Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Bigfork Valley Communities,
(CCN: 24-5529),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-15-2883

Decision No. CR4942

Date: September 27, 2017

DECISION

Petitioner, Bigfork Valley Communities (Petitioner or "the facility"), is a long-term care facility that participates in the Medicare program. Based on a survey and extended survey conducted between March 23 and 27, 2015, the Centers for Medicare & Medicaid Services (CMS) determined that Petitioner was not in substantial compliance with various Medicare participation requirements. CMS imposed against Petitioner a civil money penalty (CMP) of $3,750 per day, effective February 28, 2015 through March 26, 2015, for a total of $101,250, and a CMP of $200 per day, effective March 27, 2015 through May 14, 2015, for a total of $9,800. The total CMP imposed was $111,050. CMS also informed Petitioner that it would be prohibited from conducting a Nurse Aide Training and Competency Evaluation Program (NATCEP) for a period of two years, effective March 27, 2015.

The survey cited nineteen deficiencies (CMS Exhibits (Exs.) 1, 2), and Petitioner contests only the deficiencies cited under 42 C.F.R. § 483.25(h) (Tag F323, relating to accident prevention and adequate supervision) at the J level of scope and severity, and 42 C.F.R. § 483.75 (Tag F490, relating to the administration of the facility) at the E level of scope

and severity.[1] *See* Request for Hearing. Petitioner challenges CMS's determinations of substantial noncompliance with 42 C.F.R. §§ 483.25(h) and 483.75, and that the deficiency cited under 42 C.F.R. § 483.25(h) posed immediate jeopardy to resident health or safety.[2]

For the reasons set forth below, I sustain CMS's determinations. I find that Petitioner was not in substantial compliance with the requirements for participation at 42 C.F.R. §§ 483.25(h) and 483.75, that CMS's immediate jeopardy determination was not clearly erroneous, and that the penalty imposed is reasonable.

I. Background

The Social Security Act (Act) sets requirements for skilled nursing facility (SNF) participation in the Medicare program. The Act authorizes the Secretary of the U.S. Department of Health & Human Services (Secretary) to promulgate regulations implementing those statutory provisions. Act § 1819 (42 U.S.C. § 1395i-3). The Secretary's regulations are found at 42 C.F.R. part 483.[3]

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[1] Scope and severity levels are used by CMS and state survey agencies when selecting remedies. The scope and severity level is designated by letters A through L. Pub. 100-7, State Operations Manual, § 7400.5.1 (Factors That Must be Considered When Selecting Remedies), "Assessment Factors Used to Determine the Seriousness of Deficiencies Matrix" (table), *https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/som107c07.pdf* (last visited September 20, 2017); *see* 42 C.F.R. § 488.408. As relevant here, a scope and severity level of J indicates an isolated deficiency that poses immediate jeopardy to resident health or safety. A deficiency with a scope and severity of E indicates a pattern of deficiency that presents no actual harm but has the potential for more than minimal harm that does not amount to immediate jeopardy.

[2] Petitioner does not challenge the duration of immediate jeopardy or the amount of the CMP. Further, while Petitioner generally disagrees with the prohibition of it conducting a NATCEP, it has not presented any legal arguments that obviate the mandatory imposition of a two-year prohibition on a NATCEP. *See* 42 C.F.R. § 483.151(b)(2), (e)(1).

[3] Federal nursing home regulations substantially changed beginning on November 28, 2016. 81 Fed. Reg. 68,688 (October 4, 2016). Based on the date of the survey, which preceded the regulatory revisions, I refer to the regulations that were in effect at the time of the survey.

A facility must maintain substantial compliance with program requirements in order to participate in the program. 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 agencies to conduct periodic surveys to determine whether SNFs are in substantial compliance with the participation requirements. Act § 1864(a) (42 U.S.C. § 1395aa(a)); 42 C.F.R. §§ 488.10, 488.20. The Act and regulations require that facilities be surveyed on average every twelve months, and more often if necessary, to ensure that identified deficiencies are corrected. Act § 1819(g)(2)(A) (42 U.S.C. § 1395i-3(g)(2)(A)); 42 C.F.R. §§ 488.20(a), 488.308.

Petitioner is an SNF that operates in Bigfork, Minnesota. The Minnesota Department of Health (state agency) conducted a survey and extended survey of Petitioner that concluded on March 27, 2015. The state agency found that the facility was not in substantial compliance and the conditions constituted immediate jeopardy. CMS Ex. 1. Based on the survey findings, CMS determined that, among other deficiencies, the facility was not in substantial compliance with the participation requirement at 42 C.F.R. § 483.25(h) concerning accident prevention and adequate supervision, and that the noncompliance constituted immediate jeopardy and substandard quality of care to residents' health and safety from February 28, 2015 through March 26, 2015.[4] The state agency also determined that Petitioner was not in substantial compliance with 42 C.F.R. § 483.75 concerning administration. Based on all the cited deficiencies, by letters dated April 16, 2015 and June 17, 2015, CMS imposed a CMP in the amount of $3,750 per day effective February 28, 2015 through March 26, 2015, and a CMP in the amount of $200 per day effective March 27 through May 14, 2015. CMS Ex. 6 at 1. CMS also informed Petitioner that it would be prohibited from conducting a NATCEP for a period of two years. CMS Ex. 4 at 4-5.

[4] On August 31, 2015, the parties submitted joint stipulations in which they agreed that of the 19 deficiencies cited in the survey completed on March 27, 2017, Petitioner limited its appeal to two of those deficiencies and that Petitioner "does not contest the remaining deficiencies." To the extent that Petitioner does not challenge the deficiencies cited at the D, E, and F level of scope and severity under, *inter alia*, 42 C.F.R. §§ 483.10(b)(11), 483.25(a)(2), and 483.65, for which Petitioner returned to compliance on May 15, 2015, Petitioner therefore does not challenge the CMPs associated with those deficiencies. As such, Petitioner does not challenge the $200 per day CMP for the 49-day period from March 27 through May 14, 2015. Therefore, those deficiencies and the remedies imposed for those uncontested deficiencies are administratively final.

On June 12, 2015, Petitioner requested a hearing. Administrative Law Judge (ALJ) Joseph Grow[5] issued an acknowledgment and pre-hearing order (Pre-Hearing Order) on June 30, 2015 establishing a briefing schedule. CMS filed a pre-hearing brief (CMS Br.) and 36 exhibits (CMS Exs. 1-36), and Petitioner filed a pre-hearing brief (P. Br.) and 22 exhibits (P. Exs. 36-57). In an Order dated July 14, 2016, I admitted CMS Exs. 1-36 and P. Exs. 36-55 and 57.[6] CMS subsequently submitted a motion requesting the admission of two additional exhibits, CMS Exs. 37 and 38. Petitioner has not objected to CMS's motion seeking admission of these exhibits, and CMS Exs. 37 and 38 are admitted into evidence.

On September 7, 2016, I convened a hearing to give the parties an opportunity to cross-examine the witnesses who provided written direct testimony. Petitioner cross-examined state surveyors Rebecca Haberle, RN, Vienna Andreson, RN, and Sharron Williams, RN. *See* CMS Exs. 28, 30, and 33; Transcript (T.) at 26-149. CMS cross-examined Petitioner's witnesses, Director of Senior Services Kyle Hedlund,[7] Interim Director of Nursing Joanne Jacobson, RN, and Licensed Practical Nurse Melissa Christie. *See* P. Exs. 50, 51, and 52; T. at 152-370). In addition, Petitioner submitted the written direct testimony of David Meek, RN, and CMS did not request an opportunity to cross examine Mr. Meek. *See* P. Ex. 53. The parties submitted post-hearing briefs (CMS Post-Hearing Br.; P. Post-Hearing Br.) and post-hearing reply briefs (CMS Reply; P. Reply).

II. Issues

The issues are:

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[5] This case was reassigned to me on March 31, 2016 following Judge Grow's departure from the Departmental Appeals Board.

[6] Judge Grow explained in his Pre-Hearing Order that a hearing will be necessary only if a party files admissible, written direct testimony and the opposing party asks to cross-examine that witness, and it is the responsibility of the party who submitted the written direct testimony for a witness to produce the witness at the hearing. All written direct testimony has been admitted into the record.

[7] Mr. Hedlund formerly served as the Director of Senior Services, but several documents identify Mr. Hedlund as the Administrator. *See* CMS Ex. 5 (letter from CMS to Mr. Hedlund); CMS Ex. 17 at 3 (incident report identifying Mr. Hedlund as the Administrator); CMS Ex. 18 at 3 (incident report identifying Mr. Hedlund as the Administrator). While Mr. Hedlund did not formally serve as the facility's administrator, it appears that, at least to some extent, he handled some of the duties of that position while he served as the Director of Senior Services. The facility did not offer the testimony of then-Administrator Jim Blum.

1. From February 28 through May 14, 2015, was the facility in substantial compliance with Medicare program requirements;

2. If, from February 28 through March 26, 2015, the facility was not in substantial compliance with program requirements, did its deficiencies pose immediate jeopardy to resident health and safety; and

3. If the facility was not in substantial compliance, are the penalties imposed of $3,750 per day for 27 days of immediate jeopardy and $200 per day for 49 days of substantial noncompliance that was not immediate jeopardy reasonable?

III. Discussion[8]

A. Background

1. The facility

Petitioner is a hospital-based SNF in Bigfork, MN. P. Ex. 50 at 1. Petitioner consists of two units, the Tamarack Lodge, a 27-bed unit, and the Aspen Unit a 20-bed secure memory care unit that opened on January 12, 2015 (referred to herein as the "Tamarack" and "Aspen" units, respectively). P. Ex. 50 at 2, 4. The Aspen Unit has four exit doors. Three of the exit doors are equipped with a Wanderguard alarm system that will sound when a resident wearing a Wanderguard device (i.e., a bracelet) attempts to exit through a Wanderguard-equipped door. P. Ex. 50 at 3. The doors with alarms are the main entrance sliding doors, an emergency exit, and a door connecting the Tamarack and Aspen units. P. Ex. 50 at 3. A fourth exit door is a set of "double French doors" connecting the dining area to a patio (herein referred to as the "patio doors"). P. Ex. 50 at 3; CMS Ex. 23 at 3. The patio doors do not have an alarm, and the patio doors do not lock from the inside "so as to allow residents to move freely between the dining room and secure patio area."[9] P. Ex. 50 at 3-4; CMS Ex. 22 at 1 (Petitioner's immediate jeopardy abatement plan stating that the patio doors will be locked at 6:30 pm every evening and unlocked in the morning); T. at 226 (Interim Director of Nursing's testimony that the facility's decision to start locking the unalarmed patio doors was a change in procedures). The facility did not install an alarm system on the patio doors because "the patio area is designed to be part of the secure unit, fully enclosed by a fence without the means to exit

[8] My findings of fact and conclusions of law are in italics and bold font.

[9] Petitioner's brochure states that "Residents have warm weather access to a safe outdoor grass and garden area." CMS Ex. 25 at 1. Petitioner's brochure also, rather quizzically, highlights that a walkway surrounding the common area allows for "continuous wandering" by its residents. CMS Ex. 25 at 2.

the secure unit from the patio." P. Ex. 50 at 3. At the time of the survey, the patio area was not secure because the fence had not yet been erected because "construction was delayed until the weather permitted its completion, which was anticipated in the spring of 2015." P. Ex. 50 at 3. In its request for hearing, Petitioner explained that the patio doors "were not installed with the capacity to be locked from the inside." Request for Hearing at 3. Petitioner explained:

> Due to weather events outside the facility's control,[10] the installation of the fence around the patio was delayed until the spring of 2015. Bigfork Valley management promptly arranged to have a locking mechanism fabricated for these doors. Recognizing that the unlocked patio doors exited into a temporarily unsecured area, Bigfork Valley arranged to have a direct care staff member present and monitoring the dining room at all hours that residents have access to the dining room.

Request for Hearing at 3. Mr. Hedlund, the Director of Senior Services, testified that a parking lot and a densely wooded area are outside of the patio doors. T. at 194. Mr. Hedlund stated that "[i]f a resident were to wander into those woods, they potentially could get lost." T. at 195.

Mr. Hedlund, recognizing that the patio doors were not equipped with a Wanderguard system alarm, testified that it "is Bigfork Valley's practice that at least one staff member is stationed on the floor of the Aspen Unit to supervise residents in the common areas, including the dining area and near the exits, at all times (both day and night shifts)." P. Ex. 50 at 4. Both Mr. Hedlund and Ms. Jacobson, the Interim Director of Nursing, explained that the facility was constructed so that its staff members could easily see across the unit to monitor the exit doors, to include the patio doors. P. Ex. 50 at 2-3; P. Ex. 51 at 4. Mr. Hedlund testified that "[a]fter the Aspen Unit opened but prior to the survey, [he] ordered and purchased mesh door stop signs with alarms on them to use on the patio doors" and that "[t]hey arrived after the survey took place." P. Ex. 50 at 6; *see* CMS Ex. 23 at 3 (statement by the facility that it had ordered mesh door alarms to place over the patio doors). With respect to the other exit doors that were equipped with Wanderguard alarms, a progress note indicates that Resident # 63's Wanderguard bracelet did not activate an exit door alarm on at least one occasion. *See* CMS Ex. 19 at 4

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[10] In its plan of correction, Petitioner explained that the ground is "still frozen 12 [inches] down" that it expected that when "the ground is no longer frozen ([estimated] July) the fence will be constructed." CMS Ex. 1 at 70. I add that, even if the facility had constructed a fence prior to its opening, a set of unlocked doors to a secure patio area could have nonetheless posed a significant risk for injury, impairment, or death from cold exposure if facility staff was unaware that a resident was outdoors in extremely cold weather.

(report that Resident # 63 could walk through the Aspen doors with no alarm sounding);[11] CMS Ex. 1 at 71 (plan of correction noting that on March 27, 2015, a technician "made an adjustment to the front door that cuts the power to the door when a [Wanderguard] is present"); T. at 187 (Testimony of Mr. Hedlund that he "can't recall exactly . . . but would say yes" that adjustments were made to the Wanderguard alarm system after it was reported that Resident # 63 could walk through the Aspen doors with no alarm sounding).

The state agency began its survey on March 23, 2015, at which time it determined, *inter alia*, that a deficiency existed at the level of immediate jeopardy (CMS Ex. 1 at 68–78). The facility submitted an abatement plan in response to the notice of immediate jeopardy. CMS Ex. 23. The facility conducted in-service training on its elopement policy and elopement assessment education on March 26, 2015. CMS Ex. 23 at 5-6. The facility also informed the state survey agency that it would impose a number of interventions to abate immediate jeopardy, to include, but not limited to: locking the double French doors into the dining room at 8:00 pm each night and during non-meal times when a dietary staff member was not present; installing mesh door alarms no later than April 6, 2015; building a fence around the courtyard area and leveling the ground; obtaining a technical "audit" of the Wanderguard system; and, changing its staffing during the NOC (night) shift. CMS Ex. 23 at 3. With respect to its night shift staffing level, the facility explained the following:

> On the NOC shift we are currently running with one CNA in Aspen Circle and one CNA in Tamarack Lodge with an LPN that floats between the communities. Our preferred staffing pattern on the NOC shift is two CNAs in Aspen and one in Tamarack with the LPN floater. This shows our historical staffing patterns, however, we needed to adjust due to lack of available staff. We expect to be back to our preferred staffing level in mid-April.

CMS Ex. 23 at 3; *see* T. at 164 (testimony that the previous statement referred to the facility's staffing levels in March 2015).

2. Resident # 63

Resident # 63 was admitted to the facility on February 27, 2015. CMS Ex. 19 at 1, 12; P. Ex. 44 at 33. At the time of his admission, Resident # 63 was 65 years old, and his diagnoses included vascular dementia, alcohol-induced persisting amnestic disorder, anxiety state, unspecified, and personal history of fall. CMS Ex. 19 at 1; P. Ex. 44 at 33.

[11] The "Aspen doors" are the unit's main entrance doors exiting to the outside. T. at 188.

Resident # 63 was assessed as having a Brief Interview for Mental Status (BIMS) score of 5 in March 2015, which means that he had severe cognitive impairment. P. Ex. 43 at 7; *see* Long-Term Care Facility Resident Assessment Instrument 3.0 User's Manual, Chapter 3, Section C0050 (Summary Score), *https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/NursingHomeQualityInits/Downloads/MDS-30-RAI-Manual-V113.pdf* (last visited September 25, 2017). Resident # 63 was assessed as not requiring any setup or physical help from staff with walking in his room and in the corridor, and he did not require any assistance with locomotion on the unit. P. Ex. 43 at 15. The facility assessed that Resident # 63's wandering placed him "at significant risk of getting to a potentially dangerous place (e.g., stairs, outside of the facility)." P. Ex. 43 at 12.

A care plan initiated on February 28, 2015 addressed Resident # 63's use of anti-anxiety medication and psychotropic medications, and that he had a behavioral problem related to vascular dementia and anxiety. CMS Ex. 13 at 1, 5. The care plan also addressed that Resident # 63 was at risk for falls related to a history of frequent falls and psychoactive medications. CMS Ex. 13 at 2. A care plan intervention, dated February 28, 2015, discussed that Resident # 63 was "an elopement risk/wanderer," along with the following: "Resident wanders aimlessly. Impaired safety awareness. Disoriented to place. History of attempts to leave the facility unattended."[12] CMS Ex. 13 at 2. On March 26, 2015, Petitioner updated Resident # 63's care plan to reflect that he has a history of exit-seeking behavior and that he has "been able to get outside." P. Ex. 44 at 32. Resident # 63's care plan also focused on his "vulnerability [due to] dementia" and that he had "an alteration in neurological status [related to] syncope, disease process (Wernicke's Korsakoff Syndrome), Major Neurocognitive Disorder and short-term memory impairment" with "Confabulation-Memory disorder with spontaneous production of false memories." CMS Ex. 13 at 4.

Progress notes document that Resident # 63 was sometimes restless during the nighttime. For instance, on March 22, 2015 at approximately 3:00 am, Resident # 63 threw and broke furniture, and did not go to bed until 3:30 am. CMS Ex. 19 at 2. A March 21, 2015 progress note that was entered at 11:07 pm indicates that Resident # 63 had been awake for more than 24 hours and was "constantly trying to get out the doors." CMS Ex. 19 at 2-3. On March 3, 2015, nursing staff reported that Resident # 63 had been trying to

[12] Resident # 63's care plan included numerous interventions dating back to February 28, 2015. CMS Ex. 13 at 2-3. The facility added a "WANDER ALERT" to the care plan on February 28, 2015, and nearly a month later, on March 26, 2016, the facility added the intervention of "[p]lace an alarm mat on the floor outside the east door and outside the Tamarack hallway door for my safety." CMS Ex. 13 at 3.

get out of the doors since 5:00 am (CMS Ex. 19 at 8). Progress notes also indicate that Petitioner was administered lorazepam during the overnight shift on March 3, 13, 14, and 18. CMS Ex. 19 at 3, 5, 7 and 9.

3. Resident # 63's attempts to leave the facility

A facility incident report for an elopement authored by Minimum Data Set (MDS) Coordinator Deb Porter states that at 9:35 am on February 28, 2015, Resident # 63 "was found outside the building" and that he had "[l]eft the Dining Room through the doors." CMS Ex. 17 at 1. A contemporaneous progress note reports that Resident # 63 "eloped out the [dining room] door in Aspen and that the resident reported that he was "looking for the girls," and that facility staff requested that he "come back inside because of the cold weather."[13] CMS Ex. 19 at 12. Immediate action taken included issuance of a Wanderguard bracelet, along with "Close observation, One on One Observation."[14] CMS Ex. 17 at 1. The facility determined that he had an elopement risk score of 10, placing him in the high risk category. CMS Ex. 19 at 11.

The facility completed a second incident report on February 28, 2015 at 11:30am. CMS Ex. 18. The same author, Deb Porter, reported that Resident # 63 had a Wanderguard in place and that he had "eloped outside via the Dining Room door and eloped to Tamarack via the Aspen door." CMS Ex. 18 at 1. A progress note from 2:37 pm that day reported that Resident # 3 "has eloped outside x 3 today." CMS Ex. 19 at 11.

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[13] The National Weather Service reports that at a weather station approximately 40 minutes away from the facility, the maximum temperature recorded on February 28, 2015 was 17 degrees, and the minimum temperature recorded was negative 23 degrees. *http://w2.weather.gov/climate/xmacis.php?wfo=dlh* (last visited September 25, 2017). A Minnesota state administrative law judge, in her findings of fact, conclusions of law, and recommendation, reported that "[t]he weather in Big Fork, Minnesota, in March is generally cold and is often below freezing" and that Resident # 63 "was exposed to cold weather when he exited the Facility's front door and when he went onto the patio in February and March 2015." P. Ex. 49 at 12. The record does not contain evidence that Resident # 63 was wearing appropriate clothing for cold weather when he stepped outside.

[14] As previously discussed, a Wanderguard device will not trigger an alarm or lock the doors if the resident exits through the patio doors. P. Ex. 50 at 3. Although Resident # 63 was given a Wanderguard device after he "was found outside the building" when he "[l]eft the Dining Room through the [patio] doors" on February 28, 2015 (CMS Ex. 17 at 1), Resident # 63 again exited the facility that same day through the patio doors. CMS Ex. 18 at 1. Despite Ms. Porter's reference to the interventions of close observation and one-on-one observation, the facility did not add close observation or one-on-one observation to Resident # 63's care plan. CMS Exs. 13, 14.

A March 9, 2015 record indicates that Resident # 63 "eloped out the door during supper," and that "[s]taff shut the double doors after supper to deter him from going out here again." CMS Ex. 19 at 6.

According to a March 13, 2015 progress note, Resident # 63 "eloped out the door today x 2 . . . ." CMS Ex. 19 at 5. Facility staff "[s]hut the double doors to the kitchen as soon as possible." CMS Ex. 19 at 5.

Facility progress notes document that on March 19, 2015, Resident # 63 "eloped x 4 this pm, he got out the door x 2 this pm." CMS Ex. 19 at 3.

Petitioner submitted, as P. Ex. 42, "Late entry addenda to progress notes for Resident 63 date April 24, 2015 and April 27, 2015 (3 pages)." In six late entries to progress notes, two members of the facility's staff, Deb Porter and Melissa Christie, LPN, revealed fresh and vivid details about elopement incidents that had occurred as far back as nearly two months prior.[15] In supplementing previous reports of elopement incidents, the two staff members made such remarks as "[n]ursing staff had an eye on him the whole time during incidents," "[a]larm went off right away, staff had an eye on him at all times," "[o]bserved by staff to take two steps outside," and "exited out of [dining room] door and took 2-3 steps onto patio."[16] P. Ex. 42. In fact, Ms. Christie stated on March 9, 2015 that Resident # 63 "eloped out the doors during supper" (CMS Ex. 19 at 6), but in her late entry note six weeks later, on April 24, 2015, she reported he "did not step outside." P. Ex. 42 at 3.

[15] CMS provided a notice of imposition of remedies via certified mail on April 16, 2015, at which time it notified Petitioner that a CMP of $111,050 would be imposed. CMS Ex. 4.

[16] Petitioner offered the testimony of Ms. Christie, who testified that she did not know the meaning of the word elopement, and that after receiving training, she updated her progress notes. T. at 361, 366. Ms. Christie testified that the facility had "[t]raining on the Pathway . . . "about exit seeking versus elopement" and that the trainer critiqued staff members' progress notes. T. at 329, 337. Ms. Christie explained that she "was confused on the terminology of elopement and exit seeking." T. at 341. Ms. Christie, on cross-examination regarding her late entries more than a month after incidents, conceded that "I don't think anybody's [memory] improves over a month in time." T. at 366. Petitioner did not offer the testimony of its MDS Coordinator, Deb Porter, who authored incident reports, progress notes, and late entries regarding Resident # 63's elopements. CMS Exs. 17-19; P. Ex. 42.

4. Other residents

In addition to Resident # 63, the facility had eight other residents on the Aspen Unit who had "wandering behavior." CMS Exs 1 at 69; *see* CMS Ex. 12. While the deficiency was cited at the "isolated" level of scope, there were eight residents other than Resident # 63 whose wandering could have potentially made them at risk for elopement through unsecured doors.

5. Facility policies regarding wandering and elopements

The facility's "Wandering, Unsafe Elder" policy that was in effect at the time of the survey directed that Petitioner "will strive to prevent unsafe wandering while maintaining the least restrictive environment for elders who are at risk for elopement." CMS Ex. 20 at 1. Petitioner also had an "Elopements" policy that became effective during the survey on March 26, 2015. CMS Ex. 21. The stated purpose of the facility policy was to "define what is considered an elopement, what to do in the event of an elopement, and how to document and report the incident." CMS Ex. 21 at 1. The facility provided the following definition of elopement: "When an elder (resident) who is cognitively, mentally, or emotionally and/or chemically impaired; wanders away, runs away, escapes, or otherwise leaves the facility or environment unsupervised, unnoticed, and/or prior to their scheduled discharge." CMS Ex. 21 at 1.

B. Analysis

1. Petitioner was not in substantial compliance with 42 C.F.R. § 483.25(h) because it did not take all reasonable steps to ensure that its residents with a foreseeable risk of wandering were given adequate supervision and assistance devices to prevent elopement from the 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 –
>
> > (1) The resident environment remains as free of accident hazards as is possible; and

> (2) Each resident receives adequate supervision and assistance devices to prevent accidents.

42 C.F.R. § 483.25(h).

The Departmental Appeals Board (DAB) has explained that the stated goal of 42 C.F.R. § 483.25(h) is "to prevent 'accidents' that might harm a SNF resident." *Crawford Healthcare & Rehab.*, DAB No. 2738 at 5 (2016). 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). A facility must address foreseeable risks of harm from accidents "by identifying and removing hazards, where possible, or where the hazard is unavoidable because of other resident needs, managing the hazard by reducing the risk of accident to the extent possible." *Maine Veterans' Home - Scarborough*, DAB No. 1975 at 10 (2005) (explaining the inherent standard of care in section 483.25(h)(1)). The provisions of section 483.25(h) "come into play when there are conditions in a facility that pose a known or foreseeable risk of accidental harm." *Meridian Nursing Ctr.*, DAB No. 2265 at 9 (2009), *aff'd, Fal-Meridian, Inc. v. U.S. Dep't of Health & Human Servs.*, 604 F.3d 445 (7th Cir. 2010).

The statement of deficiencies from the March 2015 survey reports the following surveyor observations:

> The dining room was observed to have french doors on either side of the room One set was to enter the dining room and one two sets [sic] of french doors. to exit the building and enter a patio area. The patio area was a large cement slab under a covered awning. The ground was uneven as the landscaping had not yet been completed. The patio area was not fenced in which left direct access to the facility driveway. Beyond the driveway was a thick wooded area to the west and the hospital parking lot to the south. The door to the patio was not observed to have any alarm system.

CMS Ex. 1 at 71. Petitioner, in its plan of correction, did not refute this description of its facility, but rather, indicated that "[o]nce the ground thaws, a fence will be built to secure the patio area and landscaping will be completed to reduce any safety hazards with uneven ground." CMS Ex. 1 at 71; *see* CMS Ex. 23 at 3 ("Once the ground thaws and we can build our planned fence to enclose the courtyard area (secure area) and landscape (level the ground) we will unlock the dining room doors during the day while still

keeping the mesh door alarms in place for added safety."); T. at 194 (testimony that the area beyond the patio area and parking lot is a densely wooded area). Petitioner indicated that it would lock the doors during times that meals were not being served and that the mesh door alarms were on order and would be installed at a later date.[17] CMS Ex. 23 at 3.

Further, in its plan of correction, Petitioner acknowledged that it was not operating at its "preferred staffing level" because there was a "lack of available staff." CMS Ex. 23 at 3. Petitioner had one CNA assigned to the Aspen unit during the night shift, and another LPN floated between the Aspen and Tamarack units during that shift. CMS Ex. 23 at 3; T. at 156-159.[18] Mr. Hedlund testified that the walls surrounding the garden, nursing station, and activity area were constructed at a waist-high level to "facilitate clear lines of view across the unit" and that the unit "was specifically designed to incorporate unobstructed views so that staff in the common areas can easily see residents across the Unit." T. at 162. However, Mr. Hedlund acknowledged that if a member of Petitioner's nursing staff was providing care inside of a resident room in the Aspen Unit, and not in a common area, then he or she could not see what was happening in the hallway or on the floor. T. at 162.

There are 20 beds in the Aspen Unit, which means that the nursing staff is responsible for caring for up to 20 residents during the overnight shift. This can include toileting, medication administration, personal hygiene, and tending to other resident needs that may arise during the overnight hours. *See* CMS Ex. 23 at 3 (Petitioner's statement that "[w]hen needed for repositioning, or other cares [sic], we utilize the staff in the other community while having the nurse float over to ensure adequate coverage"). As evidenced by Resident # 63's progress notes, he required attention during the overnight hours on numerous occasions, such as during episodes of restlessness and behavioral issues (to include attempts to exit the facility), and when he needed medication. CMS Ex. 19. I expect that other residents would likely require nursing care during the overnight hours, which would require the nursing staff to step away from the nursing

[17] Mr. Hedlund acknowledged that "an agile resident could duck under the mesh panels and get out the patio door." T. at 193.

[18] Mr. Hedlund was asked if it "may take some amount of time" before a person could be available to come over from Tamarack. T. at 159. He responded that that he did not feel that Petitioner "ran into that situation very often," and inferred personal knowledge because he would "pop up periodically" during the night shift. Upon further questioning, Mr. Hedlund could not recall at what time he appeared during the night shift and could not recall how many times he had showed up during night shift. T. at 157-160.

station and common areas, where the exit doors are visible. As a result, a nursing staff member would not be able to see a resident exiting through a door if he or she were providing nursing care to a resident.[19]

It is important to recognize that Petitioner does not deny that, between February 28 and March 26, 2015, its exit doors were not secure and that the facility relied on its nursing and other staff to visually monitor the doors to ensure that residents did not exit. While three of its exit doors had alarms, the record indicates that, on at least one occasion, Resident # 63 could walk through one of those doors without triggering an alarm (CMS Ex. 19 at 4) and a repair technician did, in fact, make an adjustment to that door. CMS Ex. 1 at 71; CMS Ex. 3 at 3. Likewise, the patio doors adjacent to a patio and in close proximity to a parking lot and densely wooded area did not lock, nor did they have an alarm. *See, e.g.*, P. Ex. 50 at 3. Therefore, under the circumstances that existed at the time of the March 2015 survey, the *only* way the facility could have absolutely prevented an elopement would have been for its staff members to visually monitor the doors *at all times*. Petitioner has not presented evidence that it had a staff member available to monitor the exit doors *at all times*; rather, it has, at best case, presented evidence that a staff member was monitoring the exit doors at the particular times that Resident # 63's attempted to walk through those doors. Petitioner does not refute that its usual staffing level consisted of a single CNA during the overnight hours, with the addition of an LPN who floated between the Aspen and Tamarack units. *See* CMS Ex. 23 at 3. Based on this staffing level, it is simply impossible that, at every time, a staff member could monitor the exit doors, and particularly the patio doors, to make sure that Resident # 63 and other residents did not leave through those doors.

Although the parties devote a significant amount of attention to whether Resident # 63 actually eloped on any of the well more than half dozen occasions that are referenced in progress notes and incident reports (CMS Exs. 17-19, P. Ex. 42), it is unnecessary for me to determine whether Resident # 63, in fact, eloped on any of those occasions. I need only determine whether Petitioner substantially complied with 42 C.F.R. § 483.25(h), which means that I must determine whether Petitioner ensured that the resident environment was as *free of accident hazards as possible* and that each resident *received adequate supervision and assistance devices to prevent accidents*. 42 C.F.R. 483.25(h). Even if I accept as true that Petitioner's nursing staff collectively misused the term "eloped" when describing Resident # 63's movements and that Resident # 63 never actually eloped, the lack of a completed elopement is not dispositive of whether I find that Petitioner substantially complied with 42 C.F.R. § 483.25(h). It may simply mean that Resident # 63 and the facility were extremely fortunate that he did not time his

[19] Since the patio doors did not have an alarm, nursing staff would not be alerted that the patio doors had opened if a resident exited out of the sight of a staff member. Further, the facility's Wanderguard system may not have been functioning correctly on at least one other door, the main entrance door. *See* CMS Ex. 19 at 4.

numerous exit attempts to when the overnight staff was in a resident room; after all, Resident # 63 had been at the facility for only a matter of weeks, and he may have not yet learned to coordinate his attempts to when the sole nursing staff member was distracted. For whatever the reason that Resident # 63 fortuitously avoided an elopement leading to injury or a far worse consequence, his good fortune does not negate that the facility failed to maintain an environment *free of accident hazards* and that it failed to provide the supervision and assistive devices to prevent accidents. Thus, whether or not Petitioner's staff misunderstood the term elopement when they used it makes no difference under the present circumstances.[20] Rather, I must only determine whether Petitioner substantially did not comply with 42 C.F.R. § 483.25(h), which requires that it ensure that the resident environment is as free of accident hazards as possible and that each resident receives adequate supervision and assistance devices to prevent accidents. Petitioner failed to equip its doors with adequate locks and/or alarms in the absence of sufficient staffing to monitor all exit doors at all hours of the day, and this is a sufficient basis to find noncompliance with 42 C.F.R. § 483.25(h). Because resident safety hinged on whether facility staff could visually monitor its exit doors at all times, a resident who was able to exit at the right moment faced the prospect of extremely cold weather, unlevel ground, and nearby dense woods, any of which, independently or in combination, would have exposed a resident to great risk of harm, injury, or even death.[21] I need not determine that there was actually an accident to find that Petitioner did not substantially comply with 42 C.F.R. § 483.25(h).

Petitioner's Aspen unit is a "memory care unit" and is a "special environment for memory care residents." CMS Ex. 25 at 1; P. Ex. 50 at 2. Petitioner recognized that Resident # 63 was at high risk for elopement (CMS Ex. 19 at 11), and eight other residents were at risk for elopement due to wandering behavior. CMS Ex. 1 at 69; *see* CMS Ex. 12. It was therefore foreseeable that Resident # 63 was at risk for wandering and elopement from the facility, and likewise, it was foreseeable that other wandering residents of this memory care unit could attempt to elope from the unit. In the short amount of time, just weeks, between Resident # 63's admission and the start of the survey, Resident # 63 made numerous attempts to exit the facility, and some of these

[20] Mr. Hedlund testified that the facility's MDS Coordinator, who had submitted incident reports for two elopements (*see* CMS Exs. 17, 18), did not correctly use the term elopement when she submitted these reports. T. at 209. After the facility received written notice of the deficiencies and penalties that would be imposed, Ms. Porter and Ms. Christie submitted late entries to progress notes reflecting that Resident # 63 had not eloped. CMS Ex. 42. Similarly, Ms. Jacobson testified that she would not have expected a licensed nurse to have understood the difference between looking for an exit and actually eloping until the facility provided training on the topic. T. at 248-249.

[21] Being that the doors locked from the outside, it may have been difficult for a resident to get back into the facility if the resident was able to get outside.

attempts may have even been successful. *See* CMS Ex. 17 at 1 (incident report stating that Resident # 63 was "found" outside). Although Resident # 63 was given a Wanderguard bracelet on his first day in the facility after he was able to exit the patio doors (CMS Ex. 17 at 1), he immediately demonstrated that he could walk out those same patio doors without the doors either locking or sounding an alarm because those doors were not equipped with a Wanderguard system. (CMS Ex. 18 at 1). Further, even if I accept the facility's claims that its staff witnessed each of Resident # 63's exits through various doors and that Resident # 63 did not ever elope, Petitioner has not demonstrated that it had sufficient staffing that could prevent a resident from leaving through its doors, particularly the patio doors, undetected. For instance, if a CNA on the night shift was in another resident's room, then Resident # 63 could leave through the patio doors without being seen. The patio doors exited to a patio and then a parking lot and heavily wooded area, and a resident could easily become lost or injured if he or she got outside, owing to the cold weather, unlevel ground, and proximity to a densely wooded area. Petitioner thus has failed to comply with 42 C.F.R. § 483.25(h).[22]

2. CMS's determination that an immediate jeopardy level condition existed from February 28 through March 26, 2015 is not clearly erroneous.

CMS asserts that Petitioner's deficiency constituted immediate jeopardy (at the "J" scope and severity level) to resident health and safety from February 28 through March 26, 2015. Petitioner argues that if I were to find noncompliance, that such noncompliance does not constitute 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. The regulation does not require that a resident *actually* be harmed. *Lakeport Skilled Nursing Ctr.*, DAB No. 2435 at 8 (2012). I must uphold CMS's determination as to the level of a facility's substantial noncompliance (which includes an immediate jeopardy finding) unless it is "clearly erroneous." 42 C.F.R. § 498.60(c). The DAB directs 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., Barbourville Nursing Home*, DAB No. 1962 at 11 (2005) (*citing Florence Park Care Ctr.*, DAB No. 1931 at 27-28 (2004)).

[22] Although the facility contends that the Minnesota Department of Health and state fire marshal "approved the building for occupancy" prior to its opening in January 2015 (P. Br. at 7-8), Petitioner has not provided any argument that the state-level standards governing the grant of a certificate of occupancy and /or operating license are equivalent to the condition of participation that is at issue here, nor has Petitioner argued that I am bound by such a state-level determination.

Here, CMS's finding of immediate jeopardy is not "clearly erroneous." Resident # 63 was a known elopement risk, and eight other facility residents were identified as wanderers. If any of these residents succeeded in leaving the facility undetected, which based on the circumstances appeared to be inevitable if the facility had not made numerous interventions in conjunction with its efforts to remove the immediate jeopardy condition, then a resident would have faced a likely risk of serious injury or harm.[23] Resident # 63 was persistent in his efforts to leave the facility, and it is likely that he, or another resident, would have succeeded in timing an elopement for when the sole staff member on the overnight shift was tending to a resident in a resident room and was not able to observe the exit doors. A fall risk himself, Resident # 63 would have faced uneven ground, sub-freezing temperatures, and a densely wooded area where he could have gotten lost and not been able to find his way back to the facility. This circumstance unquestionably amounts to immediate jeopardy, in that the facility's noncompliance was likely to cause Resident # 63, or even other residents, serious injury, harm, impairment, or death. 42 C.F.R. § 488.301.

Further, while Petitioner furnished a state ALJ's determination that the severity designation for its noncompliance should be reduced from immediate jeopardy to no actual harm with the potential for harm that is more than minimal harm that is not immediate jeopardy (P. Br. at 2-3; *see* P. Exs. 49, 54), the state ALJ premised her determination on a belief that "[s]taff's close attention to [Resident # 63's] exit-seeking behavior was sufficient to ensure that 'serious injury, harm, impairment, or death to a resident' was not likely even though the potential existed for more than minimal harm." P. Ex. 49 at 17. The state ALJ correctly determined that "there are times when there is only one nurse or staff person on the floor" and Resident # 63 "could have exited with sufficient time to make it past the patio and onto the uneven terrain or even beyond during the time when the [patio] door was not fitted with a lock or alarm." P. Ex. 49 at 16. However, the state ALJ apparently felt that the risk of leaving undetected into a deeply wooded area in sub-freezing temperatures did not amount to a risk of serious injury, harm, impairment or death; I utterly disagree. Had Resident # 63 succeeded in leaving the facility during the overnight hours, when he was presumably wearing nothing more than pajamas, he would have been at great risk for harm, or even death, owing to the severely cold Minnesota temperatures in February and March, not to mention the risk that he would not be able to find his way out of the woods to find his way back to the facility. Even Mr. Hedlund, the Director of Social Services, admitted that the woods were dense and the potential existed for someone to get lost in those woods. T. at 195. As the ALJ presiding over this federal-level proceeding, I "provide independent impartial review at the federal level" and I am "not bound by the outcome of the State's informal

[23] I stress that the Aspen unit first opened just more than two months prior to the survey. The most significant factor accounting for the Aspen unit's success in keeping any residents out of harm from elopement prior to the survey is likely the short duration of it being in operation.

dispute resolution process." *Crawford Healthcare & Rehab.*, DAB No. 2738 at 18 (2016). Not only do I reject the determination of the state ALJ, but the state agency also correctly rejected the ALJ's recommendation that the severity level of this deficiency be reduced. P. Ex. 54.

The burden of persuasion regarding the duration of noncompliance is also Petitioner's. *Owensboro Place & Rehab. Ctr.*, DAB No. 2397 (2011). Petitioner has not made any arguments regarding the duration of the period of immediate jeopardy. Therefore, Petitioner has offered no basis to disturb CMS's finding that substantial noncompliance at the immediate jeopardy level existed from February 28, 2015, the date of Resident # 63's first elopement and/or attempt to elope, and ended on March 26, 2015, at which point the facility informed the state agency that it would lock the patio doors at night and implement other corrective measures. I note that the state agency exercised restraint in its determination of the duration of immediate jeopardy; the immediate jeopardy condition existed prior to Resident # 63's admission, in that the patio doors were unlocked and not alarmed since the Aspen unit's opening on January 12, 2015.

For the reasons explained above, I uphold the determination that immediate jeopardy existed from February 28 through March 26, 2015.

3. The facility was not in substantial compliance with 42 C.F.R. § 483.75 because the facility was not governed in a manner that enabled it to use its resources effectively to attain or maintain the highest practicable physical, mental, and psychosocial well-being of its residents.

Pursuant to 42 C.F.R. § 483.75, a facility must be governed in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident. A finding of substantial noncompliance in the facility's administration may derive from findings of substantial noncompliance in other areas. Based on the other immediate jeopardy conditions, the facility did not comply with 42 C.F.R. § 483.75. The DAB has explained:

> [W]here a facility has been shown to be so out of compliance with program requirements that its residents have been placed in immediate jeopardy, the facility was not administered in a manner that used its resources effectively to attain the highest practicable physical, mental, and psychosocial well-being of each resident.

Asbury Ctr. at Johnson City, DAB No. 1815 at 11 (2002); *see Stone County Nursing & Rehab. Ctr.*, DAB No. 2276 at 15-16 (2009). As I have already found a deficiency posed immediate jeopardy to resident health and safety, I therefore also find that the facility was not in substantial compliance with 42 C.F.R. § 483.75.

Moreover, Petitioner's failures can directly be attributed to administrative failures. The facility's administration failed to maintain a resident environment as free of accident hazards as possible and failed to make sure its residents received the supervision and assistive devices to prevent accidents. *See* 42 C.F.R. § 483.25(h). The facility was not administered in a manner that ensured that residents could not leave the facility undetected; its patio doors were left unlocked and did not have alarms, a resident was able to exit through another door without an alarm going off, and the staffing level on the night shift was insufficient to maintain a line of sight to all exit doors at all times. The facility's administration is responsible for making sure the facility is adequately staffed, and the administration is also responsible for making sure that the facility has the means and devices, such as locks and alarms on doors, to protect its residents from harm. The facility did not substantially comply with this condition, and I uphold the deficiency. Although the deficiency was cited at the E level of scope and severity and I will not disturb that determination, a citation at the immediate jeopardy level could have been appropriate.[24]

4. The penalties imposed are reasonable.

With regard to the amount of the CMP, I examine whether a CMP is reasonable by applying 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) the 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 listed 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.

The regulations specify that a CMP that is imposed against a facility on a per day basis will fall into one of two ranges of penalties. 42 C.F.R. §§ 488.408; 488.438. The upper range of a CMP, $3,050 per day to $10,000 per day, is reserved for deficiencies that pose immediate jeopardy to a facility's residents and, in some circumstances, for repeated deficiencies. 42 C.F.R. §§ 488.438(a)(1)(i); 488.438(d)(2).[25] The lower range of a CMP, $50 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 assessing the

[24] In a letter dated September 29, 2015, CMS informed Petitioner that it had reduced the scope and severity of this deficiency from F to E.

[25] CMP amounts increased, effective February 3, 2017, for violations occurring after November 2, 2015. *See* 82 Fed. Reg. 9,174 (February 3, 2017).

reasonableness of a CMP amount, an ALJ looks at the per-day amount, rather than the total accrued CMP. *See Kenton Healthcare, LLC*, DAB No. 2186 at 28 (2008). The regulations leave the decision regarding the choice of remedy to CMS, and the amount of the remedy to CMS and the ALJ, requiring only that the regulatory factors at 42 C.F.R. §§ 488.438(f) and 488.404 be considered when determining the amount of a CMP within a particular range. 42 C.F.R. §§ 488.408; 488.408(g)(2); 498.3(d)(11); *see also* 42 C.F.R. § 488.438(e)(2) and (3); *Alexandria Place*, DAB No. 2245 at 27 (2009); *Kenton Healthcare, LLC*, DAB No. 2186 at 28-29.

Unless a facility contends that a particular regulatory factor does not support the CMP amount that CMS imposed, the ALJ must sustain it. *Coquina Ctr.*, DAB No. 1860 at 32 (2002). CMS decided to impose a per-day CMP in this case, and I found that the immediate jeopardy level of noncompliance was not clearly erroneous in this case. Thus, the minimum CMP I am required to sustain is $3,050 per day. The $3,750 per day CMP CMS imposed is at the very low end of the range for immediate jeopardy level noncompliance. I find that under the circumstances the CMP is reasonable.

Petitioner has not asserted that the CMP is not reasonable, nor has it asserted in its briefing that its financial condition should be considered in mitigation of the CMP. Petitioner had 17 other deficiencies during the same survey, and the immediate jeopardy deficiency demonstrates a high level of indifference to resident safety. 42 C.F.R. § 488.438(f). In addition, Petitioner had been cited for two other instances of noncompliance with 42 C.F.R. 483.25(h) in the year preceding the March 2015 survey. CMS Ex. 3 at 1; *see* 42 C.F.R. § 438(f)(1). In light of the severity of the deficiency, the low amount of the per-day penalty, and Petitioner's failure to challenge the CMP, I uphold the total CMP of $111,050.[26]

[26] I reiterate that Petitioner has not challenged the 17 other deficiencies that are the basis for a $200 per day CMP from March 26 through May 14, 2015, and Petitioner has not presented any arguments regarding its two-year prohibition from conducting a NATCEP.

IV. Conclusion

From February 28 through May 14, 2015, the facility was not in substantial compliance with Medicare program requirements and, from February 28 through March 26, 2015, its deficiencies posed immediate jeopardy to resident health and safety. The penalties imposed – $3,750 per day for 27 days of immediate jeopardy and $200 per day for 49 days of substantial noncompliance that was not immediate jeopardy, for a total CMP of $111,050 – are reasonable.

____/s/_____
Leslie C. Rogall
Administrative Law Judge