**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

St. Andrews Place,
(CCN: 04-5313),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-14-1702

Decision No. CR4544

Date: March 10, 2016

# DECISION

I sustain the determination of the Centers for Medicare & Medicaid Services (CMS) that St. Andrews Place (Petitioner or facility) was not in substantial compliance with the Medicare participation requirements at 42 C.F.R. § 483.25(h) and find its determination that Petitioner's noncompliance constituted immediate jeopardy was not clearly erroneous. I also find as reasonable CMS's imposition of a civil money penalty (CMP) of $6,200 per day for April 9 through April 15, 2014, and a $150 per day CMP for April 16 through April 29, 2014.

## I. Procedural Background

Petitioner is a long-term care facility in Conway, Arkansas. It participates in Medicare as a skilled nursing facility and in Medicaid as a nursing facility. On April 16, 2014, the Arkansas Office of Long Term Care (state agency) completed a complaint survey because of Petitioner's report to the state agency concerning elopement of a resident (whom I will refer to as Resident 2) from the facility on April 9, 2014. By letter dated June 13, 2014, CMS notified Petitioner that it concurred with the state agency's findings, and it was imposing a CMP of $6,200 per day for seven days of immediate jeopardy to

resident health and safety beginning April 9, 2014 and continuing through April 15, 2014, and a CMP of $150 per day for 14 days beginning April 16, 2014 and continuing through April 29, 2014 for noncompliance that was not immediate jeopardy, for a total CMP of $45,500, for the deficiency cited at F-323 (42 C.F.R. § 483.25(h)) –*Free of Accidents Hazards/Supervision Devices*. CMS noted that as of the May 29, 2014 revisit, Petitioner corrected its deficiencies and achieved substantial compliance with the requirements for Medicare and Medicaid participation on April 30, 2014.

Petitioner timely requested a hearing before an administrative law judge (ALJ). I was assigned this case for hearing and decision. I issued a prehearing order, which included a briefing schedule, on August 26, 2014. The parties filed prehearing briefs (CMS PH Br. and P. PH Br.) and proposed exhibits, CMS exhibits (CMS Exs.) 1-13, and Petitioner's exhibits (P. Exs.) 1-10, which were admitted without objection. Transcript (Tr.) at 8. On August 5, 2015, I conducted a hearing by video teleconference to allow Petitioner to cross-examine two CMS witnesses. I scheduled posthearing briefing. CMS filed a posthearing brief and reply (CMS Br. and CMS Reply), and Petitioner chose to only file a posthearing brief (P. Br.).

## II. Issues Presented

1. Whether Petitioner was in substantial compliance with the Medicare participation requirement at 42 C.F.R. § 483.25(h);

2. Whether CMS's determination of immediate jeopardy was clearly erroneous; and

3. Whether the $45,500 total civil money penalty CMS imposed is reasonable in amount and duration.

## III. Controlling Law

Sections 1819 and 1919 of the Social Security Act (Act) and the regulations at 42 C.F.R. pt. 483 govern Petitioner's participation in Medicare and Medicaid. Sections 1819 and 1919 of the Act provide the Secretary of Health and Human Services with authority to impose remedies, including CMPs, against long-term care facilities for failure to comply with participation requirements.

Regulations define the term "substantial compliance" to mean:

> [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.

The applicable regulations at 42 C.F.R. pt. 488 provide that state survey agencies, on behalf of CMS, may survey facilities participating in Medicare and Medicaid to ascertain whether the facilities are complying with participation requirements. 42 C.F.R. §§ 488.10-488.28. The regulations contain special survey conditions for long-term care facilities. 42 C.F.R. §§ 488.300-488.335. Under Part 488, a state or CMS may impose a CMP against a long-term care facility if a state survey agency ascertains that the facility is not complying substantially with participation requirements. 42 C.F.R. §§ 488.406, 488.408, and 488.430.

CMS may impose a per-day CMP for the number of days a facility is not in substantial compliance or a per-instance CMP for each instance of the facility's noncompliance. 42 C.F.R. § 488.430(a). A per-day CMP, which CMS imposed in this case, may range from either $50 to $3,000 per day for less serious noncompliance or $3,050 to $10,000 per day for more serious noncompliance that poses immediate jeopardy to the health and safety of residents. 42 C.F.R. § 488.438(a)(2).

The Act and regulations make a hearing before an ALJ available to a long-term care facility against which CMS has determined to impose one or more enforcement remedies. Act §§ 1128A(c)(2), 1866(h); 42 C.F.R. §§ 488.408(g), 498.3(b)(13). The hearing before an ALJ is a *de novo* proceeding. *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 CR65 (1990), *aff'd,* 941 F.2d 678 (8th Cir. 1991). A facility has the right to appeal a certification of noncompliance leading to an enforcement remedy. 42 C.F.R. §§ 488.408(g)(1), 488.430(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 challenge the scope and severity that CMS cites only if a successful challenge would affect the range of CMP amounts that CMS imposed or would affect the facility's Nurse Aid Training and Competency Evaluation Program. 42 C.F.R. § 498.3(b)(14), (d)(10)(i). CMS's determination as to the scope and severity of noncompliance "must be upheld unless it is clearly erroneous." 42 C.F.R. §498.60(c)(2). This includes CMS's finding of immediate jeopardy. *Woodstock Care Ctr.*, DAB No. 1726, at 9 (2000), *aff'd,* 363 F.3d 583 (6th Cir. 2003); *see, e.g., Ridge Terrace*, DAB No. 1834 (2002); *Koester Pavilion,* DAB No. 1750 (2000).

The standard of proof or quantum of evidence required is a preponderance of the evidence. CMS has the burden of coming forward with evidence and making a *prima facie* showing of a basis for imposition of an enforcement remedy. The survey Statement

of Deficiencies (SOD) may constitute prima facie evidence of the undisputed facts asserted in it. *See, e.g., Universal Health Care – King*, DAB No. 2383 (2011). 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, Batavia Nursing & Convalescent Center v. Thompson,* 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), *aff'd, Hillman Rehab. Ctr. v. United States,* No. 98-3789 (GEB), 1999 WL 34813783 (D.N.J. May 13, 1999).

## IV. Findings of Fact and Conclusions of Law

### *1. Petitioner was not in substantial compliance with 42 C.F.R. § 483.25(h)(F-323) because it did not take all reasonable steps to ensure adequate supervision and assistance devices prevented a resident with a foreseeable wandering risk to elope from its facility.*

The quality of care regulation set forth in 42 C.F.R. § 483.25 generally 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 regulation imposes specific obligations upon a facility related to accident hazards and accidents. It states in relevant part:

> (h) *Accidents*. The facility must ensure that –
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> (1) The resident environment remains as free of accident hazards as is possible; and
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> (2) Each resident receives adequate supervision and assistance devices to prevent accidents.

42 C.F.R. § 483.25(h).

A facility must "take all reasonable steps to ensure that a resident receives supervision and assistance devices that meet his or her assessed needs and mitigate foreseeable risks of harm from accidents." *Briarwood Nursing Ctr.*, DAB No. 2115 at 5 (2007); *Guardian Health Care Ctr.*, DAB No. 1943 at 18 (2004). The facility must anticipate what accidents might befall a resident and take steps to prevent them. A facility is permitted the flexibility to choose the methods it uses to prevent accidents, but the chosen methods must constitute an "adequate" level of supervision under all the circumstances. *See Windsor Health Care Ctr.*, DAB No. 1902 at 5 (2003).

The SOD from the April 16, 2014 survey states that based on observation, record review, and interview, Petitioner did not meet this requirement because it did not ensure that: residents who were at risk for elopement wore Wanderguard transmitter bracelets, facility staff monitored the bracelets for placement and functioning, the Wanderguard alarm system was maintained and functioned correctly to alert staff in the event of exit-seeking behavior by residents identified as elopement risks using Wanderguard transmitter bracelets, and staff completed elopement risk assessments in order to evaluate and implement needed interventions. CMS Ex. 1 at 1-2.

It was foreseeable that Resident 2 was at risk for wandering and elopement from the facility. She was admitted to Petitioner's facility on May 10, 2013. Her diagnoses included vascular dementia with depression, altered mental status, anxiety disorder and behavioral disturbance. P. Ex. 5 at 1, 3, 18, 20, 24. Her physician also ordered that she should be monitored for wandering. P. Ex. 5 at 23, 26-27, 31, 34, 37, 39-40, 42-43, 47, 50, 53, 56, 60, 68. At the request of Resident 2's family, Resident 2 began wearing a Wanderguard bracelet in October 2013, although there is no mention of this in Resident 2's plan of care nor are there any other interventions or strategies addressing this behavior in her care plan until her elopement from the facility on April 9, 2014. CMS Ex. 8 at 25; CMS Ex. 1 at 5, 21; *but see* CMS Ex. 8 at 28, indicating that Resident 2 began wearing a Wanderguard bracelet on October 4, 2013, which was checked once a week from October 2013 through April 2014. Petitioner added goals and interventions for Resident 2's elopement problem to her care plan on April 9, 2014, *after* she eloped. The interventions call for use of a Wanderguard bracelet, staff awareness of the potential for Resident 2's possible elopement, and "frequent visual checks." CMS Ex. 8 at 25. However, there is no mention in the care plan as to what constitutes frequent visual checks and whose responsibility it is to make the frequent visual checks. A nurse's note for April 10, 2014 specifies that Resident 2 is to be checked visually every 15 minutes for 24 hours and then once an hour until further notice. CMS Ex. 8 at 35. However, the only evidence there is of visual checks being performed is a check sheet dated April 15, 2014, six days after Resident 2 eloped. P. Ex. 5 at 205.[1]

Petitioner noted Resident 2's wandering as early as May 14, 2013. P. Ex. 5 at 181. Nurses' Progress Notes for the week of June 15, 2013 stated that Resident 2 tried to go outside frequently without supervision and that she wandered the facility. P. Ex. 5 at 83-84. Petitioner noted Resident 2's increased wandering and confusion and identified these as behavioral problems. CMS Ex. 8 at 31-34; P. Ex. 5 at 85, 87, 90, and 147. Social Service Progress Notes also documented Resident 2 as a wanderer as early as August 2013, as well as on November 18, 2013 and February 14, 2014. CMS Ex. 8 at 26-27. The Minimum Data Set quarterly assessment dated February 18, 2014, noted that she

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[1] Although the form calls for visual checks every 15 minutes, a staff member primarily initialed the form on an hourly basis, beginning on April 15, 2014, after the elopement and during the survey. *See* P. Ex. 5 at 205- 31.

wandered daily. CMS Ex. 8 at 14. However, Petitioner's Wander Data Collection Tool form failed to identify Resident 2 on August 20, 2013 and November 18, 2013 as a "wanderer," despite documented instances of increased wandering to the contrary. *Compare* CMS Ex. 8 at 19-20 *with* CMS Ex. 8 at 26-27.

It is undisputed that on April 9, 2014, Resident 2 exited Petitioner's facility unnoticed and unaccompanied. The last time anyone saw Resident 2 before her exit was at 5:26 p.m., walking in the hallway by the dining room. CMS Ex. 1 at 6. Before she exited the building, staff brought her tray to the dining room, and because she was not present, a CNA went to get her for dinner at 5:30 p.m. While the CNA was looking for Resident 2 in the facility, a visitor approached the CNA and told her that an older lady was standing on the side of the road trying to catch a ride. CMS Ex. 1 at 7; CMS Ex. 8 at 44. The CNA ran outside to the road and saw Resident 2 starting to get into a car. A bystander in a car saw Resident 2 on the road, about a block from Petitioner's facility, placed her in her car, and returned her to the facility unharmed at 5:45 p.m. CMS Ex. 8 at 35, 42, 43, 44, 45, 60. Although Resident 2 wore a Wanderguard bracelet and that bracelet was intact and on the resident, she exited and entered the building without any alarm sounding and without any staff aware that she left the building. CMS Ex. 8 at 45; Tr. at 23.

Besides Resident 2, one other resident, Resident 1, wore a Wanderguard bracelet. CMS Ex. 1 at 2. With the Wanderguard system, if either of these two residents approached, neared, or tried to exit a door equipped with that system, an alarm should sound. P. Br. at 6; P. Ex. 8 at 1-2. The alarm should continue to sound until the system is reset with use of a key. P. Br. at 6. Petitioner also used a magnetic lock system on eight exit doors which are supposed to be locked 24 hours a day. P. Ex. 8 at 1.[2] To exit the facility, a staff member must enter a security code into the keypad. P. Br. at 6; P. Ex. 8.; Tr. at 19-20. However, on the morning after Resident 2 eloped, the Maintenance Supervisor discovered that at least one of the magnetic door locks on Exit North was not functioning correctly. P. Ex. 8 at 2; CMS Ex. 1 at 16.

Petitioner chose to rely on the use of a Wanderguard system and its magnetic door locks with an access code to prevent unauthorized exits by residents. Although Petitioner relied on the Wanderguard system to notify staff of any attempted elopement, Petitioner was aware of problems with the operation of the system as early as March 20, 2014. CMS Ex. 10 at 11 (invoice from Petitioner's security systems contractor regarding the Wanderguard system triggering false alarms). The Maintenance Supervisor wrote an

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[2] Although the declaration of the Maintenance Supervisor stated that eight exit doors were equipped with a magnetic lock system requiring a code to exit, Petitioner's Weekly Exit Door Inspections form indicates nine alarmed exit doors. P. Ex. 8; CMS Ex. 8 at 39. A map of the facility provided to the surveyor indicates 10 alarmed exit doors. CMS Ex. 10 at 18. The Maintenance Supervisor explained that the Main Entrance/Front Lobby Door is not included on the Weekly Exit Door Inspection form. CMS Ex. 1 at 15.

email to the contractor on Tuesday April 8, 2014 stating that the Wanderguard system was still malfunctioning. CMS Ex. 11 at 10; CMS Ex. 1 at 17 (the Maintenance Supervisor told the surveyor that there had been problems with the system for as long as he had been at the facility). By return email, the contractor said he would be sending someone on Friday, April 11, 2014, who has experience with the system who should be able to resolve the problem. CMS Ex. 10 at 11. There was supposition that at least one of the magnetic door locks was not working and that Resident 2 may have exited through the Exit North door. The surveyor reported the Maintenance Supervisor explained to her during the survey that besides the problem with the magnetic lock on that door, the Wanderguard unit for that door had been turned off. CMS Ex. 1 at 16. However, in his declaration, the Maintenance Supervisor now states that the Wanderguard system was not turned off on April 9, 2015. P. Ex. 8 at 2. Regardless, Resident 2 was able to elope from the facility, and Petitioner theorized she exited behind a visitor who had a security code. P. PH. Br. at 17. I do not find it plausible, however, that a visitor would simply let a resident exit if the Wanderguard alarm was functioning and sounded simultaneously with Resident 2's exit.

Petitioner did not take all reasonable steps to mitigate the foreseeable elopement risk of residents known to wander. Petitioner presented no evidence that it informed facility staff that the system was malfunctioning. There is no evidence that Petitioner instituted other interventions or increased its supervision for the two residents at risk for elopement in the absence of a fully functioning Wanderguard system. Petitioner's failure to adequately assess Resident 2 as a wanderer prior to her elopement, even though she began to wear a Wanderguard bracelet in October 2013, also shows a lack of adequate supervision. Petitioner should have assessed and care planned specific goals and interventions in Resident 2's care plan as soon as she was identified as a risk for wandering.

With a malfunctioning Wanderguard system, and without any increase in supervision, it was entirely foreseeable that an elopement could occur. Staff only first became aware of Resident 2's elopement because her meal tray was ready. Not one staff member was aware that Resident 2 had left the building and walked off the facility's property. It was only after a visitor notified staff that a bystander picked up a resident, walking along the side of the road, that staff realized where she was. Fortunately, Resident 2 was not injured or harmed.

Even during the survey, the Wanderguard system failed to function properly.[3] While it initially appeared to work on April 15, 2014 when the surveyor and Director of Nursing

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[3] To compound the deficiency, on April 15, 2014 the surveyor found that Resident 2 had removed her Wanderguard bracelet from her ankle without the knowledge of the care staff. CMS Ex. 1 at 13.

checked it, on April 16, 2014, it failed to sound an alarm at one door until the surveyor and Maintenance Supervisor actually placed the transmitter bracelet right next to the metal system box located at the top of the door frame. CMS Ex. 1 at 17; Tr. at 24.

In sum, the evidence establishes that Petitioner failed to provide Resident 2, who had foreseeable wandering tendencies, with adequate assistance devices and supervision to prevent her elopement from the facility. The facility did not mitigate the foreseeable risks by properly maintaining its Wanderguard system and proactively planning and implementing increased monitoring for residents at risk of wandering.

### 2. *CMS's determination that the facility's noncompliance posed immediate jeopardy to resident health and safety for the period of April 9 through April 15, 2014, is not clearly erroneous.*

Immediate jeopardy exists if a facility's noncompliance 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 as to the level of a facility's noncompliance (which would include an immediate jeopardy finding) must be upheld unless it is "clearly erroneous." 42 C.F.R. § 498.60(c). The Board has explained repeatedly that the "clearly erroneous" standard imposes on facilities a heavy burden to show no immediate jeopardy and has sustained determinations of immediate jeopardy where CMS presented evidence "from which '[o]ne could reasonably conclude' that immediate jeopardy exists." *See, e.g., Daughters of Miriam Ctr.*, DAB No. 2067 at 7, 9 (2007); *Barbourville Nursing Home*, DAB No. 1962 at 11; *Florence Park Care Center*, DAB No. 1931 at 27-28 (2004).

Petitioner's noncompliance placed Resident 2 and Resident 1, who was also an elopement risk, in immediate jeopardy, and CMS's determination was not clearly erroneous. Here, Petitioner failed to adequately supervise Resident 2 and to provide assistance devices and the kind of supervision necessary to prevent her elopement from the facility unnoticed. It was fortuitous that the Resident suffered no actual harm, which is not a requirement of an immediate jeopardy finding. The likelihood of serious harm or death to Resident 2 was great due to her cognitive impairment. Once she eloped from the facility, she was at high risk for injury from falling, being struck by a motor vehicle, and harmful prolonged exposure to the outside elements if the bystander did not happen to promptly rescue her.

### 3. *The penalties imposed are reasonable as to amount and duration.*

CMS imposed a penalty in the amount of $6,200 per day for the period of April 9 through April 15, 2014 ($43,400), for the period of immediate jeopardy, and $150 per day for the period of April 16 through April 29, 2014 ($2,100), after the immediate jeopardy was abated but the deficiency remained. Based on a revisit on May 29, 2014, CMS determined Petitioner corrected the remaining deficiencies and achieved substantial

compliance with the Medicare participation requirements on April 30, 2014. CMS Ex. 2 at 14.

CMS must consider several factors when determining the amount of a CMP (factors an ALJ considers de novo when evaluating the reasonableness of the CMP that CMS imposed): (1) the facility's history of noncompliance; (2) the facility's financial condition, i.e., its ability to pay the CMP; (3) the severity and scope of the noncompliance, the "relationship of the one deficiency to other deficiencies resulting in noncompliance," and the facility's prior history of noncompliance; and (4) the facility's degree of culpability. 42 C.F.R. §§ 488.438(f), 488.404(b), (c). In addition, the "absence of culpability is not a mitigating circumstance in reducing the amount of the penalty." 42 C.F.R. § 488.438(f)(4).

The Board has repeatedly concluded that "an ALJ or the Board properly presumes that CMS considered the regulatory factors and that those factors support the amount imposed." *See, e.g.*, *Pinecrest Nursing & Rehab. Ctr.*, DAB No. 2446 at 23 (2012). Thus, CMS did not need to present evidence regarding each regulatory factor. Instead, the burden was on Petitioner "'to demonstrate, through argument and the submission of evidence addressing the regulatory factors, that a reduction is necessary to make the CMP amount reasonable.'" *Id.* (quoting *Oaks of Mid City Nursing & Rehab. Ctr.*, DAB No. 2375 at 26-27 (2011)).

Once a facility is found to be out of substantial compliance, it remains so until it affirmatively demonstrates that it has achieved substantial compliance once again. *Premier Living and Rehab. Ctr.*, DAB No. 2146 at 23 (2008); *Lake City Extended Care*, DAB 1658 at 12-15 (1998). The burden is on the facility to prove that it is compliant with program requirements, and not on CMS to prove that deficiencies continued to exist after they were discovered. *Asbury Ctr. at Johnson City*, DAB No. 1815 at 19-20 (2002). A facility's return to substantial compliance usually must be established through a resurvey. 42 C.F.R. § 488.454(a). To be found in substantial compliance earlier than the date of the resurvey, the facility must supply documentation "acceptable to CMS" showing that it "was in substantial compliance and *was capable of remaining in substantial compliance*" on an earlier date. 42 C.F.R. § 488.456(e) (emphasis added); *Hermina Traeye Mem'l Nursing Home*, DAB No. 1810 at 12 (2002) (*citing* 42 C.F.R. §488.456(a), (e); *Cross Creek Care Ctr.*, DAB No. 1665 (1998).

Where CMS determines to impose a per-day CMP, the regulation provides for penalties of \$3,050 to \$10,000 per day for deficiencies constituting immediate jeopardy. 42 C.F.R. § 488.438(a)(1). Therefore, a \$6,200 per day CMP for the period of April 9 through April 15, 2014 is in the mid-level of the range of penalties CMS could impose for deficiencies constituting immediate jeopardy. The facility was also cited for immediate jeopardy in January 2014 for failing to properly maintain equipment, a transport van, and failing to properly train staff to use that equipment (training on how to secure a

wheelchair in the transport van). CMS Ex. 13 at 14. Petitioner also provided no evidence or argument that the amount of the CMP would present a financial hardship to pay. Finally, the facility's degree of culpability is high considering it was aware that the Wanderguard system was malfunctioning, but nevertheless staff continued to rely on it as one of the primary ways to alert staff of resident elopement.

As for the remaining CMP of $150 per day for the period of April 16 through April 29, 2014, Petitioner made no arguments regarding the penalty duration. Therefore, I find ample support for the CMP amount and the duration of the immediate jeopardy from April 9 through April 15, 2014, and the amount and duration of the $150 per day CMP until Petitioner was determined to have returned to substantial compliance based upon the results of the revisit survey.

## V. Conclusion

I conclude that Petitioner was not in substantial compliance with 42 C.F.R. § 483.25(h), CMS's determination of immediate jeopardy for the period of April 9 through April 15, 2014, was not clearly erroneous, and the CMP that CMS imposed is reasonable in amount and duration.

/s/
Joseph Grow
Administrative Law Judge