

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Advanced Clinical Solutions, Inc.
(PTAN: 6373270001),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-16-405

Decision No. CR4621

Date: May 31, 2016

DECISION

The Centers for Medicare & Medicaid Services (CMS), through an administrative contractor, revoked the enrollment of Advanced Clinical Solutions, Inc. (Advanced Clinical Solutions or Petitioner) as a Medicare supplier of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) because Advanced Clinical Solutions was not accessible and staffed during posted hours of operation under 42 C.F.R. § 424.57(c)(7), was not operational under 42 C.F.R. § 424.535(a)(5), and did not report changes to its enrollment information under 42 C.F.R. § 424.57(c)(2). Advanced Clinical Solutions requested a hearing to dispute the revocation. Because Petitioner's office was neither staffed nor accessible when a site inspector attempted to conduct a site visit during Petitioner's posted hours of operation, and because Petitioner admits that no one was present at the office on the date of the attempted site visit, I conclude that Petitioner violated 42 C.F.R. § 424.57(c)(7). However, I also conclude that Advanced Clinical Solutions was still operational and did not fail to provide updated enrollment information. Therefore, I affirm CMS's determination to revoke the enrollment of Advanced Clinical Solutions from the Medicare program based on its failure to be accessible during posted hours of operation, but, because Petitioner was operational, I modify the effective date of revocation from November 18, 2015, to January 15, 2016.

I. Background

On May 28, 2010, CMS approved Petitioner's enrollment in the Medicare program as a DMEPOS supplier. CMS Exhibit (Ex.) 1. In a December 16, 2015 initial determination, a CMS administrative contractor revoked Advanced Clinical Solutions' Medicare enrollment and billing privileges. CMS Ex. 5. The initial determination provided several reasons for revocation:

42 CFR § 424.57(c)(2) . . . [Petitioner] *failed to notify the [CMS administrative contractor] regarding changes in [Petitioner's] supplier file including, but not limited to, address or closing of your business.*

42 CFR § 424.57(c)(7) . . . *Recently, a representative of the [CMS administrative contractor] attempted to conduct a visit of [Petitioner's] facility on November 10, 2015 and on November 18, 2015; however, the visits were unsuccessful because your business was closed during hours of operation posted which indicates that your business is no longer operational. Because we could not complete an inspection of your facility, we could not verify [Petitioner's] compliance with the supplier standards. Based upon a review of the facts, we have determined that [Petitioner's] facility is not operational to furnish Medicare covered items and services. Thus, [Petitioner is] considered to be in violation of 42 CFR §§ 424.535(a)(5), all supplier standards as defined in 42 CFR 424.57(c) and pursuant to 424.535(g), the revocation is effective the date CMS determined that [Petitioner was] no longer operational.*

42 CFR § 424.57(c)(10) . . . [Petitioner's] *insurance policy on file with the [CMS administrative contractor] expired on April 21, 2014. [Petitioner] failed to have a current comprehensive liability insurance policy that is required in this standard.*

CMS Ex. 5 at 1-2. The initial determination specified that the revocation was effective November 18, 2015, the date on which CMS determined Petitioner was not operational and that Petitioner was barred from reenrollment in the Medicare program for two years. CMS Ex. 5 at 1. Finally, the initial determination stated that Petitioner could file a corrective action plan (CAP) and a request for reconsideration. CMS Ex. 5 at 3.

Advanced Clinical Solutions filed a CAP. CMS Ex. 6. Although the CMS administrative contractor accepted the CAP regarding the violation of 42 C.F.R. § 424.57(c)(10), because Petitioner provided proof of its liability insurance coverage, the contractor rejected the CAP in relation to the violations of 42 C.F.R. § 424.57(c)(2) (failure to report a change in enrollment information) and 42 C.F.R. § 424.57(c)(7) (facility not accessible during posted hours of operation). The CMS administrative contractor also noted that the regulations prohibited it from considering a CAP for a violation of 42 C.F.R. § 424.535(a)(5) (not operational). CMS Ex. 7 at 3.

Petitioner subsequently requested reconsideration. *See* CMS Ex. 8. On February 25, 2016, a hearing officer employed by the CMS administrative contractor issued an unfavorable reconsidered determination that upheld the findings that Advanced Clinical Solutions violated 42 C.F.R. §§ 424.57(c)(2) and (7), 424.535(a)(5), and that the revocation should be retroactive to November 18, 2015. CMS Ex. 9.

On March 7, 2016, Advanced Clinical Solutions requested a hearing before an administrative law judge (Hearing Request). Petitioner included a number of documents with the hearing request (Hearing Request Attachments).¹ I issued an Acknowledgment and Pre-hearing Order (Order) on March 22, 2016. In response to my Order, CMS filed a brief and ten exhibits (CMS Exs. 1-10). Petitioner filed a brief (P. Br.) and two exhibits (P. Exs. 1-2).

II. Decision on the Record

I admit all of the parties' proposed exhibits into the record because neither party objected to them. Order ¶ 7; Civil Remedies Division Procedures (CRDP) § 14(e).

Further, I admit documents into the record that Petitioner submitted with its hearing request that are not duplicative of those submitted as CMS's exhibits. Hearing Request Attachments at 18-24. Petitioner submitted these documents with its reconsideration request (*see* Hearing Request at 1-2); therefore, they are not new evidence under 42 C.F.R. § 498.56(e). Further, CMS's failure to file a copy of Petitioner's reconsideration request as one of its exhibits is unusual and unexplained. Although

¹ Petitioner's Hearing Request and Hearing Request Attachments were uploaded in a pdf format into the Departmental Appeals Board Electronic Filing System (DAB E-File) as Item #1 (titled "Request for Hearing") and #1a (titled "Original Case Decision), respectively. The Hearing Request Attachments file includes copies of the initial determination, the CAP decision, the reconsidered determination, and other documents related to Petitioner's business. The Hearing Request Attachments consists of a total of 25 pages and, in this decision, I will cite to the corresponding pdf file page when referring to a specific document.

Petitioner, which is not represented by counsel, did not resubmit the documents in Hearing Request Attachments pages 18-24 as marked exhibits, I waive that requirement. These documents are relevant and material to this case. 42 C.F.R. § 498.60(b).

I directed the parties to submit written direct testimony for each proposed witness. Order ¶ 8. CMS submitted written direct testimony from one witness (CMS Ex. 10). Petitioner did not submit written direct testimony for any witnesses. I advised the parties in my Order that an in-person hearing would only be necessary if the opposing party requested an opportunity to cross-examine a witness. Order ¶ 9 (“I will assume that Petitioner does not wish to cross-examine any proposed CMS witness if Petitioner’s brief fails to affirmatively state so.”); CRDP § 16(b). Because Petitioner did not request to cross-examine CMS’s witness, I decide this case based on the written record. Order ¶¶ 10-11; CRDP § 19(b), (d).

III. Issue

Whether CMS had a legitimate basis to revoke Petitioner’s Medicare enrollment and billing privileges.

IV. Jurisdiction

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

V. Findings of Fact, Conclusions of Law, and Analysis²

The Secretary of Health and Human Services (Secretary) has the authority to create regulations that establish enrollment standards for providers and suppliers, and to create supplier requirements for DMEPOS suppliers. 42 U.S.C. §§ 1395m(j)(1)(B)(ii), 1395cc(j). The Secretary promulgated a regulation that requires providers and suppliers to be operational. 42 C.F.R. § 424.535(a)(5). To be “operational,” a provider or supplier must be “open to the public for the purpose of providing health care related services” 42 C.F.R. § 424.502. The Secretary also promulgated regulations establishing DMEPOS supplier standards, which a DMEPOS supplier must meet and maintain. 42 C.F.R. § 424.57(c). The supplier standards require a DMEPOS supplier to report, within 30 days, any changes to information it had previously provided to CMS on its Medicare enrollment application. 42 C.F.R. § 424.57(c)(2). Further, a DMEPOS supplier must be “open to the public a minimum of 30 hours per week,” post its hours of operation, and be “accessible and staffed during posted hours of operation.” 42 C.F.R.

² My numbered findings of fact and conclusions of law are set forth below in italics and bold.

§ 424.57(c)(7)(i), (c)(30). CMS or its contractors may conduct inspections of a supplier's premises at any time to determine if a supplier is in compliance with Medicare enrollment requirements or the supplier standards. *See* 42 C.F.R. §§ 424.57(c)(8), 424.510(d)(8), 424.515(c), 424.517(a). A supplier is subject to revocation of its Medicare billing privileges if it violates the DMEPOS supplier standards or the regulatory requirements applicable to all suppliers. 42 C.F.R. §§ 424.57(e)(1), 424.535(a).

1. ***On November 16, 2015, at approximately 12:30 p.m. and November 18, 2015, at approximately 11:50 a.m., a site inspector from a CMS administrative contractor was unable to gain entry into Advanced Clinical Solutions' office at 1836 Techny Court, Northbrook, Illinois, because the door was locked and no one answered the door when the site inspectors knocked.***

On November 16, 2015, at approximately 12:30 p.m., a site inspector with a CMS administrative contractor attempted a site visit at Advanced Clinical Solutions' office at 1836 Techny Court. The site inspector knocked on the door, but no one answered. Further, the site inspector took pictures of the front door to Advanced Clinical Solutions' office, which show the date and time that the inspector took the pictures. The photographs show that Advanced Clinical Solutions' front door bears its name, hours of operation (9 a.m. to 4 p.m.), and telephone number. CMS Ex. 2 at 1, 6; CMS Ex. 3; CMS Ex. 10 ¶ 2.

On November 18, 2015, at approximately 11:50 a.m., the site inspector again attempted a site visit at Advanced Clinical Solutions' office at 1836 Techny Court. The site inspector knocked at the door, but no one answered. The site inspector again took pictures of the front door to Advanced Clinical Solutions' office. CMS Ex. 2 at 1, 6; CMS Ex. 4; CMS Ex. 10 ¶ 3.

The site inspector completed a report on November 20, 2015. CMS Ex. 2; CMS Ex. 10 ¶ 4. In that report, the inspector noted that Petitioner's office: was not in a restricted area (i.e., gated community); was accessible to the disabled; had a permanent, visible sign with Petitioner's name on it; and had its hours of operation posted. CMS Ex. 2 at 1-2. The inspector also indicated that he was unable to complete the inspection. CMS Ex. 2 at 2. Finally, the inspector provided the following comments of his investigation:

Supplier was closed on both attempts. I spoke to a neighboring business and was told that the supplier is still open. When open, it is normally earlier in the morning.

CMS Ex. 2 at 6.

Petitioner admits that its office was closed on both days the site inspector attempted to conduct its site inspection. Hearing Request at 1. Therefore, I find that the site inspector

attempted site visits at Petitioner's office on November 16 and 18, 2015, but that no one was present at Petitioner's office to allow the site inspector to enter the office.

2. CMS had a legitimate basis to revoke Petitioner's Medicare enrollment and billing privileges because Petitioner's location was not accessible and staffed during posted hours of operation in violation of 42 C.F.R. § 424.57(c)(7).

Advanced Clinical Solution's posted office hours of operation are 9:00 a.m. to 4:00 p.m., Monday to Friday. CMS Exs. 3, 4. Petitioner is obligated to be accessible and staffed during its posted hours of operation. 42 C.F.R. § 424.57(c)(7). However, during the posted hours of operation on November 18, 2015,³ Petitioner did not have staff present at its office and its office door was locked. Therefore, Petitioner failed to comply with 42 C.F.R. § 424.57(c)(7).

Petitioner asserts that it has two owners and no other employees, and that they were not present at Petitioner's office because both owners were making emergency deliveries to patients. The reason for the emergency deliveries appears to stem from the fact that Petitioner had just completed a lengthy accreditation process and the Thanksgiving holiday was approaching. Petitioner also asserts that the site inspector in this case had previously conducted site inspections at Petitioner's office and that the inspector had told Petitioner's owners that they could place a note on the door whenever they were absent during posted hours of operation. Petitioner asserts it placed such a note on the door on November 18, 2015, when both owners were absent from the office. Hearing Request at 1-2; P. Br.; P. Exs. 1-2; CMS Ex. 6.

Petitioner's arguments are not availing. The requirement to be staffed and accessible during normal hours of operation is a rule that has few exceptions. *See Norpro Orthotics & Prosthetics, Inc.*, DAB No. 2577, at 5 (2014) (indicating that the regulatory history of 42 C.F.R. § 424.57(c)(7) makes exceptions for disasters, emergencies, and state and federal holidays); *see also Benson Ejindu*, DAB No. 2572, at 6 (2014). A DMEPOS supplier is not "accessible" if the supplier's location is closed because the staff is out for lunch, on a break, making patient visits, or out of the office for any reason. *See Ita Udeobong*, DAB No. 2324, at 6-7 (2010). A supplier may not close, even temporarily,

³ The reconsidered determination is predicated on the site inspector not being able to access Petitioner's office on both November 10, 2015, and November 18, 2015. CMS Ex. 9 at 1-3, 5. The hearing officer specifically made a finding of fact that the attempted site visits occurred on November 10, 2015, and November 18, 2015. CMS Ex. 9 at 1. However, the weight of evidence in the record reveals that the site inspector did not make a failed attempt at conducting a site visit at Petitioner's office on November 10, 2015, but rather on November 16, 2015. CMS Ex. 3; CMS Ex. 10 ¶ 2; *but see* CMS Ex. 2 at 1. Due to this conflict in the evidence, I cannot find that a failed site visit occurred on November 10, 2015, as the reconsidered determination indicates.

during its posted hours of operation. *Complete Home Care, Inc.*, DAB No. 2525, at 5 (2013). Even if the staff of a DMEPOS supplier is present at its office, but the door is locked and the staff do not hear the knock of an inspector, then the office is not accessible under 42 C.F.R. § 424.57(c)(7). *Benson Ejindu*, DAB No. 2572, at 6-7. Although Petitioner indicates its owners were making emergency deliveries, it did not submit evidence to support that contention. Further, Petitioner does not contend that the Thanksgiving holiday actually took place on November 18, 2015. Finally, even if Petitioner left a note on its door indicating that staff would return, this is not a legal excuse for failing to provide an accessible office during the posted hours of operation. *See Complete Home Care*, DAB No. 2525, at 5-6.

I conclude that Petitioner violated 42 C.F.R. § 424.57(c)(7) because its office was not accessible on November 18, 2015.

3. *CMS did not have a legitimate basis to revoke Petitioner's Medicare billing privileges based on a finding that Petitioner was not operational under 42 C.F.R. § 424.535(a)(5).*

Suppliers must be operational or they are subject to revocation. 42 C.F.R. § 424.535(a)(5). A supplier is operational if 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. Although the requirement to be operational has significant similarities to the DMEPOS supplier standard that requires a DMEPOS's facility be staffed and accessible to the public during posted hours of operation (i.e., 42 C.F.R. § 424.57(c)(7)), it is important to note that the requirement to be "operational" is not a DMEPOS supplier standard. Instead, it applies to all suppliers. Therefore, a DMEPOS supplier could be "operational," but still not meet all of the strict requirements of the DMEPOS supplier standards.

In the present case, there is sufficient evidence that Petitioner was operational. The site inspector's investigation revealed that a neighboring businessman stated that Petitioner was still open, mostly in the mornings. CMS Ex. 2 at 6. Although Petitioner asserts it is staffed and open more often than just in the morning hours, it is clear that Petitioner's position is that it is open and staffed most of the time. P. Br. at 1; Hearing Request at 1. The site inspector also confirmed that Petitioner has an office, with a sign and posted

hours of operation. CMS Ex. 2 at 1-2; CMS Ex. 3; CMS Ex. 4. Further, Petitioner provided documentation that it is licensed as a medical equipment supplier until 2018, is registered as a business until 2019, insured until 2016, and has a lease for its office space until 2019. Hearing Request Attachments at 18-20, 22-24. Significantly, on November 18, 2015, the date that the CMS administrative contractor found Petitioner to be no longer operational, the Accreditation Commission for Health Care certified that Petitioner “has demonstrated a commitment to providing quality care and services to consumers through compliance with . . . nationally recognized standards for accreditation and is therefore granted accreditation for . . . DMEPOS.” Hearing Request Attachments at 21. I conclude that while Petitioner was not always open during its posted hours of operation, it was still open and staffed to provide health care related services sufficiently to avoid a violation of 42 C.F.R. § 424.535(a)(5).

4. CMS did not have a legitimate basis to revoke Petitioner’s Medicare billing privileges based on a finding that Petitioner failed to report that it closed its business within 30 days under 42 C.F.R. § 424.57(c)(2).

DMEPOS suppliers are required to report changes in the information the supplier provided to CMS on its enrollment application within 30 days of the change. 42 C.F.R. § 424.57(c)(2). There is no evidence in this case that Petitioner’s enrollment information changed. While Petitioner appears to have deviated from its hours of operation on an ad hoc basis, such a minimal change in its hours is insignificant and, as already indicated above, is properly sanctioned under 42 C.F.R. § 424.57(c)(7). To the extent that CMS asserts Petitioner’s business is closed and that this should have been reported (CMS Ex. 5 at 1), the evidence of record, as discussed above, establishes that Petitioner’s business is not closed.

5. Petitioner’s Medicare enrollment and billing privileges must be revoked, but the effective date of revocation is changed to January 15, 2016.

CMS imposed a retroactive revocation effective date in this case due to its finding that Petitioner was not operational. CMS Ex. 5 at 2, CMS Ex. 9 at 5; 42 C.F.R. § 424.535(g). However, based on my conclusion that Petitioner was not properly revoked for being non-operational, I must modify the effective date of revocation.

Because Petitioner violated 42 C.F.R. § 424.57(c)(7), CMS was required to revoke Petitioner 30 days after the date that CMS sent the revocation notice to Petitioner. 42 C.F.R. § 424.57(e)(1). CMS sent Petitioner the initial determination to revoke on December 16, 2015 (CMS Ex. 5 at 1); therefore, the effective date of Petitioner’s revocation is January 15, 2016. Petitioner may seek reimbursement for items and services provided to Medicare beneficiaries through January 14, 2016.

VI. Conclusion

I affirm CMS's revocation of Advanced Clinical Solutions' Medicare enrollment and billing privileges. I modify the effective date of revocation from November 18, 2015, to January 15, 2016.

/s/
Scott Anderson
Administrative Law Judge