Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Better Living/Better Health, LLC,

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-13-1119

ALJ Ruling No. 2014-36

Date: July 11, 2014

ORDER OF REMAND

Palmetto GBA National Supplier Clearinghouse (NSC), an administrative contractor acting on behalf of the Centers for Medicare & Medicaid Services (CMS), determined that Petitioner, Better Living/Better Health, LLC, failed to be accessible and staffed during posted hours of operation. Because NSC revoked Petitioner's Medicare billing privileges, Petitioner requested a hearing before an administrative law judge to dispute NSC's determination. For the reasons stated below, I remand this case to CMS.

I. Background

Petitioner was enrolled in the Medicare program as a supplier of durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS). *See* CMS Exhibit (Ex.) 1, at 3. On April 9 and 10, 2013, an NSC inspector attempted to conduct a site inspection at Petitioner's location on file with CMS. CMS Ex. 3, at 20-31. The NSC inspector could not complete an inspection on either date and, on April 25, 2013, NSC issued an initial determination revoking Petitioner's Medicare supplier number because Petitioner: was not operational (42 C.F.R. § 424.535(a)(5)(ii)); was not accessible or staffed during posted hours of operation (42 C.F.R. § 424.57(c)(7)); did not have comprehensive liability insurance in an amount equal to at least $300,000 (42 C.F.R. § 424.57(c)(10));

and was not accredited by a CMS-approved accrediting organization (42 C.F.R. § 424.57(c)(22)). CMS Ex. 3, at 17-18. NSC stated that the revocation was effective April 10, 2013, the date CMS determined that Petitioner's practice location was not operational. CMS Ex. 3, at 17. NSC barred Petitioner from re-enrolling in the Medicare program for two years from the effective date. CMS Ex. 3, at 17.

On May 16, 2013, Petitioner filed a timely request for reconsideration with NSC. CMS Ex. 3, at 7-19. On June 24, 2013, an NSC hearing officer issued an unfavorable reconsidered determination upholding the revocation of Petitioner's Medicare billing privileges. CMS Ex. 2. The reconsidered determination expressly upheld revocation based on Petitioner's failure to be open during posted hours of operation and not properly staffed (42 C.F.R. § 424.57(c)(7)), and failure to be accredited by a CMS-approved accrediting organization (42 C.F.R. § 424.57(c)(22)). CMS Ex. 2, at 3-4. The reconsidered determination also found Petitioner compliant with the requirement that it have liability insurance (42 C.F.R. § 424.57(c)(10)). CMS Ex. 2, at 4. The reconsidered determination did not directly address whether it upheld the failure to be operational (42 C.F.R. § 424.535(a)(5)(ii)). CMS Ex. 2.

On August 2, 2013, Petitioner timely filed a request for hearing (RFH) before an administrative law judge. On August 9, 2013, I issued an Acknowledgement and Pre-hearing Order (Order). Pursuant to the Order, CMS filed a motion for summary judgment (CMS Motion) with four exhibits (CMS Exs. 1-4). Petitioner submitted a brief in opposition to the CMS Motion (P. Opposition) with nine exhibits (P. Exs. 1-9).

My 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. Order ¶¶ 8-11; *see Vandalia Park*, DAB No. 1940 (2004); *Pacific Regency Arvin*, DAB No. 1823, at 7-8 (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 witnesses).[1] Here, CMS listed one witness, the NSC inspector, and relied on his site investigation report as his written direct testimony. *See* CMS Ex. 3, at 20-31. Petitioner requested to cross-examine the NSC inspector and listed as witnesses its owner and operator, Marlene Thomas, and two other individuals whose businesses are on the same street as Petitioner. Petitioner submitted their affidavits as P. Exs. 1, 8, and 9.

CMS filed objections to P. Exs. 1-9 and Petitioner's witnesses. CMS argued that the case should be decided on the written submissions without an in-person hearing, but expressed its intention to cross-examine Petitioner's witnesses if they were permitted to testify.

[1] Departmental Appeals Board (DAB) decisions cited in this decision are accessible on the internet at: http://www.hhs.gov/dab/decisions/index.html.

On November 20, 2013, I issued an Order, in which I ruled as follows: I denied the CMS Motion and stated that I would schedule a hearing for the purpose of allowing the parties to cross-examine their party-opponent's witnesses; I admitted CMS Exs. 1-4, except that I did not admit the NSC inspector's report (CMS Ex. 3, at 20-31) pending cross-examination of the inspector. I overruled CMS's objections to P. Exs. 1, 8, and 9, but I reserved admitting those exhibits into the record until CMS had an opportunity to cross-examine those witnesses. I sustained CMS's objection to P. Ex. 7 and I excluded that exhibit from the record as irrelevant. I reserved ruling on CMS's objections to P. Exs. 2-6 until the hearing. Order dated November 20, 2013.

I convened a hearing by video teleconference on January 28, 2014. The NSC site inspector testified, as did Ms. Thomas, and one of Petitioner's other witnesses (Petitioner's witness). At the hearing, I admitted pages 20-31 of CMS Ex. 3 (Hearing Transcript (Tr.) 80-81) and P. Exs. 1-4 (Tr. 135), 6 (Tr. 135), and 9 (Tr. 29). I did not admit P. Ex. 8 because Petitioner did not call the affiant to testify. Tr. 7-8. Petitioner withdrew P. Ex. 5. Tr. 117.

I gave the parties the opportunity to file post-hearing briefs. Petitioner filed a brief (P. Br.), and CMS subsequently filed a reply (CMS Br.). With its post-hearing brief, Petitioner requested that I admit a new exhibit, P. Ex. 10, consisting of Petitioner's Corrective Action Plan (CAP) and cover letter that it had submitted to NSC on May 6, 2013. Petitioner requested that I admit P. Ex. 10 on the grounds that it is relevant and also that it should have been included in CMS Ex. 1 as part of the correspondence between Petitioner and CMS/NSC. P. Br. at 6 n.3. In the absence of objection from CMS, I admit P. Ex. 10 into the record.

II. Issue

Whether CMS had a legitimate basis for revoking Petitioner's Medicare billing privileges for failing to be accessible and staffed during posted hours of operation (42 C.F.R. § 424.57(c)(7)).

Although the reconsidered determination upheld the initial determination's finding that Petitioner failed to be accredited by a CMS-approved accrediting organization (42 C.F.R. § 424.57(c)(22)), CMS has, in this proceeding, conceded that this is no longer a basis to revoke Petitioner's Medicare billing privileges. CMS Motion at 9 n.3; *see also* CMS Ex. 4. Therefore, this is not an issue in this case.

Further, although the reconsidered determination defined the term "operational" and found that Petitioner was not open, the reconsidered determination did not expressly uphold the initial determination's finding that Petitioner was not operational under 42 C.F.R. § 424.535(a)(5)(ii). Based on very recent DAB decisions that indicate review of issues not stated in the reconsidered determination is precluded, I will not consider

whether the initial determination's finding that Petitioner was not operational is a basis for revocation.[2] *Neb Group of Arizona LLC*, DAB No. 2573, at 7 (2014); *see also Benson Ejindu, d/b/a Joy Medical Supply*, DAB No. 2572, at 8-9 (2014).

III. Jurisdiction

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

VI. Findings of Fact, Conclusions of Law, and Analysis[3]

In order for a DMEPOS supplier to receive Medicare payments for items furnished to a Medicare-eligible beneficiary, the Secretary of Health and Human Services (Secretary) must first issue a supplier number to that supplier. 42 U.S.C. § 1395m(j)(1)(A). The Social Security Act establishes as a basic requirement that a DMEPOS supplier must maintain a physical facility on an appropriate site, but further authorizes the Secretary to create other DMEPOS supplier requirements. *Id.* § 1395m(j)(1)(B)(ii). The Secretary promulgated regulations establishing DMEPOS supplier enrollment standards, which a DMEPOS supplier must meet and maintain. 42 C.F.R. § 424.57(c).

---

[2] I believe that the regulations governing provider and supplier enrollment cases preclude new issues from being raised to an administrative law judge (*see Integrated Homecare Services Chicago Corporation*, DAB CR3070, at 3 (2014)); however, I also believe that the regulations do not consider issues articulated in the initial or reconsidered determinations to be new issues. *See* 42 C.F.R. § 498.56(a)(2); *Improving Life Home Care, LLC*, DAB CR3076, at 5 (2014). In an effort to harmonize the regulations and the decision in *Fady Fayad, M.D.*, DAB No. 2266, at 9-11 (2009), I have generally permitted CMS to raise issues in its brief from the initial determination that were not expressly ruled upon in the reconsidered determination. However, if CMS did not raise such issues in its brief, I would only adjudicate the issues in the reconsidered determination. *See NORPRO Orthotics & Prosthetics, Inc.*, DAB CR3081, at 6 (2014). Because the CMS Motion clearly raised the issue, from the initial determination, that Petitioner was not operational, I stated it was an issue at the hearing. Tr. 6. However, as stated above, I will not consider whether Petitioner was not operational as an issue in this case.

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

In addition to maintaining a physical facility on an appropriate site, the supplier standards require that the facility must be "open to the public a minimum of 30 hours per week" and the supplier must "post[] hours of operation." *Id.* §§ 424.57(c)(7)(i)(D), (c)(30). Most important for this case, the facility must be "accessible and staffed during posted hours of operation." *Id*. § 424.57(c)(7)(i)(C).

CMS may conduct on-site reviews and inspections to ascertain supplier compliance with enrollment requirements and supplier standards, and to determine if a supplier is operational. *Id*. §§ 424.57(c)(8), 424.510(d)(8), 424.515(c), 424.517(a). CMS will revoke the enrollment of a DMEPOS supplier if it fails to comply with any of the supplier standards stated in 42 C.F.R. § 424.57(c). *See Id.* § 424.57(d).

1. The NSC inspector could not gain entry to Petitioner's facility at 2901 W. Girard Avenue in Philadelphia, Pennsylvania when he attempted site inspections on April 9 and 10, 2013.

On Tuesday, April 9, 2013, at approximately 11:45 a.m., the NSC inspector attempted to conduct an unannounced site inspection at Petitioner's facility located at 2901 W. Girard Avenue in Philadelphia, Pennsylvania. CMS Ex. 3, at 22, 27. Petitioner's posted hours of operation, as indicated by the door sign, were listed as Monday through Friday from 9:00 a.m. to 5:00 p.m. CMS Ex. 3, at 29; *see also* CMS Ex. 3, at 23. In his site investigation report, the NSC inspector stated that "[n]o one answered the door during the posted hours of operation" and the "[s]upplier was not open." CMS Ex. 3, at 20, 27. On Wednesday, April 10, 2013, at approximately 9:45 a.m., the inspector attempted another site inspection. However, he reported that "[a]gain, no one responded to the bell and the doors were locked." CMS Ex. 3, at 27. The inspector documented his attempted site inspections with date and time-stamped photographs. CMS Ex. 3, at 28-31.

At the hearing, the NSC inspector testified, consistent with his inspection report, that when he arrived at approximately 11:45 a.m. on April 9, 2013, for the first site inspection, he took photos and "attempt[ed] to open the door and the door was locked." Tr. 38. The NSC inspector testified that there were two doorbells – a doorbell on the entrance door and a doorbell next to the handicapped sign on the entrance – and he rang both bells several times. Tr. 38, 43, 71, 75-76, 84. He stated that there was no response, and he waited several minutes and then left. Tr. 38, 44, 76. The NSC inspector testified that when he returned at 9:45 a.m. on April 10 for the second site visit, he took photos and attempted to open the door, but it was locked. Tr. 45; *see also* CMS Ex. 3, at 31. He stated that he rang both doorbells several times, and again, no one responded. Tr. 45, 72; *see also* CMS Ex. 3, at 27. The NSC inspector testified that "no Medicare beneficiary would have been able to access the supplier" on either April 9 or 10, 2013. Tr. 38-39. He stated that he had not encountered a situation before where, on two consecutive days, a supplier who was operational was unavailable on both site visits. Tr. 48-49.

CMS offered the NSC inspector's site investigation report and his date and time-stamped photos (CMS Ex. 3, at 20-31) as contemporaneous evidence of his site visits. As noted above, Petitioner objected to these documents, and I deferred admitting them into the record pending cross-examination of the inspector. Order dated November 20, 2013. On direct examination, the inspector confirmed that he had completed the report on April 10, 2013, and verified his signature on it. Tr. 39-41. He testified further that he took photos during the course of both of his site visits on April 9 and 10, 2013, and that he took the photos found at pages 28-31 of CMS Ex. 3. Tr. 42-45. On cross-examination, the inspector testified that he used an NSC issued digital camera that automatically stamped on the date and time on each picture he took. Tr. 72. When asked about three photos which all had the time stamp of "11:43," the inspector stated that he had no reason to question the time stamp's accuracy. Tr. 73-75. Petitioner withdrew its objection to the investigation report, but questioned whether the photos were "true and accurate depictions," and claimed that the fact that three photos all had the time stamp of "11:43" shows that the inspector's camera may not have been calibrated. Tr. 79-80. Petitioner offered no evidence to suggest the camera had a calibration problem. Noting that the inspector had thoroughly testified regarding his photos, I admitted pages 20-31 of CMS Ex. 3. Tr. 80-81.

I find that the inspector testified credibly. His testimony regarding the site visits on April 9 and 10 was consistent with his contemporaneous documentation of the attempted inspections. His investigation report indicates the dates and times of when the site visits occurred, and states that, on both visits, no one answered the door during the posted hours of operation and the facility was locked. Moreover, the dates and times in the report are corroborated by the date and time stamps on the photos the inspector took on the two visits. There are no internal discrepancies with the inspector's report. I find that his photos accurately represent what he observed on his site visits of April 9 and 10 and find no evidence that he fabricated or manipulated the taking of the photos. The fact that the NSC inspector took several photos from different locations, all bearing the same time stamp, is not, in and of itself, sufficient grounds to question the reliability of the photos and when they were taken.

Petitioner offered the testimony of two witnesses – a witness who owns a business across the street from Petitioner's office, and its owner/operator, Marlene Thomas. Petitioner's witness testified that he cannot see into Petitioner's office from his location, but he sees Ms. Thomas in the morning taking out the trash, sweeping, and watering her plants. Tr. 16, 18. When asked whether he saw Ms. Thomas on April 9, he replied that he "usually see[s] her every morning." Tr. 17. When asked whether he saw Ms. Thomas on April 10, he replied, "yes," and stated that his basis for remembering seeing her at any time during the month of April was due to the fact that he usually sees her car parked outside her shop. Tr. 17. On cross-examination, the witness confirmed that he is unable to see

inside Petitioner's office. Tr. 18-19. He testified that he was unable to confirm that Ms. Thomas was physically present in her office on April 9 and 10, but believed she was there on those dates because he saw her car parked outside. Tr. 19-20.

I do not find the testimony of Petitioner's witness to be credible. His testimony at hearing is not consistent with his written direct testimony, provided in an affidavit dated October 4, 2013. At the hearing, Petitioner's witness testified that he is unable to see into Ms. Thomas' office from his business, an important detail he omitted from his affidavit. Thus, he could not definitively state that he could see Ms. Thomas in the facility. He testified that he believed Ms. Thomas was in her office on April 9 and 10 because he had seen her car parked outside. However, in his affidavit, Petitioner's witness stated only that he observed Ms. Thomas "during the course of [his] work day" "doing the following: entering the office, cleaning up the block . . . (during the morning hours), or leaving the office at the end of the day." P. Ex. 9. Nowhere in his affidavit does the witness mention Ms. Thomas' car or claim that he was able to see Ms. Thomas' car on April 9 and 10 or even on a daily basis. Further, nowhere in the affidavit did the witness state that he believed Ms. Thomas was physically present in her office on April 9 at 11:45 a.m. and April 10 at 9:45 a.m. P. Ex. 9. In fact, the witness conceded on recross-examination that this information was not in his affidavit. Tr. 25. Given that the witness' assertions that Ms. Thomas was present on the dates of the inspections are completely unsupported by any evidence, his testimony is suspect and not definitive.

Petitioner's owner and operator, Ms. Thomas, testified on direct examination that she was present in the facility on April 9 and 10, 2013, at the times of the attempted inspections. Tr. 93-94, 104, 116; P. Ex. 1, at 4-5. She testified that she did not hear the doorbell on either date. Tr. 103-04, 112; P. Ex. 1, at 4, 5. According to Ms. Thomas, she did not conduct any "due diligence" before she submitted her request for reconsideration because she relied on the representations of an NSC employee who told her "everything should be fine" if she submitted a CAP. Tr. 114-15. Ms. Thomas testified that she only learned of the specific times of the site visits when she received the reconsideration determination from NSC. Tr. 115-16. Ms. Thomas stated that she determined she was at the facility on the inspection dates by reviewing her phone records, client files, and delivery records. *See* Tr. 93-94, 104, 109-10; *see also* P. Exs. 2-6.

On cross-examination, Ms. Thomas testified that she is the sole person working in the facility. Tr. 121. She conceded that in her May 2013 request for reconsideration, she had admitted that she had been out of the office servicing patients with setting up medical supplies at the time of the two site visits. Tr. 126, 129-30. Ms. Thomas admitted that she later retracted this admission and that her original admission was made more contemporaneously with the site inspections than was her affidavit. Tr. 126, 130. Ms. Thomas testified that the reason she had stated she was not present for the inspections

was due to her not knowing the times of the inspections. Tr. 126. Ms. Thomas testified that once she learned of the precise times of the site visits upon receiving the unfavorable reconsideration decision, "[she] immediately knew, a light like hit, I was in the office at this time." Tr. 126, 133; P. Ex. 1, at 3-4.

I do not find credible Ms. Thomas' testimony that she was present in her office at the times of the two inspections because her statements directly contradict her prior assertions contained in her request for reconsideration and her request for hearing. When Ms. Thomas submitted Petitioner's request for reconsideration in May 2013, she plainly admitted that she had not been in the office at the times of the site visits. Ms. Thomas stated, "[a]t the time of the two stated site visits above, owner/operator, Marlene Thomas, was servicing clients with set ups and/or deliveries." P. Ex. 10, at 2; CMS Ex. 3, at 11. Nowhere in the request for reconsideration did she dispute NSC's findings that Petitioner's facility was closed and no one was present on the dates of the site visits.[4]

During her testimony, Ms. Thomas claimed that she was not able to conduct her due diligence until she became aware of the precise times of the two site inspections in the June 24, 2013 reconsideration determination. Tr. 114-16, 126, 133, 141-42. However, if, as Ms. Thomas claims, seeing the times of the site visits in the reconsideration determination led to a sort of epiphany in which she realized that she had indeed been present on those dates, I would have expected Petitioner's August 2, 2013 request for hearing to reflect this. However, it does not. Petitioner's hearing request does not challenge NSC's finding that the facility was closed for the attempted inspections on April 9 and 10, 2013. It does not suggest that the facility was open or that Ms. Thomas was present and available at the relevant times. Rather, the hearing request references Petitioner's CAP and notes that the CAP had set forth new operational hours "to maintain compliance with Supplier Standards and to assure staffing." The hearing request also indicates that additional staff had been hired to ensure that someone would be present at all times during the posted hours of operation. Thus, Petitioner's statements in the hearing request are actually consistent with those expressed in her request for reconsideration and reinforce the conclusion that she was <u>not</u> present and available at the time of the attempted inspections.

It is noteworthy that, despite Ms. Thomas' claim that once she learned of the times of the site inspections from the reconsidered determination and conducted her "due diligence" review of records she chose to offer her new recollection of events in her October 13,

[4] In Petitioner's May 16, 2013 request for reconsideration, Petitioner further stated that, "[t]o avoid this absence in the future and to adhere to supplier standards," it had implemented certain changes in its policies and procedures, including posting new hours of operation and leaving a sign on the door when the office was left unattended to inform the public when someone would return. CMS Ex. 3, at 11

2013 affidavit, six months after the site inspections occurred. P. Ex. 1. In this affidavit, Ms. Thomas stated for the first time that she "was present" at Petitioner's facility on the dates of the site visits, April 9 and 10, 2013, but did not hear the doorbell ring. P. Ex. 1, at 4-5.

In light of Ms. Thomas' change in position based on learning the exact times of the site inspections on April 9 and 10 from the reconsidered determination, I posed the following question to her at the hearing: "[W]hat times were you in fact not present at your location on the dates . . . or are you withdrawing that assertion in its entirety that you were out of the office at all on the two dates, April 9th and April 10, 2013?" Tr. 136.

Ms. Thomas responded:

> To the extent that I was out of the office at any time on those dates between the posted hours of 9:00 and 5:00, no, I was not. I did on April the 10th I had a patient that I did service. And I had submitted that documentation but it was after close of business hours on April the 10th. But for April 9th and 10th the reason why I said I was servicing deliveries is I could have ran to the store.

Tr. 136-37. I find Ms. Thomas' response further highlights problems with her credibility, as I find it to be less than candid and not believable. Given her original assertion in her request for reconsideration that she had been out of the facility on April 9 and 10 servicing clients, and then her new version in which she claims that she realized she had actually been in the facility on April 9 and 10 at the times of the inspections, I would have expected an admission that she had been out of the office at *other times* on those dates. I do not find credible Ms. Thomas's statement that she was never gone from Petitioner's facility and was actually there all day on April 9 and 10.[5]

[5] I note that Ms. Thomas sent additional documentation to the Medicare Hearing Officer on June 21, 2013, in support of her request for reconsideration. As explained by Ms. Thomas, the documents include a "Client/Patient Service Agreement," which was executed by her client and herself on April 10, 2013, as well as an "Equipment Management Admission Assessment and Plan of Service" form, "which was completed at the time of the set up, service and training for the beneficiary's medical equipment which took place on April 10, 2013." CMS Ex. 3, at 33-34, 44, 45-46. Although at the hearing Ms. Thomas indicated that she serviced a client after business hours, these documents could also suggest that Ms. Thomas was out of the office for at least a portion of the day on April 10, servicing clients, as she admitted in her reconsideration request. I note further that Ms. Thomas admitted on cross-examination that, "prior to May 16th," there had been times when she left the facility unattended to go out and service clients and sometimes she "would leave a sign on the door and sometimes [she] wouldn't." Tr.

In support of her claim that she was present at Petitioner's facility on April 9 and 10, 2013, Ms. Thomas produced cellular telephone records from the dates at issue. P. Ex. 2; *see* Tr. 133. According to Ms. Thomas, when she compared her cellular telephone records to her patient files, she realized that she had been present on the inspection dates. *See* Tr. 93-94, 104, 109-10;133-34. However, cellular phone records cannot be used to prove that a DMEPOS supplier was staffed because unlike landlines, cellular phones are mobile and can be used outside of the DMEPOS supplier's offices. *See Benson Ejindu*, DAB No. 2572, at 7 n.4; *see also* 42 C.F.R. § 424.57(c)(9) (requiring DMEPOS suppliers to have a business phone, but prohibiting them from using cellular phones as their primary business telephone).

I find that Petitioner offered no evidence to corroborate the "new story" that Ms. Thomas provided in her affidavit and hearing testimony. While she may not have known the precise times of the site inspections on April 9 and 10, she knew from CMS's April 25, 2013 letter that the inspections took place during her posted business hours. Ms. Thomas thus knew that the inspector was at the facility sometime between 9:00 a.m. and 5:00 p.m. on April 9 and 10. Her testimony that she was only able to conduct her "due diligence" as to her whereabouts once she learned of the specific times of the inspections is improbable because nothing would have prevented her from immediately reviewing her records and logs after she received CMS's April 25, 2013 letter. One would expect a business person to do that when confronted with a notice such as the initial determination in this case. Ms. Thomas' testimony and affidavit clearly contradict her earlier admissions that she was away from the office and appear to constitute an after the fact attempt to rebut CMS's case and avoid revocation of Petitioner's Medicare billing privileges.

Based on the evidence of record, I find that the NSC inspector attempted to conduct site inspections of Petitioner's facility at 2901 W. Girard Avenue in Philadelphia, Pennsylvania, on April 9 and 10, 2013, during Petitioner's posted hours of operation. However, the NSC inspector was unable to gain entry to the facility and complete the inspections because Petitioner's sole employee, Ms. Thomas, was not present on those dates.

123-24. Therefore, Ms. Thomas admitted that, at times other than the two site visits, she left the facility unstaffed and unattended during posted hours of operation to service clients. CMS Br. at 12-13.

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 as required by 42 C.F.R. § 424.57(c)(7)(i)(C).

The facts in this case establish that Petitioner's facility was not open and available for the NSC inspector to conduct site inspections on April 9 and 10, 2013. Therefore, CMS had a legitimate basis to conclude that Petitioner was not in compliance with the supplier standards found at 42 C.F.R. § 424.57(c)(7)(i)(C).

Petitioner argues that Ms. Thomas was in the facility at the time of the site visits and posits that the NSC inspector waited unreasonably short amounts of time for Ms. Thomas to respond to the door, or that Ms. Thomas did not hear the doorbell because she was on the telephone, or even that the doorbell might have malfunctioned. Assuming Ms. Thomas was in her office on April 9 and 10 when the site inspections occurred, the fact that she did not hear the inspector ring the doorbells on either date in order to give him access to the facility means that the facility was not accessible under 42 C.F.R. § 424.57(c)(7)(i)(C). A supplier's place of business must remain publicly accessible during posted hours of operation and may not close, even temporarily, during its posted hours. *Complete Home Care, Inc.*, DAB No. 2525, at 5-6 (2013). A DMEPOS supplier's facility "does not 'provid[e] access' to a Medicare beneficiary," nor can it "be 'used' or physically 'reached' by the beneficiary, if its entry door is locked during posted hours, no one responds to a knock on the door, and there is no alternative means of gaining entry for a customer seeking to purchase or at least consider purchasing Medicare-covered supplies." *Norpro Orthotics & Prosthetics*, DAB No. 2577, at 6, *citing Benson Ejindu*, DAB No. 2572, at 6. Here, when the NSC inspector went to Petitioner's facility on April 9 and 10, 2013, he found it locked on both dates. At each visit, he rang two doorbells several times and waited for someone to open the door, but no one responded. The inspector encountered no staff. There were also no instructions posted on the entrance for how to obtain access and assistance from staff in the event the facility was locked. On both of the NSC inspector's visits, Petitioner's facility was, for all practical purposes, closed. Petitioner's facility was, therefore, not "accessible" within the meaning of 42 C.F.R. § 424.57(c)(7)(i)(C).

Further, as I found, the record supports a finding that Ms. Thomas was not present at Petitioner's facility on the days and times the NSC inspector attempted inspections. Since there was no one present, Petitioner's facility was also not "staffed" during its posted hours of operation as required by 42 C.F.R. § 424.57(c)(7)(i)(C). A supplier's place of business must be continually staffed during its posted hours of operation. *Complete Home Care, Inc.*, DAB No. 2525, at 6. The preamble to the proposed rule that added section 424.57(c)(7)(i)(C) to the regulations explained that a "supplier is not in compliance with this standard if no one is *available* during the posted hours of operation." 73 Fed. Reg. 4503, 4506 (Jan. 25, 2008) (emphasis added). Similarly, the

preamble to the final rule stated that exceptions to the staffing requirement have always been made for emergencies, disasters, and federal and state holidays, but emphasized that a DMEPOS 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 (Aug. 27, 2010). When the NSC inspector was on site on April 9 and 10, 2013, no one answered the door on two consecutive days, nor did the NSC inspector see anyone on the premises on either visit. There was no signage that indicated how a customer could reach an employee of Petitioner for assistance if the door was locked. Therefore, I conclude that Petitioner's office was not "staffed" in accordance with 42 C.F.R. § 424.57(c)(7)(i)(C).

In its posthearing brief, Petitioner claims for the first time that the evidence suggests that "[i]t is likely that either the doorbell malfunctioned or the Palmetto inspector did not press it hard enough."[6] P. Br. at 7-8. Petitioner points out that the NSC inspector testified that he did not hear the doorbell ring through the door on either of his visits on April 9 and 10, and this confirms Ms. Thomas' testimony that she did not hear the doorbell ring on those dates. P. Br. at 7-8; *see* Tr. 84, 103-04, 112.

I find Petitioner's attempt to undermine the validity of the NSC inspector's site visits unconvincing and unreasonable. As discussed above, I found the NSC inspector to be a credible witness. His testimony regarding the attempted inspections on April 9 and 10, 2013, was consistent with his contemporaneous documentation of the inspections. In testifying about his attempts to gain access to Petitioner's office on April 9 and 10, the NSC inspector stated that the facility was locked and the doorbells went unanswered on both visits. The fact that the NSC inspector did not hear the doorbells ringing does not, in and of itself, mean that the doorbells were not working or that he may not have "press[ed] hard enough." In suggesting that both of the doorbells may have been broken over the course of two days, Petitioner describes nothing more than a speculative scenario. Petitioner offered no evidence whatsoever, such as an invoice from a repairman, in support of its assertion that either or both of the doorbells at its facility malfunctioned when the inspector rang them on April 9 and 10. Petitioner also offered no evidence to prove that the inspector may not have properly engaged either of the doorbells.

Moreover, even accepting that both of Petitioner's doorbells were not working on the dates of the inspections, then this would further support the finding that Petitioner was not accessible to the public during its posted hours of operation. Having malfunctioning doorbells would clearly impede customer access to Petitioner's office, and, under those

[6] As testified by the inspector, there were two doorbells at Petitioner's facility – one on the entrance door and another next to the handicapped sign on the entrance. Tr. 38. I will assume that Petitioner is making the argument that both doorbells were malfunctioning on April 9 and 10 even though it only refers to "doorbell" in the singular in its brief.

circumstances, it would be incumbent upon Petitioner to institute an alternative means of gaining entry in order to satisfy the requirements of 42 C.F.R. § 424.57(c)(7). Given that Petitioner had not posted any notice for its customers specifying an alternate means of gaining entry in the event its doors were locked, its argument that its doorbells likely malfunctioned does not inure to its benefit.

With respect to Petitioner's claim that the inspections were flawed because the inspector "failed to exhaust every effort to determine if [Petitioner] was operational" on his visits, I find this argument to be without merit. P. Br. at 9. The inspector credibly testified, consistent with his investigation report, that he went to Petitioner's facility on two consecutive days, April 9 and 10, 2013, to conduct inspections. The record shows that the inspector used reasonable efforts to attempt to gain entry to Petitioner's facility on both dates, but was unable to gain access. Although Petitioner argued that the inspector should have called Petitioner's phone number when he was at the facility, an inspector is not required to telephone a supplier to find out why its location is closed. *See Complete Home Care*, DAB No. 2525, at 5-6. It is not the inspector's responsibility to chase down a supplier in order to gain access to its facility. Furthermore, I note that site inspections are supposed to be unannounced. 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). The NSC inspector acted properly in this case.

I conclude that CMS has a legitimate basis for its determination that Petitioner's facility was not accessible and staffed during posted business hours and CMS properly revoked Petitioner's Medicare billing privileges. 42 C.F.R. § 424.57(c)(7)(i)(C).

3. *Because revocation is premised only on a violation of a supplier standard and NSC failed to consider Petitioner's previously submitted CAP request, I must remand this case to CMS to fully consider Petitioner's CAP request and issue a decision as to whether CMS will reinstate or refuse to reinstate Petitioner's Medicare billing privileges.*

NSC's initial determination stated that Petitioner was "not operational" and identified 42 C.F.R. § 424.535(a)(5)(ii) as one of the bases for revocation. Due to this finding, NSC imposed retroactive revocation to April 10, 2013, the date NSC determined that Petitioner was "not operational." CMS Ex. 3, at 17. This is consistent with the regulatory provision that states "the revocation is effective with the date . . . that CMS or

its contractor determined that the . . . supplier was no longer operational." 42 C.F.R. § 424.535(g). However, that provision does not provide for a retroactive effective date for a revocation premised solely on a violation of the supplier standards. The reconsidered determination did not expressly address the effective date of revocation; therefore, I assume that CMS has maintained April 10, 2013 as the retroactive effective date in this case.

In addition to applying a retroactive effective date based on the non-operational finding, NSC also did not afford Petitioner an opportunity to file a CAP (CMS Ex. 3, at 17-19), which is consistent with CMS's finding that Petitioner was non-operational finding. *See* 42 C.F.R. § 424.535(a)(1). However, the NSC hearing officer's failure to include a non-operational finding in the reconsidered determination precludes NSC from making use of this exception.

Although the reconsidered determination does not expressly cite CMS's authority to revoke Petitioner's Medicare billing privileges for violating the supplier standards, the initial determination cited 42 C.F.R. § 424.57(e) and 424.535(a)(1). CMS Ex. 3, at 17. Because section 424.57(e) has not contained any provision related to revocations since 2011, I cannot apply a now-deleted provision in this case to uphold a revocation. However, as discussed below, 42 C.F.R. § 424.535(a)(1) provides CMS with authority to revoke Petitioner based on violations of the supplier standards. In order to do so, CMS must comply with the requirement in section 424.535(a)(1) that Petitioner be granted an opportunity to file a CAP. Because the application of recent DAB decisions to this case leads me to a remand of this case, it is necessary to explain why remand is now necessary.

In 1992, the Secretary established the supplier standards for DMEPOS suppliers at 42 C.F.R. § 424.57. 57 Fed. Reg. 27,290 (June 18, 1992). The first sentence of paragraph (d) of that new section provided for the revocation of the supplier's billing number for failing to meet the standards in paragraph (c) "effective 15 days after the entity is sent notice of the revocation." *Id*. at 27,308. Although modified over time, the substance of this sentence remained in paragraph (d) of section 424.57. In 2009, the Secretary published a final rule in which he sought to move the revocation provision in paragraph (d) to paragraph (e) so that a surety bond requirement for DMEPOS suppliers could occupy paragraph (d); the then existing paragraph (e) (renewal of billing privileges) was to be moved to become paragraph (f). 74 Fed. Reg. 166, 198-200 (Jan. 2, 2009). The Office of the Federal Register took the position that "these amendments could not be incorporated due to inaccurate amendatory instruction." *See* 42 C.F.R. § 424.57 (2009) (Editorial Note). As a result, in March 2009, the Secretary issued a "Final rule; correcting amendment" that stated:

> In FR Doc. E8-30802 issued on January 2, 2009 (74 FR 166), the final rule entitled "Medicare Program; Surety Bond

> Requirement for Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS)[”] there was a technical error that is identified and corrected in this document. The error was the result of a conflicting amendatory instruction in the ‘‘Payment Policies Under the Physician Fee Schedule and Other Revisions to Part B for CY 2009’’ final rule with comment period (73 FR 69726) that was effective January 1, 2009. The correction in this correcting amendment is effective on March 27, 2009.[7]

74 Fed. Reg. 13,345, 13,346 (Mar. 27, 2009). Therefore, as of March 27, 2009, CMS's authority to revoke billing privileges based on a violation of the supplier standards moved from paragraph (d) to paragraph (e) of 42 C.F.R. § 424.57.[8]

In 2010, the Secretary published another final rule revising paragraph (e) of 42 C.F.R. § 424.57. 75 Fed. Reg. 52,629, 52,648-52,649 (Aug. 27, 2010). As stated in the preamble to the final rule:

> In § 424.57(e) (which was proposed as § 424.57(d)), we are modifying our proposal with a change to the effective date of date of revocation. (See the Surety Bond final rule in the

---

[7] The final rule published on January 2, 2009, sought to "[r]edesignat[e] paragraphs (d) and (e) as paragraphs (e) and (f)." 74 Fed. Reg. at 198. For purposes of drafting final rules, the use of the term "'Redesignate' transfers a [Code of Federal Regulations] unit to a vacant position and assigns a new designation." National Archives and Records Administration, Office of the Federal Register, Federal Register Document Drafting Handbook 1-26 (1998) *available at* http://www.archives.gov/federal-register/write/handbook/. However, because the Secretary added a paragraph (f) to 42 C.F.R. § 424.57 effective January 1, 2009 (73 Fed. Reg. 69,726, 69,939 (Nov. 19, 2008)), the Secretary could not redesignate paragraph (e) to paragraph (f) because paragraph (f) was not vacant on January 2, 2009. Therefore, the Secretary, through the issuance of the "Final rule; correcting amendment," corrected the instructions in the January 2, 2009 final rule to read that paragraphs (d) and (e) were being redesignated as paragraphs (e) and (g). 74 Fed. Reg. at 13,346.

[8] Each edition of title 42 of the Code of Federal Regulations since 2009 has included the "Editorial Note" at the end of 42 C.F.R. § 424.57 indicating that the amendments made to paragraphs (d) and (e) could not be incorporated into that code due to the incorrect amendatory instructions in the January 2, 2009 final rule. Because the Secretary corrected that error on March 27, 2009, it is unclear why the Office of the Federal Register has continued to publish the "Editorial Note" and failed to update 42 C.F.R. § 424.57.

> March 27, 2009 Federal Register (74 FR 13345). In order to be consistent with our regulations at § 424.535(g), we are extending the effective date of revocation from 15 to 30 days after notification of the revocation.

75 Fed. Reg. at 52,645. It is clear from this quotation, which referred to the proposed rule that originally sought to amend paragraph (d) and cited the final rule correcting amendment redesignating paragraph (d) to (e), that the Secretary believed that paragraph (e) was now the location of CMS's authority to revoke billing privileges based on a violation of the supplier standards. This change to paragraph (e) was meant to harmonize the effective date of revocations (i.e., 30 days following issuance of an initial determination to revoke) for violations of the DMEPOS supplier standards with the general revocation provisions in 42 C.F.R. § 424.535. Further, the actual regulatory text referenced 42 C.F.R. § 405.874, which also provided that the effective date of a revocation was 30 days after issuance of the revocation determination. 42 C.F.R. § 405.874(b)(2) (2010).[9] The new revocation effective date provision in 42 C.F.R. § 424.57(e) was effective September 27, 2010 (75 Fed. Reg. at 52,629), and appeared in the 2010 edition of the Code of Federal Regulations.[10] *See* 42 C.F.R. § 424.57(e) (2010).

However, before the revisions to 42 C.F.R. § 424.57(e) were even effective, the Secretary proposed to completely revise paragraph (e) to require DMEPOS suppliers to revalidate every three years; the proposed rule did not mention revocations or the effective date for revocations. 75 Fed. Reg. 58,204, 58,209, 58,240 (Sep. 23, 2010). The Secretary ultimately issued a final rule effective March 25, 2011, in which paragraph (e) was revised to provide instructions regarding revalidations. 76 Fed. Reg. 5,862, 5,962 (Feb. 2, 2011). Just as was the case with the proposed rule, the preamble to the final rule did not mention the existing revocation authority in paragraph (e) of 42 C.F.R. § 424.57. *See id.* at 5,868, 5,891-5,892. Because the final rule expressly used the amendatory instruction that it was "revising" paragraph (e), the revocation provision in paragraph (e) was deleted in favor of the new text concerning revalidations. *See* National Archives and Records Administration, Office of the Federal Register, Federal Register Document Drafting Handbook 1-27 (1998) *available at* http://www.archives.gov/federal-register/write/handbook/ ("'Revise' means that an existing [Code of Federal Regulations] unit is replaced in its entirety."). The Office of the Federal Register followed the instruction in the final rule because in the 2011 edition of the Code of Federal

---

[9] This provision is now located in 42 C.F.R. § 405.800(b)(2) (2013).

[10] In the 2010 edition of the Code of Federal Regulations, 42 C.F.R. § 424.57(d) indicated that the effective date for a revocation was 15 days after issuance of the revocation determination, while 42 C.F.R. § 424.57(e) indicated that it was 30 days after issuance.

Regulations, paragraph (e) only included text about revalidations. 42 C.F.R. § 424.57(e) (2011). Therefore, despite the fact that the Code of Federal Regulations still provides obsolete text in 42 C.F.R. § 424.57(d) concerning revocations, there is no longer any valid provision in 42 C.F.R. § 424.57 that provides CMS with the authority to revoke a supplier based on a violation of the supplier standards.

I do not believe that the Secretary intentionally removed all reference to revocations from 42 C.F.R. § 424.57. Based on the confused history of paragraphs (d) and (e) of 42 C.F.R. § 424.57, it is easy to see why this mistake occurred. Further, before 2009, paragraph (e) provided rules involving renewal of billing privileges. 42 C.F.R. § 424.57(e) (2008). When one considers that the stated purpose of the 2011 amendment to paragraph (e) was to create uniformity in terminology in the regulations with the use of the word "revalidate" or "revalidation," it is clear that it was the old paragraph (e) from 2008 that was meant to be modified in 2011, not the new paragraph (e) involving revocations.[11]

It is significant that the Secretary did not intend to exempt violators of the supplier standards from revocation. This means that so long as the Secretary has granted CMS authority to revoke Medicare billing privileges based on the supplier standards somewhere in the regulations, then CMS may legitimately revoke those privileges regardless as to the history of paragraphs (d) and (e) of 42 C.F.R. § 424.57.

A review of the regulations shows that CMS has clear authority to revoke a DMEPOS supplier based on a violation of the supplier standards. CMS may revoke a currently enrolled supplier 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 . . . supplier type . . . ." 42 C.F.R. § 424.535(a)(1). DMEPOS suppliers must use a Form CMS-855S enrollment application,[12] which expressly states on page 2 that all DMEPOS suppliers must meet the supplier standards in 42 C.F.R. § 424.57(c) in

[11] As indicated earlier, the March 23, 2009 final rule (correcting the January 2, 2009 final rule) transferred paragraph (e)'s contents, i.e., the renewal provisions, to new paragraph (g) of 42 C.F.R. § 424.57. 74 Fed. Reg. at 13,346. However, the Office of the Federal Register never published a paragraph (g) in the Code of Federal Regulations, probably leading to some confusion as to the location of the renewal provision in 42 C.F.R. § 424.57.

[12] The Form CMS-855S may be found on CMS's website at http://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/CMS-Forms-Items/CMS019480.html?DLPage=1&DLFilter=855&DLSort=0&DLSortDir=ascending.

order to obtain and retain Medicare billing privileges.[13] That page summarizes the supplier standards, including the requirement, pertinent to this case, that the DMEPOS supplier's "location must be accessible to the public and staffed during posted hours of business." Therefore, there is no doubt that the supplier standards are enrollment requirements that are found in the enrollment application for DMEPOS suppliers.

Although I have concluded above that Petitioner violated the supplier standards at 42 C.F.R. § 424.57(c)(7), a violation which subjects Petitioner to revocation under 42 C.F.R. § 424.535(a)(1), I must remand this case to CMS. Before a final determination revoking a supplier may be issued under section 424.535(a)(1), the supplier must be "granted an opportunity to correct the deficient compliance requirement . . . ." 42 C.F.R. § 424.535(a)(1). According to Petitioner, she filed a CAP with NSC shortly after receiving the initial determination to revoke Medicare billing privileges; however, NSC returned the CAP to Petitioner "without due consideration." RFH at 1. Petitioner submitted a copy of the CAP she submitted to NSC. P. Ex. 10. Petitioner's assertion that NSC did not consider her CAP is corroborated by the fact that: the initial determination does not provide notice of a right to file a CAP; there is no CAP decision in the record; CMS did not object to P. Ex. 10; and NSC initially revoked billing privileges based, in part, on a finding that Petitioner was not operational – an offense for which an opportunity to correct is not afforded. CMS Ex. 3, at 17-19; 42 C.F.R. § 424.535(a)(1). As stated above, because the NSC hearing officer failed to find in the reconsidered determination that one of the bases for revocation was that Petitioner was not operational, Petitioner should have been offered an opportunity to file a CAP before a final determination was issued revoking billing privileges. There is no evidence this happened; therefore, I remand this case for NSC to consider Petitioner's CAP.

Order

Because I have not issued a decision in this case yet, I hereby remand this matter to CMS under 42 C.F.R. § 498.78(b). On remand CMS shall:

1. Consider the CAP Petitioner submitted to NSC (P. Ex. 10);

2. Consider any supplemental information that Petitioner may submit to CMS **within 14 days** of the date on this Order of Remand;

3. Conduct a full review of the CAP under 42 C.F.R. § 405.809;

[13] The regulations, consistent with the form, state that "[t]he supplier must meet and must certify in its application for billing privileges that it meets and will continue to meet the following [supplier] standards . . . ." 42 C.F.R. § 424.57(c) (introductory text).

4. Issue a decision reinstating Petitioner's Medicare billing privileges or refusing to reinstatement those privileges **within 45 days** of the date on this Order of Remand;

5. File a copy of the CAP decision with the DAB's Civil Remedies Division along with a request that I dismiss the RFH (if CMS has reinstated billing privileges) or a request that I issue a decision consistent with the findings and conclusions in this Order of Remand (if CMS has not reinstated billing privilege); and

6. Submit, with a request that I issue a decision, any argument it may want to make concerning CMS's authority to revoke Petitioner and the effective date of the revocation.

It is further ordered that Petitioner may:

1. File a reply to any submission CMS makes in response to this order **within 20 days** of receiving CMS's submission; and

2. Include with its reply any argument Petitioner may want to make with regard to CMS's authority to revoke Petitioner and the effective date of such revocation; Petitioner may make these arguments in its reply even if CMS does not address its revocation authority or the effective date for the revocation in its submission.[14]

It is so ordered.

/s/
Scott Anderson
Administrative Law Judge

[14] In filing any reply, Petitioner should understand that I do not have jurisdiction to review CMS's decision to refuse to reinstate billing privileges based on a CAP. *See* 42 C.F.R. § 405.809 (CAP decisions are not initial determinations subject to appeal under 42 C.F.R. Part 498); *Pepper Hill Nursing & Rehab. Ctr., LLC*, DAB No. 2395, at 9-10 (2011); *DMS Imaging, Inc.*, DAB No. 2313, at 7-10 (2010).