Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Keswick Multicare Center, LLC, (CCN: 21-5037),

Petitioner,

v.

Centers for Medicare & Medicaid Services

Docket No. C-15-1002

Decision No. CR4811

Date: March 22, 2017

DECISION

In this case, we again consider a long term care facility's obligation to prevent its confused and vulnerable residents from eloping.

Petitioner, Keswick Multicare Center, LLC, is a long-term care facility located in Baltimore, Maryland, that participates in the Medicare program. Based on surveys completed September 23, November 25, and December 16, 2014, the Centers for Medicare & Medicaid Services (CMS) determined that the facility was not in substantial compliance with the Medicare program requirements and that its deficiencies posed immediate jeopardy to resident health and safety. CMS imposed civil money penalties (CMPs) of \$5,000 per day for 41 days of immediate jeopardy (August 9 through September 18, 2014) and \$50 per day for 88 days of substantial noncompliance that was not immediate jeopardy (September 19 through December 16, 2014). Petitioner timely appealed CMS's determination.

Petitioner appeals just one of the cited deficiencies – 42 C.F.R. § 483.25(h) (accident prevention) – and the immediate jeopardy determination.

For the reasons set forth below, I find that, from August 9 through December 16, 2014, the facility was not in substantial compliance with Medicare program requirements; that, from August 9 through September 18, 2014, its deficiencies under 42 C.F.R. § 483.25(h) posed immediate jeopardy to resident health and safety; and that the penalties imposed are reasonable.

Background

The Social Security Act (Act) sets forth requirements for nursing facilities to participate in the Medicare program and authorizes the Secretary of Health and Human Services to promulgate regulations implementing those statutory provisions. Act § 1819. The Secretary's regulations are found at 42 C.F.R. Part 483. To participate in the Medicare program, a nursing facility must maintain substantial compliance with program requirements. To be in substantial compliance, a facility's deficiencies may pose no greater risk to resident health and safety than "the potential for causing minimal harm." 42 C.F.R. § 488.301.

The Secretary contracts with state survey agencies to conduct periodic surveys to determine whether skilled nursing facilities are in substantial compliance. Act § 1864(a); 42 C.F.R. § 488.20. Each facility must be surveyed annually, with no more than fifteen months elapsing between surveys. Facilities must be surveyed more often, if necessary, to ensure that identified deficiencies are corrected. Act § 1819(g)(2)(A); 42 C.F.R. §§ 488.20(a); 488.308. The state agency must also investigate all complaints. Act § 1819(g)(4).

In this case, surveyors from the Maryland Office of Health Care Quality (state agency) completed the facility's annual survey on September 23, 2014. Based on their findings, CMS determined that the facility was not in substantial compliance with multiple Medicare participation requirements. Specifically:

- 42 C.F.R. § 483.10(b)(4) (Tag F155 resident rights: right to refuse treatment) at scope and severity level D (isolated instance of noncompliance that causes no actual harm with the potential for more than minimal harm);
- 42 C.F.R. § 483.10(f)(2) (Tag F166 resident rights: resolution of grievances) at scope and severity level D;
- 42 C.F.R. § 483.13(c) (Tag F226 staff treatment of residents: policies to prohibit abuse and neglect) at scope and severity level D;
- 42 C.F.R. § 483.20(d), 483.20(k)(1) (Tag F279 resident assessment: comprehensive care plans) at scope and severity level D;

- 42 C.F.R. § 483.25 (Tag F309 quality of care) at scope and severity level D;
- 42 C.F.R. § 483.25(h) (Tag F323 quality of care: accident prevention) at scope and severity level J (isolated instance of noncompliance that poses immediate jeopardy to resident health and safety);
- 42 C.F.R. § 483.25(*l*) (Tag F329 quality of care: unnecessary drugs) at scope and severity level D;
- 42 C.F.R. § 483.60(b),(d), and (e) (Tag F431 pharmacy services: service consultation, labeling, and storage) at scope and severity level D;
- 42 C.F.R. § 483.70(h)(3) (Tag F468 physical environment: corridor handrails) at scope and severity level D;
- 42 C.F.R. § 483.75(d)(1)-(2) (Tag F493 administration: governing body) at scope and severity level D;
- 42 C.F.R. § 483.75 (j)(2)(i) (Tag F504 administration: laboratory services) at scope and severity level E (pattern of noncompliance that causes no actual harm with the potential for more than minimal harm);
- 42 C.F.R. § 483.75(j)(2)(ii) (Tag F505 administration: laboratory services) at scope and severity level D;
- 42 C.F.R. § 483.75(j)(2)(iv) (Tag F507 administration: laboratory services) at scope and severity level D; and
- 42 C.F.R. § 483.75(m)(2) (Tag F518 administration: disaster/emergency preparedness training) at scope and severity level D.

CMS Ex. 1; CMS Ex. 28 at 1-2.

The state surveyors returned to the facility and completed a follow-up survey on November 25, 2014. Based on the survey results, CMS determined that, as of September 19, 2014, the facility's deficiencies no longer posed immediate jeopardy to resident health and safety and that most of its deficiencies had been corrected. However, in CMS's view, the facility had not achieved substantial compliance because it was deficient under:

- 42 C.F.R. § 483.20(g)-(j) (Tag F278 resident assessment: accuracy/coordination/certification) at scope and severity level D (new deficiency); and
- 42 C.F.R. § 483.75(j)(2)(iv) (Tag F507 administration: laboratory services) at scope and severity level D (**repeat deficiency**).

CMS Ex. 31.

Following a December 16, 2014 revisit, CMS determined that the facility returned to substantial compliance on that date. CMS Ex. 28 at 6-7; CMS Ex. 46.

CMS has imposed against the facility CMPs of \$5,000 per day for 41 days of immediate jeopardy (August 9-September 18, 2014) and \$50 per day for 88 days of substantial noncompliance that was not immediate jeopardy (September 19-December 15, 2014), for a total penalty of \$209,400 (\$205,000 + \$4,400 = \$209,400). CMS Ex. 28 at 7.

Petitioner timely requested review, challenging just one deficiency finding: 42 C.F.R. § 483.25(h). CMS's determinations on the remaining deficiencies are therefore final and binding. 42 C.F.R. § 498.20(b).

The case was assigned to my colleague, Judge Joseph Grow. With his departure from the Civil Remedies Division, the case was reassigned to me.

The parties have filed pre-hearing briefs (CMS Br.; P.Br.). CMS filed a motion for summary judgment and memorandum in support (CMS MSJ). CMS submitted 64 exhibits (CMS Exs. 1-64), and Petitioner submitted four exhibits (P. Exs. 1-4). In the absence of any objections, I admit into evidence CMS Exs. 1-64 and P. Exs. 1-4. *See* Acknowledgment and Pre-hearing Order at 5 (¶ 7) (Grow) (January 23, 2015).

Petitioner proposed no witnesses and declines to cross-examine any of CMS's witnesses, so an in-person hearing would serve no purpose. The matter may therefore be decided based on the written record, and I need not consider summary judgment. Order Scheduling Briefing (Grow) (February 29, 2016).

Issues

Based on the uncontested issues, the facility was not in substantial compliance with Medicare program requirements from August 9 through December 16, 2014, and I must sustain a CMP of at least \$50 per day for those days. 42 C.F.R. § 488.408(d).

The issues before me are:

- From August 9 through September 18, 2014, was the facility in substantial compliance with 42 C.F.R. § 483.25(h) (Tag F323);
- If the facility was not then in substantial compliance with 42 C.F.R. § 483.25(h), did that deficiency pose immediate jeopardy to resident health and safety; and
- Is the penalty imposed for the period of immediate jeopardy \$5,000 per day reasonable?

Discussion

1. From August 9 through September 18, 2014, the facility was not in substantial compliance with 42 C.F.R. § 483.25(h), because its staff did not provide its vulnerable residents with the supervision and assistive devices they required. 1

Program requirements. Under the statute and the "quality of care" regulation, each resident must receive, and the facility must provide, the necessary care and services to allow a resident to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the resident's comprehensive assessment and plan of care. Act § 1819(b); 42 C.F.R. § 483.25. To achieve this, the regulation mandates, among other requirements, that the facility "ensure" that each resident's environment remains as free of accident hazards as possible and that each resident receives adequate supervision and assistive devices to prevent accidents. The facility must therefore eliminate or reduce a known or foreseeable risk of accidents "to the greatest degree practicable." Del Rosa Villa, DAB No. 2458 at 7 (2012); Clermont Nursing & Convalescent Ctr., DAB No. 1923 at 9-10, aff'd Clermont Nursing & Convalescent Ctr. v. Leavitt, 142 Fr. App'x. 900 (6th Cir. 2005); accord, Briarwood Nursing Ctr, DAB No. 2115 at 5 (2007) (holding that the facility must "take all reasonable steps to ensure that a resident receives supervision and assistance devices designed to meet his or her assessed needs and mitigate foreseeable risks of harm from accidents."). 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. Briarwood at 5; Windsor Health Care Ctr., DAB No. 1902 at 5 (2003), aff'd, Windsor Health Care Ctr. v. Leavitt, No. 04-3018 (6th Cir. 2005).

¹ My findings of fact/conclusions of law are set forth, in italics and bold, in the discussion captions of this decision.

<u>Facility policies</u>. During the September 23 survey, the facility produced its written policies governing elopement and related issues. Arguably, the policies are not completely consistent, but any potential discrepancy is not relevant to this case.

<u>Elopement policy #1</u>. According to one policy, effective 03/05/01 and revised 11/15/11, the facility keeps at the front desk pictures of residents known to be high elopement risks, along with their names and room numbers. A resident identified as high risk must wear a wanderguard bracelet. On each shift, nurses must check the bracelets to ensure that they are placed properly. The policy also requires an elopement care plan for any resident "at risk" (as opposed to "high risk") for elopement. CMS Ex. 25 at 228.

When notified that a resident is missing, the switchboard operator immediately activates "the 9-1-1 bells" to assemble a "facility response team." The security officer on duty documents the time of the notification, the resident's description, "and other details." Thereafter, the facility response team begins an orchestrated search of the campus and the building. Staff members are immediately assigned to search the perimeter of the campus and its fenced areas. Within the building, the search is coordinated to cover all floors and accessible areas. If the resident is not found within 15 minutes, the search is extended to the parking lot and the streets around the facility. The police are called and given a description of the missing resident. The facility's director of nursing (DON) or designee notifies the designated family member. CMS Ex. 25 at 228. Nursing staff must complete an "occurrence and investigation report," which includes notifying the resident's family and physician. CMS Ex. 25 at 229.

When the resident returns to the facility, staff must complete a full physical assessment and a "skin sheet." The nurse must complete an occurrence and investigation report. The DON and Director of Building & Grounds review the report "to assess the risk of further elopements and current security methods." Nursing completes an elopement risk assessment and "additional measures" are added to the care plan "as indicated." CMS Ex. 25 at 229.

The policy also provides that building services will test the wall sensors monthly. CMS Ex. 25 at 229.

<u>Elopement policy #2</u>. A second elopement policy, also effective 03/05/01 but revised 04/26/06, is similar to the first (e.g. front desk pictures, elopement care plans, wanderguard bracelets), with some differences. Under this policy, for example, staff notify the switchboard operator that a resident is missing, and the operator notifies the DON, Administrator, and Chief Executive Officer. The policy does not say how long staff should search before calling the police, but tells staff to call the police if the resident is not found. The nursing supervisor on duty prepares an incident report, which includes notifying the resident's family and physician. CMS Ex. 25 at 230.

Elopement policy #3. A third, undated, policy also tells staff how to respond after a resident disappears. It instructs all staff "in the area" to search room-to-room to confirm that the resident is missing. If the resident is not found, the charge nurse contacts the resident's responsible party and states "Resident not in room or frequented areas." If the responsible party has no information as to the resident's location, staff are to initiate a "CODE SILVER" by announcing "Code Silver" over the intercom and identifying the elopement unit or area. All leadership staff respond by going to the elopement area. Using the facility's "elopement binder," they "conduct a comprehensive search base[d] on MAPS in [the] elopement binder." If the resident is not found, they notify the director of nursing, the administrator, and the resident's responsible party; they also call 911. CMS Ex. 25 at 202.

<u>Wanderguard policy</u>. Finally, the facility produced a policy titled "Wanderguard Alarm System." This policy says that the facility provides its residents a "safe, secure environment," allowing them "to freely explore" their immediate surroundings while wearing bracelet alarms. CMS Ex. 25 at 215. Sensor boxes are mounted on all exit doors, and a wired remote box is mounted at the nurses' station. When a wanderguard bracelet comes within 36 inches of a sensor box, an alarm is activated and continues until turned off at the sensor box. The wired box at the nurses' station beeps until the sensor box is deactivated. CMS Ex. 25 at 215-216.

According to the policy, staff must obtain a physician order for use of a wanderguard. The bracelet is secured to the resident's wrist, ankle, or wheelchair. Staff document in the nurse's notes that the bracelet has been applied. Wanderguard checks "must be place[d] on the [treatment administration record]." CMS Ex. 25 at 215.

The policy includes procedures for testing the wanderguard bracelet. A licensed nurse is required to check the bracelet on the day shift *every day* and to document the check in the treatment administration record. If the test results are not "good" or "normal," the charge nurse must notify the unit manager or supervisor. CMS Ex. 25 at 216. The unit managers (or their designees) test each alarmed exit weekly and document the results. Building Services also tests the exit alarms "on a routine basis." CMS Ex. 25 at 217.

The first elopement: Resident 540 (R540). R540 was an 84-year old woman, admitted to the facility on August 3, 2014, with diagnoses of malaise and fatigue NEC (not elsewhere classified) and herpes zoster. CMS Ex. 17 at 23. She had a urinary tract infection. CMS Ex. 17 at 24. She had poor leg control, an unsteady gait, and impaired balance, which put her at risk for falls. CMS Ex. 17 at 44.

On August 5, her physician ordered that she wear a wanderguard at all times. He also ordered staff to check the wanderguard on every shift for placement—her right wrist—and functioning. CMS Ex. 17 at 33, 34. It appears that the facility relied solely on the

physician's order to determine that R540 was high risk for elopement. It did not independently assess that risk or develop a care plan to address it. CMS Ex. 61 at 4 (Cole Decl. ¶ 13); see 42 C.F.R. §§ 483.20(b) and 483.20(k) (discussed below).

Physical therapy notes dated August 8 describe R540 as "confused." The physical therapy assistant wrote that the resident had been wearing the same clothes for three days and was "packing her bags to go home each day." The therapy assistant notified the nurse. CMS Ex. 17 at 27.

At about 3:30 p.m. on August 9, 2010, a nurse aide took R540's vital signs. CMS Ex. 17 at 22. Sometime between about 3:45 and 4:00 p.m. that afternoon, the building manager at 3838 Roland Avenue called the facility to report that he found R540 sitting in the lobby of his building. The building was two or three blocks away from the facility and across a busy street. Facility staff had not realized that the resident was missing. After searching her unit to confirm that she was not there, staff went to the Roland Avenue address. They returned the resident to the facility unharmed. A wanderguard bracelet was affixed to her right ankle, even though her physician ordered that it be fastened to her wrist. CMS Ex. 17 at 14, 18, 21, 22.

Attaching the bracelet to the wrong limb is not inconsequential. The manufacturer recommends affixing the bracelet to the resident's dominant wrist. More important, not all models are effective if attached to a resident's ankle, and, at the time of R540's elopement, the facility's system could not accommodate an ankle bracelet. CMS Ex. 52 at 4; CMS Ex. 61 at 14 (Cole Decl. ¶32). No one has explained *why* staff deviated from the physician's order by placing the bracelet on R540's ankle rather than her wrist. CMS points out that the system failed no matter where the bracelet was affixed, which is true. But even if the system were otherwise working properly, an ankle bracelet would not have prevented R540's elopement, given the system in place at the time.

After returning the resident to the facility, staff tested R540's wanderguard, and it failed to activate the alarms at any of the exit doors. CMS Ex. 17 at 18.

Facility staff subsequently viewed a surveillance video that recorded R540's elopement. The video showed her leaving the building with a group of people. The wanderguard was around her ankle and the alarm did not sound. CMS Ex. 17 at 11; CMS Ex. 61 at 6-7 (Cole Decl. ¶ 17); CMS Ex. 63 at 15-16 (Gabel Decl. ¶ 41). When interviewed by surveyors on September 18, 2014, the facility's executive director did not know why the alarm failed; he could only speculate. CMS Ex. 61 at 6-7 (Cole Decl. ¶ 17).

The security guard on duty denied seeing R540 leave the premises. CMS Ex. 17 at 18.

On August 11, staff added wandering to R540's care plan. CMS Ex. 17 at 38-39. But they developed the care plan without first assessing her needs, as required by 42 C.F.R. § 483.20(b) and (k). Facility staff did not finally assess R540 for wandering and elopement until *September 18*, more than a month later; not coincidentally, this was at the time of the survey. CMS Ex. 17 at 40-41.

The second elopement: Resident 355 (R355). R355 was an 81-year old woman who was admitted to the facility on July 31, 2012, and readmitted on July 15, 2014, after a four-day hospital stay. CMS Ex. 13 at 1, 10. She was diagnosed with depression, hypertension, dementia, and a host of other conditions. She suffered cognitive loss as a result of her dementia and had become disoriented to place and time. Her ability to perform activities of daily living had declined, and she required extensive assistance from staff. CMS Ex. 13 at 17, 27, 42. She had undergone hip replacement surgery and was experiencing hip pain. CMS Ex. 13 at 1, 42. Her balance was impaired; she had an unsteady gait; and she was at risk for falls. CMS Ex. 13 at 9, 18-19, 20, 26.

A late entry to the resident's nurses' notes, dated August 7, indicates R355 "was observed sitting in her [wheel chair] roaming around the unit." Although she made no attempts to leave the unit unassisted, on that day, her physician ordered a wanderguard and one was placed on her wrist. CMS Ex. 13 at 31-32, 43. Again, staff did not perform a comprehensive assessment nor develop a care plan before they affixed the bracelet. According to the note, the wanderguard "is functioning properly." CMS Ex. 13 at 31-32.

On August 8, 2014, R355 complained to the physical therapy assistant that she wanted to go home. CMS Ex. 13 at 22.

On August 10, 2014, staff noted that they were unable to test R355's wanderguard because they had "no wanderguard tester." CMS Ex. 13 at 50.

Between 4:30 and 5:00 p.m. on August 10, one of the facility's nurse aides looked out the window and saw R355 outside in her wheelchair, wheeling herself down the walkway toward the street. R355 lived on the facility's third floor. While in a wheelchair, she managed to get herself down to the first level and out the front door without sounding an alarm or triggering an alert. CMS Ex. 61 at 10 (Cole Decl. ¶ 24). The nurse aide responsible for R355's care had been assisting another resident and was not aware of R355's elopement until the resident was returned to the facility. CMS Ex. 13 at 13.

The aide who observed R355 went after her, catching up as the resident was approaching 40th Street, at the stop sign on the edge of the property. When asked where she was going, R355 said that she wanted to go home. The resident was not wearing an identification bracelet, although her name and room number were on the wheelchair. CMS Ex. 13 at 9, 12-13, 15; *see* CMS Ex. 61 at 10-11 (Cole Decl. ¶ 24); CMS Ex. 57.

When R355 returned to the facility, staff gave her a new wanderguard. CMS Ex. 13 at 9. Nurses' notes generated later that day (August 10) describe the resident as an "elopement risk." The notes indicate that nurses should evaluate the resident's need for a wanderguard, document any attempts to elope, ensure twice daily that her wanderguard is functional, place her picture at the security desk, and inform security about her potential for elopement. CMS Ex. 13 at 25. The notes indicate that the 7-3 shift – and no other – should check the bracelet for placement and functioning (which does not seem consistent with checking twice daily). CMS Ex.13 at 26. A care plan entry dated August 12 adds wandering to R355's behaviors and directs the nursing staff to provide a wanderguard. CMS Ex. 13 at 45-46; CMS Ex. 61 at 9 (Cole Decl. ¶ 22).

As with R540, until September 18, 2014, staff did not assess the resident for wandering and elopement risk. CMS Ex. 13 at 47-48; CMS Ex. 61 at 9 (Cole Decl. ¶ 22).

The malfunctioning wanderguard system. Surveyor Jennifer Cole interviewed the facility's executive director and the facility's quality assurance nurse. They were unable to explain how R355 and R540 managed to leave the building but speculated that each left with a group of people, which might have interfered with the wanderguard bracelet's detection sensor. CMS Ex. 61 at 11 (Cole Decl. ¶ 26).

On the morning of September 18, the surveyors accompanied the facility's maintenance director, who used a handheld tester and then a bracelet to test the wanderguard alarms on R355's unit. Some of the interior doors did not respond. The maintenance director also told the surveyors that the wanderguard testers did not work on any of the "analog doors" in the building. CMS Ex. 61 at 12 (Cole Decl. ¶ 28). Even when the alarm sounded, staff did not respond or responded after a delay of two minutes or so. When Surveyor Cole mentioned staff's feeble response, the maintenance director agreed that staff were "pretty complacent." CMS Ex. 61 at 17 (Cole Decl. ¶ 38).

The facility's maintenance director also tested the wanderguard system in R540's unit. On the ground and first floors, the stairwell access sensors did not respond. CMS Ex. 61 at 12 (Cole Decl. ¶ 28). Allowing demented residents access to the stairwells creates an especially dangerous situation. *See, e.g., Asbury Ctr. at Johnson City*, DAB No. 1815 (2002). Later that morning, the facility's executive director attached a wanderguard bracelet to his own shoes in order to test the system. The alarms to the side entrances at the ground level and first floor on R540's unit did not respond to the bracelet. CMS Ex. 61 at 12 (Cole Decl. ¶ 29).²

² Note that by the September 18 survey date, the system had been upgraded to allow for placement on a resident's ankle. CMS Exs. 26, 52.

Surveyor Mark Gabel placed a wanderguard bracelet in his sock while he toured the facility. Sometimes the alarms sounded and sometimes they did not. Although an alarm sounded at the front door, it did not sound when he left the unit where R540 resided. CMS Ex. 63 at 16 (Gabel Decl. ¶ 42). When he entered the elevator on the second floor of R355's building, the alarm did not sound. CMS Ex. 63 at 17 (Gabel Decl. ¶ 44).

The surveyors reviewed maintenance records for the facility's wanderguard system. CMS Ex. 26; CMS Ex. 61 at 13 (Cole Decl. ¶31). On August 15, 2014, the maintenance company noted that some of the doors were not working properly and recommended an upgrade. CMS Ex. 26 at 7; CMS Ex. 61 at 13 (Cole Decl. ¶ 31). The company upgraded the system on August 20, but reported "electromagnetic interference issues," which impaired the system's effectiveness. CMS Ex. 26 at 8; CMS Ex. 61 at 13 (Cole Decl. ¶ 31).

Thus, even after two elopements, the facility continued to rely on a demonstrably unreliable system as its primary – in fact only – systematic method for protecting residents from eloping.

Additional failures to implement elopement policies. According to the facility policies, the facility was supposed to maintain at the front desk pictures of residents known to be elopement risks so that staff could identify any of them attempting to leave the facility. CMS Ex. 25 at 228, 230. A security guard sat at the front desk. Surveyor Cole asked the executive director and the quality assurance nurse how the two residents were able to get past the security guards undetected, particularly since the guards should have had their pictures at hand. According to the executive director, the guards "were talking to someone else." CMS Ex. 61 at 16 (Cole Decl. ¶ 37); CMS Ex. 63 at 17 (Gabel Decl. ¶ 45).

Surveyor Cole later asked the guard on duty to show her the "elopement binder" (where the resident pictures were kept). He could not find the book. Eventually, after he, the executive director, and the maintenance director searched, the guard found the book behind a wall about six feet from the security desk. CMS Ex. 61 at 16 (Cole Decl. ¶37).

Thus, contrary to facility policies for preventing elopements, pictures of high-risk residents were not readily available at the front desk. No one – not even the security guards – watched the door carefully enough to prevent high-risk residents from leaving.

No comprehensive assessments and inadequate care planning. Surveyor Cole reviewed records of residents wearing wanderguard bracelets, and *none* contained assessments of the resident's elopement risk. Staff confirmed that they had no criteria or assessment tools in place to identify "exit seeking behavior" or to evaluate residents at risk for elopement. CMS Ex. 61 at 14-15 (Cole Decl. ¶¶ 33, 34).

Accurate assessments are critically important because they form the bases for the care that the facility provides. *See*, e.g., 42 C.F.R. § 483.20(d) and (k) (directing the facility to base a resident's comprehensive care plan on the results of his comprehensive assessment). The assessments must be comprehensive and must accurately reflect the resident's functional capacity.³

With respect to R540, Petitioner points out that the resident had been admitted just seven days prior to her elopement. Under the regulations, a facility must conduct its comprehensive assessment within 14 calendar days of a resident's admission. But this does not excuse the facility for failing to plan interventions designed to keep R540 safe. The facility's policies require it to develop an elopement care plan for *every* resident "at risk" for elopement, and R540 was at high risk. CMS Ex. 25 at 228, 230. The policy allows no grace period. And plans must be based on comprehensive assessments. 42 C.F.R. § 483.20(b)(2)(i).

In any event, R540's assessment was not completed until the time of the survey, well beyond any deadline.

Petitioner also argues that the physician's August 5 order for a wanderguard shows that the resident was assessed. A physician order is not an adequate substitute for an assessment, which must describe the resident's functional capacity and must be comprehensive, accurate, standardized, and reproducible. 42 C.F.R. §§ 483.20 and 483.20(b).

Although CMS did not press the issue in the context of elopement, the facility's failing to assess its residents for elopement risks violates 42 C.F.R. § 483.20. Under that regulation, the facility must conduct "initially and periodically, a *comprehensive*, *accurate*, *standardized*, *reproducible* assessment of each resident's functional capacity." (emphasis added). Based on the assessment, the facility develops the resident's comprehensive care plan. 42 C.F.R. § 483.20(k). CMS cited deficiencies under section 483.20, but determined that the problem was isolated and concerned the facility's failing to develop care plans for three other residents, one who required dialysis and two with total incontinence. CMS Ex. 1 at 13-15. That the facility had no assessment tools for elopement risks shows a more serious, widespread problem under section 483.20.

Further, a wanderguard bracelet could be considered a restraint. An adequate assessment and care plan assure that the device is needed to treat medical symptoms and is not imposed for discipline or convenience of staff, which is strictly forbidden. 42 C.F.R. § 483.13(a).

Moreover, the facility's problems were far more serious than failing to assess and care plan a recently-admitted resident. First, R355 had been in the facility for more than 14 days and should have undergone a comprehensive assessment. More alarming, the facility did not have a method for identifying at-risk residents and assessing their needs. It was therefore not capable of ensuring that each resident receive supervision and assistive devices "designed to meet his or her assessed needs and to mitigate foreseeable risks of harm from accidents." It was therefore not in substantial compliance with 42 C.F.R. § 483.25(h).

2. CMS's determination that the facility's substantial noncompliance with 42 C.F.R. § 483.25(h) posed immediate jeopardy to resident health and safety is not clearly erroneous.

Immediate jeopardy. 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 observed 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." *Daughters of Miriam Ctr.*, DAB No. 2067 at 7, 9 (2007); *Barbourville Nursing Home*, DAB No. 1962 at 11 (2005), *aff'd Barbourville Nursing Home v. U.S. Dept. of Health & Human Servs.*, 174 F. App'x. 932 (6th Cir. 2006).

It is well-settled that the unsupervised wandering and elopement of frail and demented individuals presents very real and serious dangers:

The likelihood of serious harm is weighed . . . by considering what the episode reveals about dangers to which residents in the facility were exposed by the identified problems and how likely such dangers were to result in serious harm [T]he fact that someone who was severely mentally impaired and unable to care for her own safety could wander off entirely unnoticed and not be sought until strangers rescued her presents significant likelihood that vulnerable residents might encounter the very dangers [that the facility] calls "the usual hazards of wandering away," such as falls, traffic, etc.

Century Care of Crystal Coast, DAB No. 2076 at 24 (2007). Where, as here, a facility's deficiencies allow a cognitively impaired resident, who lacks safety awareness and is at risk for falls, to leave a facility undetected, the Departmental Appeals Board has "no trouble finding a crisis situation" that poses immediate jeopardy to resident health and safety. Mississippi Care Ctr. of Greenville, DAB No. 2450 at 16 (2012); see also Glenoaks Nursing Ctr., DAB No. 2522 at 17 (2013).

Because the facility's deficiencies were likely to cause serious harm to vulnerable residents, CMS's determination that the deficiencies posed immediate jeopardy to resident health and safety is not clearly erroneous.

3. The \$5,000 per day penalty for the period of immediate jeopardy is reasonable.

To determine whether a civil money penalty is reasonable, I apply the factors listed in 42 C.F.R. § 488.438(f): (1) the facility's history of noncompliance; (2) the facility's financial condition; (3) factors specified in 42 C.F.R. § 488.404; and (4) the facility's degree of culpability, which includes neglect, indifference, or disregard for resident care, comfort or safety. The absence of culpability is not a mitigating factor. The factors in 42 C.F.R. § 488.404 include: (1) the scope and severity of the deficiency; (2) the relationship of the deficiency to other deficiencies resulting in noncompliance; and (3) the facility's prior history of noncompliance in general and specifically with reference to the cited deficiencies.

I consider whether the evidence supports a finding that the amount of the CMP is at a level reasonably related to an effort to produce corrective action by a provider with the kind of deficiencies found, and in light of the section 488.438(f) factors. I am neither bound to defer to CMS's factual assertions nor free to make a wholly independent choice of remedies without regard for CMS's discretion. *Barn Hill Care Ctr.*, DAB No. 1848 at 21 (2002); *Cmty. Nursing Home*, DAB No. 1807 at 22 *et seq.* (2002); *Emerald Oaks*, DAB No. 1800 at 9 (2001); *CarePlex of Silver Spring*, DAB No. 1638 at 8 (1999).

Here, CMS imposes a penalty of \$5,000 per day for each day of immediate jeopardy, which is at the lower end of the immediate jeopardy range (\$3,050 to \$10,000). 42 C.F.R. §§ 488.408(e)(1)(iii); 488.438(a)(1)(i). Considering the relevant factors, the penalty is reasonable.

The facility has a less-than-stellar history. For the survey completed July 15, 2013, it was not in substantial compliance with ten requirements, including 42 C.F.R. § 483.25(h) (Tag F323). CMS Ex. 25 at 7. Nor was it in substantial compliance for surveys completed in May 2012 and June 2010. *Id.* The facility's history alone justifies imposing a CMP greater than the \$3,050 minimum.

Petitioner does not claim that its financial condition affects its ability to pay the CMP.

With respect to the remaining factors, I consider *all* of the facility's deficiencies, including the thirteen that the facility does not contest. Add to these the serious problems discussed above. For this elderly and infirm population, failing to prevent elopement can have serious, even fatal, consequences. Yet the facility was not equipped to assess resident risk. Instead, based on some unknown criteria, it attached wanderguard bracelets on some residents and relied almost exclusively on that ineffective system. For this, the facility is culpable and the penalties imposed are reasonable.

Conclusion

For all of these reasons, I find that, from August 9 through December 16, 2014, the facility was not in substantial compliance with Medicare program requirements; from August 9 through September 18, 2014, its deficiencies under 42 C.F.R. § 483.25(h) posed immediate jeopardy to resident health and safety; and the penalties – \$5,000 per day for 41 days of immediate jeopardy and \$50 per day for 88 days of substantial noncompliance that was not immediate jeopardy – are reasonable.

/s/ Carolyn Cozad Hughes Administrative Law Judge