

**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Metropolitan Urologic Specialists, PA, d/b/a Metro Urology  
(PTAN: 025299001),

Petitioner,

v.

Centers for Medicare & Medicaid Services

Docket No. C-14-1557

Decision No. CR3579

Date: January 20, 2015

**DECISION**

Palmetto GBA National Supplier Clearinghouse (NSC), an administrative contractor acting on behalf of the Centers for Medicare & Medicaid Services (CMS), determined that Petitioner, Metropolitan Urologic Specialists, PA, d/b/a Metro Urology, failed to allow NSC or its agent access to perform on-site inspections in order to ascertain Petitioner's compliance with the durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS) supplier standards. Based on this conclusion, NSC revoked Petitioner's Medicare billing privileges. Petitioner requested a hearing to dispute NSC's determination. For the reasons stated below, I uphold CMS's determination to revoke Petitioner's Medicare billing privileges because Petitioner did not comply with 42 C.F.R. § 424.57(c)(8). However, I establish a new effective date of May 9, 2014, for the revocation, which is 30 days after NSC's initial determination.

**I. Background and Procedural History**

Petitioner was enrolled in the Medicare program as a DMEPOS supplier. *See* CMS Exhibit (Ex.) 1 at 1; CMS Ex. 3 at 1, 5. On October 3, 2013, Petitioner submitted a revalidation application for its enrollment as a DMEPOS supplier. CMS Ex. 3 at 1. In

conjunction with the revalidation process, NSC directed Overland Solutions, Inc. (OSI), an NSC subcontractor, to conduct a visual inspection of Petitioner. CMS Ex. 3 at 1, 8, 9; *see also* CMS Ex. 1 at 1. On December 5, 2013, and December 12, 2013, the OSI inspector attempted to conduct site inspections at the address CMS had on file for Petitioner's place of business. CMS Exs. 1, 3, 5. The inspector was not granted access to Petitioner's facility on either date and, on April 9, 2014, NSC issued an initial determination revoking Petitioner's Medicare supplier number and related billing privileges pursuant to 42 C.F.R. §§ 405.800, 424.57(e), 424.535(a)(1), (a)(5)(ii), and 424.535(g) because Petitioner was not in compliance with two supplier standards: 42 C.F.R. § 424.57(c)(7) -Supplier Standard 7, and 42 C.F.R. § 424.57(c)(8) – Supplier Standard 8. CMS Ex. 2. The notice also indicated Petitioner was not operational under 42 C.F.R. § 424.535(a)(5)(ii). CMS Ex. 2 at 2. In its notice to Petitioner, NSC stated that the revocation was retroactive to December 12, 2013, the date CMS determined that Petitioner's practice location was not operational. CMS Ex. 2, at 1. NSC barred Petitioner from re-enrolling in the Medicare program for two years from the effective date of the revocation. CMS Ex. 2, at 1.

Petitioner filed a timely request for reconsideration with NSC. CMS Ex. 4. On May 12, 2014, an NSC hearing officer issued an unfavorable reconsidered determination upholding the revocation of Petitioner's Medicare billing privileges. CMS Ex. 4. The reconsidered determination upheld revocation based on Petitioner's failure to be accessible and staffed during posted hours of operation (42 C.F.R. § 424.57(c)(7)), and failure to allow CMS or its agents to conduct on-site inspections to determine compliance with the supplier standards (42 C.F.R. § 424.57(c)(8)). CMS Ex. 4, at 2-5. The NSC hearing officer did not indicate that Petitioner was not operational (42 C.F.R. § 424.535(a)(5)(ii)) or state the effective date of the revocation.

On July 23, 2014, Petitioner timely filed a request for hearing (RFH). On August 1, 2014, I issued an Acknowledgement and Prehearing Order (Order). In response to the Order, CMS filed a motion for summary judgment with five exhibits (CMS Exs. 1-5). Petitioner filed a brief in response (P. Br.), which included a motion for summary judgment, and two exhibits (P. Exs. 1-2).

## **II. Evidentiary Ruling and Decision on the Record**

I admit CMS Exs. 1-5 and P. Ex. 1, without objection from the parties.

I exclude P. Ex. 2 from the record. CMS objects to this exhibit because Petitioner should have submitted this exhibit with its reconsideration request and there is no good cause for the late submission. Petitioner argues that there is good cause because Petitioner did not know, at the reconsideration stage, that the inspector did not take pictures of the waiting area of Petitioner's offices (he only took pictures of the exterior as seen in CMS Ex. 1 at 1), and only learned this with the submission of CMS's exhibits in this case.

If a supplier does not show good cause for submitting new evidence at the hearing stage of a provider enrollment case, then that new evidence must be excluded from the record. 42 C.F.R. § 498.56(e)(2)(ii). I do not find good cause exists for submitting this evidence for the first time because the initial determination expressly placed Petitioner on notice that revocation was based, in part, on a lack of accessibility to its facility and a finding that Petitioner was not operational. CMS Ex. 2. Any evidence Petitioner wanted to present regarding its accessibility, or to show it was operational, should have been submitted with its reconsideration request. In any event, as explained below, the question as to whether Petitioner was non-operational is not before me and I find it is unnecessary to decide whether Petitioner was in compliance with section 424.57(c)(7). Therefore, the exclusion of P Ex. 2 does not affect this decision.

I decide this case on the written record. Both parties submitted written direct testimony (CMS Ex. 5 and P. Ex. 1); however, neither party requested to cross-examine the other party's witness as required by my Order. Order ¶ 8-10. Therefore, there is no reason for a hearing. Order ¶ 11; *Marcus Singel, D.P.M.*, DAB No. 2609, at 5-6 (2014).

### III. Issues

1. Whether CMS had a legitimate basis for revoking Petitioner's Medicare billing privileges for failing to allow the agents of CMS or NSC to conduct on-site inspections to ascertain compliance with the requirements of the supplier standards, in violation of Supplier Standard 8 (42 C.F.R. § 424.57(c)(8)).<sup>1</sup>
2. If CMS had a legitimate basis for revoking Petitioner's Medicare billing privileges under 42 C.F.R. § 424.57(c)(8), but CMS cannot rely on its previous finding of a violation under 42 C.F.R. § 424.535(a)(5)(ii) as a basis for revocation,<sup>2</sup> does the effective date of Petitioner's revocation need to be adjusted.

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<sup>1</sup> As explained below, I conclude that Petitioner violated 42 C.F.R. § 424.57(c)(8). Because a violation of one of the supplier standard is sufficient to uphold revocation (*See 1866ICPayday.com, L.L.C.*, DAB No. 2289, at 13 (2009)), I will not decide whether Petitioner violated 42 C.F.R. § 424.57(c)(7). The record shows that the site inspector encountered personnel from Petitioner's office on both visits and was able to enter the reception area, evidencing at least some level of staffing and accessibility. However, the inspector was actually unable to conduct the site visit because he was denied access to the premises. CMS Ex. 5 ¶¶ 4, 7; P. Br. at 2, 4.

<sup>2</sup> Although the reconsidered determination defined the term "operational," the NSC hearing officer did not expressly uphold the initial determination's finding that Petitioner was not operational under 42 C.F.R. § 424.535(a)(5)(ii). My review is limited to the issues in the reconsidered determination (*Neb Group of Arizona, LLC*, DAB No. 2573, at 7 (2014)), therefore, the question whether Petitioner was operational is not before me.

#### IV. Jurisdiction

I have jurisdiction to decide the issues in this case. 42 C.F.R. §§ 405.803, 498.3(b)(15), 498.3(b)(17), 498.5(1)(2); *see also* 42 U.S.C. § 1395cc(j)(8).

#### V. Findings of Fact, Conclusions of Law, and Analysis<sup>3</sup>

In order for a DMEPOS supplier to qualify for continued enrollment in the Medicare program, a supplier must satisfy the criteria set forth in the Social Security Act and Department of Health and Human Services' (HHS) regulations. 42 U.S.C. § 1395m(j); 42 C.F.R. part 424. HHS promulgated regulations establishing the supplier standards that a DMEPOS supplier must meet to enroll and to maintain enrollment. 42 C.F.R. § 424.57(c). Supplier Standard 8 mandates that a supplier allow "CMS, NSC, or agents of CMS or NSC to conduct on-site inspections to ascertain supplier compliance with the requirements of this section." 42 C.F.R. § 424.57(c)(8).

***1. On December 5 and December 12, 2013, Petitioner's employees denied an inspector, acting on behalf of NSC, entry to Petitioner's offices to perform an on-site inspection in order to ascertain whether Petitioner was in compliance with supplier standards.***

On November 5, 2013, NSC placed a work order with OSI to complete a visual inspection of Petitioner's offices. CMS Ex. 3 at 8-9. OSI sent Donald Andren, an inspector employed with OSI, a work order to conduct the site survey. CMS Ex. 5 ¶¶ 1-3. On December 5, 2013, Inspector Andren attempted to inspect Petitioner's offices. CMS Exs. 1; 5. At 1:50 p.m., Inspector Andren entered Petitioner's reception area and informed Petitioner's receptionist that he was there to inspect Petitioner for NSC. CMS Ex. 5 ¶ 4. The receptionist connected Inspector Andren by phone to Stacey Sandberg, the contact person identified in the work order he received from OSI. CMS Ex. 3 at 8. Ms. Sandberg informed Inspector Andren that he could not enter the premises without making an appointment with management. CMS Ex. 5 ¶ 4. Before leaving, Inspector Andren gave the receptionist his business card and a letter of introduction that explained that OSI is authorized to perform Medicare inspections by NSC and that failure to cooperate can result in revocation. That letter also provided a toll free number at NSC that a supplier could call to confirm authorization. The receptionist told him that someone from management would call him to make an appointment. RFH at 21; CMS Ex. 3 at 5, 8-9; CMS Ex. 5 ¶ 4.

Inspector Andren did not receive a return phone call and emailed Ms. Sandberg on December 9, 2013, attaching his work order as additional proof of his authenticity. CMS Ex. 3 at 7-9; CMS Ex. 5 ¶ 5; P. Ex. 1 ¶ 2. Ms. Sandberg responded, asking what

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<sup>3</sup> My numbered findings of fact and conclusions of law appear in bold and italics.

specifically he wanted to “come in and review.” RFH at 23; CMS Ex. 3 at 6; P. Ex. 1 ¶ 3. Inspector Andren replied that he needed only to view the supplies sold to Medicare beneficiaries to verify that Petitioner in fact has inventory. RFH at 22; CMS Ex. 3 at 6; P. Ex. 1 ¶ 4. Ms. Sandberg again said she would have to have additional information about the inspection before Inspector Andren would be allowed to conduct the site visit. RFH at 20; CMS Ex. 3 at 3; P. Ex. 1 ¶ 5.

Following the email message exchange, Inspector Andren telephoned and spoke with Ms. Sandberg. CMS Ex. 5 ¶ 6. He again gave her the NSC toll free number ((866) 238-9652), which appears on the letter of introduction, and suggested she call to confirm that he was authorized to inspect Petitioner on behalf of NSC. CMS Ex. 3 at 5; CMS Ex. 5 ¶ 6; P. Ex. 1 ¶ 7. She refused. CMS Ex. 5 ¶ 6; *see also* P. Ex. 1 (Ms. Sandberg did not testify she called NSC to verify the inspection).

On December 12, 2013, Inspector Andren returned to Petitioner’s offices to attempt to conduct the inspection. CMS Ex. 1 at 1; CMS Ex. 5 ¶ 7. He entered the reception area and asked to see Ms. Sandberg, but was informed she was not there. CMS Ex. 5 ¶ 7; *see also* P. Ex. 1 ¶ 9. Inspector asked for access to the inventory in order to conduct the inspection. CMS Ex. 5 ¶ 7. He again was informed he could not enter without an appointment with management. CMS Ex. 5 ¶ 7. As a result, Inspector Andren reported that although he attempted on two occasions to conduct a site visit of Petitioner’s offices, he was unsuccessful because he was denied access to the premises beyond the reception area. CMS Ex 1 at 1; CMS Ex. 5 ¶¶ 7-8. He could not complete an inspection and, therefore, could not verify whether Petitioner was compliant with the supplier standards.

***2. Petitioner violated Supplier Standard 8 (42 C.F.R. § 424.57(c)(8)) because Petitioner refused to allowed an inspector, acting on behalf of NSC, to enter Petitioner’s offices to perform an on-site inspection in order to ascertain whether Petitioner was in compliance with supplier standards.***

Petitioner admits it denied access to its offices to Inspector Andren, but asserts that it was obligated to do so. Petitioner argues that the site inspector did not show a photographic identification or a letter proving his authority to conduct the site inspection. P. Br. at 6-8. The record supports Petitioner’s position.<sup>4</sup> Petitioner quotes from NSC’s website frequently asked questions (FAQ) that indicates inspectors will have a photographic identification and a signed letter on CMS letterhead, and that suppliers ought not to give information to an inspector who is not properly credentialed. P. Br. at 6.

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<sup>4</sup> The site inspector’s written direct testimony states that he gave the receptionist his business card and letter of introduction, a generic letter from NSC on behalf of CMS, which explained that OSI is authorized to perform Medicare inspections by NSC and that failure to cooperate can result in revocation. CMS Ex. 5 ¶ 4.

Petitioner's concerns over the inspector's lack of credentials justify its initial refusal to permit Mr. Andren to enter its offices. However, as indicated in the NSC FAQs, Petitioner was obligated to notify NSC of the situation at the following phone number: (866) 238-9652. P. Br. at 6. Petitioner did not do this. After turning Inspector Andren away, Petitioner's receptionist said that he would receive a phone call concerning the inspection; however, Petitioner did not contact Inspector Andren.

After the inspector initially attempted to conduct a site inspection on December 5, 2013, the inspector made contact with Ms. Sandberg, one of Petitioner's managers by email, and on December 9 forwarded the work order under which the inspector was operating (the first line of the first page indicates that the work order was for a "NSC – Visual Inspection" and further down, for "Metropolitan Urological Specialists PA" at Petitioner's address). CMS Ex. 3, at 7-8. When Ms. Sandberg questioned the document, the inspector left a voicemail for the manager and then, on December 11, forwarded again by email the generic letter about the authorization to conduct the inspection. CMS Ex. 3 at 3-6. Significantly, the phone number given in the generic letter for a supplier to call to verify that the inspection was legitimate was the same number as that on the NSC's website FAQs. *Compare* CMS Ex. 3 at 5 *with* P. Br. at 6.

Although both parties portray Petitioner's manager with different degrees of motivation to call the NSC phone number and confirm that the inspection was authorized, compare CMS Ex. 5 ¶ 6 (testimony that manager refused to call the number) with RFH at 3 (indicating that Petitioner verified the inspection was authentic, but only after the Dec. 12, 2013 attempted inspection), I will accept the inspector's testimony because Petitioner's witness' testimony does not refute the inspector's testimony. P. Ex. 1.

Petitioner should have made every effort to confirm the validity of the inspection because Petitioner is under an obligation to permit inspections. Applicable regulations permit CMS to perform site inspection to verify enrollment requirements are met when applying for enrollment (42 C.F.R. § 424.510(d)(8)), seeking revalidation of enrollment (42 C.F.R. § 424.515(c)), or at any other time (42 C.F.R. § 424.517). The regulations also provide that CMS may deny enrollment or revoke enrollment if, based upon on-site review, it determines that the supplier fails to satisfy Medicare enrollment requirements. 42 C.F.R. §§ 424.530(a)(5) and 424.535(a)(5). Petitioner was a DMEPOS supplier that had recently filed a revalidation application. Petitioner should have expected the possibility of an inspection. When an inspector appeared, Petitioner was obligated to take action to confirm whether the inspection was legitimate.

For his part, the inspector tried to convince Petitioner he was acting under NSC's authority. NSC conducts unannounced inspections and the time the inspector spent attempting to persuade Petitioner that he was authorized to conduct the inspection had the potential for undermining the purpose behind conducting an unannounced inspection. 75 Fed. Reg. 52,629, 52,637-52,638 ("We have found unannounced on-site visits to be a

very effective tool in combating fraud and abuse and to protect the Medicare Trust Fund from unscrupulous suppliers. Moreover, CMS and our designated contractor, the NSC, have conducted unannounced on-site visits since 2000 to ensure compliance with those standards which only can be verified by visual inspection.”), 52,644 (“maintain[ing] a minimum number of hours open to the public . . . will ensure that the DMEPOS supplier is operational and allows CMS, the NSC or agents of CMS or the NSC to conduct unannounced site visits to ensure compliance with the standards set forth at § 424.57.”) (Aug. 27, 2010).

Although it is unclear why Inspector Andren does not appear to have the credentials listed on the NSC FAQs, Inspector Andren provided Petitioner with the necessary information for Petitioner to confirm that NSC authorized the inspection. I conclude that Petitioner’s refusal to allow the inspector to conduct the site visit in conjunction with Petitioner’s refusal to contact NSC to confirm whether the inspection was valid is a violation of 42 CFR 424.57(c)(8).

- 3. Because revocation is premised only on a violation of Supplier Standard 8 and not a finding that Petitioner was not operational, the retroactive effective date of the revocation imposed by CMS in the initial determination is no longer appropriate, and the effective date must be changed from December 12, 2013, to May 9, 2014, which is 30 days after the date CMS mailed its initial determination to revoke Petitioner’s billing privileges in this case.***

NSC’s April 9, 2014 initial determination imposed an effective date of revocation that was retroactive to December 12, 2013, the date that Petitioner was found not to be operational. CMS Ex. 2, at 1. This is appropriate under 42 C.F.R. § 424.535(g) when CMS has made a finding that a supplier is not operational pursuant to 42 C.F.R. § 424.535(a)(5)(ii). However, because the reconsidered determination in this case failed to make a finding that Petitioner was not operational, there is no longer a valid reason to impose a retroactive effective date of revocation.

As a recent DAB decision on this issue:

Because the sole basis for revocation properly decided by the ALJ and affirmed by the Board in this appeal is [Petitioner’s] noncompliance with Supplier Standard 7, the effective date of revocation should be determined in accordance with section 424.57(e)’s effective-date provision . . . . Applying that rule here, we conclude that the proper effective date of the revocation is . . . 30 days from the date of NSC’s letter notifying [Petitioner] of the revocation.

*Orthopaedic Surgery Associates*, DAB No. 2594, at 8 (2014).

Having found that Petitioner was not in compliance with Supplier Standard 8 (42 C.F.R. § 424.57(c)(8)), I uphold CMS's revocation of Petitioner's Medicare billing privileges, but set a new revocation effective date of May 9, 2014. This is 30 days from the date of the April 9, 2014 initial determination in this case.

## **VI. Conclusion**

For the reasons stated above, I affirm CMS's revocation of Petitioner's Medicare billing privileges, but modify the effective date of the revocation to May 9, 2014.

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/s/  
Scott Anderson  
Administrative Law Judge