 2012, while Petitioner's application was still pending, Rolando O. García-Morales, MD, MHSA, Petitioner's medical director and authorized official, contacted First Coast to determine the status of its application. First Coast documented that Dr. Garcia-Morales stated that the lab was going to start seeing patients once First Coast approved the Medicare enrollment application. The First Coast representative advised Petitioner that First Coast could not approve the application until after Petitioner had begun seeing patients. The First Coast representative instructed Dr. Garcia-Morales to contact First Coast once Petitioner began seeing patients so that they could disclose that information on the application. CMS Ex. 7 at 3. Despite this discussion, First Coast continued to process Petitioner's application and approved Petitioner's enrollment just nine days later. First Coast established Petitioner's effective date as December 13, 2011. CMS 1 at 19; RFH.

Shortly thereafter, on April 6, 2012, the contractor conducted an on-site inspection of Petitioner's facility. During this inspection, Dr. García-Morales informed the inspector that Petitioner had not seen any patients yet, as recently discussed with First Coast. Dr. García-Morales stated that Petitioner intended to start seeing patients in about two weeks. CMS Ex. 2.

Two months later, First Coast revoked Petitioner's enrollment. CMS Ex. 3. The letter notified Petitioner that the revocation was based on providing false or misleading information under section 424.535(a)(4). The letter further informed Petitioner that it was also barred from reenrolling for three years. CMS Ex. 3. Petitioner appealed. The contractor reconsideration decision added two additional bases for revocation: that Petitioner was not operational under section 424.535(a)(5), and that Petitioner had failed to report a change in practice location under section 424.535(a)(9). CMS Ex. 6.

On appeal, CMS relies only on the "not operational" provision as the basis for revocation. CMS argues that Petitioner was properly revoked pursuant to 42 C.F.R. § 424.535(a)(5)(ii) because Petitioner was not operational at the time that the on-site inspection was conducted. Petitioner argued in its request for hearing that the facility has been operational since before September 1, 2011, because that by that time:

a. All of our personnel had performed exhaustive clinical testing in all of our instruments.
b. The experts for the State of Florida - Agency for Health Care Administration's Laboratory Unit had thoroughly inspected the laboratory and approved its licensure and,
c. A State of Florida - Clinical Laboratory License was received with effective date as of December 13, 2011.

RFH at 2.

When used in the context of this case, the term "operational" is a term of art specific to the regulations regarding Medicare enrollment and billing privileges. The regulations define "operational" as follows:

> [T]he 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 regulations do not further detail the "operational" requirement. However, the Board has indicated that once enrolled, the supplier must not only *be able to provide* the items or service, but *actually be providing* the items or service. Specifically, the Board has explained that the requirement that Petitioner "be 'operational' means it must have a qualified physical practice location and *actually be furnishing the types of covered Medicare services* that it holds itself out as furnishing ." (emphasis added) *CompRehab*, DAB No. 2406 at 7 (2011), *citing* 42 C.F.R. § 424.502; *see also A To Z DME, LLC*, DAB No. 2303 at 9-10.

A supplier disputing a CMS revocation under section 424.535(a)(5)(ii) must show that it in was in fact operational during the time period relevant to the on-site review. Under the regulations, it is insufficient for a supplier to demonstrate that it became operational at a later point in time. *A To Z DME, LLC*, DAB No. 2303 at 6-8; *see* 73 Fed. Reg. 36,448, 36,542 (June 27, 2008). Accordingly, for Petitioner to prevail, Petitioner must show that it was operational — furnishing laboratory services to patients — around the April 6, 2012 inspection.

However, Petitioner has never argued that it was conducting laboratory testing at or around April 6, 2012. Quite to the contrary, Petitioner has answered openly that it had

not seen patients at the time of enrollment, or during its on-site inspection. RFH; P. Br. at 4-5. For example, during the on-site inspection, Dr. García-Morales noted "N/A no Patients" on the inspector's form requesting a sample of current patient medical records. CMS Ex. 2 at 6. Petitioner explains that it had a physical practice location that was properly staffed, equipped, and stocked, and open to the public for the purpose of providing laboratory services. P. Br. at 2-4. Petitioner clarified that "[up to the date of the [inspection, Petitioner] did not see any Medicare patients because no Medicare patients had been referred to be tested . . . up to that point . . . ." P. Br. at 4. Unfortunately, the term "operational" is interpreted for enrollment and billing purposes to include the requirement that the provider or supplier actually be providing the service or items that it was approved to provide.

Moreover, there simply is no exception to the regulations for businesses in "start-up mode" at the time of the on-site review. *A To* Z *DME, LLC*, DAB No. 2303, at 5. In *A to* Z *DME* v. *CMS,* the petitioner asserted that it was operational as shown by its receipt of a Blue Cross/Blue Shield number, receipt of loans, insurance, bank account, among others. In that case, the Board explained, "merely planning or preparing to do business with the public is not equivalent to being actually operational as required." *Id*. at 5.

I do not have the authority to review CMS's discretionary act to revoke a supplier's Medicare status. *Letantia Bussell*, DAB No. 2196, at 13 (2008). I must sustain CMS's revocation determination if a legitimate basis exists for that determination and where the facts established noncompliance with one or more of the relevant regulations. *1866ICPayday.com,* DAB No. 2289, at 13 (2009). As the Board has stated, "the right to review of CMS's determination by an ALJ serves to determine whether CMS had the authority to revoke [the supplier's] Medicare billing privileges, not to substitute the ALJ's discretion about whether to revoke." *Bussell*, DAB No. 2196, at 13.

I must sustain a revocation where the facts establish that the provider or supplier was not operational. There is nothing in the regulations that authorizes me to make an exception on a petitioner's showing of good cause for noncompliance, nor do I have the authority to waive the regulations' strict requirements on a showing of extenuating circumstances or as a matter of equity.

V. Conclusion

The undisputed evidence establishes that CMS was authorized to revoke Petitioner's enrollment as a Medicare supplier because it was not operational in accordance with 42 C.F.R. § 424.535(a)(5). Accordingly, I GRANT summary judgment in favor of CMS.

The revocation of Petitioner's enrollment in the Medicare program must be, and it is, AFFIRMED.

/s/
Richard J. Smith
Administrative Law Judge