

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Community Medical Lab, LLC,

Petitioner,

v.

Centers for Medicare and Medicaid Services.

Docket No. C-12-646

Decision No. CR2635

Date: October 2, 2012

DECISION

TrailBlazer Health Enterprises (TrailBlazer), an administrative contractor acting on behalf of the Centers for Medicare and Medicaid Services (CMS), found Petitioner not to be operational and denied Petitioner's application for enrollment as a supplier in the Medicare program. Petitioner appealed. For the reasons stated below, I affirm the determination to deny Petitioner's application for enrollment.

I. Background and Procedural History

In May 2011, TrailBlazer received Petitioner's application (Form CMS-855B) for enrollment in the Medicare program as an independent clinical laboratory. CMS Exhibits (CMS Exs.) 1; 2, at 3; 9. Petitioner is a "one-man operation" in which its owner, Claxton Arthur, is "frequently in the field" drawing blood from patients at their homes; Mr. Arthur then returns to the laboratory to analyze the blood samples. Request for Hearing (RH) at 1; Petitioner's Brief (P. Br.) at 3; CMS Exs. 5, at 1; 7, at 64.

Trailblazer attempted to conduct a site visit of the business location identified in Petitioner's enrollment application (5200 West Loop South, Suite 204, Bellaire, Texas 77401) at 9:10 a.m. on October 19, 2011, to determine if Petitioner was operational.

CMS Ex. 3, at 1. However, the inspector documented that she could not complete the visit because the name on the business at Petitioner's address was Bridal Connection Mall (Mall); the exterior signage indicated that the hours of operation were 11:00 a.m. to 7:00 p.m.; and the facility appeared not to be operational. CMS Ex. 3, at 1. In its November 3, 2011 initial determination, TrailBlazer denied Petitioner's application to enroll in the Medicare program pursuant to 42 C.F.R. § 424.530(a)(5)(i) or (ii), because Petitioner failed a site survey. CMS Ex. 4, at 1.

Petitioner, through Mr. Arthur, filed a timely request for reconsideration of TrailBlazer's denial of enrollment. CMS Ex. 5, at 1. Petitioner contested TrailBlazer's finding that Petitioner was not operational by asserting that it was one of a variety of small businesses in the Mall and that Mr. Arthur observed TrailBlazer's inspector arrive in the parking lot of the Mall on October 19, 2011, and then drive away without coming inside the building or finding its office. CMS Ex. 5, at 1. In addition to filing a request for reconsideration, Petitioner filed another enrollment application (Form CMS-855B). CMS Ex. 7.

On March 5, 2012, at 2:00 p.m., TrailBlazer attempted to conduct another site visit at Petitioner's location. CMS Ex. 8, at 1. The inspector documented that Petitioner was not open for business and did not appear to be operational. Further, the inspector indicated that Petitioner did not appear to have: employees present; signs of customer activity present; and inventory. CMS Ex. 8, at 1. Further, Petitioner's sign at the entrance to its office does not indicate Petitioner's hours of operation. CMS Ex. 8, at 2. On April 5, 2012, TrailBlazer issued an unfavorable reconsideration determination noting that Petitioner failed site surveys on October 19, 2011, and March 5, 2012. CMS Ex. 9.

Petitioner timely filed a request for a hearing with the Departmental Appeals Board, Civil Remedies Division. In response to my May 9, 2012 Acknowledgment and Pre-hearing Order (Pre-hearing Order), CMS filed a pre-hearing brief (CMS Br.), nine proposed exhibits, and a witness list. Petitioner filed a brief on June 27, 2012, but did not file any exhibits or object to CMS's exhibits. In the absence of an objection, I admit CMS Exs. 1 through 9 into the record.¹

The Pre-hearing Order advised the parties that they must 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. Pre-hearing Order ¶¶ 8, 9, 11; *Vandalia Park*, DAB No. 1940 (2004); *Pacific Regency Arvin*, DAB No. 1823, at 8 (2002) (holding that the use of written direct-testimony for witnesses is permissible so long as the opposing party has the opportunity to cross-examine those

¹ Petitioner submitted two documents with its request for hearing. CMS also submitted these documents and they have been admitted into the record. See CMS Ex. 7, at 6, 20.

witnesses). Petitioner did not offer any witnesses that CMS could request to cross-examine. Although CMS submitted a witness list, Petitioner did not request to cross-examine those witnesses.² See Pre-hearing Order ¶ 10. Consequently, I will not hold an in-person hearing in this matter. See *Kate E. Paylo, D.O.*, DAB CR2232, at 9 (2010). Accordingly, the record is closed and I will evaluate the documentary evidence admitted into the record. See Pre-hearing Order ¶¶ 11, 12.

II. Discussion

Petitioner is a supplier for purposes of the Social Security Act (Act) and the regulations. See 42 U.S.C. §§ 1395x(d), 1395x(u); 42 C.F.R. § 498.2. In order to participate in the Medicare program as a supplier, individuals and entities must meet certain criteria to enroll and receive billing privileges. 42 C.F.R. §§ 424.505, 424.510. CMS will enroll a supplier into the Medicare program only when the supplier “successfully completes the enrollment process including, if applicable, a State survey and certification or accreditation process” 42 C.F.R. § 424.510(a). During the enrollment process, CMS may perform on-site reviews to verify the accuracy of a supplier’s enrollment information, to determine the supplier’s compliance with Medicare enrollment requirements, and to determine whether the supplier is no longer operational. 42 C.F.R. §§ 424.510(d)(8), 424.517(a).

A Medicare 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 qualified 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 (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.

² CMS’s witness list identifies two witnesses. However, CMS failed to submit written direct testimony for either witness. Pre-hearing Order ¶¶ 8, 9. Because CMS neither objected to this requirement nor requested that I waive the requirement, I will not accept testimony from these witnesses. See *Golden Living Center – Frankfort*, DAB No. 2296, at 4 (2009) (noting that the petitioner had not “made any request below to require particular witnesses to present their direct testimony in person”); *The Laurels at Forest Glenn*, DAB No. 2182, at 10 (2008) (noting that a party failed to object to the pre-hearing order’s direct testimony requirement “at the time”). Although CMS submitted a witness list, CMS also requested that I render a decision on the written record. CMS Br. at 1.

CMS may deny enrollment in the Medicare program where, upon on-site review, CMS determines that the supplier is not operational or does not meet the enrollment requirements to furnish Medicare covered items or services. 42 C.F.R. § 424.530(a)(5).

A. Issue

The issue in this case is whether CMS has a legitimate basis to deny Petitioner enrollment as a supplier in the Medicare program based on a determination that Petitioner was not operational under 42 C.F.R. § 424.530(a)(5).

B. Findings of Fact, Conclusions of Law, and Analysis³

CMS argues that Petitioner was properly denied enrollment in the Medicare program because Petitioner was not operational to furnish Medicare covered items or services. CMS alleges that on two occasions, October 19, 2011, at about 9:10 a.m., and March 5, 2012, at about 2:00 p.m., a TrailBlazer inspector attempted to complete an on-site visit of Petitioner's address but was unable to do so because Petitioner was not open. CMS Exs. 3, 8.

Petitioner does not dispute that the surveyors attempted to inspect its premises on these dates and times. However, Petitioner argues that the October 19, 2011 visit was not completed because the inspector did not "try hard enough to locate my business." RH at 1. Further, Petitioner asserts that because his laboratory has only one employee, and Mr. Arthur provides services for patients in their homes, TrailBlazer needs to schedule any site visit with Petitioner in advance. RH at 1-2.

1. The March 5, 2012 site visit could not be conducted because Petitioner was closed.

Petitioner does not dispute that Mr. Arthur was not at its office location at 2:00 p.m. on March 5, 2012, when TrailBlazer's inspector attempted a site visit. RH at 1; P. Br. at 3. CMS submitted the inspector's report of the attempted visit along with photographs of the exterior portions of Petitioner's offices (CMS Ex. 8) and Petitioner did not object to this evidence or otherwise dispute its authenticity. Therefore, I find that Petitioner was closed when the inspector attempted to conduct the March 5, 2012 site visit.

2. The March 5, 2012 site visit complied with CMS's procedures.

Although Petitioner does not dispute that Mr. Arthur was not present when the inspector appeared for a site visit on March 5, 2012, Petitioner asserts that Mr. Arthur was working

³ My findings of fact and conclusions of law are set forth in italics and bold font.

with a TrailBlazer enrollment analyst, Robert Maurer, on completing Petitioner's enrollment application and that Mr. Maurer allegedly agreed that an inspector would call Mr. Arthur before coming to the laboratory for the site visit. P. Br. at 3.

Petitioner offers no documentary or other evidence to support this agreement with Mr. Maurer. Although the record contains evidence of communication between Mr. Maurer and Mr. Arthur regarding missing and incomplete documentation on Petitioner's November 28, 2011 enrollment application, nowhere in this communication does Mr. Maurer suggest that the site inspector will contact Petitioner before attempting a site visit. CMS Ex. 6. To the contrary, Petitioner had been previously informed by TrailBlazer that site inspectors "will not call – just show up," a fact acknowledged by Petitioner in a letter he wrote. CMS Ex. 7, at 60, 64.

The Medicare Program Integrity Manual (MPIM) outlines the policy and procedure for conducting site visits for suppliers. The manual states that a contractor will conduct a site visit for independent clinical laboratories "to ensure that the supplier is still in compliance with CMS's enrollment requirements," and the visit will be conducted under the general site visit procedures for suppliers and providers. MPIM, Ch. 15, § 15.4.2.2(D). Under those procedures, inspectors determine whether the supplier meets four specified elements. MPIM, Ch. 15, § 15.19.2.2(B). The specific procedures for site visits require the inspector to conduct the visit on weekdays during a facility's posted business hours. MPIM, Ch. 15, § 15.20.1(B). If the facility has no posted business hours, site visits should occur between 9:00 a.m. and 5:00 p.m. *Id.* "If, on the first attempt the facility is closed but there are no obvious indications the facility is non-operational, a second attempt on a different day during posted hours of operation should be made." *Id.*

I find the March 5, 2012 site visit complied with the MPIM. The site inspector arrived on a weekday between 9 a.m. and 5 p.m., entered the Mall, found Suite 204, and recorded that the door was locked and that no-one was present or answered the door. CMS Ex. 8, at 1. There were no posted business hours on the sign on the door. CMS Ex. 8, at 2. The inspector's report indicates that: the facility was not open; there were no personnel at the facility; there were no customers at the facility; and the facility did not appear to be operational. CMS Ex. 8, at 1. Based on the inspector's findings, TrailBlazer properly conducted a site visit and was not required to make a second attempt to inspect Petitioner's facility.⁴ *See* MPIM, Ch. 15, § 15.20.1(B).

⁴ CMS's position is that TrailBlazer attempted to conduct two site visits of Petitioner's facility, on October 19, 2011 and March 5, 2012. CMS Br. at 7. However, Petitioner disputes that the October 19, 2011 site visit was properly attempted. RH at 1. The inspector's notes and photographs related to this attempted visit (CMS Ex. 3), and Mr. Arthur's observations of the inspector as detailed in his reconsideration request (CMS Ex. 5), request for hearing, and brief, appear consistent. The inspector arrived at the Mall at

3. CMS has a legitimate basis to deny Petitioner enrollment in the Medicare program because Petitioner was not operational pursuant to 42 C.F.R § 424.530(a)(5).

As indicated previously, a Medicare supplier “must be operational to furnish Medicare covered items or services before being granted Medicare billing privileges” and CMS may conduct a site visit to determine whether a supplier is operational. 42 C.F.R. § 424.510(d)(6), (8). Under the site visit procedures in the MPIM for determining whether a facility is operational, an inspector must observe whether: the facility is open; personnel are at the facility; customers are at the facility (if applicable); and the facility appears to be operational. MPIM, Ch. 15, § 15.19.2.2(B). Significantly, CMS has directed its contractors that “[i]f any of the 4 elements . . . are not met, the enrollment contractor will . . . deny the provider’s enrollment application” because it is not operational under 42 C.F.R. § 424.530(a)(5)(i) or (ii). *Id.* In the present case, the inspector noted, during the March 5, 2012 site visit, that Petitioner’s facility was closed and, based on observations from outside of Petitioner’s facility, determined that none of the four elements were met. CMS Ex. 8, at 1. Consequently, TrailBlazer denied Petitioner’s application.

Petitioner argues that if an inspector was able to conduct a site visit when he was present, the inspector would see that Petitioner’s facility is operational. However, Petitioner acknowledges that Mr. Arthur is Petitioner’s only employee and that Petitioner is regularly out of the office during the work day because he is in the field. P. Br. at 2-3. Thus, Petitioner has continually requested advance notice or scheduling of the site visit. RH at 1-2; P. Br. at 3; CMS Ex. 5, at 1. Petitioner may believe that, because of the unique nature of its approach to gathering blood samples for testing, it is not required to have a representative physically present in its laboratory in order to be “operational” within the meaning of the law. However, to be “operational,” a Medicare supplier must be “open to the public for the purpose of providing health care related services . . . and [be] properly staffed . . . to furnish these services.” 42 C.F.R. § 424.502. A supplier cannot be “open to the public” nor “properly staffed” if a supplier’s business location is closed and no staff is present to allow a site inspector access to the facility. Even if, given the nature of its business, Petitioner might not be expected to have a customer

9:10 a.m., and determined that the posted hours of operation for the Mall indicated that it would not open until 11 a.m. CMS Ex. 3, at 1, 5. The inspector only took external photographs of the Mall. CMS Ex. 3, at 3-5. There is no evidence that the inspector attempted to enter the Mall and find Petitioner’s suite (CMS Ex. 7, at 60) and Petitioner asserts that the inspector did not appear at its door. RH at 1; CMS Ex. 5, at 1. Because I find that TrailBlazer’s March 5, 2012 attempted site visit was sufficient under the procedures in the MPIM, I do not need to decide whether the October 19, 2011 attempted site visit complied with those procedures.

presence, CMS still reasonably expects personnel to be present at the premises of that business. *See Suitable Homehealth Care, Inc.*, DAB CR2488, at 7 (2012).

TrailBlazer complied with CMS's procedures and applied CMS's policy to deny the enrollment application. Although the MPIM is not binding on me, I agree with *Suitable Homehealth Care, Inc.* that, based on the need to maintain the integrity of the Medicare program, CMS's policies are not unreasonable nor are they are inconsistent with the regulatory scheme. *Id.* Therefore, CMS had a legitimate basis to deny Petitioner's application under 42 C.F.R. § 424.530(a)(5).

III. Conclusion

Petitioner was not operational because it was not open and accessible to the site inspector on March 5, 2012. CMS's denial of Petitioner's application to enroll as a supplier in the Medicare program is affirmed.

/s/

Scott Anderson
Administrative Law Judge