Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Courtyard Healthcare Center
(CCN: 15-5689),

Petitioner,

v.

Centers for Medicare and Medicaid Services.

Docket No. C-11-796

Decision No. CR2712

Date: March 1, 2013

DECISION

Petitioner, Courtyard Healthcare Center, was not in substantial compliance with program participation requirements from June 7 through 9, 2011, due to a violation of 42 C.F.R. § 483.25(h)[1] that posed immediate jeopardy on June 7, 2011 and a risk for more than minimal harm without actual harm or immediate jeopardy on June 8 and 9, 2011. A civil money penalty (CMP) of $3,550 for June 7 and $100 per day for June 8 and 9, 2011, is reasonable.

I. Background

Petitioner is located in Goshen, Indiana, and participates in Medicare as a skilled nursing facility (SNF) and the state Medicaid program as a nursing facility (NF). Petitioner was surveyed by the Indiana State Department of Health (state agency) from June 6 through 9, 2011. The survey concluded that Petitioner was not in substantial compliance with program participation requirements. Centers for Medicare and Medicaid Services (CMS) Exhibit (Ex.) 6. CMS notified Petitioner by letter dated July 12, 2011, that it was

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[1] References are to the 2010 revision of the Code of Federal Regulations (C.F.R.), which was in effect at the time of the survey, unless specifically indicated.

imposing the following enforcement remedies: a CMP of $3,550 for June 7, 2011; a CMP of $100 per day beginning June 8, 2011, and continuing until Petitioner returned to substantial compliance; termination effective December 9, 2011, if Petitioner did not return to substantial compliance prior to that date; and a denial of payment for new admissions (DPNA) effective September 9, 2011, if Petitioner did not return to substantial compliance prior to that date. CMS also notified Petitioner that it was ineligible to conduct a Nurse Aide Training and Competency Evaluation Program (NATCEP) for a period of two years based on the partial extended survey the state conducted. CMS Ex. 1. CMS subsequently determined that Petitioner returned to substantial compliance effective June 10, 2011, and the termination and DPNA remedies were not effectuated. CMS Exs. 2, 19. Thus, the remedies at issue are the CMP of $3,550 for June 7 and $100 per day for June 8 and 9, 2011.

Petitioner requested a hearing before an administrative law judge (ALJ) on September 12, 2011. The case was assigned to me for hearing and decision on September 21, 2011, and an Acknowledgement and Prehearing Order was issued at my direction. On May 1, 2012, a hearing was convened in Indianapolis, Indiana. A transcript (Tr.) of the proceedings was prepared. CMS offered CMS exhibits (CMS Exs.) 1 through 24 that were admitted as evidence. Tr. 18-19, 32. Petitioner offered Petitioner exhibits (P. Exs.) 1 through 4 that were admitted as evidence. Tr. 20. CMS called the following witnesses: Surveyor Ellen Ruppel, RN; and Surveyor Brenda Meredith, RN. Petitioner called the following witnesses: Paula Hoover; and Brian Cook, Petitioner's Administrator. The parties filed post-hearing briefs (CMS Br. and P. Br.) and post-hearing reply briefs (CMS Reply and P. Reply). Petitioner offered P. Ex. 5 with its post-hearing reply, CMS filed no objections, and P. Ex. 5 is admitted.

II. Discussion

A. Issues

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

Whether the remedy imposed is reasonable.

B. Applicable Law

The statutory and regulatory requirements for participation of a SNF in Medicare are found at section 1819 of the Social Security Act (Act) and at 42 C.F.R. Part 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.[2] 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 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 other remedies such as 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* 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. Part 483, subpart B. Noncompliance refers to any deficiency that causes a facility not to be in substantial compliance. 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. CMS may impose a CMP against a facility on a per day basis. The regulations provides for two ranges of CMPs. 42 C.F.R. §§ 488.408, 488.438. The upper range, $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). "*Immediate jeopardy* means a situation in which the provider's noncompliance with one or more requirements of participation has caused, or

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[2] Participation of a 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.

is likely to cause, serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301 (emphasis in original). The lower range of 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).

Petitioner was notified in this case that it was ineligible to conduct a NATCEP for two years. Ineligibility to be approved to conduct a NATCEP is by operation of law and is not an enforcement remedy that CMS or the state agency imposes. 42 C.F.R. §§ 483.151(b)(2); 488.406. Pursuant to sections 1819(b)(5) and 1919(b)(5) of the Act, SNFs and 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. Part 483, subpart 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 skilled nursing or nursing facility 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.

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); 42 C.F.R. §§ 488.330(e), 498.3. 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 33 (2012) (citation omitted). The standard of proof, or quantum of evidence required, 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 imposition of an enforcement remedy. The Board has stated that CMS must come forward with "evidence related to disputed findings that is sufficient (together with any undisputed findings and relevant legal authority) to establish a prima facie case of noncompliance with a regulatory requirement." *Evergreene Nursing Care Ctr.*, DAB No. 2069, at 7 (2007); *Batavia Nursing and Convalescent Ctr.*, DAB No. 1904 (2004), *aff'd, Batavia Nursing and Convalescent Ctr. v. Thompson,* 129 F. App'x 181 (6th Cir. 2005). "Prima facie" means generally that the evidence is "[s]ufficient to establish a fact or raise a presumption unless disproved or rebutted." *Black's Law Dictionary* 1228 (8th ed. 2004). The Board described the elements of the CMS prima facie case in general terms as follows:

> HCFA [now known as CMS] must identify the legal criteria to which it seeks to hold a provider. Moreover, to the extent that a provider challenges HCFA's findings, HCFA must come forward with evidence of the basis for its determination, including the factual findings on which HCFA is relying and, if HCFA has determined that a condition of participation was not met, HCFA's evaluation that the deficiencies found meet the regulatory standard for a condition-level deficiency.

Hillman Rehab. Ctr., DAB No. 1611, at 11 (1997), *aff'd, Hillman Rehab. Ctr. v. United States,* No. 98-3789 (GEB), 1999 WL 34813783 (D.N.J. May 13, 1999). Thus, CMS has the initial burden of coming forward with sufficient evidence to show that its decision to impose an enforcement remedy is legally sufficient under the statute and regulations. To make a prima facie case that its decision was legally sufficient, CMS must: (1) identify the statute, regulation or other legal criteria to which it seeks to hold the provider; (2) come forward with evidence upon which it relies for its factual conclusions that are disputed by the Petitioner; and (3) show how the deficiencies it found amount to noncompliance that warrants an enforcement remedy, i.e., that there was a risk for more

than minimal harm due to the regulatory violation. In *Evergreene Nursing Care Ctr.*, the Board explained its "well-established framework for allocating the burden of proof" on the issue of whether a SNF is out of substantial compliance as follows:

> CMS has the burden of coming forward with evidence related to disputed findings that is sufficient (together with any undisputed findings and relevant legal authority) to establish a prima facie case of noncompliance with a regulatory requirement. If CMS makes this prima facie showing, then the SNF must carry its ultimate burden of persuasion by showing, by a preponderance of the evidence, on the record as a whole, that it was in substantial compliance during the relevant period.

DAB No. 2069, at 7. CMS makes a prima facie showing of noncompliance if the credible evidence CMS relies on is sufficient to support a decision in its favor absent an effective rebuttal. The regulation gives Petitioner notice of the criteria or elements it must meet to comply with the program participation requirement established by the regulation. 5 U.S.C. §§ 551(4), 552(a)(1). Therefore, in order to make a prima facie showing of noncompliance, CMS must show that Petitioner violated the regulation by not complying with one or more of the criteria or elements of the regulation, which is a deficiency. CMS must also show that 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. *See Jennifer Matthew Nursing & Rehab. Ctr.*, DAB No. 2192, at 20 n.12 (2008).

The Board has long held that 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, *aff'd*, *Batavia Nursing & Convalescent Ctr. v. Thompson*, 129 F. App'x 181; *Emerald Oaks*, DAB No. 1800 (2001); *Cross Creek Health Care Ctr.*, DAB No. 1665 (1998); *Hillman Rehab. Ctr.*, DAB No. 1611, *aff'd*, *Hillman Rehab. Ctr. v. United States*, No. 98-3789 (GEB), 1999 WL 34813783. However, only when CMS makes a prima facie showing of noncompliance, is the facility burdened to show, by a preponderance of the evidence on the record as a whole, that it was in substantial compliance or had an affirmative defense. *Evergreene Nursing Care Ctr.*, DAB No. 2069, at 7. A facility can overcome CMS's prima facie case either by rebutting the evidence upon which that case rests, or by proving facts that affirmatively show substantial compliance. "An effective rebuttal of CMS's prima facie case would mean that at the close of the evidence the provider had shown that the facts on which its case depended (that is, for which it had the burden of proof) were supported by a preponderance of the evidence." *Id.* at 7-8 (citations omitted).

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, although not all may be specifically discussed in this decision. I discuss the credible evidence given the greatest weight in my decision-making.[3] 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.

CMS alleges based upon the survey that ended June 9, 2011, that Petitioner was not in substantial compliance with program participation requirements from June 7 through 9, 2011, based upon a violation of 42 C.F.R. § 483.25(h) (Tag F323), and that the violation posed immediate jeopardy on June 7, 2011.

1. Petitioner was not in substantial compliance with program participation requirements due to a violation of 42 C.F.R. § 483.25(h) (Tag F323) from June 7 through 9, 2011.

2. Petitioner has not shown that it returned to substantial compliance prior to June 9, 2011.

a. Facts

The state agency survey was triggered by complaints. The sister of Resident B complained that residents might not be able to exit the facility during a fire because keypads at exit doors did not function properly. She also complained that limits had been imposed on the visits of Resident B and his sister and girlfriend. CMS Ex. 11; Tr. 37. The complaint investigation began on June 6, 2011. CMS Ex. 6 at 1. On June 7, 2011, at about 7:44 a.m., one of Petitioner's staff found Resident B approximately one block from the facility near a busy intersection. The surveyors cited Petitioner for violation of 42 C.F.R. § 483.25(h) (Tag F323) for failure to provide supervision to prevent the elopement

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[3] "Credible evidence" is evidence that is worthy of belief. *Black's Law Dictionary* 596 (18th ed. 2004). The "weight of evidence" is the persuasiveness of some evidence compared to other evidence. *Id*. at 1625.

of Resident B. The surveyors determined that the violation was an isolated incident of noncompliance that posed immediate jeopardy. CMS Ex. 6 at 2.

Surveyor Ellen Ruppel, RN, testified that she wrote the Statement of Deficiencies (SOD). Tr. 36; CMS Ex. 6. Surveyor Ruppel testified that Petitioner was cited for the deficiency because Petitioner did not know exactly how Resident B exited the facility. Tr. 66. Surveyor Ruppel testified that Petitioner is situated in an urban area near the edge of town. A street and a highway near the facility carry a lot of traffic. There are no sidewalks on either side of the road. The highway is located less than one block from the facility. Tr. 44-46. Surveyor Ruppel testified that she believed that serious injury was likely to happen because Resident B was cognitively impaired, at risk for falls, at risk for wandering, and he could have been hit by a car. Tr. 61, 64, 66. Surveyor Brenda Meredith, RN, was the supervisor for Surveyor Ruppel. Surveyor Ruppel called Surveyor Meredith to the facility when she suspected there was immediate jeopardy. Tr. 122-25. Surveyor Meredith testified that she concluded that Petitioner was not in compliance because Resident B got away; Petitioner's staff did not know the resident was out; and Petitioner's interventions to prevent elopement were not effective. Tr. 127. The surveyors concluded that after removing the immediate jeopardy, Petitioner continued not to be in substantial compliance because there continued to be a risk for more than minimal harm. CMS Ex. 6 at 2-3, 6. The surveyors determined based upon a revisit survey conducted on July 14, 2011, that Petitioner returned to substantial compliance effective June 10, 2011. CMS Ex. 2 at 1.

Petitioner's clinical records show that Resident B was an 83-year-old former state policeman. He was admitted to Petitioner's facility on May 3, 2011. Upon arrival he was found to be alert and oriented, cooperative with assessment, and protective of his personal privacy. P. Ex. 1; CMS Ex. 14 at 1, 4. Resident B had diagnoses including Alzheimer's disease, muscle weakness, atherosclerosis, congestive heart failure, diabetes, gout, neuropathy, and anxiety. P. Ex. 1 at 1; CMS Ex. 14 at 10. Prior to his admission, Resident B had been living alone at his personal residence and driving his own vehicle. Resident B arrived at the facility with his daughters, who held his power of attorney (POA). Resident B stated that he was "overwhelmed," in that he had learned only that day that he would be moving from his personal residence to the facility. P. Ex. 1 at 1; CMS Ex. 14 at 4, 31-38. Surveyor Ruppel interviewed Resident B on June 6, 2011, prior to his elopement, and found him to be well-dressed and well-groomed. She testified that he could have been mistaken for a visitor. However, she also testified that she doubted he had the capacity to recall a four-digit code for the door alarm. Tr. 46-47, 67-68.

Petitioner does not dispute that Resident B was assessed as at risk for elopement at admission on May 3, 2011 and again on May 25, 2011. CMS Ex. 9 at 30-31; CMS Ex. 14 at 1. On May 3, 2011, a wander alert bracelet that would trigger an alarm was placed

on the resident's ankle to alert staff if he attempted to exit the facility.[4] P. Ex. 1 at 1; CMS Ex. 9 at 34; P. Ex. 2 at 1. On May 6, 2011, Petitioner initiated a care plan to address Resident B's elopement risk. The goal for Resident B was that he would have no successful elopement attempts. Petitioner planned interventions to meet the goal: one-to-one (1:1) supervision when necessary; encouraging activity attendance; obtaining information from family regarding interventions that worked in the past; placing the wander alert bracelet and checking its functioning every shift; and, checking Resident B's whereabouts every 15 minutes as needed. CMS Ex. 9 at 33; CMS Ex. 14 at 12. Although the care plan required that the function of the alarm bracelet be checked every shift, Petitioner's treatment flow sheet requires checking the function once per day in the evening or night but checking the placement every shift. CMS Ex. 14 at 52; P. Ex. 3 at 1, 3. The physician's order for the wander alert bracelet specified, consistent with the treatment flow sheets, but inconsistent with the care plan, that function be checked every night and placement every shift. P. Ex. 2.

Nurse's progress notes document that Resident B verbalized a desire to leave and that he attempted to leave on multiple occasions between his admission on May 3, 2011 and his final elopement from Petitioner on June 7, 2011. The progress notes show the following events:

- May 6: Resident B verbalized frustration at being at the facility and later attempted to leave the facility with his girlfriend.[5] There is no indication in the notes whether the wander alert system sounded. P. Ex. 1 at 2; CMS Ex. 14 at 6.

- May 8: Resident B's sisters took him out of the facility against the direction of the nurse, without permission of the POA, and without signing him out. When Resident B returned to the facility he did not have on his wander alert bracelet and the resident reported that his sisters had cut it off. A new bracelet was affixed. P. Ex. 1 at 3; CMS Ex. 14 at 6-7. The missing bracelet was not found in the facility. Tr. 201. There is no indication in Petitioner's records in evidence that the wander alert system sounded when the resident departed the building.

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[4] Alarm systems of this type are generally designed to alert staff when a resident attempts to exit or comes too close to a door. Generally, such systems involve a bracelet fixed on the resident's arm, ankle, wheelchair, or walker; a door lock mechanism; and an alarm or alarm sensor or trigger mounted near exit doors. The systems are commonly referred to by their trade names such as WanderGuard® or Code Alert®.

[5] The nurse's progress note incorrectly identifies the girlfriend as Resident B's spouse.

- May 10: Resident B refused to leave his room while waiting for his family to "get him 'the hell out of here.'" Resident B also was observed attempting to make a phone call with his television remote. P. Ex. 1 at 3; CMS Ex. 14 at 7.

- May 25: Resident B packed his belongings and stated he is "leaving today." Resident B planned on leaving with his girlfriend. Staff began checking the resident every 15 minutes. P. Ex. 1 at 3; CMS Ex. 14 at 7.

- May 27: Resident B noted to be confused and constantly voiced to staff his intention to leave. Resident B made calls asking to be picked-up. Resident B continued on 15-minute checks for elopement risk. His daughter took him to a physician's appointment in the afternoon. P. Ex. 1 at 4; CMS Ex. 14 at 8-9.

- May 28: Resident B packed all his personal belongings, stripped his bed and unplugged his television. He stated that he was waiting for a ride back to his house. Resident B did not attempt to leave the facility. P. Ex. 1 at 4; CMS Ex. 14 at 9.

- May 29: Resident B was observed resting in his recliner, but his television was still unplugged and his belongings packed. P. Ex. 1 at 4; CMS Ex. 14 at 9.

- June 1: Resident B was noted to have his bags packed. P. Ex. 1 at 5.

- June 3: Resident B was placed on 15-minute checks in the morning when he was overheard on the phone stating he was going to walk uptown to meet someone. Later in the morning, Resident B packed his belongings and called friends and family for transportation. Resident B's sister called the facility to ask when to pick him up as he had called to tell her he was being released. The sister was told to disregard the request for transportation. Resident B became more anxious and staff attempted to calm him and redirect his behaviors. Resident B threatened to kick a door open. He then exited the facility when someone came in. There is no indication in Petitioner's records that the wander alert alarm sounded when the resident exited. Staff attempted to redirect him, but he was adamant, so staff shadowed him outside. Several different staff members attempted to redirect him back inside the building without success. He stated he was going to "walk home" in order to "take care of business." Resident B returned to the facility when notified his daughter would meet with him in

his room. Resident B was given Xanax, a prescription, psychoactive drug typically prescribed for anxiety. He was assisted with unpacking his belongings. However, after his daughter left, Resident B again started to pack his belongings and requested transportation to his residence. Staff continued 15-minute checks. P. Ex. 1 at 5; CMS Ex. 14 at 10. Administrator Cook testified that because there is no mention in the nurse's notes that an alarm sounded, it is a good assumption it did not. Tr. 222.

- June 4: Resident B talked about leaving the facility all day. Staff continued 15-minute checks. Resident B called family members to pick him up. Resident B was unable to be redirected and carried his magazine rack to a side door and sat on it by the doorway. Resident B asked visitors why nobody would let him outside. Resident B argued with his girlfriend. Resident B wanted his wander alert bracelet cut off. He wanted to go home. Resident B agreed to stay until Monday and then see about going home. P. Ex. 1 at 6; CMS Ex. 14 at 10.

- June 5: Resident B continued on 15-minute checks. Resident B did not voice any desire to leave the facility. P. Ex. 1 at 6; CMS Ex. 14 at 10.

- June 6: Resident B requested scissors to cut off his wander alert bracelet. Resident B stated his daughters were coming to pick him up and he needed it removed. Xanax was offered because Resident B became increasingly frustrated with not being able to obtain scissors. Resident B called family members and friends, but stopped talking to them when staff approached. Resident B declined to participate in activities or eat in the main dining room, but did interact with his roommate and peers. Staff continued to conduct 15-minute checks. P. Ex. 1 at 6.

Petitioner does not dispute that Resident B eloped from its facility between about 7:30 and 7:45 a.m. on June 7, 2011. Petitioner does not dispute that the resident was found about 100 yards from the facility. Tr. 152; Petitioner's Proposed Findings of Fact (PPFF) ¶ 37. There is no dispute that when the resident left the facility on June 7, 2011, no staff heard an alarm from the wander alert system.

Nurse's progress notes dated June 7, 2011, show that Resident B remained on 15-minute checks. P. Ex. 1 at 7; CMS Ex. 14 at 11. Although the 15-minute checks were to be on the hour, quarter, and half-hour, Petitioner's records show that the 7:30 a.m. check on June 7, was actually done at 7:24 a.m., six minutes early. CMS Ex. 14 at 3. At 7:24 a.m., Resident B was observed to be seated in his recliner in his room. He did not display any anxiety or agitation. Subsequently, Paula Hoover, a Social Service Designee for Petitioner, was on the way to the facility and observed Resident B walking along a street several hundred yards away from the facility. Ms. Hoover called the facility at 7:44 a.m.,

according to her cell phone log, to notify staff of the resident's location and to get assistance. Ms. Hoover stayed with the resident until additional staff arrived to assist her. The nurse's note states that the resident was alert and oriented as appropriate for him. His only complaint was that he was tired. He was wearing a short-sleeve shirt, jeans, a jacket and a hat. The temperature was in the mid 70s and humid. The nurse's note states that the resident's wander alert bracelet was intact on his left ankle but the note does not show that the operation of the bracelet was tested. Resident B was persuaded by a staff member to go to a café for coffee. P. Ex. 1 at 6-7; CMS Ex. 9 at 55-56; CMS. Ex. 14 at 11; PPFF ¶¶ 37-39; Tr. 150-52. Following his elopement, Resident B was sent to a psychiatric hospital and then to a facility with a secured Alzheimer's unit. P. Ex. 1 at 6; CMS. Ex. 7 at 1; CMS Ex. 9 at 56; CMS Ex. 14 at 11; Tr. 206; PPFF 39.

Surveyor Ruppel testified that she and a staff member tested the wander alert systems on all facility doors equipped with the system and found that all worked on June 6, 2011, the day before Resident B eloped. Tr. 43-44, 78. Surveyor Ruppel testified that she interviewed staff on June 7, 2011, to determine whether they heard an alarm sound when Resident B eloped. No staff member that she interviewed reported hearing an alarm sound at the relevant time. CMS Ex. 12 at 5, 16; Tr. 61, 73, 87-88, 97-98. She also checked the code alert system with a member of Petitioner's maintenance staff and determined that the alarm system was working properly at about 11:30 a.m. on June 7, 2011, following the resident's elopement. CMS Ex. 12 at 8; Tr. 63. Surveyor Ruppel testified that she did not investigate whether one of Resident B's sisters gave the code to him because she did not think he was sufficiently cognitively aware, based on her interview, to remember a code. Tr. 67-68.

Brian Cook, Petitioner's Administrator, testified credibly regarding the operation of Petitioner's wander alert system. Mr. Cook testified that Petitioner does not generally have residents who require a locked or secure unit. However, on June 7, 2011, when Resident B eloped, all 15 facility exit doors could be locked, 12 were regularly locked and were used as emergency exists only, and the three not locked had a wander alert system. When the three doors with the wander alert systems were unlocked from 6:00 a.m. to 8:00 p.m., anyone without a wander alert bracelet could enter or exit just by opening the door. However, when a wander alert bracelet was within about four feet of the door, a magnetic lock was triggered that secured the door. A code had to be entered to unlock the door and, if the bracelet was still in range, the alarm would sound. A code then had to be entered to silence the alarm. Petitioner used two four-digit codes primarily: a four-digit visitor code for visitors to unlock the door after hours, 8:00 p.m. to 6:00 a.m., when all doors were locked; and a four-digit bypass code that staff entered to disable or silence the alarm and unlock the door. The visitor code would unlock the door but not disable or shut-off the alarm, so that if a resident with a wander alert bracelet followed a visitor through a door the alarm would sound. Tr. 159-67. The company that serviced Petitioner's wander alert system determined that there was a problem with the system on the Birch Wing (Unit B on CMS Ex. 24), the B wing door, on the day of the

elopement because the visitor code and the staff bypass codes had both been programmed to the number 0611. Tr. 176. Mr. Cook testified that even though the bypass code and visitor code were the same, a resident with a wander alert bracelet that approached a closed door would cause the activation of the magnetic lock. Tr. 162. The staff bypass code was changed the first Monday of every month using a mmyy format so on June 6, 2011, the first Monday of that month, the staff bypass code was changed by someone to 0611. The visitor code was not changed regularly and it had been 0611 for some period of time. Mr. Cook opined that staff would not have noticed that the visitor code and staff bypass code were the same because the doors functioned no differently, except that the alarm would not sound if the door was open and a resident with a bracelet approached too closely or crossed the threshold. Tr. 167-69; 208-10. I infer, therefore, that staff was not doing a daily check of the function of the door alarm system, at least not whether a bracelet passing through an open door would trigger the wander alert alarm.

Mr. Cook testified that after Resident B eloped, it was surmised that the resident's most likely escape route was a door. Therefore, every door, exit, lock, magnetic look, and door alarm was checked to ensure all functioned properly. It was discovered that the exit on the Birch Wing, the B wing door, did not work correctly. The B wing door was being used at the time as the main facility entrance and exit during renovation in the area of the regular main entrance. There is no dispute that Resident B's room, Room 132, was the fifth room away from the B wing door. CMS Ex. 24; P. Ex. 4; Tr. 49, 76, 180. According to Mr. Cook, when a wander alert bracelet was near the door, the magnetic lock locked. However, when the door was open and the bracelet passed the threshold, the alarm did not sound. The company that serviced the facility system was called and discovered that the staff bypass code and visitor code were the same. Tr. 175-76, 195-96. Mr. Cook did not know whether a contractor or staff member changed the staff bypass code so that it was the same as the visitor code. Tr. 198-200, 208. Mr. Cook testified that the problem was corrected between 10:00 a.m. and Noon on June 7, 2011, before the surveyors announced they had discovered immediate jeopardy. Tr. 177-78. Mr. Cook testified that it was concluded that the code was entered into the wander alert system key pad on the B wing door and that Resident B exited through that door. He opined that there was no other way out. It was further deduced that the resident entered the code, which prevented the magnetic lock from engaging, as vendors and construction workers probably would not know the code; no staff reported seeing the resident exit; and there were no visitors in at the time that anyone recalled. Tr. 182-83. Mr. Cook suggested that Resident B obtained the code from his sisters who did not like that he was in the facility, and he knew that was mentioned during informal dispute resolution. Mr. Cook could not recall if it was mentioned to the surveyors during the survey, but thought not as that theory developed later. Tr. 191-93. He opined that there was nothing the facility could have done to prevent Resident B from obtaining the code and it was not foreseeable that the visitor code and staff bypass codes would be set to the same number. Tr. 197. I do not find weighty Administrator Cook's opinion that nothing could have been done. For example, if staff had properly tested the function of the door on June 6 or June 7, 2011,

by unlocking the door with the code 0611 and then passing a wander alert bracelet over the threshold, it should have been obvious that the alarm did not function. Petitioner also had the option of changing the visitor code after it was learned that the sisters were willing to violate policy and remove the resident without signing him out. Thus, while Administrator Cook was no doubt honest in his belief that nothing more could be done, he clearly had not considered all the approaches Petitioner could have reasonably implemented to protect the resident. On cross-examination he testified that the visitor code is generally provided to family when a resident is admitted to the facility, but he is not certain how Resident B's family obtained the code in this case. Tr. 212-15.

CMS alleged for the first time in its prehearing brief the possibility that Resident B could have eloped through the window in his first-floor room. Petitioner objected at hearing to my consideration of this theory on grounds that it was not cited in the SOD and constitutes a violation of Petitioner's due process right to notice. Petitioner accurately notes that had the surveyors advised Petitioner of a concern about the window during the survey or in the SOD, Petitioner would have had the opportunity to develop evidence related to the windows at the time of the elopement and survey. CMS does not deny that no facts related to the window in the resident's room were cited in the SOD but CMS argues that its prehearing brief provided adequate notice. Tr. 23-25. I allowed the parties to develop the evidentiary record on this issue prior to ruling upon Petitioner's objection. Tr. 29. I conclude that, while Petitioner is correct that CMS failed to provide adequate notice of additional grounds for the citation of deficiency, Petitioner suffers no prejudice as CMS failed to prove the additional grounds.[6] Surveyor Ruppel testified that she interviewed Resident B in his room, Room 132, on June 6, 2011. She testified that the window of his ground floor room was not blocked and could be opened all the way. She made a note to this effect in her surveyor notes (CMS Ex. 12 at 17). She opined that that was an accident hazard as he could elope through his window. She testified that she spoke with a maintenance man about the window. She testified that Petitioner could have removed the accident hazard by simply blocking the window so it only opened a short

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[6] The attempt by CMS to prove a different factual basis for a citation of deficiency than that cited in the SOD is markedly different than CMS articulating a new legal theory for liability in its prehearing brief or at hearing. The latter may be permissible. *Cf. Illinois Knights Templar Home*, DAB No. 2369, at 2 n.2 (2011); *Azalea Court*, DAB No. 2352 (2010); *Cedar View Good Samaritan*, DAB No. 1897 (2003); *Oak Lawn Pavilion, Inc.*, DAB No. 1638, at 8-12 (1997), *aff'd*, *Oak Lawn Pavilion. Inc. v. HHS*, 2000 WL 1847597 (N.D. Ill. Dec. 14, 2000). The former is not. *Life Care Ctr. of Bardstown*, DAB No. 2479, at 7 (SOD notifies a facility "of the nature, scope, and severity of the deficiencies found and the factual basis for the survey agency's conclusion that regulatory standards had been violated") (citing *Western Care Mgmt. Corp., d/b/a Rehab Specialties Inn*, DAB No. 1921 (2004) and *Pacific Regency Arvin*, DAB No. 1823 (2002)); *cf. Hillman Rehab. Ctr.*, DAB No. 1611, at 8.

distance. Tr. 47-49, 63. On cross-examination Surveyor Ruppel testified that she concluded that the window could be opened fully because she pushed it open. She then clarified that she did not push the window all the way open but she stated that she did not see anything that would prevent the window from opening fully. She testified that there was no screen. She agreed that she failed to place in her surveyor notes that she spoke with the maintenance man about the window. Tr. 75-76. In response to my questioning, she stated that she only opened the window 10 to 12 inches and saw nothing to prevent it from opening further. She testified that Resident B could not have passed through an opening of only 10 to 12 inches. Tr. 106-08. Mr. Cook testified that he discussed the window in Resident B's room with maintenance personnel when CMS first made the allegation about the window in its prehearing brief. He was told by his maintenance man that all windows had been secured prior to the survey and he was told by his superior that the direction to secure windows had been given four years before. He checked the window and found it was secure. He testified there was no evidence that the screen on the window had been removed and reinstalled. Tr. 186-88. In response to my questions, he explained that the windows were secured by a screw placed in the window track so that the window could not be opened more than about six inches. He opined that Resident B could not exit through the six inch gap of the opened window. Tr. 203-04. He testified that maintenance had checked that all windows were secured on about June 20, 2011, as part of Petitioner's own plan to ensure that the facility was secure. Tr. 205-06. I find Mr. Cook's testimony that the window was blocked from opening more than six inches at the time Resident B eloped is more credible than the testimony of Surveyor Ruppel that the window was not blocked but could open freely. Surveyor Ruppel did not actually attempt to open the window fully; her testimony was that she was looking for a block to prevent the window from opening rather than a screw in the track which could have the same effect as a block; and she did not bother to list the window as a hazard in the SOD, which I consider to be an indication that she did not view it as a hazard at the time that merited citation.

There is no evidence that the wander alert ankle bracelet that Resident B was wearing when he eloped actually worked.

The evidence does not show the path or route by which Resident B exited the facility.

b. Analysis

The general quality of care regulation, 42 C.F.R. § 483.25, requires that a facility ensure that each resident receives 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 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). CMS instructs its surveyors that the intent of 42 C.F.R. § 483.25(h)(1) and (2) 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." The 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. State Operations Manual (SOM), CMS Pub. 100-07, app. PP, Guidance to Surveyors Long Term Care Facilities, F323 (Rev. 27; eff. Aug. 17, 2007).

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

> 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*, *Century Care of Crystal Coast v. Leavitt*, 281 F. App'x 180 (4th Cir. 2008); *Liberty Commons Nursing and 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 regulation does not make a facility strictly liable for accidents that occur, but it does require that a facility take all reasonable steps to ensure that a resident receives supervision and assistance devices that meet his or her assessed needs and mitigates foreseeable risks of harm from accidents. *Woodstock Care Ctr. v. Thompson*, 363 F.3d at 589 (noting a SNF must take "all reasonable precautions against residents' accidents"). 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. Whether supervision is "adequate" depends in part upon the resident's ability to protect him or herself from harm. *Id*. Based on the regulation and the cases in this area, CMS meets its burden to show a prima facie case if the evidence demonstrates that the facility failed to provide adequate supervision and assistance devices to prevent accidents, given what was reasonably foreseeable. *Alden Town Manor Rehab. & HCC*, DAB No. 2054, at 5-12 (2006). An "'[a]ccident' refers to any unexpected or unintentional incident, which may result in injury or illness to a resident. This does not include adverse outcomes that are a direct consequence of treatment or care that is provided in accordance with current standards of practice (e.g., drug side effects or reaction)." SOM, app. PP, Tag F323.

I conclude that CMS has made a prima facie showing of noncompliance under Tag F323 due to a violation of 42 C.F.R. § 483.25(h). The CMS evidence shows that:

> 1. Resident B was assessed upon admission on May 3, 2011, as at risk to elope and it was foreseeable that he would attempt to elope. CMS Ex. 9 at 30-31; CMS Ex. 14 at 12.
>
> 2. On May 3, 2011, Petitioner applied a wander alert bracelet to the resident's ankle. CMS Ex. 14 at 5. The wander alert system was a form of supervision that locked a closed door when a resident with a bracelet approached a properly operating door too closely and alerted staff by sounding an alarm when a resident with a bracelet passed through an open door.
>
> 3. On May 6, 2011, Resident B's interdisciplinary team (IDT) adopted a care plan to address Resident B's elopement risk, which required one-to-one supervision when necessary; encouraging activity attendance; obtaining information from family regarding interventions that worked in the past; placing the wander alert bracelet and checking its functioning every shift; and, checking Resident B's whereabouts every 15 minutes as needed. CMS Ex. 14 at 12. Petitioner's treatment flow sheet required that the function of the wander alert bracelet be

checked, but only once per day in the evening or night, contrary to what was required by the care plan. The flow sheets did require that placement be checked every shift, but it also appears that placement was only checked once per day. CMS Ex. 14 at 52. The treatment flow sheets show that the care plan was violated because the function and placement of the wander alert bracelet was only checked on the evening shift and not every shift as required by the care plan.

4. On May 6, 2011, Resident B attempted to leave the facility with his girlfriend. The evidence does not show whether the wander alert system worked. CMS Ex. 14 at 6. The evidence does not show a review of the care plan by the IDT to determine the effectiveness of current interventions or the need for new interventions given that it was foreseeable that the girlfriend on future visits might provoke exit seeking behavior.

5. On May 8, 2011, Resident B left the facility with his sisters without permission and without following procedures. CMS Ex. 14 at 6-7. There is no indication that the wander alert system functioned when Resident B exited. Although the evidence shows that the resident returned without his wander alert bracelet, it is not clear whether the bracelet was removed before or after his elopement. Administrator Cook conceded the bracelet was not found in the facility, an indication that it was transported outside the facility in some manner. Tr. 201. The evidence does not show that the IDT met to review the effectiveness of current interventions or the need for new interventions, particularly in light of the new evidence that the sisters facilitated the elopement; likely destroyed the wander alert bracelet; that their future visits might provoke exit seeking behavior; and that a wander alert bracelet was removed from the facility without triggering an alarm.

6. On May 8, 10, 25, 27, and 28, Resident B expressed a desire to leave the facility and, in some instances, engaged in overt acts consistent with his intent to leave. Staff did implement the intervention of 15-minute checks. CMS Ex. 14 at 7-9. However, there is no evidence that staff implemented other care plan provisions that required distracting the resident with activities, except on May 10 when he refused activities (CMS Ex. 14 at 7); or consulting the family for other interventions that might distract or reduce his desire to elope. There is no evidence that the IDT assessed the effectiveness of current interventions or the need for new interventions.

7. On June 3, 2011, Resident B exited the facility but staff was watching and supervised his exit and return to the facility. The evidence does not show that his wander alert bracelet triggered the door alarm as he followed a visitor through the exit. CMS Ex. 14 at 10. There is no evidence that the IDT assessed the effectiveness of current interventions or the need for new interventions. Resident B was given Xanax to reduce his anxiety. The use of psychotropic medications to

> control anxiety or behavior is not mentioned on either the elopement or the anxiety care plans. CMS Ex. 14 at 12, 23.
>
> 8. On June 4, 2011, Resident B's vocalizations and exit seeking behavior continued. There is no evidence of action by the IDT. CMS Ex. 14 at 10.
>
> 9. On June 7, 2011, Resident B eloped without knowledge of Petitioner's staff and was found a block away from the facility. There is no evidence that any alarm sounded. Resident B was transferred to a different facility and never returned to Petitioner. CMS Ex. 14 at 11.

The CMS evidence shows that it was foreseeable that Resident B would attempt to elope because he was assessed as an elopement risk by Petitioner and then exhibited behavior consistent with an intent and desire to elope. The evidence shows that the resident required care and services in the form of supervision or assistive devices to prevent him from eloping and to protect him from accidental injury secondary to elopement. The resident's elopement care plan is evidence that the resident's IDT recognized the risks. The clinical records offered by CMS show that prior to June 7, Resident B had exited the facility and the evidence does not affirmatively show that the Petitioner and the resident's IDT determined that the wander alert system operated effectively to alert staff so that staff could prevent his elopement. The CMS evidence shows that the wander alert system was not effective supervision on June 7, 2011, as staff was not alerted by an alarm that the resident had departed the facility. Petitioner learned that the codes on the "B door exit" were incorrectly set so that a single code, a code that had been previously released to family members, contractors, and likely others, would disable the wander alert alarm. Administrator Cook's testimony shows that Petitioner accepted that a highly unlikely sequence of events occurred, i.e., Resident B's sisters told him the code on some unknown date; Resident B was able to recall the code despite his dementia and the passage of some unknown amount of time; and the day before his elopement the code that disabled the wander alert alarm was accidentally changed to the same code that the resident's sisters gave to the resident. Because Petitioner accepted its rather unlikely scenario it does not appear from the evidence that Petitioner fully investigated other potential scenarios. For example, the evidence does not show that Petitioner, as part of its investigation, tested the wander alert bracelet that the resident was wearing to see if it worked or if it had been damaged by the resident or his visitors since last checked the prior evening. Petitioner failed to test the operation of the bracelet the resident was wearing at the time he eloped despite the knowledge that the sisters had previously destroyed a wander alert bracelet and Petitioner had been looking for means to remove the bracelet. I conclude that the CMS evidence shows that the wander alert system was not an effective form of supervision to prevent Resident B from eloping. Petitioner failed to assess the effectiveness of the intervention; failed to determine that it was ineffective; and failed to consider alternatives.

The evidence shows that the intervention to check Resident B every 15 minutes was effective as an intervention to prevent elopement. The evidence shows that the intervention permitted staff to supervise the resident's exit on June 3, 2011. However, the intervention was not correctly implemented on the morning of June 7, 2011 when the resident eloped, because the check at 7:24 a.m. was early.

In summary, the CMS evidence shows that Petitioner failed to follow Resident B's elopement care plan; failed to evaluate the effectiveness of care planned interventions to reduce the risk for accidental injury secondary to elopement; and failed to implement revised or new interventions when existing interventions were shown to be ineffective. The CMS evidence also shows that Petitioner was located near busy roadways that posed a risk for more than minimal harm to Resident B, who had little ability to protect himself due to his dementia. Accordingly, CMS has presented sufficient evidence, which absent effective rebuttal, establishes Petitioner's noncompliance, i.e. a prima facie case.

Therefore, the burden is upon Petitioner to rebut the CMS prima facie case or to establish an affirmative defense to excuse its noncompliance, by a preponderance of the evidence. Petitioner offers no affirmative defense, but makes several arguments that CMS failed to make a prima facie showing. Petitioner fails to meet its burden.

Petitioner argues that it was not foreseeable that Resident B could leave the facility by following a staff member through an exit without the staff member taking some action to stop the resident. Petitioner argues that it was not foreseeable that a visitor would fail to notify staff if a resident followed the visitor through an exit. Petitioner also argues that it was not foreseeable that Resident B would be able to obtain and use a bypass code to exit the facility. P. Br. at 13; P. Reply at 4-5. However, Petitioner concedes that it was possible that Resident B's sisters gave him the door code (P. Reply at 5) and that Resident B could use a code to unlock an exit door even while wearing a wander alert bracelet (P. Reply at 2). Petitioner did not prove by a preponderance of the evidence that Resident B followed a staff member or visitor out the door on June 7 or that he used a code to disable the alarm. The scenarios hypothecated by Petitioner are not factual bases sufficient to rebut the CMS prima facie showing, rather, they are pure speculation. Even if accepted, Petitioner's speculations about how the resident may have escaped the facility do not show that Petitioner's interventions were adequate supervision to minimize the risk for accidental injury secondary to an attempted or actual elopement in light of the foreseeable risks for elopement or attempted elopement and secondary injury. Resident B attempted to leave with his girlfriend and he left with his sisters, therefore it was foreseeable that he might attempt to leave with them again. He also successfully followed another visitor out a door, albeit while under observation of staff. Therefore, contrary to Petitioner's argument, it was foreseeable that the resident could follow someone out the door, whether visitor or staff. Petitioner has never denied the assertion of Surveyor Ruppel that Resident B could be mistaken for a visitor based on his appearance, and Petitioner has not introduced evidence that all staff knew or could

recognize Resident B. Because the evidence does not show that the wander alert bracelet triggered the alarm on prior occasions, Petitioner cannot rely upon an inference that the wander alert bracelet that the resident was wearing was reliable and worked consistently to trigger door locks or door alarms. Petitioner argues that correcting the problem with the visitor code and the bypass code for the door system eliminated the possibility that another resident could exit the facility without triggering a door alarm. P. Br. at 14. While Petitioner's assertion may be correct, Petitioner did not do a thorough evaluation of how Resident B managed to elope. Petitioner focused on only one possible contributing factor, the incorrect door code. Petitioner did not address: staff's failure to implement other interventions specified in the care plan; staff's failure to conduct 15-minute checks as care planned; the IDT's failure to assess the effectiveness of care planned interventions and to modify existing interventions or to implement new interventions; and Petitioner never checked the ankle bracelet the resident wore when he eloped to determine whether it was defective or damaged. Thus, unlike the surveyors, I would not have found that Petitioner returned to substantial compliance simply because Petitioner fixed the door code. Nevertheless, I will not disturb the surveyors' conclusion that Petitioner returned to substantial compliance effective June 10, 2011.

3. Petitioner was ineligible to be approved to conduct a NATCEP because a partial extended survey was conducted on June 9, 2011.

CMS notified Petitioner by its July 12, 2011 letter that Petitioner was ineligible for two years to be approved to conduct a NATCEP because Petitioner had been subject to a partial extended survey. Petitioner argues that it should not be ineligible to conduct a NATCEP because no partial extended survey was conducted. P. Br. at 4; P. Reply at 3; Tr. 7-8, 26.

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 skilled nursing facility 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. The second and third conditions do not exist in this case. Thus, the issue is whether or not an extended or partial extended survey was conducted.

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. Petitioner's violation of 42 C.F.R. § 483.25(h) posed immediate jeopardy for one day and amounted to substandard quality of care, which should have triggered an extended or partial extended survey.

Ineligibility to conduct a NATCEP is triggered under 42 C.F.R. § 483.151(b)(2) if there is a finding of substandard quality of care and the state agency conducts an extended or partial extended survey. A finding of substandard quality of care alone does not cause ineligibility. The Act provides that each SNF found by a standard survey to have provided substandard quality of care "shall be subject to an extended survey." Act § 1819(g)(2)(B)(i). The Act requires that the extended survey be conducted within two weeks of the completion of the standard survey. Act § 1819(g)(2)(B)(ii). The Act requires that for the extended survey the survey team reviews "policies and procedures" that resulted in the substandard quality of care; the survey team must determine whether the facility has complied with all conditions of participation specified in the Act; the extended survey must include an expanded sample of residents; and the extended survey must consider staffing and in-service training and consultant contracts, if necessary. Act § 1819(g)(2)(B)(iii). Pursuant to 42 C.F.R. § 488.301, an extended survey is a survey that evaluates additional participation requirements subsequent to a finding of substandard quality of care during a standard survey. A partial extended survey is a survey that evaluates additional participation requirements subsequent to a finding of substandard quality of care during an abbreviated standard survey, which includes a complaint survey such as that conducted in this case.

The SOD in this case includes a line that states "[e]xtended date: 6/9/11" and "Supplemental sample 2." CMS Ex. 6 at 1. Surveyor Ruppel and Surveyor Meredith both asserted that an extended survey was conducted. Tr. 36, 141-42. However, Surveyor Ruppel did not describe what was done on the extended survey and Surveyor Meredith admitted she was not present when the extended survey was allegedly done, but she stated that there should have been a record of what was done for the extended survey. Administrator Cook testified to the activity of Surveyor Ruppel on June 9 and the activity he observed did not include review of facility policies and procedures and an expanded sample of residents. Tr. 178-79. The SOD does not include alleged findings and conclusions related to an extended survey. CMS Ex. 6. Surveyor notes indicate that an extended or partial extended survey was conducted on June 9, 2011. CMS Ex. 12 at 1. The surveyor notes reflect additional interviews, policy review, and review of in-service training on June 9, 2011. CMS Ex. 12 at 13, 18. The CMS evidence also includes Petitioner's policies regarding wandering and elopement and records of in-service training performed on June 8, 2011. CMS Exs. 15, 18. I conclude that the evidence is consistent with Surveyor Ruppel having conducted a partial extended survey on June 9, 2011. Therefore, Petitioner was ineligible to be approved to conduct a NATCEP by operation of law. Even if I concluded, as Petitioner advocates, that there was no partial

extended survey, Petitioner has cited no authority for me to remedy an erroneous declaration by CMS that Petitioner was ineligible to be approved to conduct a NATCEP.

4. Petitioner has not shown that the determination that immediate jeopardy was present on June 7, 2011, was clearly erroneous.

The CMS determination of immediate jeopardy must be upheld, unless Petitioner shows the declaration of immediate jeopardy clearly erroneous. 42 C.F.R. § 498.60(c)(2). Immediate jeopardy is "a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301. CMS's determination of immediate jeopardy is presumed to be correct, and Petitioner has a heavy burden to demonstrate clear error in that determination. *Yakima Valley Sch.*, DAB No. 2422, at 8-9 (2011); *Cal Turner Extended Care Pavilion*, DAB No. 2384, at 14 (2011); *Maysville Nursing and Rehab. Facility*, DAB No. 2317, at 11 (2010); *Brian Ctr. Health and Rehab./Goldsboro*, DAB No. 2336, at 9 (2010) (citing *Barbourville Nursing Home*, DAB No. 1962, at 11 (2005), *aff'd, Barbourville Nursing Home v. U.S. Dep't of Health & Human Servs.*, 174 F. App'x 932 (6th Cir. 2006); *Liberty Commons Nursing and Rehab. Ctr.– Johnston*, DAB No. 2031, at 18-19 (2006), *aff'd, Liberty Commons Nursing & Rehab. Ctr.–Johnston*, 241 F. App'x 76, at 3-4 (4th Cir. 2007). Once CMS presents evidence supporting a finding of noncompliance, CMS does not need to offer evidence to support its determination that the noncompliance constitutes immediate jeopardy, rather, the burden is on the facility to show that that determination is clearly erroneous. *Cal Turner Extended Care Pavilion*, DAB No. 2384, at 14-15; *Liberty Commons Nursing & Rehab. Ctr. – Johnston*, 241 F. App'x 76, at 3-4. Petitioner argues that the declaration of immediate jeopardy was clearly erroneous. P. Br. at 14. However, Petitioner presented no weighty evidence that Resident B was not likely to sufferer serious harm, injury, impairment, or death wandering in the neighborhood of the facility with its busy streets.

5. There is a basis for the imposition of an enforcement remedy from June 7 through 9, 2011.

6. A CMP of $3,550 for June 7 and $100 per day for June 8 and 9, 2011, is reasonable.

I have concluded that Petitioner violated 42 C.F.R. § 483.25(h) and that the violation posed immediate jeopardy on June 7, 2011 and a risk for more than minimal harm to one or more facility residents on June 8 and 9, 2011. Accordingly, I conclude that there is a basis for the imposition of a CMP.

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. 42 C.F.R. § 488.430(a). The regulations provide for two ranges of CMPs. 42 C.F.R. §§ 488.408, 488.438. The upper range, $3,050 per day to $10,000 per day, is reserved for deficiencies that pose immediate jeopardy to a facility's residents. 42 C.F.R. § 488.438(a)(1)(i), (d)(2). The lower range of 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). In this case, CMS proposes a $3,550 per-day CMP, for one day of immediate jeopardy on June 7, 2011, which is at the low end of the authorized range. CMS proposes a $100 per day CMP, which is also at the low end of the authorized range, for June 8 and 9, 2011.

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), the same factors CMS and/or the state were 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, and safety. 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 or 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. I am 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 9-13; *CarePlex of Silver Spring*, DAB No. 1683, at 14–18 (1999); *Capitol Hill Comm. Rehab. and Specialty Care Ctr.*, DAB No. 1629 (1997).

Petitioner challenges the deficiency and the declaration of immediate jeopardy but does not otherwise specifically challenge the reasonableness of the amount of the proposed CMP. Request for Hearing; Prehearing Brief; P. Br.; P. Reply. CMS introduced

evidence that Petitioner was previously cited for a violation of 42 C.F.R. § 483.25(h) in May 2008 and that the violation posed a risk for more than minimal harm. CMS Ex. 3 at 1. CMS introduced a "Statement of Cash Flows" for Petitioner for the period ending December 31, 2010. CMS Ex. 4. Petitioner does not argue that it is unable to pay the total CMP of $3,750. Administrator Cook testified regarding the negative financial impact of a survey that finds a deficiency that posed immediate jeopardy. Tr. 189-91. I have considered the testimony to the extent it reflects upon the present and future financial condition of the facility, but conclude that the evidence does not show Petitioner's financial condition will be impaired by the payment of a total CMP of $3,750. I consider the deficiency serious, consistent with the conclusion that there was immediate jeopardy, but I concur with the surveyors that the scope and severity was "J" (CMS Ex. 6 at 2), i.e., it was an isolated deficiency. I also find that Petitioner was culpable; particularly to the extent that Petitioner did not ensure that the resident's care plan was followed, reviewed, and revised.

I conclude that a CMP of $3,550 for June 7 and $100 per day for June 8 and 9, 2011, a total CMP of $3,750, is reasonable.

III. Conclusion

For the foregoing reasons, I conclude that Petitioner was not in substantial compliance with program participation requirements from June 7 through 9, 2011, due to a violation of 42 C.F.R. § 483.25(h) that posed immediate jeopardy on June 7, 2011 and a risk for more than minimal harm without actual harm or immediate jeopardy on June 8 and 9, 2011. I further conclude that a CMP of $3,550 for June 7 and $100 per day for June 8 and 9, 2011, is reasonable.

/s/
Keith W. Sickendick
Administrative Law Judge