

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

AUM Pharmaceuticals, Inc. d/b/a/ AUM RX

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-16-917

Decision No. CR4843

Date: May 8, 2017

DECISION

The Centers for Medicare & Medicaid Services (CMS) revoked the Medicare supplier number and billing privileges of Petitioner, AUM Pharmaceuticals, Inc. d/b/a AUM RX, after it concluded that Petitioner was not operational at the practice location on file with CMS and that it was not accessible and staffed during posted hours of operation to beneficiaries and to CMS. The Medicare administrative contractor for the National Supplier Clearinghouse (NSC), Palmetto GBA, upheld the revocation in a reconsidered determination, and Petitioner requested a hearing to dispute the revocation. I affirm the revocation of Petitioner's Medicare enrollment and billing privileges.

I. Background

Petitioner was enrolled in the Medicare program as a supplier of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) that had a location on file with the NSC of 869 South East Street in Anaheim, CA. *See* CMS Exhibit (Ex.) 7 at 1, 7. On April 25 and 26, 2016, a site inspector attempted to conduct a site inspection at Petitioner's location on file with CMS. CMS Ex. 2. The inspector reported that the posted weekday hours of operation were from 9:00 am to 6:00 pm (CMS Ex. 2 at 4), and

that she was unable to access Petitioner's facility at 1:19 pm on April 25, 2016, and at 12:28 pm on April 26, 2016. CMS Ex. 2 at 1, 8. The inspector reported that "[t]he supplier was closed during both attempts," and that "[b]oth attempts were conducted during posted hours of operation." CMS Ex. 2 at 8. The inspector reported that "[t]here was no response to several knocks made at the locked entrance." CMS Ex. 2 at 8.

Palmetto GBA thereafter, on May 9, 2016, issued an initial determination revoking Petitioner's Medicare supplier number, retroactive to April 26, 2016. CMS Ex. 3. Palmetto GBA informed Petitioner that it was not in compliance with the supplier standards at 42 C.F.R. § 424.57(c)(7) and (26), and that Petitioner was non-operational pursuant to 42 C.F.R. § 424.535(a)(5).¹ The letter provided the following information:

Recently, a representative of the NSC attempted to conduct visits of your facility on April 25, 2016 and April 26, 2016; however, the visits were unsuccessful because the location was closed on both attempts during posted hours of operation. The entrance was locked and knocks were unanswered. Because we could not complete an inspection of your facility, we could not verify your compliance with the supplier standards. Based on a review of the facts, we have determined that your facility is not operational to furnish Medicare covered items and services. Thus, you are considered to be in violation of 42 [C.F.R. §] 535.535(a)(5), all supplier standards defined in 42 [C.F.R.] 424.57(c) and pursuant to [42 C.F.R. §] 424.535(g), the revocation is effective the date CMS determined that you were no longer operational.

CMS Ex. 3 at 6 (emphasis omitted). Palmetto GBA also notified Petitioner that it would be barred from reenrolling in the Medicare program for a period of two years from the date of postmark of the letter. CMS Ex. 3 at 5. The letter informed Petitioner that if it believed the determination was incorrect, it should file a request for reconsideration. CMS Ex. 3 at 7.

In an undated letter, Petitioner admitted that on both April 25 and 26, 2016, "a representative of NSC had attempted to come and inspect the pharmacy, [and] unfortunately it was closed both times." CMS Ex. 3 at 1. Petitioner explained that "[t]he pharmacist . . . went to engage the local doctors in the area and could not be at the pharmacy at the stated hours. The stated hours on the door are Monday to Friday 9 am to 6 pm." CMS Ex. 3 at 1. Petitioner offered a "corrective action plan" in which it stated

¹ The reconsidered determination did not sustain the finding of noncompliance with 42 C.F.R. § 424.57(c)(26). CMS Ex. 5; *see* CMS Ex. 3 at 5 (letter from Petitioner's surety company notifying Palmetto GBA that Petitioner did not have a lapse in its surety bond coverage).

that the pharmacist “will change the hours of operation to reflect the day and times the pharmacy will be open.” CMS Ex. 3 at 1.

On June 8, 2016, Palmetto GBA informed Petitioner that it had rejected the aforementioned undated letter because it was untimely and had not been signed by an owner, authorized official or delegated official on file. CMS Ex. 4 at 1. Thereafter, Petitioner submitted a reconsideration request that mirrored the substantive content of the previous undated letter. CMS Ex. 6 at 1-2.

A Medicare Hearing Officer issued a reconsidered determination on July 25, 2016 that denied Petitioner’s request for reconsideration. CMS Ex. 5. The reconsidered determination upheld the determinations that Petitioner was not open during the posted hours of operation and that it was closed during both site visit attempts. CMS Ex. 5 at 3-4. The reconsidered determination found that Petitioner was noncompliant with 42 C.F.R. § 424.535(a)(5) and 42 C.F.R. § 424.57(c). CMS Ex. 5 at 2-3. The reconsidered determination stated, in pertinent part:

The NSC reserves the right to perform on-site inspections as a means of verifying information on file with the NSC and confirm compliance with the Supplier Standards. If during an on-site review a facility is found closed or not accessible, this becomes grounds for denial because the facility was found not in operation. A supplier must be found “operational” upon the site inspection in order to verify compliance with the Medicare Enrollment requirements. “*Operational* means the provider or supplier has a qualified physical practice location, is open to the public for the purpose of providing healthcare related services, is prepared to submit valid Medicare claims and is properly staffed, equipped, and stocked.”

The fact remains that the site inspector could not access Aum Pharmaceuticals Inc. facility to verify compliance with the supplier standards because the location on file with the NSC was not open or accessible during posted hours of operation.

CMS Ex. 5 at 4 (emphasis in original).

Petitioner, through counsel, filed a request for hearing before an administrative law judge on September 23, 2016.² On September 30, 2016, I issued an Acknowledgement and Pre-Hearing Order (Order). Pursuant to the Order, CMS filed its brief and motion for summary judgment (CMS Br.), along with seven exhibits (CMS Exs. 1-7). Petitioner submitted a letter, dated January 25, 2017, that I have construed as its brief (P. Br.). While Petitioner electronically filed three “exhibits” contemporaneously with its brief,

² On December 12, 2016, I granted Petitioner’s counsel’s motion to withdraw as counsel.

these exhibits do not provide any evidence pertaining to Petitioner's revocation; rather, these documents were submitted in response to a procedural Order.³ Therefore, in the absence of any objections, I admit CMS Exs. 1 through 7.

Because neither party has submitted written direct testimony, there is no need for a hearing for the purpose of cross-examination of witnesses. Order, §§ 9, 10. I consider the record to be closed and the matter ready for a decision on the merits.⁴

II. Issue

Whether CMS had a legitimate basis for revoking Petitioner's Medicare billing privileges for failing to comply with Supplier Standard 7 (42 C.F.R. § 424.57(c)(7)) and failing to be operational (42 C.F.R. § 424.535(a)(5)).

III. Jurisdiction

I have jurisdiction to decide this case. 42 C.F.R. §§ 498.3(b)(17), 498.5(l)(2); *see also* 42 U.S.C. § 1395cc(j)(8).

IV. Findings of Fact, Conclusions of Law, and Analysis⁵

To receive Medicare payments for items furnished to a Medicare beneficiary, a supplier of medical equipment and supplies must have a supplier number issued by the Secretary of Health and Human Services. Social Security Act (Act) § 1834(j)(1)(A); 42 C.F.R. § 424.505. To obtain and retain its supplier number, a DMEPOS supplier must meet the standards set forth in 42 C.F.R. § 424.57(c), and CMS may revoke its billing privileges if it fails to do so. 42 C.F.R. §§ 424.57(c)(1), (e); 42 C.F.R. § 424.535(a)(1). To receive direct-billing privileges, a DMEPOS supplier must meet and maintain each of the

³ The first two exhibits consist of email communications between Petitioner's director and an attorney-advisor who had previously assisted me with this case. These email communications do not provide any substantive evidence in support of Petitioner's case. The third exhibit includes a September 9, 2016 letter from Petitioner, and that same letter is incorporated as pages 2 and 3 of Petitioner's brief. Exhibit 3 also contains a copy of the request for hearing, which is the first docket entry on the DAB E-File record of this case.

⁴ CMS has argued that summary disposition is appropriate. It is unnecessary in this instance to address the issue of summary disposition, as neither party has requested an in-person hearing.

⁵ My findings of fact and conclusions of law are set forth in bold and italics.

supplier enrollment standards, including the requirement to maintain a physical location that is accessible and staffed during posted hours. 42 C.F.R. § 424.57(c)(7)(i)(C). The supplier must also permit CMS or its agents to conduct on-site inspections to ascertain its compliance with governing regulations and ensure its location is accessible to various entities such as the public, CMS, and the NSC. 42 C.F.R. § 424.57(c)(7),(8).

CMS may revoke a currently enrolled DMEPOS supplier's Medicare enrollment and billing privileges if CMS determines, upon on-site review, that the DMEPOS supplier is no longer operational to furnish Medicare covered items or services, or the supplier fails to satisfy any 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.

§ 424.535(a)(5)(ii). After a DMEPOS supplier's Medicare enrollment and billing privileges are revoked, it is barred from reenrolling in the Medicare program for a period of one to three years. 42 C.F.R. § 424.535(c).

1. Petitioner's location at 869 South East Street in Anaheim, CA, was not open, accessible, and staffed when an inspector attempted to conduct a site inspection on both April 25 and 26, 2016.

On April 25, 2016, at 1:19 pm, and April 26, 2016, at 12:28 pm, a site inspector visited Petitioner's 869 South East Street location and observed that the door was locked and that no one answered the door when she knocked on it. CMS Ex. 2 at 3, 8. The inspector reported that Petitioner's hours of operation during weekdays were 9:00 am to 6:00 pm (CMS Ex. 2 at 4), and this is confirmed by Petitioner's enrollment application that was of record at the time of the attempted site visits. CMS Ex. 7 at 7. Petitioner admitted that it was "closed both times" and that the pharmacist "went to engage the local doctors in the area and could not be at the pharmacy at the stated hours," which were from "Monday – Friday 9 am to 6pm." CMS Exs. 3 at 1; 6 at 1.

Based on the undisputed evidence of record, the site inspector attempted to conduct two separate site inspections of Petitioner's location at 869 South East Street on April 25, 2016 at 1:19 pm, and April 26, 2016 at 12:28 pm, but the inspector was unable to complete the inspection because the office was closed and Petitioner's personnel were not present at the location.

2. CMS had a legitimate basis to revoke Petitioner's Medicare billing privileges because Petitioner's location was not accessible and staffed during posted hours of operation, and was not operational, as required by 42 C.F.R. §§ 424.57(c)(7) and 424.535(a)(5).

For a supplier to be “operational,” it 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 (emphasis added). Further, DMEPOS suppliers must permit CMS or its agents to conduct on-site inspections to ascertain supplier compliance with enrollment standards, and the supplier must be accessible and staffed during posted hours of operation to beneficiaries and to CMS. 42 C.F.R. § 424.57(c)(7)(i)(C). CMS may perform periodic site visits to determine whether the supplier is operational and complying with Medicare enrollment requirements. 42 C.F.R. §§ 424.510(d)(8), 424.515(c), 424.517(a).

The facts in this case establish that Petitioner’s location was not open and available for the site inspector to conduct an inspection on both April 25 and 26, 2016. Therefore, CMS had a legitimate basis to conclude that Petitioner was not operational under 42 C.F.R. § 424.535(a)(5)(ii) and was not in compliance with the supplier standards found at 42 C.F.R. § 424.57(c)(7)(i)(C).

A DMEPOS supplier is neither “open to the public” nor “accessible,” if the supplier location is closed because the staff is out for lunch, on a break, or making patient deliveries or visits. *See Ita Udeobong, d/b/a Midland Care Med. Supply & Equip.*, DAB No. 2324 at 6-7 (2010). Even if Petitioner’s pharmacist was not at its location because she was meeting with doctors in the area, such circumstances do not excuse Petitioner’s failure to be accessible and properly staffed when the site inspector attempted two separate inspections during Petitioner’s posted hours of normal operation. CMS Ex. 2 at 3, 8. A supplier may not close, even temporarily, during its posted hours of operation. *Complete Home Care Inc.*, DAB No. 2525 at 5 (2013). It is incumbent on Petitioner to make whatever reasonable arrangements are necessary to keep its business open while allowing for visits to doctors, patient consultations, and any necessary breaks for staff members. *See A to Z DME, LLC*, DAB CR1995 at 6 (2009), *aff’d* DAB No. 2303 (2010) (stating that a Medicare supplier is different than a private business and the requirement to be open at all times during normal business hours “reflects CMS’s determination that a supplier must be available to beneficiaries to meet their needs and to alleviate their medical conditions.”). Further, the rulemaking that clarified, revised, and added to the supplier standards in 42 C.F.R. § 424.57 addresses that the Secretary considered allowing facilities to temporarily close during posted hours to account for circumstances including short-term closures, and nonetheless chose to emphasize that a supplier’s place of business must always remain publicly accessible during posted hours. *Complete Home Care Inc.*, DAB No. 2525 at 6. The rulemaking explained, in addressing comments requesting an exemption for temporary closures due to reasons such as emergencies and unforeseen occurrences, that 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).

The undisputed evidence establishes that Petitioner's 869 South East Street location was not operational because it was not accessible and staffed during posted business hours; CMS properly revoked Petitioner's Medicare billing privileges. 42 C.F.R. §§ 424.57(c)(7)(i)(C), 424.535(a)(5). *See Care Pro Home Health Care*, DAB No. 2723 at 6 (2016) (holding that CMS lawfully revoked a supplier's Medicare enrollment based on its non-operational status at a single location); *see also Viora Home Health, Inc.*, DAB No. 2690 at 13 (2016) (holding that CMS properly revoked Medicare enrollment when a practice location of record was not operational upon onsite review).

In its brief, Petitioner does not dispute that it was not in compliance with 42 C.F.R. §§ 424.57(c)(7) and 424.535(a)(5). Rather, Petitioner's director explains that he attempted to obtain guidance from a Departmental Appeals Board attorney-advisor regarding how it could withdraw its request for hearing, and after he did not receive the requested information, he opted to file a brief seeking the following relief: "My only request is that you allow me to make a voluntary action for revocation instead of a penalty from CMS. I will not reapply based on an allotted [sic] time you recommend." P. Br. at 1 (emphasis omitted).

While Petitioner asks only that I allow it to "make it a voluntary action for revocation instead of a penalty from CMS," such relief is outside of my authority. The question before me is whether CMS had a legitimate basis to revoke Petitioner's Medicare enrollment and billing privileges. Based on the aforementioned reasons, CMS had a legitimate basis to revoke Petitioner's Medicare enrollment. Therefore, I cannot direct CMS to allow Petitioner to voluntarily terminate its Medicare enrollment.

V. Conclusion

I affirm the revocation of Petitioner's DMEPOS supplier number and Medicare billing privileges, effective April 26, 2016, pursuant to 42 C.F.R. §§ 424.57(c)(7)(i)(C) and 424.535(a)(5)(ii).

/s/
Leslie C. Rogall
Administrative Law Judge