

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Meadowwood Nursing Center,
(CCN: 34-5307),

Petitioner,

v.

Centers for Medicare and Medicaid Services.

Docket No. C-12-18

Decision No. CR2829

Date: June 17, 2013

DECISION

Petitioner, Meadowwood Nursing Center (Petitioner or facility), is a long-term care facility located in Gastonia, North Carolina, that participates in the Medicare program. Based on a complaint investigation, recertification, and revisit survey, the Centers for Medicare and Medicaid Services (CMS) determined that Petitioner was not in substantial compliance with Medicare participation requirements. CMS imposed against Petitioner a civil money penalty (CMP) of \$3,550 per day, effective March 7 through July 7, 2011.

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) (Tag F323, relating to accident prevention and adequate supervision) and that the penalty CMS imposed is reasonable.

I. Background

The Social Security Act (Act) sets forth requirements for skilled nursing facility participation in the Medicare program. The Act authorizes the Secretary of the U.S.

Department of Health and 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. To participate in the program, a 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. CMS has the burden of coming forward with evidence and making a prima facie showing of a basis for imposition of an enforcement remedy. Petitioner bears the burden of persuasion to show by a preponderance of the evidence that it was in substantial compliance with participation requirements or any affirmative defense. *Batavia Nursing & Convalescent Inn*, DAB No. 1911 (2004); *Batavia Nursing & Convalescent Ctr.*, DAB No. 1904 (2004), *aff'd*, *Batavia Nursing & Convalescent Ctr. v. Thompson*, 129 F. App'x 181 (6th Cir. 2005); *Emerald Oaks*, DAB No. 1800 (2001); *Cross Creek Health Care Ctr.*, DAB No. 1665 (1998); *Hillman Rehab. Ctr.*, DAB No. 1611 (1997), *aff'd*, *Hillman Rehab. Ctr. v. United States*, No. 98-3789 (GEB), 1999 WL 34813783 (D.N.J. May 13, 1999).

The Secretary contracts with state agencies to conduct periodic surveys to determine whether skilled nursing facilities are in substantial compliance. 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 12 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 a 50-bed skilled nursing facility. Surveyors from the North Carolina State Survey Agency (state agency) conducted a complaint investigation, recertification, and revisit survey of Petitioner concluding on July 8, 2011. Based on their findings, CMS determined that the facility was not in substantial compliance with the participation requirement at 42 C.F.R. § 483.25(h) (Tag F323), concerning accident prevention and adequate supervision, and that the noncompliance constituted immediate jeopardy and substandard quality of care to residents' health and safety from March 7 through July 8, 2011. Based on its immediate jeopardy determination, by letter dated August 9, 2011, CMS imposed a CMP in the amount of \$3,550 per day effective March 7 through July 7, 2011.

On October 3, 2011, Petitioner requested a hearing. The case was assigned to me for hearing and decision. On October 12, 2011, I issued an acknowledgment and initial prehearing order establishing a briefing schedule. In accordance with the schedule, the parties filed prehearing exchanges, including prehearing briefs (CMS Prehearing Br. and P. Prehearing Br., respectively), exhibit and witness lists, and proposed exhibits.

I held a prehearing conference, by telephone, on March 5, 2012. During the conference, I admitted into the record the exhibits the parties exchanged (CMS exhibits (CMS Exs.)) 1-36 and Petitioner's exhibits (P. Exs.) 1-29, including P. Ex. 12A).

I held a hearing by videoconference on May 23, 2012, for purposes of cross-examination of witnesses as the parties previously exchanged written direct testimony. The parties and their witnesses convened in Charlotte, North Carolina, while I presided in Washington, D.C. Testifying for CMS were state agency surveyors Carol S. Hermann, R.N., M.S.N., and Van P. Grinwis, R.N. (the team leader for the July 8 survey). Testifying for Petitioner were Annette O'Brien, R.N., who Petitioner retained as an expert "to provide some background to the Administrative Law Judge regarding the appropriate use of side rails on patient beds as assistance devices" (P. Ex. 29, at 2); Paula Evans Kizer, L.P.N.; Richard Doster, Petitioner's Director of Maintenance; Wendell Phillips, Vice President of Operations for Petitioner's management services company and Petitioner's interim Administrator immediately before and during the July 8 survey at issue; and Marjorie Massey, R.N., Petitioner's Director of Nursing (DON) since June 6, 2011. At hearing I admitted P. Exs. 37 and 38. Tr. 7-8.

Both parties submitted post-hearing briefs (CMS Br. and P. Br., respectively) and response briefs (CMS Response and P. Response, respectively).

II. Issues

The issues stated in my March 5, 2012 Order, as agreed to by the parties, are:

- 1) Whether Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.25(h) (Tag F323, relating to accident prevention and adequate supervision with regard to side rails¹);
- 2) With regard to this alleged noncompliance, whether CMS's assessment of immediate jeopardy was clearly erroneous; and
- 3) Whether the penalty that CMS imposed, \$3,550 per day for 123 days of immediate jeopardy noncompliance from March 7 through July 7, 2011 (\$436,650 total) is reasonable.

¹ I use the terms "side rails" and "bed rails" interchangeably in this decision.

III. Findings of Fact and Conclusions of Law

A. Petitioner was not in substantial compliance with 42 C.F.R. § 483.25(h) because it did not address foreseeable risks of harm from accidents involving entrapment in bed side rails.

Program requirements. Subsection 483.25(h) is part of the quality of care regulation, which states that “[e]ach resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.” Subsection 483.25(h) imposes specific obligations upon a facility related to accident hazards and accidents, as follows: 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.

The Departmental Appeals Board (the Board) has held that subsection 483.25(h)(1) requires that a facility 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 Board has held that subsection 483.25(h)(2) requires that a facility take “all reasonable steps to ensure that a resident receives supervision and assistance devices that meet his or her assessed needs and mitigate foreseeable risks of harm from accidents.” *Briarwood Nursing Ctr.*, DAB No. 2115, at 11 (2007), *citing Woodstock Care Ctr.*, DAB No. 1726 (2000) (facility must take “all reasonable precautions against residents’ accidents”), *aff’d*, *Woodstock Care Ctr. v. Thompson*, 363 F.3d 583, 589 (6th Cir. 2003).

The potential dangers of side rail use are well known and include entrapment. The dangers impose on facilities the duty to address and assess their risk. *See, e.g., Laurelwood Care Ctr.*, DAB No. 2229, at 9 (2009). The Food and Drug Administration’s March 10, 2006 *Guidance for Industry and FDA Staff Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment* (2006 FDA guidance) describes an “entrapment” as “an event in which a patient/resident is caught, trapped or entangled in the space in or about the bed rail, mattress, or hospital bed frame.” The FDA guidance notes that “[p]atient entrapments may result in deaths and serious injuries.” CMS Ex. 28, at 6. The FDA states that “[t]he population most vulnerable to entrapment are elderly patients and residents, especially those who are frail, confused, restless, or who have uncontrolled body movement.” CMS Ex. 28, at 6. As a result of the potential safety risks presented by side rails, the FDA states: “We suggest

that facilities and manufacturers determine the level of risk for entrapment and take steps to mitigate the risk. Evaluating the dimensional limits of the gaps in hospital beds is one component of an overall assessment and mitigation strategy to reduce entrapment.” *Id.* at 5. The FDA recommends a dimensional limit of less than 4.75 inches for the area between rails and also between the rail and the mattress. *Id.* at 18-20. *See also Good Samaritan*, DAB No. 1844 (2002) (upholding an ALJ who construed an FDA safety alert to apply to a gap more than 4.5 inches into which bodies, heads, or necks could fit.)

The state operations manual (SOM), which provides Agency guidance on the Secretary’s regulations, addresses side rails and notes that these assistive devices can be therapeutic, beneficial, and can assist with transfer and positioning. P. Ex. 19, at 15-16. The SOM states, however, that while side rails can assist with transfer and positioning, they can increase safety risk, and it references FDA’s August 23, 1995 FDA Safety Alert: *Entrapment Hazards with Hospital Bed Side Rails* (1995 FDA Safety Alert). P. Ex. 19, at 16; CMS Ex. 27; *see also* CMS Ex. 28.² The SOM notes that those most at risk for entrapment are the frail or elderly who have conditions such as agitation, delirium, confusion, pain, uncontrolled body movement, hypoxia, fecal impaction, etc., that may cause them to move about the bed or try to exit the bed. The SOM notes that entrapment may occur when a resident is caught between a mattress and side rail, and in the side rail itself. The SOM notes that “[t]echnical issues, such as proper sizing of mattresses, fit and integrity of bed rails or other design elements . . . can also affect the risk of resident entrapment.” P. Ex. 19, at 16.

1. Petitioner was placed on notice of a foreseeable risk of harm when Resident 2’s neck became entrapped in her bed’s side rails.

In a statement of deficiencies (SOD) from July 8, 2011, CMS cited Petitioner for failure to position mattresses and side rails in such a way as to maintain safety for two residents (Residents 2 and 8). CMS Ex. 4, at 1. The SOD does not specify which subsection(s) of the regulation Petitioner was in violation of – i.e., 42 C.F.R. § 438.25(h)(1) or (2) – nor does CMS so specify in its briefs. Instead, in its response brief, CMS encapsulates its argument by stating that Petitioner “knew or should have known of the risks posed by [side] rails, but failed to protect residents from those risks.” CMS Response at 2.

CMS asserts that Petitioner’s noncompliance began on March 7, 2011, when Petitioner’s staff found Resident 2 in bed with one of her side rails resting on her neck. Surveyors first cited this incident as noncompliance at the July 2011 survey, during which the surveyors also cited Petitioner for noncompliance after observing a gap of approximately eight inches between the side rail and the mattress on Resident 8’s bed, indicating to them an ongoing danger with respect to side rails. CMS Ex. 4, at 1-14.

² The 2006 FDA Guidance represents the FDA’s “current thinking on this topic.” CMS Ex. 28, at 4.

At the time of her entrapment, Resident 2 was a 74-year-old woman with multiple impairments. CMS Ex. 11. Her diagnoses included stroke with left-sided paralysis, aphasia, anxiety disorder, depression, and schizophrenia. CMS Ex. 11, at 58-59, 115, 118, 120; P. Ex. 8; P. Ex. 12, at 17-18; P. Ex. 12A. Resident 2's minimum data set (MDS) from December 2010 indicates she had short and long-term memory problems and severe cognitive impairment. CMS Ex. 11, at 48. Resident 2 needed extensive staff assistance for bed mobility and transfers. CMS Ex. 11, at 55. She had a physician order for side rails as an enabling device, which Petitioner's staff re-evaluated. CMS Ex. 11, at 123; P. Ex. 10, at 2. Resident 2 used the side rails to move about in bed as an aid in turning and positioning. CMS Ex. 11, at 115; P. Ex. 10, at 2.

Shortly after 11:00 p.m. on March 7, 2011, a certified nursing assistant (CNA) performing rounds found Resident 2 with her head under her side rail. LPN Faile documented in nursing notes that:

At approximately 11:10 p.m. last night this nurse was informed that resident had somehow gotten [her] head under [the] left bedrail & it was resting on [the] resident's neck on [the right] side of [her] neck [with] substantial pressure. No apparent injury found upon physical assessment. R.P. notified via phone call but unable to leave message [due to] DSS office being closed. Passed along to oncoming nurse to contact DSS office when opens [at] 8 a.m. also [nurse practitioner] notified

CMS Ex. 11, at 32. By "substantial pressure" LPN Faile meant the actual weight of the side rail itself. CMS Ex. 4, at 4-5; CMS Ex. 11, at 14. Mr. Phillips testified that the rail weighed perhaps five or six pounds. P. Ex. 25, at 3.

The record does not clearly reflect how long the rail was resting on Resident 2's neck. The CNA who found Resident 2 started her shift at 11:00 p.m. and discovered Resident 2 entrapped at approximately 11:10 p.m. CMS Ex. 4, at 4-5; CMS Ex. 11, at 32; CMS Ex. 34, at 5-6. The facility did not present any evidence to specifically show when Resident 2 may have been last observed prior to the entrapment incident. Due to Resident 2's impairments, which included aphasia, short and long-term memory problems, and severe cognitive impairment, Resident 2 was not able to explain how her neck became entrapped under the side rail and how long the rail rested on her neck. Tr. 44. Similarly, she was unable to verbalize whether she sustained any physical pain or mental trauma from the incident.

During the survey, Mr. Doster gave Surveyor Hermann manufacturer's information related to the bed Resident 2 used. CMS Ex. 26, at 4. The manufacturer cautioned that when the head of the bed was in the semi-fowler position, i.e., raised approximately 30 to 45 degrees, there could be a gap that posed an entrapment risk unless the bed rails were in

the “MID” position. MID is one of three positions the rail could be in, the others being an upper and a lower position. In the MID position, as the head of the bed raises up, the rail remains below the top of the mattress so there is very little gap, in which to get entrapped. CMS Ex. 26, at 3, 4; CMS Ex. 4, at 2; Tr. 69-70. Surveyor Hermann testified that she understood the head of the bed was raised 20 to 30 degrees on the night in question and the side rail was “all the way up.” Tr. 70.

Surveyor Hermann interviewed LPN Faile during the survey. CMS Ex. 11, at 11, 14, 25; CMS Ex. 34, at 4-5. LPN Faile stated he released the side rail to remove it from Resident 2’s neck but did not find her in respiratory distress or see bruising on her neck. LPN Faile faxed a note to the resident’s physician but did not send the resident to the hospital for further assessment. On March 8, 2011, Mr. Doster removed Resident 2’s side rails and placed a mat on the floor at her bedside. The facility also used a personal alarm as a fall intervention for Resident 2. CMS Ex. 4, at 4; CMS Ex. 11, at 32; CMS Ex. 34, at 4-5; P. Ex. 18, at 1.

Petitioner admits that Resident 2 somehow maneuvered her head and neck under the side rail of her bed. However, Petitioner asserts that the positioning of Resident 2’s side rail met all FDA standards and fell into a category of accident the FDA recognizes cannot be explained. Petitioner asserts that Resident 2 was not injured. Resident 2 was reassessed and her side rail was removed. Petitioner also made numerous revisions to its side rail assessment and use policies and practices as a routine quality assurance response to Resident 2’s accident. Petitioner also asserts that it purchased additional equipment to protect resident safety. P. Br. at 1-2, 5-12, 15, 20-23; P. Ex. 5.

Petitioner’s counsel attempts to downplay the significance of Resident 2’s entrapment by reciting and illustrating principles of “simple geometry.” P. Br. at 13 n.9; 14 n.11. Petitioner’s counsel uses his own mathematical calculations to propose that the gap in Resident 2’s side rails was within the 2006 FDA guidelines (where the gap between the side rail and mattress should be less than 4.75 inches) and that Resident 2’s accident was somehow a “freak” accident where the resident maneuvered her head against a gap in the rail. P. Br. at 12-15. Counsel’s geometric estimations are unavailing with regard to the issue before me. The fact remains that the gap was large enough, possibly in conjunction with the flexibility of the mattress, for Resident 2 to become entrapped, effectively placing Petitioner on notice of a foreseeable risk of harm for entrapments. *See* CMS Ex. 28, at 20.

It is undisputed that Resident 2’s bed was raised somewhere approximating 30 degrees, and her side rails were fully raised. Considering Resident 2’s head actually became entrapped shows that there was a very serious concern for the facility, despite its inability to conclusively determine what that problem was. Tr. 39; CMS Ex. 4, at 5; *see Good Samaritan*, DAB No. 1844 (2002) (upholding an ALJ’s finding that a side rail and mattress combination was not compatible when two residents were found entrapped in

large gaps). Although, Petitioner disputes whether it was at fault for the entrapment of Resident 2, I find that once it occurred, Petitioner was on specific notice of a foreseeable risk of harm starting March 7, 2011.

2. *Petitioner took some reasonable steps to eliminate the foreseeable risk of accidents involving bed side rail entrapment.*

On March 8, 2011, Petitioner's then DON, Glenda Pulliam, emailed Petitioner's then Administrator, Nichola Johnson, to request that Petitioner conduct a safety audit on all residents using side rails. Ms. Pulliam also asked Ms. Johnson to look into other safety options "due to the high risk of injury related to using full side rails." DON Pulliam was prompted to do this because of the incident report she received regarding Resident 2, and she noted that Petitioner had already removed side rails from Resident 2's bed and outfitted her with an alarm.³ P. Ex. 6.

Petitioner conducted two side rail audits. A side rail audit on March 8, 2011 found broken, bent and improperly fitting side rails. CMS Ex. 24, at 1. However, a March 10, 2011 "Audit" note stated that no gaps of more than 4" were found. P. Ex. 7. A side rail audit on April 1, 2011 found "large" spaces at the heads of beds when the beds were in the up position for several residents. CMS Ex. 24, at 2. Mr. Doster testified that during the audits he measured the gaps and spaces between mattresses and side rails and started removing full side rails. Tr. 166-67.

Mr. Doster testified that the facility no longer uses full side rails. He reported checking side rails every week to determine if there was damage, as well as checking for damage to other items in resident rooms, such as furniture. At the time of survey, he replaced a broken side rail at least once a month, sometimes more often. Most rails were bent, but on a "handful" of occasions over the three years he has worked at the facility a latch, spring, or some other part of the rail was broken. Mr. Doster kept a maintenance book at the nurses' station where the nurses wrote down anything needing his attention, which he checked several times a day. With regard to side rails, he kept a supply of side rails on hand so he could change a side rail immediately if it broke. He would not note when he fixed or replaced a side rail. The only place broken side rails would be documented was in the maintenance book where the nurses wrote down problems that needed repair and which Mr. Doster checked daily. P. Ex. 28; Tr. 164, 168-69.

As part of its review of Resident 2's accident, in May 2011, Petitioner asserts it adopted a new assessment tool. P. Br. at 9; P. Ex. 4; P. Ex 26, at 3.

³ Administrator Long testified that DON Pulliam and Administrator Johnson were not available during the survey to discuss the changes to the side rail assessment and policies and procedures they implemented following Resident 2's entrapment. P. Ex. 24, at 2.

3. *Petitioner did not reasonably address all foreseeable risks of accidents involving bed side rail entrapment because Petitioner did not correct a gap between the mattress and the side rail in Resident 8's bed.*

Despite some credible evidence that Petitioner took some steps to address the foreseeable risk of resident entrapment in bed side rails, other compelling evidence proves it did not take all reasonable steps as the standard of care required.

At the prehearing conference, Petitioner objected to the admission of CMS Ex. 23, arguing that a risk management consultant prepared the document for Petitioner's quality assurance committee and that I should strike it from the record. Petitioner later followed-up with a motion to strike, to which CMS responded, with attached exhibits 37 and 38 (the supplemental declarations of surveyors Carol S. Hermann, R.N., M.S.N., and Van P. Grinwis, R.N., who were under the impression that a facility administrator created the document). At hearing, I ruled that it was undisputed that the surveyors did not improperly obtain the document nor compel its disclosure. The document was not specifically marked as prepared for the facility's quality assessment and assurance committee, and Petitioner asserts that the committee never considered the document. Accordingly, I ruled that there was no sufficient showing that CMS Ex. 23 was prepared in good faith pursuant to 42 C.F.R. § 483.75(o)(4), and therefore it should remain in the record.

The May 6, 2011 document, titled "Community Performance Improvement Plan," did not note anywhere who prepared it. The document noted for "Restraints/Side Rails" that side rails throughout the facility were not properly assessed. CMS Ex. 23, at 1. Under "Accidents/Hazards" it noted that two⁴ residents were found between side rails, but no interventions were in place to minimize injury. *Id.* at 2-3. A side rail was removed from one bed without a mat on the floor to minimize injury. *Id.* Further, it noted entrapment zones were not assessed on a regular basis and recommended that the maintenance director measure the entrapment zones. *Id.* at 2, 4.

For corrective action the document recommended to: order new side rail assessment flow sheets; update every resident's side rail assessment; remove inappropriate side rails and put other interventions in place to minimize injury; implement safety interventions such as ¾ rails, alarms and mats; and review new admission records at the next nurse's meeting. *Id.* at 1. The "Timeline/Responsible Person" for these actions was noted as "Open" and that "equipment will be purchase[d] immediately following any negative outcomes." The "Administrator/DON/MDS coordinator" were responsible for implementation. *Id.*

⁴ CMS only cited the entrapment of Resident 2 prior to July 2011. The record is unclear who the second resident was or what transpired.

Then, in July 2011, a surveyor was still able to expose a lack of facility vigilance in recognizing and addressing a dangerous gap in a resident's bed with side rails. The FDA recommends a dimensional limit of less than 4.75 inches for the area between the inside surface of the bed rail and the compressed mattress. CMS Ex. 28, at 20; *see also Good Samaritan*, DAB No. 1844 (upholding an ALJ who construed an FDA safety alert to apply to a gap more than 4.5 inches into which bodies, heads, or necks could fit). However, it is undisputed that staff repeatedly observed Resident 8 in her bed with a gap larger than 4.5 inches.

As of the July survey, Resident 8 was a 72-year-old woman. Her diagnoses included dementia and obesity. P. Ex. 14, at 14-15. Resident 8 was 62 inches tall and weighed 274.3 pounds in July 2011. P. Ex. 21. Her MDS revealed she had impaired mobility in both of her lower extremities, but she was able to feed herself with set-up help only. CMS Ex. 13, at 3; P. Ex. 14, at 11. Her April 19, 2011 side rail assessment indicated side rails were ordered to serve as an enabler to promote independence in position and bed mobility, noted Resident 8 expressed a desire to have side rails, and noted that Resident 8 expressed a desire to have the side rails raised while she was in bed. CMS Ex. 13, at 12.

Surveyor Grinwis observed Resident 8 on three separate occasions on July 5, 2011, from just before noon until almost 5:30 p.m. Surveyor Grinwis testified that:

The resident was on her back with her head and shoulders positioned in the middle of the mattress. Both full side rails were up. The left side rail fit flush with the bed frame. However, the right side rail was splayed outward at the head of the bed with the mattress shifted against that portion of the side rails. This left the bed frame on the left side exposed, leaving a gap of approximately 8 inches between the mattress and the head of the left side rail. I measured by placing my hand in the space created between the mattress and bedrail. My hand fit into the gap fingertip to wrist. Then I measured my hand fingertip to wrist on a ruler which was 8". I observed the resident again at 3:15 p.m., and the resident, side rails and mattress were all in the same positions. I observed the resident next at 5:27 p.m., when she was eating her supper without assistance. The head of the bed was up, as well as both side rails. The gap at the head of the bed remained.

CMS Ex. 33, at 4; CMS Ex. 13, at 3-4; *see* Tr. 79-80. The gap remained until Surveyor Grinwis called it to the attention of Mr. Doster and other staff. Surveyor Grinwis testified that her concern was that staff did not recognize that the gap was a problem. Tr. 82, 87-88, 114, 116-18.

Mr. Doster testified that during the survey he knew he saw Resident 8's side rail "separated from the mattress by five or six inches because the spring that holds the side rail tight to the bed had become disengaged. [He] saw that the rail was still attached to

the bed in a vertical position, but was pulled away from the mattress.” P. Ex. 28, at 2-3. Mr. Doster reportedly repositioned and re-latched the rail to fix the situation. P. Ex. 25, at 7; Tr. 172-73.

Mr. Phillips testified that he was present when the survey team observed Resident 8 in bed. He asserts that one of the side rails was pulled away from the mattress perhaps five or six inches, which is slightly more than the maximum gap (4.75 inches) recommended by the FDA guidance (CMS Ex. 28, at 10, 20). Mr. Phillips reasoned, however, that because Resident 8 was obese, the FDA recommendations would not cover her because obese individuals are unlikely to suffer entrapment. Mr. Phillips notes the rails were spring-loaded, and it appeared here that the latching mechanism was unlatched. He admits the side rail should have been closer to the mattress but states that given Resident 8’s size there is no realistic way she could have been entrapped. Moreover, Resident 8 could move by herself enough that had she become wedged against the side rail she could have extricated herself. P. Ex. 25, at 7; Tr. 172-73, 180-82.

DON Massey testified that because Resident 8 was obese and had various ailments requiring staff assistance with bed mobility, it was not even theoretically possible for her to become entrapped in a six or eight inch gap between the mattress and side rail. P. Ex. 26, at 6. In addition, on cross-examination she testified that conducting side-rail audits was on her list of things to do, since she started her employment on June 6, 2011, but “we just didn’t get there before the State came.” Tr. 194, *cf.* P. Ex. 26, at 5 (direct testimony stating that she was continuing to reassess side-rail use after arriving in June); P. Ex. 26, at 1.

It is not disputed that when Surveyor Grinwis observed Resident 8 on three separate occasions on July 5, 2011, there was a large gap between the side rails and her bed. Surveyor Grinwis credibly testified that she measured the gap to be eight inches. CMS Ex. 33, at 4. During cross-examination, she agreed with Petitioner’s counsel that her hand was about eight inches and discussed measuring a gap of six to eight inches. Tr. 79-80. Petitioner’s witnesses estimated the gap between the side rail and the bed as somewhat less, about five to six inches. Even if the gap was only five to six inches, however, that such a large gap could persist over three separate observations without facility staff noting it and ensuring its correction indicates Petitioner’s continued noncompliance with the requirements of 42 C.F.R. § 483.25(h).

Petitioner asserts that Resident 8 could not have maneuvered herself into a dangerous situation due to her large size and immobility and was thus not at risk of any harm. P. Br. 17, 23-24; Tr. 80, 90-91, 94-96, 117, 191; P. Ex. 26, at 6. However, I find Petitioner’s assertion conflicts with Resident 8’s side rail assessment, which indicated that although Resident 8 demonstrated poor bed mobility moving to a sitting position on the side of her bed, Resident 8 did have some independent bed mobility. Further, the assessment indicated that her side rails “serve as an enabler to promote independence in position &

bed mobility” (CMS Ex. 13, at 12), and Mr. Phillip’s testimony indicates she had some bed mobility too.

Petitioner further argues that Resident 8 was obese, and therefore she was excepted from the 2006 FDA Guidance, which Petitioner’s expert did acknowledge as at least an informative tool for side rail manufacturers and nursing home users.⁵ P. Br. at 8; Tr. 147. Contrary to Petitioner’s argument and its expert witness’ testimony (P. Ex. 29, at 6-7, 13), bariatric (obesity) beds, not bariatric patients, were excluded from FDA’s recommendations because FDA did not use anthropometric data for individuals in bariatric beds when determining the recommended dimensional limits of entrapment zones. CMS Ex. 28, at 11. There is no evidence that Resident 8 was in a bariatric bed and, in fact, Surveyor Grinwis testified that Resident 8 was in what appeared to be a normal, not a bariatric, bed. Tr. 80.

Even if I were to find Resident 8 was in a bariatric bed, however, the 2006 FDA guidance suggests that it is up to the facility utilizing such a bed to identify and address areas of potential entrapment through a comprehensive bed safety program. CMS Ex. 28, at 5, 10. Given that Petitioner offered no testimony regarding Resident 8’s actual head measurement, it does not appear such an assessment was done as part of a bed safety program. Further, evidence that staff did not heed the danger because they believed Resident 8’s head, neck, or body could not fit into a gap more than 4.75 inches did not surface at the time of the survey, but it instead arose as a post hoc rationalization. This does not persuade me that the facility was vigilant with regard to recognizing a foreseeable risk of entrapment.

Petitioner also argues that there is no evidence that Resident 8’s side rail was broken or had been misused. Instead Petitioner notes that, as soon as the surveyor pointed it out, Mr. Doster re-latched the side rail. Petitioner argues that unlatched side rails are not uncommon in nursing facilities. Br. at 21; P. Response at 5.

The failure to note and correct the problem with the gap between the side rail and the mattress on Resident 8’s bed, and to ensure her safety until the gap was remediated,

⁵ Petitioner references statements in the 2006 FDA guidance that its analysis and recommendations are nonbinding, that side rail accidents are very rare, and that not all patients are at risk for entrapment. Petitioner asserts that the surveyors testified that they were generally aware of this guidance and that the guidance was referred to in the SOM but argues that I cut off questioning regarding their understanding, so it is not clear whether the FDA guidance is incorporated into section 483.25(h). P. Br. at 8; Tr. 46-48. I note that I interrupted Petitioner’s line of questioning because the witness testified that she did not recall the language of the FDA guidance specific to nursing homes, and I reminded counsel that CMS was ultimately responsible for arguing the standard of care. Tr. 48.

shows Petitioner was not yet fixing a foreseeable problem absent a negative outcome and substantiates Petitioner's noncompliance with the regulation. Petitioner's description of the gap in Resident 8's bed, caused by the unlatched side rail, as "an unusual but not unheard of malfunction" is troubling (P. Br. at 21), especially considering Petitioner did not recognize the foreseeable hazardous condition on Resident 8's bed until Surveyor Grinwis called it to staff's attention after they entered her room several times that day to provide her care. Tr. 89-91. If the facility was aware of latch malfunctions that caused dangerous gaps in beds, it should have reasonably replaced that equipment before any resident entrapment might occur, or at least it should have identified and remedied a dangerous gap between a side rail and mattress immediately upon sight.

B. CMS's determination of immediate jeopardy is not clearly erroneous.

CMS asserts that Petitioner's deficiency constituted immediate jeopardy (at a level "J" – isolated occurrence) to resident health and safety from March 7 through July 7, 2011. Petitioner argues that if I were to find noncompliance, that 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 Board 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), *citing Koester Pavilion*, DAB No. 1750 (2000).

Here, CMS's finding of immediate jeopardy is not "clearly erroneous." Resident 2 was found with her head actually entrapped in side rails, and Petitioner states it was never able to conclusively determine why it happened. As of April 1, large gaps were still being found in resident beds. During the July survey, an approximate eight-inch gap was discovered in Resident 8's bed and was not corrected until Surveyor Grinwis pointed out the situation to Petitioner's staff. Therefore, the facility was not taking all reasonable steps to prevent the foreseeable risk of resident entrapments in the side rails of beds.

The evidence in the record clearly suggests that entrapments are likely to lead to serious injury or death to a resident. For example, the 2006 FDA guidance reports:

FDA received approximately 691 entrapment reports over a period of 21 years from January 1, 1985 to January 1, 2006 [footnote omitted]. In these reports, 413 people died, 120 were injured, and 158 were near-miss events with no serious injury as a result of intervention. These entrapment events have occurred in openings within the bed rails, between the bed rails and mattresses, under bed rails, between split rails, and between the bed rails and head or foot boards. The population most vulnerable to entrapment are elderly patients and residents, especially those who are frail, confused restless, or who have uncontrolled body movement. Entrapments have occurred in a variety of patient care settings, including hospitals, nursing homes, and private homes. Long-term care facilities reported the majority of entrapments.

CMS Ex. 28, at 6-7. Ms. Herman referenced the 2006 FDA guidance and also credibly opined that Resident 2's entrapment could have seriously injured or killed her. CMS Ex. 34, at 6. Petitioner's witness Mr. Phillips, a licensed nursing home administrator, also acknowledged that entrapment could cause a loss of breathing. P. Ex. 25, at 3. Surveyor Grinwis also credibly testified that, considering facility staff did not notice the gap in Resident 8's bed, it constituted an act that was likely to cause a serious injury, such as Resident 8's head getting caught in the gap between the bed rail and the bed mattress. CMS Ex. 33, at 4-5; Tr. 86-88.

On December 3, 2012, Petitioner filed a motion to supplement the record with P. Ex. 30, an October 11, 2012 memorandum of the Consumer Product Safety Commission on the topic of adult bed rail death and injury data from January 2003 through September 2012, which was released to the public after the hearing. Petitioner asserts the memorandum shows that only 25 deaths of nursing facility residents were associated with portable bed rails during the ten-year period, and thus mishaps involving side rails are "very unlikely to cause serious injury or death." CMS objected to its admission given that the briefing in this case concluded several months earlier and also because the memorandum should not be viewed as stating the risk of injury due to side rails is so minimal that Petitioner should be viewed as in compliance with 42 C.F.R. § 483.25(h). In accordance with my prehearing order, I only allow parties to supplement their evidentiary exchanges with good cause, and I do not find good cause here because Petitioner proposed the exhibit after the hearing and post-hearing briefing periods concluded. Accordingly, I deny the motion. Even if I were I to admit this document, I do not see it benefiting Petitioner's position in this case because: (1) the reported fatalities for all injury locations is 155 based on 160 reported incidents related to adult portable bed rails, and (2) with specific regard to side rail entrapment incidents, 143 out of 145 reported incidents resulted in fatalities.

C. The CMP that CMS imposed is reasonable in amount and duration.

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). The lower range of 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 reasonableness of a CMP amount, an ALJ looks at the per day amount, rather than the total accrued CMP. *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); *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 determined to impose a per day CMP in this case. I found immediate jeopardy level noncompliance not to be clearly erroneous here. Thus, the minimum CMP I am required to sustain is \$3,050 per day. The \$3,550 per day CMP CMS imposed is in the very low range for immediate jeopardy level noncompliance.

In evaluating the regulatory factors, I find that Petitioner's history of noncompliance fully supports the relatively low CMP considering Petitioner had been cited under 42 C.F.R. § 483.25(h) (Tag F323) during the May 5, 2011 survey, and also cited under Tag F323 following a survey conducted in September 2008, which also found immediate jeopardy. CMS Ex. 21, at 8, 9. Over the years, Petitioner has also been cited for numerous other deficiencies. *See* CMS Ex. 21. Based on this regulatory factor alone, a CMP that is only \$500 higher than the minimum amount I am required by regulation to sustain is not

unreasonable. However, Petitioner's deficiency is also serious (constituting immediate jeopardy to its residents) and Petitioner is culpable for identifying risks but not reasonably addressing those foreseeable risks of entrapment.

Petitioner asserted that its financial condition should be considered in mitigation of the CMP, arguing that the CMP imposed is greater than its annual operating budget, despite there being no showing or clear allegation that Petitioner or its staff committed any regulatory violation. Specifically, Mr. Phillips testified (without the benefit of any documentary evidence supporting his testimony) that the CMP imposed "represents about the entire annual costs for payroll, benefits, food, supplies and medicine combined, and would be devastating to the facility." P. Ex. 25, at 2.

Petitioner bears the burden of proving that payment of the CMP would result in closure of its facility or compromise in resident health and safety. *Oceanside Nursing & Rehab. Ctr.*, DAB No. 2382, at 22-23 (2011). Petitioner has not done so. Petitioner has not submitted any sort of easily accessible financial information to support Mr. Phillips' testimony, such as tax returns, balance sheets, income statements, or cash flow statements. I find Mr. Phillips' testimony lacks support and only assign it little weight. Accordingly, I am unable to assess Petitioner's actual financial condition based on Mr. Phillips' testimony alone. Considering Petitioner's burden, I do not mitigate the CMP imposed based on this factor.

The burden of persuasion regarding the duration of noncompliance is also Petitioner's. In the case of *Owensboro Place & Rehab. Ctr.*, DAB No. 2397 (2011), the Board stated:

The burden of persuasion is on the facility. The Board has made it clear that the facility bears the burden of showing that it returned to substantial compliance on a date earlier than that determined by CMS and has rejected the idea that CMS must establish a lack of substantial compliance during each day in which a remedy remains in effect. . . .

Owensboro Place, DAB No. 2397, at 12-13 (citations omitted).

Here Petitioner was put on notice on March 7, 2011, when Resident 2 was found entrapped, that it had a side rail issue that risked resident safety. Although Petitioner did begin to address the problem, the noncompliance continued. As of April 2011 Petitioner was still finding large gaps between side rails and resident beds. It appears that some of Petitioner's corrective actions may have been suspended pending "negative outcome[s]." Then, in July 2011, a surveyor confirmed a lack of facility vigilance when Petitioner's staff did not recognize, until Surveyor Grinwis pointed it out, that there was an approximate eight-inch gap between the unlatched side rail and Resident 8's bed. CMS found Petitioner back in substantial compliance after it submitted a credible allegation of compliance regarding both Residents 2 and 8 and any other residents with side rails.

CMS Ex. 4, at 9-14. Petitioner has not met its burden to persuade me to find the facility returned to substantial compliance at any point earlier than CMS's determination.

IV. Conclusion

For the reasons set forth above, I sustain CMS's determinations. I find that Petitioner was not in substantial compliance with the participation requirement at 42 C.F.R. § 483.25(h) and that the CMP imposed, a \$3,550 per day CMP effective March 7 through July 7, 2011, is reasonable.

/s/

Joseph Grow
Administrative Law Judge