Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Good Shepherd Home for the Aged, Inc., d/b/a The Good Shepherd Home, (CCN: 36-5093),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-14-1973

Decision No. CR4785

Date: February 7, 2017

DECISION

Petitioner, Good Shepherd Home for the Aged, Inc., d/b/a The Good Shepherd Home, did not violate 42 C.F.R. § 483.25(h)¹ from June 24 through August 13, 2014, as alleged by the Centers for Medicare & Medicaid Services (CMS). There is no basis for the imposition of enforcement remedies from June 24 through August 13, 2014. Petitioner did violate 42 C.F.R. § 483.35(i) from August 14 through 19, 2014. There is a basis for the imposition of enforcement remedies from August 14 through 19, 2014. The proposed \$100 per day civil money penalty (CMP) for August 14 through 19, 2014, a total CMP of \$600, is reasonable.

I. Background

Petitioner is located in Ashland, Ohio, and participates in Medicare as a skilled nursing facility (SNF). On June 26, 2014, the Ohio Department of Health (state agency)

¹ References are to the 2013 revision of the Code of Federal Regulations (C.F.R.), unless otherwise stated.

completed a complaint investigation and partial extended survey at Petitioner's facility. The state agency concluded that Petitioner was not in substantial compliance with program participation requirements due to a violation of 42 C.F.R. § 483.25(h) that posed immediate jeopardy. Parties' Joint Stipulation of Undisputed Facts (Jt. Stip.) ¶¶ 1-2; CMS Exhibit (Ex.) 1 at 5.

CMS notified Petitioner on July 17, 2014, that CMS was imposing a CMP of \$3,550 per day for June 24, 2014, and a CMP of \$100 per day beginning June 25, 2014, and continuing until Petitioner returned to substantial compliance or its participation in Medicare was terminated. Jt. Stip. ¶¶ 7-8; CMS Ex. 1 at 6. CMS also advised Petitioner that: Petitioner was ineligible to conduct a nurse aide training and competency evaluation program (NATCEP) for two years; a mandatory denial of payments for new admissions (DPNA) would be triggered effective September 26, 2014, if Petitioner did not return to substantial compliance before that date; and termination of Petitioner's provider agreement would occur on December 26, 2014, if it did not return to substantial compliance before that date. Jt. Stip. ¶ 9; CMS Ex. 1 at 6, 8.

The state agency completed a revisit survey on August 14, 2014. The survey found that Petitioner corrected, effective August 14, 2014, the alleged violation of 42 C.F.R. § 483.25(h) from the June 2014 survey. However, the survey concluded that Petitioner had not returned to substantial compliance due to a violation of 42 C.F.R. § 483.35(i) that posed a risk for more than minimal harm. Jt. Stip. ¶ 5; CMS Exs. 1 at 1; 5. On September 3, 2014, the state agency conducted a second revisit survey and determined that Petitioner returned to substantial compliance effective August 20, 2014. Jt. Stip. ¶ 6; CMS Ex. 1 at 1. CMS notified Petitioner by letter dated October 6, 2014, that the CMP imposed was: \$3,550 for one day of immediate jeopardy on June 24, 2014, and a CMP of \$100 per day for 56 days from June 25 through August 19, 2014, a total CMP of \$9,150. Jt. Stip. ¶¶ 7-8; CMS Ex. 1 at 1. CMS also advised Petitioner that the DPNA and termination were rescinded and/or not effectuated because Petitioner returned to substantial compliance on August 20, 2014. CMS Ex. 1 at 1-2.

On September 16, 2014, Petitioner requested a hearing (RFH) before an administrative law judge (ALJ). Petitioner challenged the findings and conclusions of the June 26, 2014 partial extended survey and the proposed enforcement remedy related to that survey. Petitioner did not request review related to the survey completed on August 14, 2014. I note that Petitioner had not been advised at the time the request for hearing was filed that CMS was imposing any enforcement remedy based on the August 14, 2014 survey. RFH. Petitioner has now stipulated that it does not seek review of the noncompliance based on a violation of 42 C.F.R. § 483.35(i) cited by the August 14, 2014 survey. Jt. Stip. ¶ 11. Accordingly, the findings and conclusions of the August 14, 2014 survey became final and binding on December 5, 2014, 60 days after the October 6, 2014 notice. 42 C.F.R. § 498.20(b), 498.40(a)(2), 498.70(c).

The case was assigned to me for hearing and decision on October 7, 2014, and an Acknowledgment and Prehearing Order was issued at my direction. On July 9, 2015, a hearing was convened by video teleconference. A transcript (Tr.) of the proceedings was prepared. CMS offered CMS Exs. 1 through 14 that were admitted as evidence. Petitioner offered Petitioner's exhibits (P. Exs.) 1 through 12 that were admitted as evidence. Tr. 28-29. CMS called Surveyor Cathy Wagner, RN, CRRN, as a witness (Tr. 32-120). Petitioner called the following witnesses: Mehrdad Tavallaee, M.D., Petitioner's Medical Director (Tr. 123-40); Sarah Kerr, RN, BSN, Petitioner's Director of Nursing (DON) (Tr. 142-68); Ashley Corban, Occupational Therapist (OT) (Tr. 169-97); and Lorie White, LSW, Petitioner's Director of Social Services (Tr. 198-221). The parties filed post-hearing briefs (CMS Br. and P. Br., respectively) and post-hearing reply briefs (CMS Reply and P. Reply, respectively).

II. Discussion

A. Issues

Whether there is a basis for the imposition of an enforcement remedy; and

Whether the remedy proposed is reasonable.

B. Applicable Law

The statutory and regulatory requirements for participation of a SNF in Medicare are at section 1819 of the Social Security Act (Act) and 42 C.F.R. pt. 483. Section 1819(h)(2) of the Act authorizes the Secretary of Health and Human Services (Secretary) to impose enforcement remedies against a SNF for failure to comply substantially with the federal participation requirements established by sections 1819(b), (c), and (d) of the Act.³ The Act requires that the Secretary terminate the Medicare participation of any SNF that does not return to substantial compliance with participation requirements within six months of being found not to be in substantial compliance. Act § 1819(h)(2)(C). The Act also

² Petitioner's exhibit lists filed February 4, 2015 and March 6, 2015 list P. Ex. 1 as comprising 663 pages of medical records for Resident 1. My review of P. Ex. 1 reveals that it contains 663 pages of medical records for Resident 19.

³ Participation of a nursing facility (NF) in Medicaid is governed by section 1919 of the Act. Section 1919(h)(2) of the Act gives enforcement authority to the states to ensure that NFs comply with their participation requirements established by sections 1919(b), (c), and (d) of the Act.

requires that the Secretary deny payment of Medicare benefits for any beneficiary admitted to a SNF, if the SNF fails to return to substantial compliance with program participation requirements within three months of being found not to be in substantial compliance – commonly referred to as the mandatory or statutory DPNA. Act § 1819(h)(2)(D). The Act grants the Secretary discretionary authority to terminate a noncompliant SNF's participation in Medicare, even if there has been less than 180 days of noncompliance. The Act also grants the Secretary authority to impose other enforcement remedies, including a discretionary DPNA, CMPs, appointment of temporary management, and a directed plan of correction. Act § 1819(h)(2)(B).

The Secretary has delegated to CMS and the states the authority to impose remedies against a long-term care facility that is not complying substantially with federal participation requirements. "Substantial compliance [complying substantially] means a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm." 42 C.F.R. § 488.301 (emphasis in original). A deficiency is a violation of a participation requirement established by sections 1819(b), (c), and (d) of the Act or the Secretary's regulations at 42 C.F.R. pt. 483, subpt. B. Therefore, a facility may violate a statutory or regulatory requirement, but it is not subject to enforcement remedies if the violation does not pose a risk for more than minimal harm. The term "noncompliance" refers to any deficiency (statutory or regulatory violation) that causes a facility not to be in substantial compliance; that is, a deficiency that poses a risk for more than minimal harm. 42 C.F.R. § 488.301. State survey agencies survey facilities that participate in Medicare on behalf of CMS to determine whether the facilities are complying with federal participation requirements. 42 C.F.R. §§ 488.10-.28, 488.300-.335. The regulations specify the enforcement remedies that CMS may impose if a facility is not in substantial compliance with Medicare requirements. 42 C.F.R. § 488.406.

Petitioner was notified in this case that it was ineligible to conduct a NATCEP for two years.⁴ Pursuant to sections 1819(b)(5) and 1919(b)(5) of the Act, SNFs and nursing

⁴ Petitioner did not have a NATCEP at the time of the June 26, 2014 survey but requests that I rescind the penalty. P. Br. at 2 n.2. Petitioner became ineligible to be approved to conduct a NATCEP for two years by operation of law and I have no authority to declare the ineligibility invalid except to the extent that I conclude that there was no trigger to the ineligibility. The two-year period of ineligibility began on June 26, 2014 and ended on June 25, 2016. CMS Ex. 1. Although the period of ineligibility has already expired, the ineligibility to conduct a NATCEP remains an issue as it triggers Petitioner's right to request review of the scope and severity determination that triggered the ineligibility to be approved to conduct a NATCEP.

facilities (NFs) may only use nurse aides who have completed a training and competency evaluation program. Pursuant to sections 1819(f)(2) and 1919(f)(2) of the Act, the Secretary was tasked to develop requirements for approval of NATCEPs and the process for review of those programs. Sections 1819(e) and 1919(e) of the Act impose upon the states the requirement to specify what NATCEPs they will approve that meet the requirements that the Secretary established and a process for reviewing and re-approving those programs using criteria the Secretary set. The Secretary promulgated regulations at 42 C.F.R. pt. 483, subpt. D. Pursuant to 42 C.F.R. § 483.151(b)(2) and (f), a state may not approve and must withdraw any prior approval of a NATCEP offered by a SNF or NF that has been: (1) subject to an extended or partial extended survey under sections 1819(g)(2)(B)(i) or 1919(g)(2)(B)(i) of the Act; (2) assessed a CMP of not less than \$5,000; or (3) subject to termination of its participation agreement, a DPNA, or the appointment of temporary management. Extended and partial extended surveys are triggered by a finding of "substandard quality of care" during a standard or abbreviated standard survey and involve evaluating additional participation requirements. "Substandard quality of care" is identified by the situation where surveyors identify one or more deficiencies related to participation requirements established by 42 C.F.R. § 483.13 (Resident Behavior and Facility Practices), § 483.15 (Quality of Life), or § 483.25 (Quality of Care) that are found to constitute either immediate jeopardy, a pattern of or widespread actual harm that does not amount to immediate jeopardy, or a widespread potential for more than minimal harm that does not amount to immediate jeopardy and there is no actual harm. 42 C.F.R. § 488.301. In this case the alleged violation of 42 C.F.R. § 438.25 posed immediate jeopardy, which constituted substandard quality of care, and thereby triggered an extended or partial extended survey and the ineligibility to conduct a NATCEP. 42 C.F.R. § 498.3(b)(14)(ii) & (16) (finding of substandard quality of care that results in loss of approval of NATCEP is an initial determination subject to review).

The Act and regulations make a hearing before an ALJ available to a long-term care facility against which CMS has determined to impose an enforcement remedy. Act §§ 1128A(c)(2), 1866(h); 42 C.F.R. §§ 488.408(g), 498.3(b)(13). A facility has a right to appeal a "certification of noncompliance leading to an enforcement remedy." 42 C.F.R. §§ 488.408(g)(1), 488.330(e), 498.3(b)(13). However, the choice of remedies, or the factors CMS considered when choosing remedies, are not subject to review. 42 C.F.R. § 488.408(g)(2). A facility may only challenge the scope and severity level of noncompliance determined by CMS if a successful challenge would affect the range of the CMP that may be imposed or impact the facility's authority to conduct a NATCEP. 42 C.F.R. § 498.3(b)(14), (d)(10)(i). The CMS determination as to the level of noncompliance, including the finding of immediate jeopardy, "must be upheld unless it is clearly erroneous." 42 C.F.R. § 498.60(c)(2); *Woodstock Care Ctr.*, DAB No. 1726 at 9, 38 (2000), *aff'd*, 363 F.3d 583 (6th Cir. 2003). The Departmental Appeals Board (the Board) has long held that the net effect of the regulations is that a provider has no right to challenge the scope and severity level assigned to a noncompliance finding, except in the

situation where that finding was the basis for an immediate jeopardy determination. *See, e.g., Ridge Terrace*, DAB No. 1834 (2002); *Koester Pavilion*, DAB No. 1750 (2000). ALJ review of a CMP is subject to 42 C.F.R. § 488.438(e).

The hearing before an ALJ is a de novo proceeding, i.e., "a fresh look by a neutral decision-maker at the legal and factual basis for the deficiency findings underlying the remedies." Life Care Ctr. of Bardstown, DAB No. 2479 at 32 (2012) (citation omitted); The Residence at Salem Woods, DAB No. 2052 (2006); Cal Turner Extended Care, DAB No. 2030 (2006); Beechwood Sanitarium, DAB No. 1906 (2004); Emerald Oaks, DAB No. 1800 at 11 (2001); Anesthesiologists Affiliated, DAB No. CR65 (1990), aff'd, 941 F.2d 678 (8th Cir. 1991). The standard of proof is a preponderance of the evidence. CMS has the burden of coming forward with the evidence and making a prima facie showing of a basis for the imposition of an enforcement remedy. Petitioner bears the burden of persuasion to show by a preponderance of the evidence that it was in substantial compliance with participation requirements or any affirmative defense. Batavia Nursing & Convalescent Inn, DAB No. 1911 (2004); Batavia Nursing & Convalescent Ctr., DAB No. 1904 (2004), aff'd, 129 F. App'x 181 (6th Cir. 2005); Emerald Oaks, DAB No. 1800; Cross Creek Health Care Ctr., DAB No. 1665 (1998); Hillman Rehab. Ctr., DAB No. 1611 (1997) (remand), DAB No. 1663 (1998) (aft. remand), aff'd, Hillman Rehab. Ctr. v. United States, No. 98-3789 (GEB), 1999 WL 34813783 (D.N.J. May 13, 1999).

C. Findings of Fact, Conclusions of Law, and Analysis

My conclusions of law are set forth in bold text followed by my findings of fact and analysis. I have carefully considered all the evidence and the arguments of both parties, though not all may be specifically discussed in this decision. I discuss in this decision the credible evidence given the greatest weight in my decision-making.⁵ I also discuss any evidence that I find is not credible or worthy of weight. The fact that evidence is not specifically discussed should not be considered sufficient to rebut the presumption that I considered all the evidence and assigned such weight or probative value to the credible evidence that I determined appropriate within my discretion as an ALJ. There is no requirement for me to discuss the weight given every piece of evidence considered in this case, nor would it be consistent with notions of judicial economy to do so. Charles H. Koch, Jr., *Admin. L. and Prac.* § 5:64 (3d ed. 2013).

⁵ "Credible evidence" is evidence that is worthy of belief. *Black's Law Dictionary* 596 (8th ed. 2004). The "weight of evidence" is the persuasiveness of some evidence compared to other evidence. *Id.* at 1625.

Petitioner was cited by the survey completed on June 26, 2014, for noncompliance with 42 C.F.R. § 483.25(h) (Tag F323⁶) at a scope and severity of "J," – an isolated incident that posed immediate jeopardy to only Resident 19 on June 24, 2014. The surveyor found that Petitioner removed the immediate jeopardy on June 24, 2014, but the alleged noncompliance continued thereafter at a scope and severity of "E" – no actual harm but with the potential for more than minimal harm, and no immediate jeopardy. CMS Exs. 4 at 1-3; 12 at 2-4. Petitioner requested review as to this alleged deficiency and whether or not it is a basis for imposition of an enforcement remedy. RFH: Jt. Stip. ¶ 11.

Petitioner did not request my review of the noncompliance cited by the survey completed August 14, 2014, a violation of 42 C.F.R. § 483.35(i) (Tag F371) at a scope and severity of "E," which means the deficiency posed a risk for more than minimal harm but without actual harm or immediate jeopardy. Jt. Stip. ¶ 11; CMS Ex. 1 at 1. However, Petitioner argues that it was not properly notified that the \$100 CMP from August 14 through 19,

⁶ This is a "Tag" designation as used in CMS Pub. 100-07, State Operations Manual (SOM), Appendix PP – Guidance to Surveyors for Long Term Care Facilities (http://www.cms.hhs.gov/Manuals/IOM/list.asp). The "Tag" refers to the specific regulatory provision allegedly violated and CMS policy guidance to surveyors. Although the SOM does not have the force and effect of law, the provisions of the Act and regulations as interpreted in the SOM clearly do have such force and effect. *Ind. Dep't of Pub. Welfare v. Sullivan*, 934 F.2d 853 (7th Cir. 1991); *Northwest Tissue Ctr. v. Shalala*, 1 F.3d 522 (7th Cir. 1993). Thus, while the Secretary may not seek to enforce the provisions of the SOM, she may seek to enforce the provisions of the Act or regulations as interpreted by the SOM.

Scope and severity levels are used by CMS and a state when selecting remedies. The scope and severity level is designated by an alpha character, A through L, selected by CMS or the state agency from the scope and severity matrix published in the SOM, Chap. 7, § 7400E. A scope and severity level of A, B, or C indicates a deficiency that presents no actual harm but has the potential for minimal harm, which is not considered "noncompliance," and which is an insufficient basis for imposing an enforcement remedy. Facilities with deficiencies of a level no greater than C remain in substantial compliance. 42 C.F.R. § 488.301. A scope and severity level of D, E, or F indicates a deficiency that presents no actual harm but has the potential for more than minimal harm that does not amount to immediate jeopardy. A scope and severity level of G, H, or I indicates a deficiency that involves actual harm that does not amount to immediate jeopardy. Scope and severity levels J, K, and L indicate deficiencies that constitute immediate jeopardy to resident health or safety. The matrix, which is based on 42 C.F.R. § 488.408, specifies which remedies are required and optional at each level based upon the frequency of the deficiency.

2014, was based on the deficiency cited by the survey completed on August 14, 2014. Petitioner argues that the CMP should not be upheld based upon the deficiency cited by the August 14 survey. P. Br. at 2-3.

Therefore, the alleged noncompliance at issue before me is the violation of 42 C.F.R. § 483.25(h) that allegedly posed immediate jeopardy. The enforcement remedies at issue are the proposed \$3,550 per day CMP for one day, June 24, 2014, and the proposed \$100 per day CMP for 56 days from June 25 through Aug. 19, 2014.

- 1. Petitioner did not violate 42 C.F.R. § 483.25 (Tag F323) as alleged by the survey completed on June 26, 2014, in the example of Resident 19.
- 2. There is no basis for the imposition of an enforcement remedy from June 24 through August 13, 2014.

a. Facts

This case turns on facts related to the nature and amount of supervision required for Resident 19 to prevent or mitigate accident hazards while he used his motorized wheelchair, and the sufficiency of the supervision that Petitioner provided. The CMS position, in short, is that Petitioner should have given Resident 19 more and closer supervision, even to the extent of restricting Resident 19 to the facility. Petitioner's position is that it did all it could considering Resident 19's care plan and the fact that Petitioner had no legal authority to confine or restrict Resident 19 to the facility premises.

I find in this case that the most credible evidence of the assessed needs of Resident 19 and the efforts of Petitioner to meet those needs are Resident 19's medical records and the testimony of Resident 19's treating physician, Mehrdad Tavallaee, M.D., and DON Kerr, both of whom were on Resident 19's Interdisciplinary Team (IDT). Surveyor Wagner agreed during her testimony that the IDT was responsible for Resident 19's care planning. Tr. 108. I find credible the testimony of Surveyor Wagner but the weight of her testimony regarding Resident 19 is limited by the fact that her knowledge of Resident 19 and his needs was limited to her review of his clinical record and conversations she had with staff. She did not interview Resident 19 or his attending physician, Dr. Tavallaee. She did not attempt to assess Resident 19's cognitive ability, safety awareness, or his ability to avoid accident hazards without the supervision of facility staff, or render any opinion in that regard, except to refer to the assessment of OT Corban discussed in more detail hereafter.

(1) Surveyor Wagner's Observations, Opinions, and Conclusions

The incident involving Resident 19 that is the basis for the alleged violation of 42 C.F.R. § 483.25(h) occurred on June 24, 2014, the first day of the complaint investigation and partial extended survey. On her way to survey Petitioner's facility around 9:20 a.m. on June 24, Surveyor Wagner observed an individual she suspected might be one of Petitioner's residents traveling in his motorized wheelchair down the two-lane, two-way, Center Street near the facility. According to Surveyor Wagner, the suspected resident was in the middle of Center Street's southbound lane, and he was traveling north in the direction of oncoming traffic, though she did not testify that there was any oncoming traffic at the time of the observation. Surveyor Wagner was traveling to Petitioner's facility in her car headed east on Walnut Street, waiting to make a right turn on to Center Street. Surveyor Wagner was stopped for a red light at the intersection of the two streets while the suspected resident, who had the green light, went through the intersection in front of her. As he crossed the intersection, the resident was talking on his cell phone, and at one point he stopped under the traffic light while talking on the phone. Surveyor Wagner noted that the resident had no orange flag or slow-moving vehicle sign on his wheelchair. She testified that if she had made a right turn on the red light, she would have hit the resident. Tr. 37-41, 73-74; CMS Exs. 4 at 3-4; 6, 7, 9; P. Ex. 12 at 3. Surveyor Wagner's testimony about her observations is unrebutted, not disputed, and fully credible.

Surveyor Wagner subsequently arrived at Petitioner's facility. She reported her observations of the suspected resident to DON Kerr, who confirmed that Surveyor Wagner had seen Resident 19. DON Kerr told Surveyor Wagner that Resident 19 went to the local grocery store pretty much daily. Surveyor Wagner suggested to the DON and Administrator that the facility should find Resident 19 but their response was that Resident 19 goes out daily on his own and returns. Surveyor Wagner then focused on Resident 19 as part of her investigation. Surveyor Wagner testified that she looked at Resident 19's assessment for operating a motorized wheelchair. She learned that Resident 19 left the facility at will. She also learned that staff was aware and had no concerns. Tr. 42-44. Surveyor Wagner testified that pursuant to Petitioner's policy in evidence as CMS Ex. 10, it was the responsibility of the occupational therapist to assess Resident 19's ability to safely operate a motorized wheelchair. She testified that according to CMS Ex. 11, an occupational therapist did evaluate Resident 19 on April 17, 2014, and the occupational therapist determined that Resident 19 should only use the motorized wheelchair in the facility and to go out to smoke, but nowhere else without supervision. Surveyor Wagner opined, based on Petitioner's policy (CMS Ex. 10, page 2, section e), that if Resident 19's condition changed so that it was okay for him to use his wheelchair without supervision off the facility premises, he should have been reassessed. Tr. 45-49. Surveyor Wagner opined that Resident 19's use of his motorized wheelchair off facility premises without supervision constituted a violation of his care plan. Tr. 58. Surveyor Wagner testified that she determined that Resident 19 was not compliant with the facility smoking policy and sign-out policy. Tr. 59-60. Resident 19 refused to grant Surveyor Wagner an interview. Tr. 60-61. Surveyor Wagner testified that Resident 19

had the right to be independent, to refuse treatment, and to come and go as he chose. Tr. 64, 86. She testified that she did not conclude that Resident 19 eloped. Tr. 69. She testified that a resident agrees to supervision as part of an admission agreement. Tr. 70. No copy of Resident 19's admission agreement is in evidence. I do not accept her opinion on what amounts to a legal issue. Surveyor Wagner testified on crossexamination that under Ohio law, an individual using a motorized wheelchair on a roadway is treated as a pedestrian and must use the left lane facing traffic if there are no sidewalks. She knew there were sidewalks in the area where she saw Resident 19 but she did not know why he did not use the sidewalk. Tr. 81-83. She testified that Resident 19's record reflected that he knew he was considered a pedestrian. Tr. 85-86. Surveyor Wagner opined that Resident 19 was known to exercise poor judgment and that was his right but that Petitioner was obliged to ensure his safety given his poor judgment. She stated that Resident 19 had the right to decline treatment, but his caregiver had to be notified. Tr. 86-87. Surveyor Wagner testified that in her opinion Resident 19 was not permitted to leave Petitioner's facility on his motorized wheelchair without permission based on the occupational therapy assessment that he required supervision. Tr. 88-91. She opined that if Resident 19's physician, Dr. Tavallaee, did not think it necessary for Resident 19 to have supervision, contrary to the recommendation of the occupational therapist, there should have been "strong documentation." Tr. 97. Although I accept that it would be good practice to document the physician's orders regarding Resident 19's use of the motorized wheelchair, Surveyor Wagner pointed to no legal requirement for such documentation, a standard of practice, or other enforceable requirement. I also note that Petitioner was not cited for any care planning violation under 42 C.F.R. § 483.20 or a documentation error under 42 C.F.R. § 483.75(*l*).

Surveyor Wagner testified in response to my question that she would not have cited Petitioner but for the statement of the occupational therapist in her evaluation (CMS Ex. 11 at 1) that Resident 19 required supervision except for going out to smoke and in the facility. She testified that the motorized wheelchair Resident 19 used was owned by the facility. Surveyor Wagner explained that because motorized wheelchairs are expensive and difficult to obtain, it is common for facilities to provide the wheelchair initially so that the ability to use it can be assessed. She agreed that the facility could have resolved the problem by simply taking the wheelchair from Resident 19, but the facility made the decision not to because that would have limited his independence. Tr. 101-03. She testified that:

As a citizen, [Resident 19] can leave anytime he wants to, but when you're living in a facility, you have to either refuse the treatment plan . . . or just completely go against the treatment plan and you just can't walk out if your treatment plan says you need supervision. It's not like you and I in our homes, you know?

Tr. 104. Surveyor Wagner did not explain the clear inconsistency in her testimony that on one hand, Resident 19 was a citizen and can leave anytime he wants, while on the other hand, he cannot leave without supervision. But she agreed that you cannot simply lock a resident in a facility. She agreed that a resident cannot be tied down without a physician order. Surveyor Wagner testified that a facility must make sure a resident follows the treatment plan and, if the resident is not, the facility must let someone know. She asserted that she could find no documentation that the physician was contacted, and she does not specify what other individual or entity should have been contacted. Tr. 104-05. Based on my review of Resident 19's medical evidence, particularly P. Ex. 1, and the testimony offered by Petitioner, I find that Resident 19's treating physician, Dr. Tavallaee, and the resident's IDT were well aware of Resident 19's departures from facility grounds in his motorized wheelchair and considered that in establishing and reassessing his plan of care.

Surveyor Wagner alleges in the Statement of Deficiencies for the June 26, 2014 survey that Petitioner violated 42 C.F.R. § 483.25(h) because "the facility failed to provide adequate supervision, based on the safety assessment" for Resident 19, one of three residents reviewed for the independent use of a motorized wheelchair. CMS Ex. 4 at 2. Surveyor Wagner testified that she cited Petitioner because Petitioner failed to supervise Resident 19 outside the facility to prevent accidents or hazards. She testified that Petitioner should have followed the occupational therapist's assessment. Tr. 66-67. Surveyor Wagner alleges that the violation was an isolated incident that posed immediate jeopardy for Resident 19 because he was operating his motorized wheelchair in the street toward oncoming traffic without Petitioner's staff being aware. CMS Ex. 4 at 1-2. Surveyor Wagner testified that Petitioner abated immediate jeopardy on June 24, 2014, the same date as the incident, by subjecting Resident 19 to one-on-one supervision. She testified that Petitioner did not return to substantial compliance until staff was educated to ensure Resident 19 signed out and to instruct him to return at a certain time, and to use other interventions including securing a WanderGuard®, a device applied to a resident's body that triggers an alarm when the resident passes too close to a door or other alarmed exit. Tr. 68-69. I am not bound by Surveyor Wagner's factual findings and conclusions. I must review all the evidence de novo and decide what is more likely true than not true. Then I must determine whether the facts constitute a violation of the regulation that amounts to noncompliance.

(2) Resident 19

Resident 19 was 38 years old at the time of the survey. He was first admitted to Petitioner's facility on March 21, 2014, three months prior to the survey. His primary attending physician was Mehrdad Tavallaee, M.D. Resident 19 was responsible for his own care and was his own guarantor. P. Ex. 1 at 1, 514. His primary diagnosis was human immunodeficiency virus (HIV), and secondary diagnoses included an open wound without complication on his buttock (pressure ulcer), syphilis, hypertension, and malaise

and fatigue. Resident 19 had a history of encephalopathy, generalized muscle weakness, pneumonia, and encephalitis myelitis. He had no psychiatric diagnoses listed in his admission record or his initial assessment. P. Ex. 1 at 3, 114, 511-52; Tr. 54. However, he was treated for anxiety with Xanax during his stay with Petitioner. P. Ex. 1 at 45, 108, 186, 223, 239, 256. Dr. Tavallaee's opinion was that Resident 19 was alert, oriented, and able to make his own decisions throughout his stay with Petitioner. CMS Ex. 13 at 6; Tr. 128. Resident 19 was weak due to his medical condition when initially admitted. In a social services note dated April 10, 2014, the day of his readmission to Petitioner, Resident 19's case manager reported that the physician at the hospital stated that Resident 19's prognosis was poor and he would be appropriate for hospice when his skilled services ended. The social services note also indicates that Resident 19 was end-stage syphilis. P. Ex. 1 at 479. Resident 19's IDT assessed him as being at risk for falls; care planned interventions such as having a call light within reach and encouraging use of the call light; and specified that Resident 19 needed a safe environment with even floors free of spills or clutter, glare free light, handrails, and his personal items within reach. P. Ex. 1 at 187. Resident 19's care plan also provided that he needed to be reminded to sign in and out and that he needed to be supervised by family or friends when using his motorized wheelchair off facility grounds. But the copy of the care plan in evidence does not reflect dates for when that intervention was added by the IDT. P. Ex. 1 at 191-93.

Resident 19 was initially provided a regular wheelchair but that was changed to a power wheelchair to increase his independence. Tr. 152-54. Petitioner's occupational therapist, Ashley Corban, assessed Resident 19 for using a motorized wheelchair first on April 15, 2014. Her initial assessment was that he needed additional training before he could use a motorized wheelchair. After three 30-minute training sessions, including Resident 19 going through doorways, maneuvering around obstacles such as cones, and moving on gravel and through potholes on the facility parking lot, OT Corban approved his use of the power chair. OT Corban credibly testified that she approved Resident 19's use of the motorized wheelchair because she assessed that he was competent and safe to use the power chair independently. Tr. 174-77, 185-86; P. Ex. 1 at 113, 151-52, 158-60; CMS Ex. 11 at 1.8 She noted the approval in a Resident Status Change form, dated April 17,

⁸ After the June 24 incident involving Resident 19, OT Corban reassessed Resident 19's skills in using the motorized wheelchair. Resident 19 passed safety checks for 18 out of the 27 relevant skills assessed at that time. During the assessment, OT Corban found him easily distracted, very lethargic, and slow to respond at times; he had difficulty turning and rolling backwards; and she judged that he was at increased risk for hitting someone. She reported that he remained independent for use of his chair within the facility and on campus but required supervision off Petitioner's property. She explained on cross-examination that she recommended supervision off Petitioner's property because she had *Continued on next page*.

2014, which she distributed to the nursing staff. CMS Ex. 11 at 1; P. Ex. 1 at 113, 158; Tr. 178. In the Resident Status Change form, OT Corban wrote that Resident 19 "can only utilize [the motorized wheelchair] to go outside to smoke and within the facility – nowhere else outside without [supervision]." CMS Ex. 11 at 1; P. Ex. 1 at 113, 158. She explained at hearing that she only assessed Resident 19 within the facility and on the grounds of the facility, and she did not assess him for use of his power wheelchair on city streets. P. Ex. 1 at 159-60; Tr. 173-75. OT Corban testified that she did not evaluate Resident 19 for using his wheelchair off facility premises and that is why she stated he required supervision except when going out to smoke and within the facility. Tr. 179-80, 184. Her testimony was unrebutted by any other testimony and is fully credible.

There is no dispute that Resident 19 was a difficult resident for Petitioner's staff to control throughout his stay. Resident 19 checked himself out of Petitioner's facility on April 3, 2014, against medical advice, and he was readmitted from the hospital on April 10, 2014. P. Ex. 1 at 481. Resident 19 frequently violated the facility smoking policy, including smoking in his room, despite frequent reminders by staff and management. P. Ex. 1 at 106, 315, 317, 322, 390, 398, 481, 483, 510. Physical and occupational therapy were discontinued on April 29, 2014, due to Resident 19's noncompliance with his plan of care for those services. P. Ex. 1 at 58-59. Resident 19 refused treatment for his pressure ulcers many times throughout his stay at Petitioner. P. Ex. 1 at 268-510. There is no dispute that after Resident 19 was given his power wheelchair, he often left the facility unsupervised and without signing out, contrary to the requirement of facility policy. P Ex. 1 at 302, 316-17, 326, 350, 354, 431, 434. Surveyor Wagner's notes reflect her conversations with staff, including Petitioner's Administrator and DON, and they forthrightly reported to her that Resident 19 left facility property daily in his wheelchair and without signing out. Surveyor Wagner's notes show that the Administrator and DON told her that they repeatedly spoke with Resident 19 about leaving the facility grounds and not signing out but he refused to comply. CMS Ex. 6 at 2-3; Tr. 59, 96-97, 116, 156-57, 210-11. The Administrator told Surveyor Wagner that there was never a safety problem reported to him related to Resident 19 leaving the facility. CMS Ex. 6 at 3.

DON Kerr explained at hearing that Resident 19 was given a motorized wheelchair to give him some freedom to do what he wanted without having to rely upon staff and to provide him some privacy and maintain his personal dignity. He was independent before admission to Petitioner, and the plan was for him to return to being independent. DON Kerr testified that Resident 19 worked daily on housing and credit applications and

(Footnote continued.)

not evaluated him for that environment. She also recommended that he not use his cell phone while operating the power chair. P. Ex. 1 at 161-62; Tr. 190-93.

getting his finances in order. Tr. 145-47, 152-54. Her testimony is consistent with the resident's clinical record and the testimony of Social Worker White. See e.g., CMS Ex. 13 at 11, 16-17, 19, 21, 23; Tr. 204-07. DON Kerr testified that staff regularly reminded Resident 19 of the need to sign out of the facility. Tr. 147-49. She testified that Petitioner usually has five to six residents with motorized wheelchairs that operate those chairs off the facility grounds, and there had not been any incidents during the 14 years she worked at Petitioner. Tr. 149-50. Resident 19 had a cell phone and staff would call him when necessary. In DON Kerr's opinion, Resident 19 had the right to leave the facility grounds if he chose to. Tr. 150-51, 155. In response to my questioning, she testified that the IDT was aware that Resident 19 was using his motorized wheelchair off the facility property; observations were that he operated his wheelchair safely; he never had an incident with the chair; he was alert and oriented; and the IDT decided that he was alert and oriented and had the right to make choices and his own decisions. Tr. 163. DON Kerr testified that she was comfortable with Resident 19 leaving the facility unsupervised. She noted that Resident 19 took a cell phone with him when he went out, that his cell phone number was in his chart if facility staff needed to contact him while he was out, and that facility staff "were always able to reach him by his cell phone." Tr. 150, 155. Petitioner's policy for use of motorized wheelchairs specifies that when off the facility premises, a resident must have a charged cell phone in his or her possession. CMS Ex. 10 at 2. Resident 19's records placed in evidence reflect his phone number and show that he was contacted on multiple occasions while out of the facility. P. Ex. 1 at 1, 316, 350, 354. DON Kerr told Surveyor Wagner during the survey that Resident 19 was alert and oriented and had the right to be independent. CMS Ex. 6 at 3. DON Kerr testified that an alert and oriented resident who is capable of making decisions has the right to self-determination and to leave without supervision if he or she chose to. Tr. 150. DON Kerr's testimony is unrebutted and fully credible.

Dr. Tavallaee became Petitioner's Medical Director in 2007, and he was Resident 19's treating physician. Tr. 125. He testified that Resident 19 was admitted to Petitioner for rehabilitation and wound care. Tr. 126. Resident 19 lived independently prior to admission and the plan was for him to be discharged to live independently. Tr. 133-34. Dr. Tavallaee testified that he has many patients who use motorized wheelchairs for independence, most of whom use their motorized wheelchairs on the street every day. In his opinion, as long as his patients are alert, oriented, and able to use their hands, he does not impose any restrictions on their use of the wheelchair or require that they be supervised. Tr. 126-28. Dr. Tavallaee testified that Resident 19 "was alert and oriented, and he was able to make his own decisions," and he did not see a need for supervision when Resident 19 was off facility grounds. Tr. 128. His assessment of Resident 19's

mental status is supported by the evidence. P. Ex. 1 at 559-64; 601-06.9 Thus, in Dr. Tavallaee's opinion, Resident 19 did not need supervision when he left the facility grounds. Tr. 128, 135. Dr. Tavallaee noted also that he had no concerns about Resident 19's safety when using the motorized wheelchair and that based on his observations of Resident 19 using the chair, he had no concerns about Resident 19's competence to use the wheelchair. Tr. 133, 135-36. Dr. Tavallaee maintained this opinion despite knowing that Resident 19 exercised poor judgment at times. ¹⁰ Dr. Tavallaee testified that "people can make wrong decisions, but it doesn't necessarily make him incompetent." Tr. 129. He testified in response to my questioning that he was aware that Resident 19 left the facility, the matter was discussed by the IDT, and no changes were made to Resident 19's care plan as he was okay with Resident 19 leaving. Tr. 139-40. On cross-examination Dr. Tavallaee testified that he was not bound to follow the recommendations of the occupational therapist but he agreed he would normally document a decision not to follow an occupational therapist's recommendation. Tr. 138-39. Dr. Tavallaee was fully credible and his testimony was unrebutted. I give his testimony great weight because he was Resident 19's treating physician, and as such, he had the most extensive knowledge of Resident 19's medical conditions, his cognitive status, his safety awareness, his ability to fend for himself in the community, and his treatment needs.

b. Analysis

An assessment done on June 25, 2014, reflects some altered level of consciousness and psychomotor retardation consistent with the observations of OT Corban during her assessment on that date. P. Ex. 1 at 644. Resident 19's mental status on June 25, 2014, reflects a decline from prior reports in his chart since admission. P. Ex. 1 at 268-510. However, his chart for June 25, 2014, reflects that on that date he had a significant procedure done to address his pressure ulcer, he was reporting significant pain (a level 9), he was drinking beer, and he was making frequent requests for medications. Also, a note on June 24, 2014, indicates that Resident 19 reported feeling more tired due to his new order for Neurontin. P, Ex. 1 at 99, 270-72; CMS Ex. 13 at 11-13; Tr. 52-53.

¹⁰ For example, nursing notes which I find credible show that Resident 19 insisted on drinking alcohol against his doctor's orders, smoked in his room in violation of Petitioner's smoking policy and lied about it to facility staff, possessed drug paraphernalia, admitted to using illegal drugs, and declined to disavow illegal drug use. CMS Ex. 13 at 12, 24-26.

Surveyor Wagner agreed that Resident 19, as his own responsible party, was entitled to make his own decisions despite his poor judgment—including the decision to leave the facility. Tr. 86, 89.

(1) SNF/NF Responsibility to Protect Residents from Accident Hazards

The first step in this analysis is to consider Petitioner's obligations under the Act and the Secretary's regulations to provide its residents, and Resident 19 in particular, a safe environment that is as free of accident hazards as possible and such supervision and assistance devices as necessary to prevent accidents.

The general quality of care regulation, 42 C.F.R. § 483.25, requires that a facility ensure each resident receives "the necessary care and services to attain or maintain the [resident's] highest practicable physical, mental, and psychosocial well-being, in accordance with the resident's comprehensive assessment and plan of care." The quality of care regulations impose specific obligations upon a facility related to accident hazards and accidents. The regulation states:

The facility must ensure that –

- (1) The resident environment remains as free of accident hazards as is possible; and
- (2) Each resident receives adequate supervision and assistance devices to prevent accidents.

42 C.F.R. § 483.25(h). The requirements of these two subsections are different. Subsection (1) specifically limits itself to the "resident environment," but subsection (2) includes no such limitation. Subsection (2) also seems to impose an absolute requirement upon a facility to prevent accidents, but that is not so according to the Board.

CMS is clear in its instructions to its surveyors that the intent of 42 C.F.R. § 483.25(h) is "to ensure the facility provides an environment that is free from accident hazards **over which the facility has control** and provides supervision and assistive devices to each resident to prevent **avoidable accidents**." SOM app. PP Tag F323 (rev. 27; eff. Aug. 17, 2007) (emphasis added). A facility is expected to: identify, evaluate, and analyze hazards and risks; implement interventions to reduce hazards and risks; and monitor the effectiveness of interventions and modify them when necessary. SOM app. PP Tag F323. The policy limits facility responsibility to preventing avoidable accidents, not all accidents. The policy introduces the concept of accident hazards over which a facility has control.

The regulation obligates Petitioner to ensure that the "resident environment" is as free of accident hazards as possible. Therefore, it is important to the analysis to know what is considered to be the resident environment that Petitioner must ensure is as safe as

possible. Is the "resident environment" the bubble of space that surrounds a resident wherever they go? For example, does "resident environment" include the place a resident stays while on furlough, the physician's office during an appointment, the emergency room during an assessment of an irregular heartbeat, or the local convenience store while buying beer and cigarettes? CMS provides its interpretation and guidance to surveyors in the SOM under Tag F323. The "resident environment" as defined by CMS is the physical surroundings to which the resident has access, and examples listed include the room, unit, common use areas, and facility grounds. The SOM discussion of what is the resident environment and what accident hazards a facility is obligated to mitigate or eliminate strongly supports a conclusion that the environment for which a facility is responsible is not the bubble around a resident wherever they may be, but rather the environment that the facility creates for the resident where the resident is supposed to be while under the control of the facility. Thus, Petitioner's building and grounds that are accessible to its residents are included within the resident environment. If Petitioner provides transportation for a resident or residents, arguably the transport would be resident environment. If a resident rides in a vehicle operated by the resident's son, daughter, or friend who is not employed by or contracted by the facility to provide transportation, the resident is arguably not in the "resident environment" for which the facility is responsible. Generally, a location not subject to control by a facility, such as a private home, a hospital, physician office, or a business, should not be treated as "resident environment" because the facility cannot exercise control of those environments. However, if a facility takes one or more residents to an activity or event, the environment in which the resident or residents are placed, whether the transport or the destination, clearly is "resident environment" that the facility is obligated to make as safe as possible to the extent that the facility does or should exercise control over the environment in which it places a resident. A facility, a state agency, and CMS have no legal authority to inspect private residences or places of business absent some authorization and, therefore, a facility should not be responsible for making such environments, over which they can exercise no control, safe for its residents. However, when a facility determines to place its residents in a particular environment, then the facility clearly must be responsible for making that environment as safe as possible by addressing those hazards over which the facility has control and preventing avoidable accidents. Whether or not a particular environment in which a resident is located is "resident environment" within the meaning of 42 C.F.R. § 483.25(h) depends upon the facts. The mere presence of a resident at a particular place in time does not alone make that place "resident environment" for which a facility is responsible. A facility is responsible only for that environment that is properly determined to be "resident environment." But "resident environment" is clearly not limited to a facility's building and grounds.

In this case, Resident 19 was leaving Petitioner without signing out, in violation of Petitioner's policy. However, when Resident 19 went downtown for the day, he was not being treated as having checked out against medical advice. It was known by Dr. Tavallaee and Petitioner's staff that Resident 19 was leaving Petitioner's grounds but it

was expected that he would return. The facts clearly show that despite the absence of documentation in the care plan and other medical evidence (a documentation error was not alleged under 42 C.F.R. § 483.75(*l*)), Resident 19 left facility grounds with the consent of Dr. Tavallaee and Petitioner's staff. Thus, the question is: did "downtown" become resident environment because Dr. Tavallaee and Petitioner's staff did not object to or prevent Resident 19's forays to town? The Act and regulations do not specifically require that interpretation. Indeed, Resident 19's trips to town are more akin to an alert and oriented resident departing during the day on furlough, than a planned trip to the zoo under Petitioner's supervision. Arguably, Petitioner had no responsibility for Resident 19 once he exercised free will and his right to depart Petitioner's property. But Petitioner was responsible for ensuring safety to the maximum extent possible while Resident 19 remained on Petitioner's grounds and for ensuring he was prepared to be as safe as possible when he departed those grounds.

The next question is: what hazards are facilities required to eliminate or mitigate to protect its residents? CMS explains that the phrase "hazards over which the facility has control" refers to hazards in the "resident environment" where reasonable efforts by the facility can influence the risk for injury or illness. SOM app. PP Tag F323. This explanation clearly excludes hazards not in the "resident environment"; for example, once Resident 19 left facility grounds, he was confronted with hazards, many of which would not be present on facility grounds, such as the potential for being struck by a truck on the city street, being wounded in an armed robbery at the liquor store, being held up or mugged for his drug stash in the alley, and similar hazards. While it may be argued that Petitioner could protect Resident 19 against the hazards in the community which are not present in the facility by simply confining Resident 19 to the facility by taking his wheelchair or locking him in his room, that protection could only be accomplished by abridging Resident 19's freedom and preventing his exercise of free will. The phrase "as free of accident hazards as is possible," as explained by CMS, means to be free of accident hazards over which the facility has control. CMS explains to its surveyors:

The facility is responsible for providing care to residents in a manner that helps promote quality of life. This includes

The surveyor, Resident 19's physician, and Petitioner's staff all accept that because Resident 19 was not subject to guardianship or other court order, he was free to come and go from Petitioner's facility at will. Neither CMS nor Petitioner has suggested that Petitioner, the state agency, CMS, or any other governmental entity had the authority to confine or restrict Resident 19 to Petitioner's facility and grounds. Nor is there any legal authority cited by the parties supporting an argument that any governmental authority can require that Petitioner must accomplish what the state cannot do itself, that is, confining Resident 19 to Petitioner's facility and grounds.

respecting residents' rights to privacy, dignity and self determination, and their right to make choices about significant aspects of their life in the facility.

For various reasons, residents are exposed to some potential for harm. Although hazards should not be ignored, there are varying degrees of potential for harm. It is reasonable to accept some risks as a trade off for the potential benefits, such as maintaining dignity, self-determination, and control over one's daily life. The facility's challenge is to balance protecting the resident's right to make choices and the facility's responsibility to comply with all regulations.

The responsibility to respect a resident's choices is balanced by considering the potential impact of these choices on other individuals and on the facility's obligation to protect the residents from harm. The facility has a responsibility to educate a resident, family, and staff regarding significant risks related to a resident's choices. Incorporating a resident's choices into the plan of care can help the facility balance interventions to reduce the risk of an accident, while honoring the resident's autonomy.

SOM app. PP Tag F323. This CMS policy statement is clear that CMS considers a facility responsible for the "resident environment"; the facility is required to make reasonable efforts to eliminate or reduce the risk for injury or illness due to hazards over which the facility has some control within the "resident environment"; and the facility is required to protect the residents from injury or illness while respecting resident rights. The policy statement shows that CMS does not consider a facility under an absolute duty to prevent all risks associated with accident hazards and accidents.

The Board has provided interpretative guidance for adjudicating alleged violations of 42 C.F.R. § 483.25(h)(1) and (2):

The standard in section 483.25(h)(1) itself -- that a facility "ensure that the environment is as free of accident hazards as possible" in order to meet the quality of care goal in section 483.25 -- places a continuum of affirmative duties on a facility. A facility must determine whether any condition exists in the environment that could endanger a resident's safety. If so, the facility must remove that condition if possible, and, when not possible, it must take action to protect residents from the danger posed by that condition. [Footnote

omitted.] If a facility has identified and planned for a hazard and then failed to follow its own plan, that may be sufficient to show a lack of compliance with [the] regulatory requirement. In other cases, an ALJ may need to consider the actions the facility took to identify, remove, or protect residents from the hazard. Where a facility alleges (or shows) that it did not know that a hazard existed, the facility cannot prevail if it could have reasonably foreseen that an endangering condition existed either generally or for a particular resident or residents.

Maine Veterans' Home – Scarborough, DAB No. 1975 at 6-7 (2005).

The Board has also explained the requirements of 42 C.F.R. § 483.25(h)(2) in numerous decisions. Golden Living Ctr. – Riverchase, DAB No. 2314 at 7-8 (2010); Eastwood Convalescent Ctr., DAB No. 2088 (2007); Century Care of Crystal Coast, DAB No. 2076 (2007), aff'd, 281 F. App'x 180 (4th Cir. 2008); Liberty Commons Nursing & Rehab. - Alamance, DAB No. 2070 (2007); Golden Age Skilled Nursing & Rehab. Ctr., DAB No. 2026 (2006); Estes Nursing Facility Civic Ctr., DAB No. 2000 (2005); Northeastern Ohio Alzheimer's Research Ctr., DAB No. 1935 (2004); Woodstock Care Ctr., DAB No. 1726. The Board has often stated that the regulation does not make a facility strictly liable ¹³ for accidents that occur or a failure to deliver adequate supervision and assistance devices even absent an accident. Rather, it is necessary to look at what the facility did or did not do in any given situation to determine whether the actions of the facility were reasonable and adequate. In Woodstock the Board stated that "while the regulations do not make facilities unconditional guarantors of favorable outcomes, the quality of care provisions do impose an affirmative duty to provide services (in this case, supervision and devices to prevent accidents) designed to achieve those outcomes to the highest practicable degree." Woodstock, DAB No. 1726 at 25. A facility, actually the IDT which is charged with caring for a resident (42 C.F.R. § 483.20(k)), is permitted the flexibility to choose the methods of supervision it uses to prevent accidents, but

Strict liability is generally considered to be "[1]iability that does not depend upon actual negligence or intent to harm, but that is based on the breach of an absolute duty to make something safe." *Black's Law Dictionary* 934 (8th ed. 2004). *Black's* explains that strict liability is most often an issue in cases involving ultra-hazardous activities or product liability. Strict liability and absolute liability are synonymous. The term "liability" simply means that one is legally obligated, accountable, or responsible to another or society. *Id.* at 932.

the chosen methods must be adequate under the circumstances. Whether supervision is "adequate" depends in part upon the ability of the resident to protect himself or herself from harm. *Id.* at 29-30.

Based on 42 C.F.R. § 483.25(h), the CMS guidance to surveyors in SOM app. PP Tag F323, and the Board's guidance in years of decisions, Petitioner's obligation to prevent accidents or mitigate the risk for harm associated with accidents is clear. Petitioner is responsible to eliminate or mitigate accident hazards to the extent possible in the environment it creates for its residents, including preparing a resident for trips outside the "resident environment" created by Petitioner. Petitioner must also provide adequate supervision and assistive devices to prevent or mitigate the risk for harm from foreseeable and/or avoidable accidents, even those outside the resident environment. A facility is expected to: identify, evaluate, and analyze hazards and risks; implement interventions to reduce hazards and risks; and monitor the effectiveness of interventions and modify them when necessary. SOM app. PP Tag F323. The Board has not hesitated to find a violation of 42 C.F.R. § 483.25(h) when a facility failed to identify a hazard, plan interventions to eliminate or mitigate the hazard, implement planned interventions, or monitor effectiveness and modify as necessary to meet the objective of the regulation. *See, e.g., Maine Veterans' Home – Scarborough*, DAB No. 1975 at 6-7.

(2) Resident Rights

The CMS policy set forth in the SOM app. PP Tag F323 recognizes the need to balance a resident's rights against the need to protect the resident. CMS instructs its surveyors that "[i]t is reasonable to accept some risks as a trade off for the potential benefits, such as maintaining dignity, self-determination, and control over one's daily life." SOM app. PP Tag F323.

It is necessary to consider what a resident's rights are. Surveyor Wagner agreed that Resident 19 had the right to be independent and make his own judgments regarding his treatment. Tr. 64-65. Under the Act, a resident has the right to pick his or her physician, and unless adjudged incompetent, to participate in care planning and treatment decisions; the right to be free from restraint imposed for discipline or convenience and not required to treat the resident's medical condition and then only upon order of a physician; and the right to reasonable accommodation of individual needs and preferences, unless health and safety would be endangered, among others. Act § 1819(c)(1)(A) (42 U.S.C. § 1395i-3(c)(1)(A)). Under the federal regulations, a resident has rights as a facility resident and as a citizen or resident of the United States. 42 C.F.R. § 483.10(a). A resident has the right to refuse treatment. 42 C.F.R. § 483.10(b)(4). Petitioner is located in Ohio, and Ohio law is applicable as well as the federal statutes and regulations. Under Ohio law, a

resident has the right to be free from physical or chemical restraints except to protect the resident, others, or property, and then only under orders of his or her attending physician. Ohio Rev. Code § 3721.13(A)(13) (2013). ¹⁴ A SNF/NF resident has the right to exercise all civil rights, unless adjudged incompetent; to access opportunities that enable the resident to reach his or her highest potential; and to use alcohol or tobacco unless the attending physician orders otherwise or unless contrary to a written admission policy. Ohio Rev. Code § 3221.13(A)(15)-(18). A resident has the right to observe religious obligations and participate in religious activities to maintain cultural identity, and the right to meet with and participate in the activities of social and community groups. Ohio Rev. Code § 3721.13(A)(20). The Ohio law recognizes and preserves many other rights for residents and permits the attending physician, not an occupational therapist, to limit a resident's free exercise of rights. Although not specifically enumerated in the Act, the regulations, or the Ohio code, the parties agree that Resident 19 was free to come and go from Petitioner's facility, albeit subject to the requirement to sign out to ensure Petitioner's staff knew his whereabouts. The Act, the regulations, and the Ohio code do not grant residents rights, but rather require that their rights be observed by facilities, the state agency, and CMS. Common to all is that only the treating physician can authorize limitation of a resident's rights and then only when necessary to ensure the health and safety of the resident. My interpretation of the Act and the Ohio code is that Resident 19's freedom to come and go from the facility could be limited by his physician for safety or treatment reasons. Certainly, nothing prohibited Petitioner from asking that Resident 19 sign in and out, and the evidence shows that Petitioner's staff did remind Resident 19 to do so. But whether or not Petitioner could sanction or punish Resident 19 for failure to stay on facility grounds or for failure to sign out by taking his motorized wheelchair or by ejecting him from the facility is not an issue I can or need to address in this decision.

(3) The CMS Prima Facie Case

In this case, Surveyor Wagner and CMS allege that Petitioner failed to provide Resident 19 the supervision he needed for the "independent use of motorized wheelchairs" as determined by the safety assessment administered by OT Corban. CMS Ex. 4 at 1-2; CMS Br. at 1, 13-24; CMS Reply at 1, 4-8. Surveyor Wagner testified that she would not have cited Petitioner for this deficiency if OT Corban had not required supervision for Resident 19 as she did. Surveyor Wagner was clear that she did not cite Petitioner with a violation of 42 C.F.R. § 483.25(h) because she determined that Resident 19 was using his motorized wheelchair in an unsafe manner when she observed him on the city street on June 24, 2014. Under Ohio law, a person using a motorized wheelchair is treated as a pedestrian. Ohio Rev. Code § 4511.491 (1990). When a sidewalk is available and its use

¹⁴ Citations are to the Ohio Revised Code available at www.codes.ohio.gov.

is practicable, it is unlawful for a pedestrian to walk along and upon the adjacent roadway. Ohio Rev. Code § 4511.50(A) (2004). However, if there is no sidewalk or use of it is not practicable, and there is no shoulder, the pedestrian must walk along the roadway as near as practicable to the outside edge, and if it is a two-way road, on the left side of the road. Ohio Rev. Code § 4511.50(C). A pedestrian on a roadway must yield the right of way to all vehicles. Ohio Rev. Code § 4511.50. There is no requirement under Ohio law that a motorized wheelchair on a roadway have a slow-moving vehicle sign, lights, or a flag. Ohio Rev. Code § 4513.11 (2009). Surveyor Wagner was clearly initially concerned upon seeing Resident 19 riding his motorized wheelchair in the traffic lane in the direction of oncoming traffic, particularly because she thought he was likely one of Petitioner's residents. But Surveyor Wagner did not cite Petitioner because Resident 19 was violating Ohio traffic laws.

Surveyor Wagner testified that she did not believe that Resident 19 eloped from Petitioner. She testified that Resident 19 did not sign out so Petitioner did not know his whereabouts, but he always came back. Tr. 69. Surveyor Wagner's understanding of elopement is faulty. CMS policy is that an elopement occurs whenever a resident leaves the facility or a safe area without facility authorization such as at discharge or furlough and/or without necessary supervision. SOM app. PP Tag F323. Under the CMS definition of elopement, Resident 19 effectively eloped each time he left Petitioner without authorization. However, Petitioner was not cited for a violation of 42 C.F.R. § 483.25(h) because Resident 19 eloped and CMS does not argue that Petitioner was noncompliant for this reason.

According to the Board, CMS meets its burden to make a prima facie case if the evidence demonstrates that the facility failed to provide adequate supervision and assistance devices to prevent accidents, ¹⁵ given what was reasonably foreseeable. *Alden Town Manor Rehab. & HCC*, DAB No. 2054 at 5-6, 7-12 (2006). CMS must also show that there was a risk for more than minimal harm for the regulatory violation to amount to

¹⁵ An "accident" is an unexpected, unintended event that can cause a resident bodily injury, excluding adverse outcomes associated as a direct consequence of treatment or care (e.g., drug side effects or reactions). SOM app. PP Tag F323; *Woodstock Care Ctr.*, DAB No. 1726 at 4. In this case there was no accident, but CMS is not required to show there was in order to make its prima facie showing. *Woodstock Care Ctr.*, DAB No. 1726 at 17, 36-37.

noncompliance that will support imposition of an enforcement remedy. 42 C.F.R. §§ 488.301; 488.402(b). I conclude that CMS made a prima facie showing that Petitioner failed to provide Resident 19 with adequate supervision and assistance devices. ¹⁶

The regulations give Petitioner notice of the criteria or elements it must meet to comply with the program participation requirement established by the regulation. See 5 U.S.C. §§ 551(4), 552(a)(1); Act § 1871 (42 U.S.C. § 1395hh). Therefore, in order to make a prima facie showing of noncompliance, CMS must show that: (1) Petitioner violated the regulation by not complying with one or more of the requirements or elements of the regulation, which is a deficiency; and (2) the deficiency amounted to "noncompliance," i.e., that Petitioner was not in substantial compliance because the deficiency posed a risk for more than minimal harm. In this case, the elements of the CMS prima facie case established by 42 C.F.R. § 483.25(h) are: (1) an accident hazard existed within the resident's environment, in this case, the environment in which he operated his motorized wheelchair according to CMS; (2) Petitioner failed to eliminate or mitigate the accident hazard to the extent possible; or (3) Petitioner failed to ensure a resident received supervision and assistive devices necessary to prevent accidents; and (4) the deficiency posed a risk for more than minimal harm to Resident 19 or other residents. The Board has stated that "[i]f a facility has identified and planned for a hazard and then failed to follow its own plan, that may be sufficient to show a lack of compliance with [the] regulatory requirement." Maine Veterans' Home – Scarborough, DAB No. 1975 at 6-7.

On or about March 24, 2014, at the time of his initial admission to Petitioner, Resident 19's IDT assessed him as at risk for falls; planned interventions such as having a call light within reach and encouraging use of the call light; and specified that Resident 19 needed a safe environment with even floors free of spills or clutter, glare free light, handrails, and his personal items within reach. P. Ex. 1 at 187. A fall is an accident hazard for which Resident 19 was assessed and for which interventions were planned. I see no evidence that this assessment of a problem and interventions were updated or changed during the course of Resident 19's residence at Petitioner's facility. Resident 19's unsupervised departure from Petitioner's facility clearly violated this part of his care

The Board has never clearly defined what quantum of evidence is required for CMS to make a prima facie showing. In this case, I am satisfied that the CMS case rests upon more than the mere allegations of the surveyor and more than a scintilla of evidence. The exception is the element of the risk for more than minimal harm, which is based only upon the allegation of the surveyor that the failure to supervise Resident 19 posed a risk to him for more than minimal harm, even though that harm is never specifically identified by the surveyor in the SOD or in testimony. I find it unnecessary to further analyze the adequacy of the evidence as to that element as I conclude that Petitioner rebutted the CMS prima facie case as to the other elements of the deficiency citation.

plan. For example, while outside the facility and off facility grounds, Resident 19's call light was not within easy reach; there were no handrails; he was in an unsafe environment with potentially uneven surfaces; and there was no ability for Petitioner's staff to control spills, lighting, or clutter. Thus, the unrebutted evidence shows that Petitioner care planned for an accident hazard but then failed to follow the care plan because Resident 19 was allowed to depart the facility building.

It appears that at the time of the complaint survey, on or about June 24, 2014, Petitioner's staff updated Resident 19's care planning document in his clinical record to include interventions to remind Resident 19 to sign out when leaving the facility and various interventions related to his use of the motorized wheelchair. It is not clear that the care plan document specifically addressed Resident 19's leaving the facility grounds or the use of a motorized wheelchair prior to the June survey. However, Resident 19 was assessed for use of the motorized wheelchair on April 15, 2014, with specific interventions, some implemented and some proposed by OT Corban. ¹⁷ Her initial assessment was that he needed additional training before he could use a motorized wheelchair. Thereafter, OT Corban conducted three 30-minute training sessions, including going through doorways, maneuvering around obstacles such as cones, and moving on gravel and through potholes on the facility parking lot. After training Resident 19, OT Corban approved his use of the motorized wheelchair. OT Corban credibly testified that she approved Resident 19's use of the motorized wheelchair because she assessed that he was competent and safe to use the power chair independently. Tr. 174-77, 185-86; P. Ex. 1 at 113, 151-52, 158-60; CMS Ex. 11 at 1. However, in the Resident Status Change form in Resident 19's medical record, OT Corban wrote that Resident 19 "can only utilize [the motorized wheelchair] to go outside to smoke and within the facility – nowhere else outside without [supervision]." CMS Ex. 11 at 1; P. Ex. 1 at 113, 158. OT Corban's assessment does not state why she determined that Resident 19 could only use his power chair to go outside to smoke and within the facility but nowhere else outside without supervision. Surveyor Wagner observed

C.F.R. § 483.20(k); SOM Tag F279 (eff. Jun. 1, 2004). The regulations and the SOM do not require that a care plan be in a specific form. However, a care plan must obviously be documented in some form, or the facility cannot prove that assessment and care planning were done as required by 42 C.F.R. § 483.20(d) and (k) (Tag F279). Petitioner was not charged with violating either 42 C.F.R. § 483.20(d) or (k). Petitioner was also not charged with a documentation or clinical records error in violation of 42 C.F.R. § 483.75(*l*) (Tag F514). Pursuant to 42 C.F.R. § 483.75(*l*)(5), the clinical record must contain sufficient information to identify the resident; records of resident assessments; the plan of care and services provided; the results of preadmission screening by the state; and progress notes.

Resident 19 on the street off facility grounds, not smoking and without supervision. Surveyor Wagner's observation of Resident 19 off the facility grounds operating his power wheelchair and the assessment from OT Corban are sufficient evidence to support Surveyor Wagner's finding that Petitioner planned for the risk of Resident 19 going outside other than to smoke and that plan required that Resident 19 receive supervision in that circumstance. Accordingly, I conclude that, in the absence of rebuttal evidence, CMS has made a prima facie showing of a violation of 42 C.F.R. § 483.25(h) because the evidence reviewed by Surveyor Wagner in Resident 19's clinical record showed that Petitioner planned for an accident hazard for Resident 19 and Surveyor Wagner's observation showed Petitioner failed to follow the care plan.

(3) Petitioner Rebutted the CMS Prima Facie Case – Balancing Resident Rights and the Duty to Protect Against Accident Hazards

The burden is upon Petitioner to rebut the CMS prima facie showing. The language of the regulation establishes impossibility as a potential defense.

- (1) The resident environment remains as free of accident hazards **as is possible**; and
- (2) Each resident receives adequate supervision and assistance devices to prevent accidents.

42 C.F.R. § 483.25(h). The Board has also suggested that the unforeseeability of a risk for an accident or more than minimal harm due to an accident are possible defenses by suggesting that a facility is only responsible to eliminate or mitigate reasonably foreseeable risks for accidental injury. Maine Veterans' Home – Scarborough, DAB No. 1975 at 6-7. The Board has also signaled that it may be willing to accept that a facility met its duty to a resident by providing "adequate supervision and assistance devices," albeit not perfect or flawless supervision and assistance devices. The Board has stated that a facility is permitted the flexibility to choose the methods of supervision it uses to prevent accidents, but the chosen methods must be adequate under the circumstances. Further, whether supervision is "adequate" depends in part upon the ability of the resident to protect himself or herself from harm. Woodstock, DAB No. 1726 at 29-30. Therefore, Petitioner is obliged to show in this case by a preponderance of the evidence that adequate supervision or other interventions were implemented to mitigate or eliminate the risk for occurrence of an accident or more than minimal harm; or that it was impossible to eliminate or mitigate this accident risk; or that the accident risk and risk for more than minimal harm caused by Resident 19's use of his motorized wheelchair was unforeseeable. Petitioner satisfies its burden in this case based on the credible testimony

of Resident 19's attending physician and evidence that more supervision than Petitioner provided was not required to satisfy the requirement of 42 C.F.R. § 483.25(h) in the case of Resident 19.

The decision-making and supervisory roles of the attending physician are of paramount importance in the care and treatment of SNF/NF residents. Pursuant to 42 C.F.R. § 483.40(a)(1), a facility must ensure that the medical care of every resident is supervised by a physician. As already discussed, under the Act, the regulations, and Ohio law, it is the treating physician who has the authority to determine whether or not to limit a SNF/NF resident's rights to benefit the health and safety of the resident. Act § 1819(c)(1)(A); 42 C.F.R. § 483.10(a), (b)(4); Ohio Rev. Code § 3721.13(A)(13), (15)-(18), (20). CMS policy articulated in SOM app. PP Tag F323 recognizes the need to balance resident rights and the need to keep the resident safe.

When Resident 19 was readmitted to Petitioner on April 10, 2014, his prognosis was poor, he was end-stage syphilis, and it was opined that he would be appropriate for hospice. P. Ex. 1 at 479. Resident 19 was weak and assessed as a fall risk. P. Ex. 1 at 187. He had difficulty using a regular wheelchair and on April 15, 2014, his IDT had him assessed by OT Corban for the use of a motorized wheelchair. On April 15, Resident 19 could not safely operate the motorized wheelchair so OT Corban provided him training. She subsequently reassessed him as safe to use the wheelchair. Tr. 152-54, 174-77, 185-86; P. Ex. 1 at 113, 151-52, 158-60; CMS Ex. 11 at 1. In the record of her assessment dated April 17, 2014, OT Corban stated that Resident 19 was approved to use his motorized wheelchair to go outside to smoke and within the facility, but nowhere else without supervision. CMS Ex. 11 at 1; P. Ex. 1 at 113, 158. She explained at the hearing that she only assessed Resident 19 within the facility and on the grounds of the facility, and she did not assess him for use of his power wheelchair on city streets. P. Ex. 1 at 159-60; Tr. 173-75. She testified that she did not evaluate Resident 19 for using his wheelchair off facility premises and that is why she stated he required supervision except when going out to smoke and within the facility. Tr. 179-80, 184. She did not reassess Resident 19 until asked to do so during the survey. OT Corban's testimony was credible and unrebutted by any other testimony. The evidence shows that shortly after Resident 19's readmission to Petitioner, the IDT intended to maintain his dignity by giving him as much independence as possible and, if possible, return him to the community to live. Tr. 145-47, 152-54; CMS Ex. 13 at 11, 16-17, 19, 21, 23; Tr. 204-07.

Dr. Tavallaee, Resident 19's attending physician, was clear in his testimony that he was not bound to follow the recommendation of OT Corban that Resident 19 have supervision using his wheelchair except within the facility and when out to smoke. Tr. 138-39. Dr. Tavallaee's understanding of his responsibility to direct his patient's care as the attending physician with the advice of the IDT is consistent with the Act, the Secretary's regulations, and Ohio law. He testified that he was aware that Resident 19 left the facility unsupervised, the matter was discussed by the IDT, and no changes were made to

Resident 19's care plan because he was okay with Resident 19 leaving the facility unsupervised. Tr. 139-40. Dr. Tavallaee testified that Resident 19 "was alert and oriented, and he was able to make his own decisions," and he did not see a need for supervision when Resident 19 was off facility grounds. 18 Tr. 128. His assessment of Resident 19's mental status is supported by the evidence. P. Ex. 1 at 559-64, 601-06. In Dr. Tavallaee's opinion, Resident 19 did not need supervision when he left the facility grounds. Tr. 128, 135. Dr. Tavallaee noted also that he had no concerns about Resident 19's safety when using the motorized wheelchair and that, based on his observations of Resident 19 using the chair, he had no concerns about Resident 19's competence to use the wheelchair. Tr. 133, 135-36. Dr. Tavallaee maintained this opinion despite knowing that Resident 19 often exercised poor judgment. 19 Dr. Tavallaee's opinion was based on his knowledge of Resident 19 and his professional expertise. He testified that he has many patients who use motorized wheelchairs for independence, most of whom use their motorized wheelchairs on the street every day. In his opinion, as long as his patients are alert, oriented, and able to use their hands, he does not impose any restrictions on their use of the wheelchair or require that they be supervised. Tr. 126-28. Under the Act, the Secretary's regulations, and Ohio law, it is the attending physician who is responsible to determine if and how to limit a resident's freedom for the treatment and safety of the resident. Neither Surveyor Wagner nor CMS suggests that they have any authority to substitute their medical judgment for that of Dr. Tavallaee. Surveyor Wagner was clear that she cited the deficiency because of OT Corban's recommendation for supervision. Dr. Tavallaee was equally clear that his medical judgment was that Resident 19 was able to take care of himself while using his motorized wheelchair and he did not require supervision when using the motorized wheelchair off facility grounds. Although more clear documentation in Resident 19's clinical record, including the care plan document, would have been desirable, Surveyor Wagner did not cite Petitioner for either a care planning or a clinical record (documentation) error. The evidence shows that staff and

¹⁸ Unlike the situation in *Woodstock* (DAB No. 1726 at 24), Resident 19 was not demented or determined to be incapable of protecting himself.

¹⁹ Resident 19's decision to ride his chair in the street may be evidence of poor judgment or it may reflect a reasonable judgment that the street was smoother and safer for him than riding on the sidewalk that was reported to be in bad repair and may have caused him pain due the pressure ulcer in his sacral area. Tr. 82, 176-77, 183; P. Ex. 1 at 2. Resident 19's exact position in the traffic lane when Surveyor Wagner observed him is subject to some dispute. CMS Br. at 20-21, P. Br. at 16. But Surveyor Wagner did not cite Petitioner because Resident 19 may not have been riding close enough to the gutter when she saw him.

management were aware of Resident 19's conduct and how to locate him by telephone when necessary despite the fact that the documentation in the clinical record was not more clear or comprehensive.

CMS argues that Petitioner violated 42 C.F.R. § 483.25(h) by failing to keep track of Resident 19's whereabouts and expected return times when he left the facility. CMS Br. at 14, 22-23. CMS argues that Petitioner's failure to keep track of Resident 19 posed risks to Resident 19's health because his off-site trips interfered with his medical care. CMS Br. at 22-23. CMS argues further that this failure reveals "larger problems with the care and services [Petitioner] provided to [Resident 19]" and independently establishes Petitioner's noncompliance with 42 C.F.R. § 483.25(h). CMS Br. at 22-23. CMS cites Heritage Park Rehab. & Nursing Ctr., DAB No. 2231 at 12 (2009) and Eastwood Convalescent Ctr., DAB No. 2088 at 15 (2007), in support of this argument. CMS Br. at 14, 23. There are two flaws with the CMS chain of reasoning. First, Petitioner had a policy that required residents to sign out when they wanted to leave the facility premises. Tr. 59, 96, 156, 210. Resident 19 knew about the policy, yet despite Petitioner's attempts to ensure his compliance with that policy through education and efforts to make it easier for him to sign out, he repeatedly failed to sign out. Tr. 96-97, 210-11; P. Ex. 1 at 268-71, 274-76, 283, 300-02. Resident 19 was not Petitioner's prisoner, and Petitioner did what it reasonably could to enforce its sign-out policy but it was to no avail. 20 Tr. 96-97. 210-11; P. Ex. 1 at 268-71, 274-76, 283, 300-02. I conclude that Petitioner took adequate steps to enforce its sign-out policy without eliminating Resident 19's independence. Second, even if Petitioner's affirmative efforts to monitor Resident 19's location were insufficient, any shortcomings were offset by its policy requiring residents to take a charged cell phone with them when they left the facility—a policy Resident 19 obeyed. Tr. 150, 155; CMS Ex. 10 at 2; P. Ex. 1 at 1, 316, 350, 354. Petitioner's employees

There is no question that Petitioner could have kept Resident 19 in the facility by the simple expedient of taking away his motorized wheelchair, thereby eliminating his ability to leave without signing out, but also eliminating his independence. There are other approaches Petitioner could have taken. Theoretically, CMS could require by regulation that to monitor the location of a resident, a facility must apply ankle monitors to residents, similar to those used by law enforcement and the courts to monitor the whereabouts of convicts serving probation. Chain link fencing with guards may also be an efficient and effective deterrent to residents leaving facility grounds without permission and without signing out. CMS does not specifically advocate that Petitioner should have deprived Resident 19 of his liberty in order to comply with 42 C.F.R. § 483.25(h), but that is the logical extension of the effort of CMS to establish liability for Petitioner's failure to constantly supervise Resident 19 or restrict him to the facility premises contrary to the judgment of his attending physician.

needed only to call Resident 19 if they wanted to discover where he was and when he expected to return to the facility, and the evidence shows that they did so on several occasions. These facts distinguish this case from the cases CMS cites²¹ and justify a different conclusion. In light of Petitioner's adequate efforts and procedures to ensure it knew where Resident 19 was and when he expected to return, I conclude that Petitioner did not violate 42 C.F.R. § 483.25(h) by any failure to keep track of Resident 19's whereabouts and expected return times.

I conclude that Petitioner has rebutted the CMS prima facie showing of a violation of 42 C.F.R. § 483.25(h). Petitioner did not violate 42 C.F.R. § 483.25(h). I further conclude that there was no basis for imposing any enforcement remedy from June 24 through August 13, 2014, because there was no other cited noncompliance during that period. CMS Exs. 1 at 5; 5.

3. Petitioner violated 42 C.F.R. § 483.35(i) (Tag F371) as determined by the revisit survey completed on August 14, 2014.

²¹ The deficiency cited in *Heritage Park* involved a SNF leaving unsupervised a resident who posed a risk of elopement in a way that posed a foreseeable risk of further elopement. DAB No. 2231 at 8-10. On that ground alone, Heritage Park is distinguishable from the present case because here, CMS does not allege that Resident 19 eloped or posed a risk of elopement, and in Surveyor Wagner's words, Resident 19 "did not elope from the facility." Tr. 69. Furthermore, to the extent the Board concluded in Heritage Park that the facility should have ensured that it knew where the resident posing an elopement risk was going by, for example, enforcing its sign-out policy (DAB No. 2231 at 10-12), this case is distinguishable in that Petitioner did its best to remind and encourage Resident 19 to comply with its sign-out policy. Also, Resident 19 carried a working cell phone with him when he left the facility, as required by Petitioner's policy, which permitted Petitioner's staff to contact him when necessary. Eastwood is similarly distinguishable. The deficiency cited in Eastwood involved a SNF that failed to conduct a search for a missing resident after that resident left the facility's premises with her husband and failed to return within the timeframe (an hour and a half) her husband established for her return. DAB No. 2088 at 8-9. In this case, Resident 19 habitually left the facility, often without signing out or providing information about his return times; he always returned; and he was accessible by cell phone. CMS Ex. 6 at 2-3; Tr. 116, 150, 155; P. Ex. 1 at 1, 316. In short, Resident 19 was not missing on these occasions, and the IDT and attending physician concluded that Petitioner did not need to search for Resident 19 when he went off facility property or monitor his comings and goings, which materially distinguishes this case from *Eastwood*.

- 4. Petitioner's violation of 42 C.F.R. § 483.35(i) (Tag F371) posed a risk for more than minimal harm for Petitioner's residents with no actual harm or immediate jeopardy, and Petitioner was not in substantial compliance with program participation requirements due to the violation of 42 C.F.R. § 483.35(i) at a scope and severity of E.
- 5. There is a basis to impose an enforcement remedy from August 14 through 19, 2014.
- 6. Petitioner received adequate notice of the CMS initial determination to impose an enforcement remedy based on the noncompliance cited by the survey completed on August 14, 2014.

Petitioner did not request review of the results of the revisit survey conducted on August 14, 2014. Jt. Stip. ¶ 11. Accordingly, CMS's determination based on the August 14 survey that Petitioner violated 42 C.F.R. § 483.35(i) (Tag F371) at a scope and severity of E (Jt. Stip. ¶ 5) is final and binding. 42 C.F.R. §§ 498.20(b), 498.70(a). CMS's October 6, 2014 letter notified Petitioner that CMS was imposing enforcement remedies including, among other things, a per day CMP of \$3,550 for one day on June 24, 2014, and a CMP of \$100 per day from June 25, 2014 through August 19, 2014. The letter explained that a revisit survey on September 3, 2014, determined that Petitioner returned to substantial compliance with program participation requirements (that is, all noncompliance was corrected), effective August 20, 2014. CMS Exs. 1 at 1-2. The state agency determined that effective August 14, 2014, Petitioner had corrected the noncompliance under Tag F323 cited by the June 24, 2014 survey. CMS Ex. 5. Therefore, the CMP imposed from August 14 through 19, 2014, was based on Petitioner's alleged noncompliance with 42 C.F.R. § 483.35(i) at a scope and severity of E. Because Petitioner did not seek review of the allegation of noncompliance with 42 C.F.R. § 483.35(i), that determination is final and binding. The determination that Petitioner was not in substantial compliance with 42 C.F.R. § 483.35(i) during the period August 14 through 19, 2014, is a basis for the imposition of an enforcement remedy. The remedy proposed by CMS is a \$100 CMP from August 14 through 19, 2014.

Although Petitioner did not seek review of the noncompliance under 42 C.F.R. § 483.35(i), Petitioner argues that it was not properly notified that the \$100 CMP for the period August 14 through 19, 2014, was based on that noncompliance. Petitioner argues that due to the defective notice, the CMP should not be upheld based upon the noncompliance under 42 C.F.R. § 483.35(i) cited by that August 14, 2014 survey. P. Br. at 2-3; Tr. 15-17.

Petitioner is correct that the October 6, 2014 CMS notice does not specifically state that CMS proposed a \$100 per day CMP based upon the noncompliance with 42 C.F.R. § 483.35(i) at a scope and severity of E as cited by the August 14, 2014 survey. However, the letter only cites the noncompliance under 42 C.F.R. § 483.35(i) (Tag F371) at a scope and severity of E with no reference to the noncompliance under 42 C.F.R. § 483.25(h) cited by the June 24 survey as a continuing basis for the CMP. Although the October 6, 2014 letter may have been more specific, the evidence shows that the August 14, 2014 survey specifically determined that Petitioner had corrected the noncompliance under 42 C.F.R. § 483.25(h) cited by the June 24, 2014 survey as of August 14, 2014. CMS Ex. 5. Therefore, after August 13, 2014, the noncompliance under 42 C.F.R. § 483.25(h) was no longer the basis for an enforcement remedy. Petitioner does not argue and has not presented evidence that Petitioner was not informed that the noncompliance under 42 C.F.R. § 483.25 was corrected effective August 14. I infer Petitioner was informed of the findings of the August 14, 2014 survey. Therefore, the only reasonable reading of the October 6, 2014 notice by Petitioner was that the only basis for an enforcement remedy from August 14 through 19, 2014, was the alleged noncompliance under 42 C.F.R. § 483.35(i) from the August 14, 2014 survey. I conclude that Petitioner's argument that it did not have adequate notice of the basis for the proposed enforcement remedy, a \$100 CMP from August 14 through 19, 2014, is without merit.

7. Petitioner does not dispute that a CMP of \$100 per day from August 14-19, 2014, is a reasonable enforcement remedy.

I have concluded that from August 14 through 19, 2014, Petitioner was not in substantial compliance with program participation requirements due to its violation of 42 C.F.R. § 483.35(i). If a facility is not in substantial compliance with program requirements, CMS has the authority to impose one or more of the enforcement remedies listed in 42 C.F.R. § 488.406, including a CMP. CMS may impose a per day CMP for the number of days that the facility is not in compliance or a per instance CMP for each instance that a facility is not in substantial compliance, whether or not the deficiencies pose immediate jeopardy. 42 C.F.R. § 488.430(a). The upper range of a per day CMP, \$3,050 per day to \$10,000 per day, is reserved for deficiencies that pose immediate jeopardy to a facility's residents, and, in some circumstances, for repeated deficiencies. 42 C.F.R. § 488.438(a)(1)(i), (d)(2). The lower range of per day CMPs, \$50 per day to \$3,000 per day, is reserved for deficiencies that do not pose immediate jeopardy, but either cause actual harm to residents, or cause no actual harm but have the potential for causing more than minimal harm. 42 C.F.R. § 488.438(a)(1)(ii). I conclude that there is a basis for the imposition of a per day CMP at the lower range for the deficiency cited under 42 C.F.R. § 483.35(i) that posed a risk for more than minimal harm but not immediate jeopardy.

If I conclude, as I have in this case, that there is a basis for the imposition of an enforcement remedy and the remedy proposed is a CMP, my authority to review the reasonableness of the CMP is limited by 42 C.F.R. § 488.438(e). The limitations are: (1) I may not set the CMP at zero or reduce it to zero; (2) I may not review the exercise of discretion by CMS in selecting to impose a CMP; and (3) I may only consider the factors specified by 42 C.F.R. § 488.438(f) when determining the reasonableness of the CMP amount. In determining whether the amount of a CMP is reasonable, the following factors specified at 42 C.F.R. § 488.438(f) must be considered: (1) the facility's history of non-compliance, including repeated deficiencies; (2) the facility's financial condition; (3) the seriousness of the deficiencies as set forth at 42 C.F.R. § 488.404(b), which are the same factors CMS and/or the state were required to consider when setting the CMP amount; and (4) the facility's degree of culpability, including, but not limited to, the facility's neglect, indifference, or disregard for resident care, comfort, or safety, and the absence of culpability is not a mitigating factor. The factors that CMS and the state were required to consider when setting the CMP amount and that I am required to consider when assessing the reasonableness of the amount are set forth in 42 C.F.R. § 488.404(b): (1) whether the deficiencies caused no actual harm but had the potential for minimal harm; no actual harm with the potential for more than minimal harm, but not immediate jeopardy; actual harm that is not immediate jeopardy; or immediate jeopardy to resident health and safety; and (2) whether the deficiencies are isolated, constitute a pattern, or are widespread. My review of the reasonableness of the CMP is de novo and based upon the evidence in the record before me. I am not bound to defer to the CMS determination of the reasonable amount of the CMP to impose, but my authority is limited by regulation as already explained. The Board has explained that my task is to determine whether the amount of any CMP proposed is within reasonable bounds considering the purpose of the Act and regulations. Emerald Oaks, DAB No. 1800 at 10; CarePlex of Silver Spring, DAB No. 1683 at 14-16 (1999); Capitol Hill Cmty. Rehab. & Specialty Care Ctr., DAB No. 1629 (1997).

CMS proposes a CMP of \$100 per day based on the single deficiency for the period August 14 through 19, 2014. Petitioner does not challenge the reasonableness of the \$100 per day CMP, other than the allegation of insufficient notice which I have rejected. P. Br. at 30. My review of the required factors leads me to conclude that the \$100 per day CMP is reasonable. Petitioner does not argue that it cannot afford to pay the total CMP of \$600, and Petitioner offered no testimony or documents related to its financial condition. Petitioner has a history of noncompliance, including a prior violation of 42 C.F.R. § 483.35(i). CMS Ex. 3 at 1-3. The deficiency was not very serious, but it was part of a pattern of noncompliance, rather than an isolated instance. The record does not reveal, and the parties do not argue, the degree of the facility's culpability with respect to the violation of 42 C.F.R. § 483.35(i). The \$100 per day CMP is at the low end of the authorized range. I conclude that a CMP of \$100 per day from August 14 through 19, 2014, is a reasonable enforcement remedy.

8. Other issues raised by Petitioner are not within my authority to decide.

Petitioner raises numerous Constitutional and statutory arguments and challenges to the validity of the Secretary's regulations and the procedures and policies related thereto. RFH at 8-13. Some of the challenges are rendered moot by this decision and others exceed my authority to resolve. Petitioner does not seek my ruling upon the issues for which I have no jurisdiction but states it desires to preserve those issues for possible appeal in the United States Circuit Court of Appeals. P. Br. at 30. Indeed, I have no authority to find invalid or refuse to follow statutes, regulations, or secretarial delegations of authority. 42 C.F.R. § 1005.4(c)(1); *1866ICPayday.com*, *L.L.C.*, DAB No. 2289 at 14 (2009).

III. Conclusion

For the foregoing reasons, I conclude that Petitioner did not violate 42 C.F.R. § 483.25(h) during the period June 24 through August 13, 2014, and there is no basis for imposing a CMP for that period. However, Petitioner was not in substantial compliance with program participation requirements from August 14 through 19, 2014, due to a violation of 42 C.F.R. § 483.35(i) that posed a risk for more than minimal harm. Accordingly, there is a basis for an enforcement remedy for the period August 14 through 19, 2014, and a \$100 per day CMP, a total CMP of \$600, is reasonable.

/s/

Keith W. Sickendick Administrative Law Judge