Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Laurelwood Care Center,	)	Date: May 30, 2008
(CCN: 39-5812),	)	
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-07-222
	)	Decision No. CR1796
Centers for Medicare & Medicaid	)	
Services.	)	
	)	

DECISION

Petitioner, Laurelwood Care Center, is a long-term care facility located in Johnstown, Pennsylvania, that is certified to participate in the Medicare program as a provider of services. After receiving a report that a resident was found dead, with his face and arm caught in his bed's side rail, surveyors from the Pennsylvania Department of Health, Division of Nursing Care Facilities (State Agency) surveyed the facility. As a result of their findings, the Centers for Medicare & Medicaid Services (CMS) determined that: 1) from August 22 through November 27, 2006, the facility was not in substantial compliance with the program requirement that the resident environment remain as free of accident hazards as possible (42 C.F.R. § 483.25(h)(1)); and 2) from August 22 through 25, 2006, its deficiencies posed immediate jeopardy to resident health and safety. CMS imposed civil money penalties (CMPs) of $5000 per day for four days of immediate jeopardy, and $100 per day for 94 days of substantial noncompliance that was not immediate jeopardy ($29,400 total). Petitioner here challenges those determinations.

For the reasons set forth below, I find that the facility was not in substantial compliance with program requirements for the period in question, and that, from August 22 through 25, 2006, its deficiencies posed immediate jeopardy to resident health and safety. I find reasonable the CMP amounts.

I. Background

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

The Secretary contracts with state survey agencies to conduct periodic surveys to determine whether skilled nursing facilities are in substantial compliance with program participation requirements. Act § 1864(a); 42 C.F.R. § 488.20. The regulations require that each facility be surveyed once every twelve months, and more often, if necessary, to ensure that identified deficiencies are corrected. Act § 1819(g)(2)(A); 42 C.F.R. §§ 488.20(a); 488.308.

In this case, on August 21, 2006, the facility reported that a 64-year-old facility resident (R1) had been found dead, caught in one of the side rails attached to his bed. CMS Exhibit (Ex). 10; Tr. 121. Surveyors went to the facility to investigate. They determined that the facility had not ensured that R1's environment was as free of accident hazards as possible. Although the facility placed R1 in a bed with side rails that were 8 inches apart – a gap much wider than the Food and Drug Administration (FDA) recommended maximum of 4¾ inches – no documentation showed that staff had adequately assessed the potential safety hazards posed by putting him in a bed with such side rails. CMS Ex. 2, at 4 *et seq*.; CMS Ex. 58, at 15, 18. The surveyors also determined that the facility had inadequately assessed for safety the use of similar side rails on the beds of 53 other residents reviewed, and that this failure posed immediate jeopardy to resident health and safety. CMS Ex. 2, at 3. Based on the survey findings, CMS determined that the facility was not in substantial compliance because it failed to ensure that the resident environment remained as free of accident hazards as possible – as required by 42 C.F.R. § 483.25(h)(1) – at scope and severity level K (pattern of immediate jeopardy).

CMS has imposed CMPs of $5000 per day for four days of immediate jeopardy, and $100 per day for 94 days of substantial noncompliance that was not immediate jeopardy. CMS Ex. 9.

The facility timely requested a hearing, and the matter was assigned to me. I held a hearing in Pittsburgh, Pennsylvania on November 6 through 7, 2007. Mr. Christopher S. Lucas appeared on behalf of Petitioner, and Mr. Alan C. Horowitz appeared on behalf of CMS.

I admitted CMS Exs. 1-71 and Petitioner (P.) Exs. 1-8 and 10-31. Transcript (Tr.) 2-3; *Ruling on Petitioner's Motion to Exclude CMS's Proposed Exhibits, and Petitioner's Request for Issuance of Subpoenas* (October 19, 2007). I declined to admit P. Ex. 9, autopsy photographs of the deceased resident. While I recognize the occasional need to introduce intrusive or even seemingly disrespectful evidence, I find the probative value of these photographs insufficient to justify their admission. Petitioner argued that the pictures would help establish that R1 was not wedged between the rails, but was instead caught between his mattress and side rail. As discussed below, establishing that R1 died wedged between mattress and side rail would not further Petitioner's case. Moreover, Petitioner had the opportunity to make its point through the testimony of its witnesses, including the attending pathologist, who could simply describe their observations, including whatever marks they observed on R1's neck. Tr. 3-4.[1]

The parties have filed initial briefs (Br.) and closing briefs (Cl. Br.).

II. Issues

This case presents the following questions:

1. Whether, from August 22 through November 27, 2006, the facility was *not* in substantial compliance with requirements for facilities participating in the Medicare program, specifically 42 C.F.R. § 483.25(h)(1), because it failed to ensure that the resident environment was as free of accident hazards as possible.

2. If the facility was not in substantial compliance from August 22 through 25, 2006, did its deficiencies then pose immediate jeopardy to resident health and safety?

3. If the facility was not in substantial compliance, were the CMPs – $5000 per day for the period of immediate jeopardy and $100 per day for the period of substantial noncompliance that was not immediate jeopardy – reasonable?

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[1] Petitioner incorrectly suggests that it was not allowed to present expert testimony regarding whether the resident was injured by the gaps in his bed rails. P. Cl. Br. at 23. Although the pictures were not admitted, the witnesses had every opportunity to address the cause of R1's death. *See* P. Ex. 3 (Lees Decl.); P. Ex. 4 (Ashcraft Decl.); Tr. 299 *et seq*., 304 *et seq*.

III. Discussion

A. The facility was not in substantial compliance with 42 C.F.R. § 483.25(h)(1) (quality of care) because it routinely used side rails without adequately assessing the potential safety hazards they posed to the individual residents, and because it failed to make sure that the side rails in use were as safe as possible.[2]

Under the statute and the "quality of care" regulation, each resident must receive, and the facility must provide, the necessary care and services to allow a resident to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the resident's comprehensive assessment and plan of care. Act § 1819(b); 42 C.F.R. § 483.25. Among other requirements, the facility must ensure that the resident environment is as free of accident hazards as possible. 42 C.F.R. § 483.25(h)(1).

1. Facility policies did not reflect the standard of care, which mandates that: a) side rails be used only where an individualized resident assessment establishes that their potential benefit outweighs safety risks; and b) the facility takes steps to minimize the risk of entrapment whenever side rails are used.

No one disputes that side rails can represent an accident hazard. At one time they were used more-or-less routinely in hospitals and nursing homes, but health care professionals and others now recognize the risks their use presents, particularly to the elderly and infirm.

> [S]ide rails present an inherent safety risk, particularly when the patient is elderly or disoriented. Even when a side rail is not intentionally used as a restraint, patients may become trapped between the mattress or bed frame and the side rail.

CMS Ex. 60, at 5 (quoting U.S. Department of Health and Human Services, Health Care Financing Administration, *State Operations Manual Provider Certification Transmittal 17*, A-182-183 (June 2000) (guidance to surveyors in the implementation of 42 C.F.R. Part 482 Medicare and Medicaid Programs)).

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[2] My findings of fact and conclusions of law are set forth, in italics and bold, in the discussion captions.

The FDA has issued alerts and other warnings describing the dangers posed by side rail use. In an alert dated August 23, 1995, for example, the FDA warned that individuals with pre-existing conditions such as confusion, restlessness, lack of muscle control, or a combination of these factors, were at "high risk for entrapment." CMS Ex. 57, at 2. "Entrapment" is defined as an event in which the individual is "caught, trapped, or entangled in the space in or about the side rail, mattress, or hospital bed frame." CMS Ex. 58, at 6.

The standard of care mandates that side rails be used only where an individualized resident assessment establishes that their potential benefit outweighs the risks. An interdisciplinary team performs the assessment and makes the determination. Tr. 22, 56. The assessment should include consideration of the resident's diagnoses, behavioral symptoms, sleep habits, medications, cognition, communication, mobility (in and out of bed), risk of falling, and any other relevant concerns. It should include consideration of the sleeping environment and the resident's care plans. Hospital Bed Safety Workgroup, *Clinical Guidance for the Assessment and Implementation of Bed Rails in Hospitals, Long Term Care Facilities, and Home Care Settings* (April 2003); CMS Ex. 60, at 6-14; CMS Ex. 66, at 4-5 (Osterweil Decl. ¶ 13); Tr. 107, 114, 188, 214, 269.

Beryl D. Goldman, Ph.D, RN, NHA is the outreach leader for the FDA's Hospital Bed Safety Workgroup. CMS Ex. 65, at 1 (Goldman Decl. ¶ 1); Tr. 102. She is also the director of the Pennsylvania Restraint Reduction Initiative, and has written and lectured widely on issues involving the elderly and long term care. Dr. Goldman opined that side rails should be the exception, not the norm. Facilities should begin with the presumption that side rails not be used, and should place the burden on the side rail proponent to demonstrate that their use is appropriate. Tr. 107, 114; *see also* CMS Ex. 43, at 8 ("The automatic use of bed rails may pose unwarranted hazards to patient safety.") and 10 ("Avoid the *automatic* use of bed rails of any size or shape."). The facility's medical director, Balkissoon Maharajh, M.D., acknowledged that the American Medical Directors Association "prefer[s] that side rails be used at a minimum, if at all they have to be used." Tr. 214.

Dan Osterweil, M.D., C.M.D. (Certified Medical Director) is a physician who specializes in geriatrics and long term care, and is obviously well-qualified to discuss standards of care for nursing homes.[3] CMS Ex. 66, at 1-2 (Osterweil Decl. ¶ 1), 9-31 (Osterweil

[3] Among other accomplishments, Dr. Osterweil is a clinical professor of medicine at the University of California in Los Angeles, editor-in-chief of the Journal of the American Medical Directors Association, research associate in gerontology services at

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Curriculum Vitae). Dr. Osterweil agreed that the standard of care requires that nursing personnel perform an individualized risk assessment before side rails are ordered or used. CMS Ex. 66, at 4-5 (Osterweil Decl. ¶ 13); Tr. 53-54.

Petitioner's own witnesses, including its Director of Nursing (DON), Terri Russo, agreed that the facility must assess whether the side rail benefits outweigh the risks to resident safety. P. Ex. 11, at 3 (Russo Decl. ¶ 23); Tr. 188; *see also* P. Ex. 13, at 2 (Polantz Decl. ¶ 12); Tr. 269.

Dr. Goldman also testified that if rails are not to be used, they should be removed entirely from the bed to prevent their unauthorized use, which seems a sensible precaution that is easily implemented. Tr. 99.[4]

Although Petitioner claims that its staff were well aware of the FDA's concerns, it does not seem that they took those warnings very seriously. Indeed, notwithstanding its denials, the evidence suggests a strong facility bias *in favor* of side rails. DON Russo acknowledges that the risks posed by side rails include entrapment, injury, and death, but she characterizes those risks as "remote," and suggests that *failing* to provide side rails creates even greater risks, which, in her view, include immobility, bed sores, helplessness, and depression. P. Ex. 11, at 1, 3 (Russo Decl. ¶¶ 8, 9, 29).[5] According to DON Russo,

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[3](...continued)
UCLA/Jewish Home for the Aging Borun Center for Gerontological Research, and medical director for the Gerontology Services at Sherman Oaks Hospital & Health System. He has also written and lectured widely on issues involving geriatrics and nursing home care. CMS Ex. 66, at 9-31.

[4] Every bed in the facility was equipped with side rails, which created a risk of unauthorized use. CMS Ex. 68, at 15 (LaMantia Decl. ¶ 45). Petitioner attempts to minimize the significance of this fact with a declaration from the facility's medical records director, which claims that "not all of the [facility] residents. . . on August 20, 2006 had bed rails in use." P. Ex. 12 (Rietscha Decl. ¶ 3). But the medical records director later conceded that he did not know how many side rails were in use. "I wouldn't know. I'd have to actually look at the bed and that is not part of my job." Tr. 236. When afforded the opportunity to refute the surveyor assertion that every bed in the facility was equipped with side rails, DON Russo either could not or would not answer the question. Tr. 175 ("I can't speak to that.")

[5] In contrast, Dr. Goldman pointed out that padded side rails (which all agree are necessary to fill in gaps wide enough to entrap a head or body) might alleviate some risks,
(continued...)

without side rails, residents will not "feel enabled" and "will die." P. Ex. 11, at 2 (Russo Decl. ¶¶ 12, 13). "[S]taff simply cannot provide the support that a good side rail can provide." P. Ex. 11, at 2 (Russo Decl. ¶ 17). Jolene Polantz, RN, corporate quality nurse for Petitioner's parent organization, also claims that the "much higher prevalence of pressure ulcers" compared to entrapments "skews the risk-benefit analysis in favor of interventions that prevent pressure ulcers. . . ." According to Nurse Polantz, "There is an immediate and tangible benefit to the resident that is not automatically outweighed by the serious but rare risk of entrapment." P. Ex. 13, at 2 (Polantz Decl. ¶ 10); *see also* P. Ex. 14, at 1 (Klein Decl. ¶ 3).

The facility's practices reflected its bias in favor of side rails. Instructions to staff posted at the nurses station stated, "Starting today [June 21, 2006], when a new admission comes in[,] write the preventative order as . . . Side Rails up X 2 for transfers/repositioning." The instruction is signed by Terri Kibler, Wound Care. CMS Ex. 36. The facility concedes that the two-month-old notice was there, but denies that it reflected facility policy. P. Ex. 11, at 1 (Russo Decl. ¶ 5); Tr. 174-179, 191. Petitioner's denials are not credible. First, no one has explained anything about the origins of the notice, or its purpose if not to direct staff to justify the wide-spread use of side rails for new admissions. Nor has Petitioner explained why the notice remained posted for two months, if not reflective of facility policy. Second, and more significant, the facility operated as if that were its policy. Side rails were affixed to every bed. CMS Ex. 68, at 15 (LaMantia Decl. ¶ 45); Tr. 179. The 53 residents in the surveyors' sample, as well as R1, all had orders for side rails. Tr. 183. And, as discussed below, staff cited "repositioning" to justify an order for rails, even where, as with R1, the resident was wholly incapable of using side rails for that purpose.

In what it characterizes as R1's individualized assessment, for example, staff checked "yes" in response to question 7 of the Side Rail Screen: "Is the resident currently using the side rail for positioning or support?" P. Ex. 20, at 10. Yet, R1 was obviously not using side rails for these purposes – he was incapable of voluntary movement and was not able to use his side rails. P. Ex. 21, at 93; CMS Ex. 15, at 6; CMS Ex. 68, at 14 (LaMantia Decl. ¶ 40); P. Cl. Br. at 5. Moreover, for the vast majority of the "assessments" that mention side rails, staff have checked "yes" to question 7. For those with an accompanying assessment team narrative, staff have written some variation of: "Bilateral elevated side rails for positioning." P. Ex. 20, at 10, 13, 14, 15, 16, 20, 22, 24,

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but could also make the resident lying in the bed surrounded by pads feel like he/she is lying in a coffin "so from a psychological perspective[,] I would really be opposed to using them." Tr. 89.

25, 26, 27, 28, 30, 31, 32, 34, 36, 38, 39, 40, 41, 42, 44, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 60, 62, 63, 64, 65, 66, 67, 68, 70, 71, 72, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 94, 96, 98, 99, 100, 101, 102, 103, 104, 105, 106, 108, 110, 111, 112, 113, 114, 115, 118, 119, 120, 121, 122, 124, 126, 128, 130, 131,132, 134, 135, 136, 138, 140, 141, 142, 143, 144, 146, 148, 149, 150, 151, 152, 154, 156, 158, 162, 164, 166, 168, 169, 170, 172; *see also* CMS Ex. 41. In virtually all of these documents, the only justification for side rails listed by the assessment team is "positioning." This fact, together with the posted instructions (CMS Ex. 36) show that use of rails was, at the least, the facility's *de facto* policy. Moreover, as the following discussion explains, the facility policy favoring side rail use seems invariably to have trumped safety considerations.

2. The facility's use of side rails without adequate assessments jeopardized resident health and safety.

As discussed above, the parties recognize that individualized assessments are critical for determining whether the benefits derived from side rail use justify their risks. However, they dispute whether the facility adequately assessed its residents for side rails. According to CMS, the facility did not first determine whether any potential benefit outweighed the safety risks. All 53 residents in the surveyors' sample (as well as R1) were in beds with rails and had orders for rails. Yet none had been adequately assessed for safety. Tr. 183-184.

When surveyors asked the facility administrator, James E. Neely, for safety assessments, he told them that the facility considered only whether side rails were "enablers" or restraints. CMS Ex. 68, at 23 (LaMantia Decl. ¶ 72). Administrator Neely has not denied that he gave the surveyors that information. *See* P. Ex. 10 (Neely Decl.). In fact, during his testimony, he reiterated that staff's concern was to demonstrate that they did not employ rails as restraints:

> [U]p until this incident [R1's entrapment] there was no question that ever came to our committee or to my attention that gee, we should be doing something about these rails because we were looking at them as enablers. . . . It was my understanding that the Department of Health was more concerned about whether they were used as enablers or restraints.

Tr. 204.

Similarly, DON Russo and Corporate Quality Nurse Polantz told the surveyors that they had no assessments of side rail safety risks. CMS Ex. 68, at 33 (LaMantia Decl. ¶ 101). Neither has denied making that statement. *See* P. Ex. 11 (Russo Decl.); P. Ex. 13 (Polantz Decl.). LPN James Winters told the surveyors that all of the residents' beds had side rails, and that they were used routinely. CMS Ex. 68, at 10 (LaMantia Decl. ¶ 31).

Notwithstanding the statements DON Russo and her colleagues made to the surveyors, Petitioner now argues that its "Initial Restraint Assessment" form demonstrates that it performed the necessary individualized safety assessments, and justifies its use of side rails. P. Ex. 20, at 10-173; P. Ex. 11, at 4 (Russo Decl. ¶¶ 31, 32). But review of those documents confirms that, at most, the facility considered only whether the rails were restraints, and did not consider safety.[6]

The "Initial Restraint Assessment" form is a two page document. P. Ex. 20, at 10, 11. Page 1 includes a section titled "Side Rail Screen," consisting of eight yes-or-no questions. Page 2 includes a section for the assessment team to fill in, indicating who comprised the team, and with a space in which to write its notes. *See, e.g.*, P. Ex. 20, at 10, 11; Tr. 255.

The expert witnesses agreed that the form is insufficient as a tool for assessing the costs/benefits of side rail use. CMS Ex. 65, at 2, 6-7 (Goldman Decl. ¶¶ 3, 10, 12, 13); CMS Ex. 66, at 3-5 (Osterweil Decl. ¶¶ 8, 11, 13, 14, 15). It provides some information, but does not suggest how a side rail is more of a benefit than a risk for any particular individual. Tr. 119-120. Dr. Goldman also explained that an adequate individualized assessment requires consideration of the environment, i.e., the bed system,[7] as well as the individual. None of these forms say anything about the environment. Tr. 104; *see* CMS Ex. 60, at 9-14. Petitioner's own expert, Engineer Mark Bruley, who was also a member of the FDA's Hospital Bed Safety Group, agreed that the document addresses restraint use, but is not adequate for assessing the safety of a bed system. Tr. 271-272.

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[6] The facility used the same rationale ("positioning") to justify its use of side rails for each of the residents reviewed, apparently without regard to individual characteristics, a practice that raises questions about the facility's use of restraints. However, CMS has cited no deficiency under the restraint regulation, 42 C.F.R. § 483.13(a), so I do not consider that issue.

[7] The "bed system" is comprised of the bed, mattress, bed rails, and any pads or accessories in or on the bed. P. Ex. 5, at 1 (Bruley Decl. ¶ 4).

Although Petitioner suggests that other facility documents, such as Occupational Therapy (OT) Assessments, might contain evidence of side rail safety assessments, it has not produced such documents. Petitioner's consulting occupational therapist, Angela Klein, who talked about the potential benefits of side rails (repositioning, assisting with self-care, increasing independence, aid in transfer), admitted under cross-examination that the OT evaluations did not address safety risks associated with side rails. P. Ex. 14, at 1 (Klein Decl. ¶ 3); Tr. 73.[8]

The inadequacies of the facility's reliance on the "Initial Restraint Assessment" form for assessing resident safety are well illustrated by the situation of R1. R1 was the type of individual that the FDA Alerts placed at high risk for entrapment. He was a 64-year-old mentally retarded man with a seizure disorder who required complete care. He was a very small man, just 4'10" and 120 pounds, and he was incapable of voluntary movement. CMS Ex. 15, at 11; CMS Ex. 12, at 2. The facility kept him in a bed with the side rails up. Tr. 37-38, 41. According to his Initial Restraint Assessment, R1 is "currently using the side rail for positioning and support." P. Ex. 20, at 10. This, of course, is patently incorrect; R1 was not capable of any voluntary movement. On the second page of that purported assessment is a space for indicating who comprised the assessment team and for writing in any notes. P. Ex. 20, at 11; Tr. 255. But, for R1, that entire page is blank, which, as Corporate Quality Nurse Polantz conceded, indicates that the assessment team did not meet. Tr. 256; P. Ex. 20, at 11.

CMS's experts also agreed that side rails are not the best means for protecting an individual with a seizure disorder or who cannot move voluntarily, an opinion that Petitioner's experts have not challenged. Tr. 41, 87-88. Even Engineer Bruley testified that "forces involved in a seizure could be more than sufficient to separate the hook and loop closures used to attach the foam filled bed rail pad . . . ." P. Ex. 5, at 2 (Bruley Decl. ¶ 14). And, as discussed below, the experts agreed that such padding is essential to protect the resident from becoming entrapped in the 8 inch gap between side rails. Tr. 59, 101, 102, 218, 280. Yet, no one in the facility seems to have considered this very real safety issue before putting R1 into a bed with such rails. Instead, R1's Initial Restraint Assessment simply lists "seizure disorder" as a medical symptom "requiring restraint use." Under the summary section of the form, the assessment team is supposed to indicate "how the use of the restraint promotes or maintains the resident's highest practicable physical, mental, and psychosocial well-being." Again without explanation, someone has written in "seizure disorder." P. Ex. 20, at 10. Nothing suggests that

[8] Therapist Klein also admitted that she educated therapists who worked in the facility, but had no personal knowledge of its residents. Tr. 71.

anyone considered the dangers that side rails, particularly widely-spaced side rails, could pose to an individual with a seizure disorder.[9]

Medical Director Maharajh, who was R1's physician, initially testified that the placement of padded side rails on R1's bed was "within the standard of care," but he also admitted that he did not participate in any risk/benefit analysis with respect to the use of side rails for R1. Tr. 224. He could not recall any conversations with staff regarding R1's need for side rails. Tr. 229. He had never before seen R1's initial restraint assessment. Tr. 231. He had not signed off on it, and had not even seen "this type of document" before. Tr. 232, 233. Dr. Maharajh also agreed that another approach – placing R1 in a low bed with adjacent mats – would have been "reasonable." Tr. 225.

Engineer Bruley could not recall seeing any evidence that the facility had conducted an appropriate risk/benefit analysis of side rail hazards for R1. Tr. 269-270.

3. The facility did not ensure that its bed systems were as safe as possible.

If side rails are required, close attention must be given to their design and the relationship between the rails and the other parts of the bed. Among other considerations, "[t]he bars within the bed rails should be closely spaced to prevent a patient's head from passing through the openings and becoming entrapped." CMS Ex. 60, at 14. The FDA recommends inspection of all hospital bed frames, side rails, and mattresses as part of a regular maintenance program to identify areas of possible entrapment, as well as the use of protective barriers to close off open spaces in which patients might accidently become entrapped, CMS Ex. 57, at 2, 3. Alignment of the bed frames, side rail, and mattress "should leave no gap wide enough to entrap a patient's head or body." CMS Ex. 57, at 2. To this end, the FDA recommends that rails be no more than 4¾ inches apart. CMS Ex. 52.

Petitioner claims that R1's bed was "totally [excluded]" from the FDA guidelines because it was an "air fluidized therapy" bed. P. Cl. Br. at 3-4. In a May 10, 2006 issuance, the FDA recognized that certain pressure reduction therapeutic products

> may pose an additional risk of entrapment when used with conventional hospital bed systems. When these types of

[9] The document is also inconsistent. On the one hand, it suggests that side rails were not restraints, but "enablers" used for "positioning." On the other hand, it says that they were restraints, justified by R1's seizure disorder. P. Ex. 20, at 10.

> mattresses compress, the space between the mattress and the bed rail may increase and pose an additional risk of entrapment. While entrapments have occurred with the use of framed flotation therapy beds (specialty air beds built into a hospital bed frame) and air mattress replacements, these products are excluded from the dimensional limit recommendations, *except for those spaces within the perimeter of the rail.*

CMS Ex. 58, at 12 (U.S. Department of Health and Human Services, Food and Drug Administration, *Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment*) (emphasis added). The recommendations explain that the exemption is due to the highly compressible nature of the mattresses, which present technical difficulties in measuring. Nevertheless, the FDA re-emphasizes that, before using these products, facilities take steps "to ensure that the therapeutic benefit outweighs the risk of entrapment." *Id*. In a published interview, Engineer Bruley re-emphasized that "users [of these products] should identify and address areas of potential entrapment for each resident through a comprehensive bed safety program." CMS Ex. 53, at 6.

Thus, the FDA's so-called exemption does not even apply to the spaces between the rails – the maximum 4¾ inch recommendation still applies to them. With respect to other gaps in the bed system, the FDA acknowledges how difficult it is to come up with standard measurements that would render all the systems safer. If anything, this means that the facility has an even greater responsibility to examine carefully the safety of its bed system when these products are used. And the manufacturer's instructions reflect this concern. They emphasize "*Ensure against any gaps that might entrap the patients' head or body*." CMS Ex. 48, at 3 (emphasis in original).

In any event, although far from ideal, I am satisfied that widely-spaced bed rails do not *per se* violate any standard of care.[10] According to Engineer Bruley – and CMS does not

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[10] The bed systems in question are quite old, and the appearance of the widely-spaced side rails is startling to anyone accustomed to newer models. *See* P. Ex. 8, at 7; P. Ex. 10, at 1 (Neely Decl ¶ 9) (referring to age and frequency of repair); Tr. 203-204; Tr. 61 (Dr. Osterweil: "And it kind of reminds me of maybe a picture from [Romania] or from some very different place than I'm used to being or maybe the United States 50 years ago.") I questioned witnesses and counsel about the appearance of the rails, as well as the significance of the FDA spacing guidelines. Citing my questions and comments, Petitioner asked that I recuse myself from this case, a motion I denied in orders dated

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appear to disagree – such bed systems can be made acceptably safe by eliminating the excessive gaps. High density foam and foam-filled pads may be used "to mitigate entrapment hazards posed by the 8" gaps between the vertical bed rails" as well as other gaps in a bed system. P. Ex. 5, at 1, 2 (Bruley Decl. ¶¶ 6, 12).

Engineer Bruley opines that R1's bed system was "not an accident hazard." P. Ex. 5, at 2 (Bruley Decl. ¶ 10). In his view, the foam-filled pad used to separate R1 from the bed rail "was a reasonable accessory to use to mitigate entrapment hazards posed by the 8" gaps between the vertical bed rails." P. Ex. 5, at 2 (Bruley Decl. ¶ 12). On the other hand, viewing what Petitioner represents as a photograph of R1's bed system (or reasonable facsimile), both Drs. Goldman and Osterweil pointed out multiple, significant problems. P. Ex. 8, at 7. According to Dr. Osterweil,

> You can easily stick a hand between the pad and the mattress in each of those [8 inch] gaps. You have exposed edges and you can actually stick a part of your body between the head of the bed and the headboard. You have only one support to that rail at the far end of the bed – the right side of the picture allows you to lower it or raise it, and that even is not very safe for caregivers because once they do it they can actually catch their hand in between the metal frame and the rail. And it kind of reminds me of maybe a picture from [Romania] or from some very different place than I'm used to being or maybe the United States 50 years ago.

Tr. 61.

Dr. Goldman agreed that the side rails in use presented significant risk to resident safety; the gaps between the rails were too great; the gap between the headboard and the rail presented a problem. She also noted the psychological damage of putting the side panels up because it makes the bed feel "like a coffin." Tr. 89, 101-102.

I find more plausible the observations from CMS's experts, which are also consistent with Engineer Bruley's underlying premise – that excessive gaps in bed systems are accident hazards unless they are filled in – than Engineer Bruley's conclusion. Engineer Bruley does not explain how the bed can be safe in light of the obvious, significant gaps. Nor

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[10](...continued)
December 13, 2007, and January 15, 2008. In fact, based on responses to my comments, I resolve questions of a *per se* violation in Petitioner's favor.

does he explain how a resident with a seizure disorder can safely rely on a rail pad if his seizure activity "could be more than sufficient" to separate the pad from the rail. P. Ex. 5, at 2 (Bruley Decl. ¶ 14).

Even if I accepted Engineer Bruley's conclusion about the safety of R1's bed system (which I do not), I would still find that the facility did not ensure that its bed systems were as safe as possible because so many residents were in beds with widely-spaced rails that had *no* padding or other fillers to protect them from entrapment between the rails. Of the residents sampled, only two had padded side rails. The surveyors observed that the others had the widely-spaced but unpadded rails.[11] Tr. 142-144, 150. All of the experts, including Petitioner's witnesses Bruley and Maharajh, agreed that, without the padding, the side rails are simply unsafe. They pose an accident hazard and are not within the standard of care. Tr. 218, 280.

The surveyors also found problems with those few beds that had padding. For R2, the padding was not attached to the side rail, exposing side rail gaps. R2 was in bed, leaning toward the unpadded section of the rail. CMS Ex. 68, at 16 (LaMantia Decl. ¶ 48). Similarly, when his body was found wedged between the rails, R1's rail pad was no longer attached to the rail but was "hanging down toward the floor." CMS Ex. 22, at 1.[12]

4. The facility inadequately responded to evidence of problems with the side rails.

Administrator Neely justifies the absence of safety assessments by claiming that "investigation of accidents and analysis of their frequency are key tools in preventing accidents in the future." P. Ex. 10, at 1 (Neely Decl. ¶ 6). No one would disagree about the importance of investigation and analysis of accidents. But the evidence here establishes that the facility neither adequately investigated accidents in which side rails were implicated, nor adequately analyzed and responded to the problems they posed.

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[11] One resident (R11) had bed rails that were 7 ½ inches apart. All of the others were 8 inches apart. CMS Ex. 68, at 33 (LaMantia Decl. ¶ 100); Tr. 143.

[12] Engineer Bruley produced a side rail pad which he identified as the pad attached to R1's bed. P. Ex. 31; Tr. 282-284. I find it highly unlikely that this was R1's actual pad. *Compare* P. Ex. 8, at 7 *with* P. Ex. 31; *see* Tr. 285-287, 292-295. In any event, the pad is well worn, with holes in it, and I was able to detach its velcro holder using only a pinky finger. Tr. 284.

According to Administrator Neely, in 18 years, "there has never been an accident involving the vertical side rails or mattress gaps." P. Ex. 10, at 1 (Neely Decl. ¶ 8). But facility incident reports suggest otherwise. Although the facility's investigations and reports provide incomplete information, they show that side rails were implicated in multiple incidents involving resident injuries. For example, an incident report dated July 3, 2006, shows that R1suffered an abrasion on his left leg above the knee (although the body diagram indicates his right knee). A short note instructs staff to be "extra careful when transferring resident with lift," and "be careful not to bump resident on side rail." CMS Ex. 13, at 15. But the facility did not assess the risk of continued use of side rails, nor explore alternatives. CMS Ex. 68, at 25 (LaMantia Decl. ¶ 78); *see also* Tr. 106. In fact, when staff completed R1's 30-day "restraint review" form on August 4, 2006, they omitted any mention of the incident, cited no problems, and recommended "continue [with] padded side rails." CMS Ex. 13, at 4.

R5 was in a bed with the side rails up. On August 19, 2006, at about 8:10 a.m., his bed alarm sounded. He had managed to get out of bed, and was urinating on the floor. CMS Ex. 29, at 6. Staff did not consider the safety issue of his climbing out of bed, but returned him to his bed and left his rails up. At 11:00 that night, his alarm went off again, and they found him out of bed, on the floor, with the side rails still up. CMS Ex. 29, at 1; Tr. 104-105.

Other incident reports suggest additional injuries, which staff suspected were related to side rails. CMS Exs. 25, 27, 28. Yet, in none of these cases did the facility assess the risk of continuing their use. Indeed, DON Russo conceded that it had not occurred to her that side rail related injuries could be a problem. Tr. 192.

More troubling, the facility did not revisit its practices with respect to side rails, even following R1's death. That side rails were implicated in R1's death is beyond doubt. Every document generated by facility staff at the time of his death confirms that staff found him lying on his right side, with his head, arm, and part of his shoulder caught between the side rails. He was blue. CMS Exs. 11; 13 at 1; 18; 22; 23. He died from "positional asphyxia." CMS Exs. 11; 12 at 1.

Petitioner's efforts to cast doubt on that factual scenario are both unpersuasive and irrelevant. They are unpersuasive because they rely on witnesses' half-hearted and, ultimately, not credible efforts to distance themselves from their earlier statements. LPN James Winters, for example, was not able to provide a coherent explanation for the discrepancies between the account he wrote at the time of the incident (he entered the room and found R1 "on his [right] side, left arm and his head facing down caught in [right] sided side rail") and his written declaration (he entered the room and found R1

"partly on his right side and partly face down in the area between the bed rail and the mattress.") Tr. 260-264; *compare* CMS Ex. 23 *with* P. Ex. 2 (Winters Decl. ¶ 3).

Petitioner also presents declarations from the county deputy coroner and from the attending pathologist for R1's autopsy disavowing their earlier statements that R1 died wedged between side rails, claiming instead that he died wedged between his mattress and side rails. Under cross-examination, Pathologist Harold G. Ashcraft, M.D., admitted to errors in his report, and conceded that R1 had marks on his neck likely caused by a "firm object that was elongated . . . such as a side rail." Tr. 301-303. And, in testimony that ranged from evasive to incredible, Deputy Coroner Jeffrey Lees failed to explain why, long after the incident, he chose to disregard *all* of the statements from the actual eye witnesses in favor of vague suggestions from individuals (whom he did not specifically name) who did not see the body until it was removed from the rails. *See* Tr. 307 *et seq*.

But the issue is irrelevant because, even if R1 had been caught between his bed rail and mattress, the rails would have been equally implicated in his death, and should have triggered a response from the facility. Remarkably, no one at the facility even considered it necessary to re-examine its side rail practices. Until these proceedings compelled the facility to act, the facility left its residents in beds with side rails. It reported to the State Agency that "[t]o prevent this from happening again to a resident in a similar situation, all residents currently in house will be re-assessed for the need/or no need for siderails and/or padded rails and careplans adapted as needed." CMS Ex. 10, at 2. But when the surveyors arrived at the facility, no safety assessments had been performed.

Administrator Neely told the surveyors that the facility had changed the bed systems for 16 residents identified as suffering from seizure disorder. But when the surveyors looked at six of those 16 residents (R9, R10, R11, R15, R27, R28), their beds had not been changed. CMS Ex. 68, at 15-16 (LaMantia Decl. ¶ 47).

B. CMS's determination that the facility's deficiencies posed immediate jeopardy was not clearly erroneous.

Immediate jeopardy exists if the facility's noncompliance has caused *or is likely to cause* "serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301. CMS's determination as to the level of a facility's noncompliance – which includes its immediate jeopardy finding – must be upheld unless it is "clearly erroneous." 42 C.F.R. § 498.60(c). The Departmental Appeals Board has observed repeatedly that the "clearly erroneous" standard imposes on facilities a "heavy burden" to show no immediate jeopardy, and has sustained determinations of immediate jeopardy where CMS presented evidence "from which '[o]ne could reasonably conclude' that immediate jeopardy exists." *Barbourville*

Nursing Home, DAB No. 1962, at 11 (2005) (citing *Florence Park Care Center*, DAB No. 1931, at 27-28 (2004) (quoting *Koester Pavilion*, DAB No. 1750 (2000))).

Here, compelling evidence establishes that R1 died trapped between side rails, and I find it more likely than not that Petitioner's deficiencies contributed to his death. But I need not even reach that conclusion in order to sustain the immediate jeopardy finding. So long as the facility's noncompliance "is likely to cause serious injury, harm [or] impairment," its deficiencies pose immediate jeopardy. Petitioner's routine use of bed rails without assessing their risks creates the likelihood of serious injury or harm. Further, as Engineer Bruley explained, a bed system is unsafe if it presents excessive gaps. P. Ex. 5, at 1 (Bruley Decl. ¶ 6). Here, the facility routinely left its vulnerable individuals in beds with widely spaced rails, without filling in any of the gaps. CMS's determination that such practices pose immediate jeopardy to resident safety was not clearly erroneous.

C. The amount of the CMP – $5000 per day for the period of immediate jeopardy and $100 per day for the period of noncompliance that was not immediate jeopardy – is reasonable.

Having found a basis for imposing a CMP, I now consider whether the amount imposed is reasonable, 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) 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. 42 C.F.R. § 488.438(f). The factors in 42 C.F.R. § 488.404 include: 1) the scope and severity of the deficiency; 2) the relationship of the deficiency to other deficiencies resulting in noncompliance; and 3) the facility's prior history of noncompliance in general and specifically with reference to the cited deficiencies.

It is well-settled that, in reaching a decision on the reasonableness of the CMP, I may not look into CMS's internal decision-making processes. Instead, I consider whether the evidence presented on the record concerning the relevant regulatory factors supports a finding that the amount of the CMP is at a level reasonably related to an effort to produce corrective action by a provider with the kind of deficiencies found and in light of the other factors involved (financial condition, facility history, culpability). I am neither bound to defer to CMS's factual assertions, nor free to make a wholly independent choice of remedies without regard for CMS's discretion. *Barn Hill Care Center*, DAB No. 1848, at 21 (2002); *Community Nursing Home*, DAB No. 1807, at 22 *et seq*. (2002); *Emerald Oaks*, DAB No. 1800, at 9 (2001); *CarePlex of Silver Spring*, DAB No. 1683, at 8 (1999).

CMS has imposed a penalty of $5000 per day, which is toward the mid-range for immediate jeopardy situations ($3050 – $10,000). It has imposed a penalty of $100 per day for the remaining period of noncompliance, which is at the low end of the penalty range ($50 – $3000). 42 C.F.R. § 488.438(a)(1).

The parties have provided me little assistance on this issue. Petitioner says only that it was not culpable because it acted appropriately, which the evidence belies, as the above discussion establishes. CMS, for its part, does not address the issue at all except to point out that deficiencies involving side rail usage were cited in an earlier survey.

So, with respect to the facility history, CMS alleges that, in 2005, the State Agency cited deficiencies based on problems with the facility side rails, and Petitioner has not denied that assertion. CMS Ex. 68, at 3 (LaMantia Decl. ¶ 11).

Petitioner has not argued that its financial condition affects its ability to pay the penalty.

With respect to the other factors, Petitioner's deficiencies constituted a pattern of noncompliance that posed immediate jeopardy to resident health and safety. I consider this significant enough in scope and severity to warrant a substantial penalty. Moreover, I disagree that the facility was not culpable. The evidence establishes that the facility employed side rails without any serious regard for the risks they posed. Staff did not assess safety considerations in its so-called assessments. In fact, those documents seemed geared exclusively toward convincing examiners that the rails were not used as restraints. Nor did staff ensure that the bed systems they used were as safe as possible. Even following R1's unfortunate death, the facility did not reexamine its practices. I find that this level of culpability, as well as the scope and severity of the deficiencies, justify the penalties imposed.

IV. Conclusion

For all of the reasons discussed above, I find that Petitioner was not in substantial compliance with program participation requirements from August 22 through November 27, 2006. I find that from August 22 through 25, 2006, its deficiencies posed immediate jeopardy to resident health and safety. I find reasonable the imposition of a $5000 per day CMP for the period of immediate jeopardy, and a $100 per day CMP for the period of substantial noncompliance that was not immediate jeopardy.

/s/
Carolyn Cozad Hughes
Administrative Law Judge