Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Rehabilitation & Care Center of Jackson County, (CCN: 14-5395)	)	Date: May 1, 2007
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-03-418
	)	Decision No. CR1590
Centers for Medicare & Medicaid Services.	)	
	)	

DECISION

I sustain the determination of the Centers for Medicare & Medicaid Services (CMS) to impose a per-instance civil money penalty (CMP) totaling $4,050 against Petitioner, Rehabilitation & Care Center of Jackson County. I deny Petitioner's motion for a directed finding in its favor.

I. Background

On February 18, 2003, the Illinois Department of Public Health (IDPH) completed a survey of Petitioner's facility. On the basis of this survey, CMS determined that Petitioner failed to comply substantially with two participation requirements stated at 42 C.F.R. §§ 483.20(b) (Resident Assessment, Tag F 272) and 483.25(h)(2) (Quality of Care, Tag F 324). Both deficiencies were cited under the past noncompliance data Tag F 698. By letter dated August 12, 2003, CMS imposed upon Petitioner a per-instance CMP of $1,000 for the past noncompliance identified at 42 C.F.R. §§ 483.20(b) (Resident Assessment, Tag F 272) and a per-instance CMP in the amount of $3,050 for the past noncompliance identified at 42 C.F.R. §§ 483.25(h)(2) (Quality of Care, Tag F 324). CMS also imposed a two-year prohibition against offering a Nurse Aide Training and/or Competency Evaluation Program (NATCEP), effective February 18, 2003.

Petitioner requested a hearing on May 1, 2003, and the case was assigned to me for a hearing and a decision. I conducted a hearing in Benton, Illinois, from September 21-22, 2004. At the hearing, CMS offered into evidence 34 exhibits (CMS Exs. 1-34) and Petitioner offered into evidence 19 exhibits (P. Exs. 1-19). I admitted into evidence CMS Exs. 1-34 and P. Exs. 1-19. At the hearing, Petitioner moved for a directed finding. I deny Petitioner's motion for a directed finding.

CMS presented two witnesses, both surveyors, Robin Martin, Registered Nurse (R.N.), and Karen Lapington, sanitarian. Petitioner presented seven witnesses: Merle Taylor, Administrator; Stephanie Green, Director of Nurses (DON); Laura Ticer, Licensed Practical Nurse (LPN) Supervisor and Care Plan Coordinator; Vickie Holford, R.N., a restorative and rehabilitation nurse; Regina Pierson, Environmental Services Director; Robin Morse, Certified Nurse Assistant (CNA); and Dr. Dale Blaise, Medical Director and attending physician.

CMS's post-hearing brief (CMS Br.) was received on December 21, 2004. On January 31, 2005, Petitioner filed its post-hearing brief (P. Br.), accompanied by one attachment. On February 18, 2005, CMS filed it post-hearing reply brief (CMS Reply Br.).

II. Applicable law and regulations

Petitioner is considered a long-term care facility under the Social Security Act (Act) and regulations promulgated by the Secretary of Health and Human Services (Secretary). The statutory and regulatory requirements for participation by a long-term care facility are found at sections 1819 and 1919 of the Act and at 42 C.F.R. Part 483.

Sections 1819 and 1919 of the Act invest the Secretary with authority to impose CMPs against a long-term care facility for failure to comply substantially with federal participation requirements.

Pursuant to the Act, the Secretary has delegated to CMS and the states the authority to impose remedies against a long-term care facility that is not complying substantially with federal participation requirements. 42 C.F.R. Part 488 provides that facilities participating in Medicare may be surveyed on behalf of CMS by state survey agencies in order to determine whether the facilities are complying with federal participation requirements. 42 C.F.R. §§ 488.10-488.28. The regulations contain special survey conditions for long-term care facilities. 42 C.F.R. §§ 488.300-488.335. The regulations at 42 C.F.R. Part 488 give CMS a number of different remedies that can be imposed if the

facility is not in compliance with Medicare requirements. Under Part 488, a state or CMS may impose a per-instance or per-day CMP against a long-term care facility when a state survey agency concludes that the facility is not complying substantially with federal participation requirements. 42 C.F.R. §§ 488.406, 488.408, 488.430.

The regulations specify that a CMP that is imposed against a facility can be either a per day CMP for each day the facility is not in substantial compliance, or a per-instance CMP for each instance that a facility is not in substantial compliance. 42 C.F.R. § 488.430(a). When penalties are imposed for an instance of noncompliance, the penalties will be in the range of $1,000-$10,000. 42 C.F.R. § 488.438(a)(2).

The regulations define the term "substantial compliance" to mean "a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm." 42 C.F.R. § 488.301.

Substantial noncompliance that is immediate jeopardy is defined as "a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." *Id.*

Substandard Quality of Care is defined as "one or more deficiencies related to participation requirements under § 483.13, Resident behavior and facility practices, § 483.15, Quality of life, or § 483.25, Quality of care . . . , which constitute immediate jeopardy to resident health or safety . . . ." A finding of substandard quality of care, triggers an extended survey, which in turn results in the loss of approval for a facility of its NATCEP. 42 C.F.R. § 498.3(b)(13), (14)(ii).

The Act and regulations make a hearing before an administrative law judge (ALJ) available to a long-term facility against whom CMS has determined to impose a CMP. Act, section 1128A(c)(2); 42 C.F.R. §§ 488.408(g), 498.3(b)(12), (13). The hearing before an ALJ is a *de novo* proceeding. *Anesthesiologists Affiliated, et al.*, DAB CR65 (1990), *aff'd*, 941 F.2d 678 (8th Cir. 1991). A facility has a right to appeal a "certification of noncompliance leading to an enforcement remedy." 42 C.F.R. § 488.408(g)(1); *see also* 42 C.F.R. §§ 488.330(e) and 498.3. However, the choice of remedies by CMS or the factors CMS considered when choosing remedies are not subject to review. 42 C.F.R. § 488.408(g)(2). A facility may only challenge the scope and severity level of noncompliance found by CMS if a successful challenge would affect the amount of the CMP that could be collected by CMS or impact upon the facility's nurse aide training program. 42 C.F.R. §§ 498.3(b)(14) and (d)(10)(i). CMS's determination as to the level

of noncompliance "must be upheld unless it is clearly erroneous." 42 C.F.R. § 498.60(c)(2). This includes CMS's finding of immediate jeopardy. *Woodstock Care Center*, DAB No. 1726, at 9, 38 (2000), *aff'd, Woodstock Care Center v. U.S. Dept. of Health and Human Services*, 363 F.3d 583 (6th Cir. 2003).

When a penalty is imposed and appealed, CMS must make a *prima facie* case that the facility has failed to comply substantially with federal participation requirements. To prevail, a long-term care facility must overcome CMS's showing by a preponderance of the evidence. *Batavia Nursing and Convalescent Center*, DAB No. 1904 (2004); *Batavia Nursing and Convalescent Inn*, DAB No. 1911 (2004); *Emerald Oaks*, DAB No. 1800 (2001); *Cross Creek Health Care Center*, DAB No. 1665 (1998); *Hillman Rehabilitation Center*, DAB No. 1611 (1997), *aff'd, Hillman Rehabilitation Center v. U.S. Dept. of Health and Human Services*, No. 98-3789 (D.N.J. May 13, 1999).

III. Issues

The issues in this case are:

(1) whether CMS has shown a basis upon which to assess penalties against Petitioner for substantial noncompliance with the requirements for participation in Medicare and Medicaid; and, if so,

(2) whether the amount of the assessed penalties is reasonable.

IV. Findings of fact and conclusions of law

I make findings of fact and conclusions of law (Findings) to support my decision in this case. I set forth each Finding below as a separate heading. I discuss each Finding in detail.

Prior to discussing the individual deficiencies, it is necessary to address the issue of the credibility of the surveyors. Petitioner attacks the credibility of the surveyors based on Surveyor Martin's lack of recent nursing experience (Surveyor Martin has not worked in a nursing facility since 1995) and Surveyor Lapington's lack of a medical background (Surveyor Lapington is a sanitarian and has never worked in a long-term care facility). Petitioner claims that the surveyors are not qualified to give expert opinions on the foreseeability of the January 19, 2003 entrapment incident at issue before me. This is an administrative proceeding to which the formal rules of evidence do not strictly apply. However, if I apply Fed. R. Evid. 702 and the decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), I find that the two surveyors have scientific, technical, or other special knowledge as a surveyor or nurse surveyor that can help me

make a decision on the facts in issue. Thus, it was appropriate to allow them to testify to their opinions based upon the evidence, giving such weight as is appropriate in light of the factors listed in Fed. R. Evid. 702 – sufficiency of facts or data, reliability of principles or methods, and reliability of the application of principles or methods to the facts. Further, 42 C.F.R. § 488.26(c)(3) establishes a presumption of professional competence for surveyors. Petitioner bears the burden to rebut this presumption. In this case, the fact that Surveyor Martin has been out of actual nursing practice for a period of years[1] does not detract from her credibility or from the probative value of her testimony absent some evidence from a more credible source indicating that her testimony is in error rather than just disputed. Also, the fact that Surveyor Lapington is a sanitarian and has no medical training does not detract from the credibility due her as a result of her training as a surveyor[2] and her experience as a surveyor of long term care facilities for 12 years.[3] Petitioner also misses the primary point of the surveyors' testimony, which is to allow them to elaborate upon the reasons why they alleged deficiencies and to give Petitioner an opportunity to cross-examine them.

I found the testimony of Surveyors Martin and Lapington to be more credible, unbiased, objective, and consistent than that of the other witnesses who testified. I found their testimony to be supported by the documentary evidence and more persuasive than that of the other witnesses who testified. I, therefore, gave the testimony of the two surveyors greater weight in my deliberations.

A. Petitioner's motion for a directed finding is denied.

At the close of CMS's case-in-chief, Petitioner made an oral motion for a directed finding. A motion for directed finding or verdict is granted when all the evidence, viewed in the light most favorable to the opponent, favors the movant so that no contrary verdict could stand. In other words, a directed verdict should be granted if the opponent, CMS, has not established a *prima facie* case. I deny Petitioner's oral motion for a directed finding. CMS has clearly established a *prima facie* case, as I discuss further below.

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[1] Surveyor Martin has been a surveyor for eight years, had 22 years of nursing experience, and has had experience providing direct care to residents in nursing homes. Tr. 37, CMS Ex. 31.

[2] Surveyor Lapington testified the she received training on the proper use of side rails, including the difference between using side rails as restraints or as enablers and how to assess the need and purpose of side rails. Tr. 68.

[3] Surveyor Lapington has been involved with other surveys where a resident has become entrapped between side rails and a mattress, although none of those residents died as a result of the entrapment. Tr. 90.

B. Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.20(b).

The February 18, 2003 survey found that Petitioner was not in substantial compliance with the regulation at 42 C.F.R. § 483.20(b) which provides:

> (b) *Comprehensive Assessments.*
>
> > (1) *Resident assessment instrument.* A facility must make a comprehensive assessment of a resident's needs, using the resident assessment instrument (RAI) specified by the State. The assessment must include at least the following:
> >
> > . . .
> >
> > (xv) Special treatments and procedures.

The Resident Assessment Instrument (RAI) consists of three basic components: the Minimum Data Set (MDS), the Resident Assessment Protocols (RAPs), and the RAI Manual (RAI Manual).[4] CMS contends that Petitioner failed to comprehensively assess whether Resident 1 needed to continue using half side rails. CMS argues that the use of quarter, half, and full side rails have risks associated with them and, therefore, a facility has the duty, under section 42 C.F.R. § 483.20(b)(1)(xv), to assess and address those risks. CMS Br. at 10. This deficiency, as well as the deficiency discussed in Part IV.C. of this Decision, involve the same resident, Resident 1.

Resident 1 was an 88 year old female whose diagnoses included generalized weakness, Alzheimer's disease, dementia, and organic brain syndrome. Tr. 39, 71, 366; CMS Ex. 8, at 1. Resident 1 was fed through a gastric tube. *Id.* Resident 1's most recent MDS was dated November 25, 2002. The November 25, 2002 MDS documented that Resident 1 had short and long-term memory problems, moderately impaired cognitive skills, was unable to understand others or make herself understood, resisted care, was non-ambulatory, and was totally dependent on staff for bed mobility, transfers, toileting, and other activities of daily living. Tr. 39-40, 73; P. Ex. 18, at 2-3.

Resident 1 had half side rails on her bed. She was unable to use her half side rails to reposition herself. Tr. 234, 247, 284, 295. However, Resident 1 could hold onto the half side rails if a staff member placed her hand on the half side rail. Tr. 174, 284, 295. Resident 1 was assessed at risk of falls related to her attempts to self transfer off of her

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[4] The MDS, RAPs, and Manual are found at http://www.cms.hhs.gov/quality/mds20/.

bed and Petitioner had documented falls on January 12, 2000, November 1, 2001, December 15, 2001, March 2, 2002, and March 12, 2002. Tr. 45, 78. The falls on November 1, 2001, December 15, 2001, March 2, 2002, and March 12, 2002, were all falls from Resident 1's bed while her half side rail was in use. CMS Exs. 9, 10, 14, at 1-2.

On March 12, 2002, at 12:20 a.m., Resident 1 was found on the floor with her back against the bed, holding onto one of the half side rails with both hands, with her neck wedged between the half side rail and the mattress. CMS Exs. 10, 16. Resident 1 was not able to remove herself from between the mattress and the half side rail, but was uninjured as a result of this fall. Tr. 45; CMS Ex. 10.

At the time of the March 12, 2002 fall, Resident 1's care plan already documented her risk for falls as a result of her attempts to self transfer. CMS Ex. 16, at 1, 6, 13, 18, 23, 27, 31, 34, 38, 42. The approaches of the facility to address Resident 1's risk for falls included: 30 minute monitoring; ensuring she had a hazard free environment; using right and left half side rails to assist in bed mobility; and scheduled toileting. *Id.* After the March 12, 2002 fall, where Resident 1's neck was found wedged between the half side rail and the mattress, no changes were made to her care plan. *Id.* There was no documentation to show that Petitioner's staff ever considered discontinuing the use of half side rails after the March 12, 2002 fall, even though she had been found with her neck wedged between the half side rail and the mattress. Tr. 333-34.

Resident 1's medical chart included her most recent side rail assessment, which was dated prior to the March 12, 2002 fall. CMS Ex. 17. The side rail assessment showed that the purpose of the use of side rails was to assist in bed mobility, transfers, and safety concerns. Tr. 163; CMS Ex. 17. The side rail assessment did not indicate that the benefits of using side rails outweighed the risk of using side rails. CMS Ex. 17. The side rail assessment was not updated at any time after the March 12, 2002 fall. There is no documentation to show that, after the March 12, 2002 incident, Petitioner's staff ever reconsidered or reweighed the benefits and risks of using side rails. Resident 1 did not fall again until January 19, 2003.

On January 19, 2003, at 4:05 a.m., CNA Morse found Resident 1 on the floor next to her bed with her head wedged between the half side rail and the mattress. Tr. 392, 412; CMS Ex. 22, at 1. CNA Morse determined that Resident 1 had no pulse or heartbeat. LPN Kupczak confirmed that Resident 1 had no pulse, respiration, and blood pressure. *Id.* The DON, Dr. Blaise (Resident 1's attending physician and Petitioner's Medical

Director), the sheriff's department, and the deputy coroner were all notified. The police report indicted that Resident 1's death was accidental strangulation. CMS Ex. 12. The death certificate listed the cause of death as asphyxiation-positional, extrinsic compression of the neck, and neck trapped under the bed rail. CMS Ex. 13.

After Resident 1's death, Petitioner reassessed all the residents that used side rails. This reassessment resulted in three changes. CMS Ex. 1, at 3-4. Petitioner also checked all side rails to determine if the side rails were functioning properly and trained its staff regarding alarms and the use of side rails. CMS Ex. 23.

Entrapment of a resident between a mattress and side rails is a known risk in the nursing home industry. For example, in *Maine Veterans' Home-Scarborough,* DAB No. 1975, at 8 (2005), an appellate panel of the Departmental Appeals Board (Board) cited to a 2001 Veterans' Administration Patient Safety Alert concerning dangers posed by bed rail entrapment which directed VA facilities to measure gaps between bed rails and mattresses, and a 1995 Food and Drug Administration (FDA) Safety Alert to long-term care facilities on dangers posed by gaps associated with bed rails, particularly to frail and confused residents. In *Wellington Specialty Care & Rehabilitation Center*, DAB CR548 (1998), the ALJ discussed the FDA Alert, stating:

> [S]ide rails can be dangerous to residents of long-term care facilities. There exists a risk that some residents under certain circumstances may suffer injuries from side rails . . . on occasion, individuals have become wedged in the gaps between side rails, resulting in injuries or death to those individuals . . . . The dangers posed by side rails impose on long-term care facilities a duty to assess and address the risk of using side rails . . . . On August 21, 1995, the Food and Drug Administration (FDA) sent an "Alert" to hospitals and long term care facilities which warned them of the dangers that side rails posed . . . . This Alert stated that since January 1990 [a period of a little over five and one half years], the FDA had received 102 reports of incidents involving entrapment of individuals in hospital bed side rails . . . . The FDA noted that it had received reports of 68 deaths, 22 injuries, and 12 entrapments without injuries occurring in hospitals, long-term care facilities, and private homes.

Id. at 11-12. The FDA Alert shows that gaps between side rails and mattresses pose a real risk of harm, injury, or even death to residents in nursing homes and is a risk generally known in the nursing home industry.

CMS, in its brief, also referred to the FDA Alert mentioned in *Wellington*. Petitioner argues that these FDA warnings were "an impermissible attempt by CMS to introduce materials from the Food and Drug Administration . . . when CMS failed to offer any such evidence in this case." P. Br. at 23. I find that I can consider the FDA Alert for the purpose of showing that entrapment is a risk known to the nursing home industry and not for the purpose of showing that Petitioner, in particular, received such written warnings from the FDA.

In addition to the known risk of entrapment from the use of side rails, in the case before me, Resident 1 was particularly at risk from entrapment because she was weak and confused. Petitioner's care plan documented that Resident 1 was at risk for falls relating to her attempts the self transfer. CMS Ex. 16, at 1, 6, 13, 18, 23, 27, 31, 34, 38, 42. Resident 1 was diagnosed with Alzheimer's Disease, dementia, and generalized weakness. Tr. 39, 71, 366; CMS Ex. 8, at 1. Resident 1 was weak, confused, and would be less able to extricate herself should she, in fact, become entrapped. Surveyor Martin testified that residents who are diagnosed with weakness, confusion, Alzheimer's Disease and dementia, like Resident 1, are at increased risk of becoming entrapped between their side rails and mattresses. Tr. 42. Most telling, however, was that Resident 1 had already had a prior experience of being entrapped on March 12, 2002. Resident 1 was discovered prior to suffering any injuries, but was unable to extricate herself during the March 12, 2002 incident. Fortunately, on that occasion, Resident 1 was uninjured. As a long-term care SNF, however, Petitioner knew or should have known of the risks of entrapment from the use of side rails. Indeed, Petitioner had actual notice, that Resident 1 was at particular risk of entrapment because of the incident on March 12, 2002.

Section 483.20(b) requires facilities to engage in a *comprehensive* assessment of a resident's needs. Evaluating the benefits and risks of a particular service initiated by a facility, such as the use of side rails, must be part of a comprehensive assessment. Resident safety is a basic facility responsibility. 42 C.F.R. § 483.25(h). Survey instruments, such as the RAI, cannot incorporate every possible factor a facility should consider in a resident assessment. *Maine Veterans' Home-Scarborough,* DAB No. 1975, at 17. The Board in *Maine Veterans' Home-Scarborough,* citing to the RAI Manual, stated that "completion of the MDS/RAPs does not necessarily fulfill a facility's obligation to perform a comprehensive assessment. Facilities are responsible for assessing areas that are relevant to individual residents regardless of whether or not the appropriate areas are included in the RAI." *Id.* The scope of the RAI does not limit the facility's responsibility to assess and address all care needed by the resident. *Id.* at 17-18.

The Board in *Maine Veterans' Home-Scarborough*, further explained that this interpretation is reasonable because:

> (1) the wording of section 483.20(b)(1) is that an assessment "must include at least" certain specified elements, and more generally refers to a "comprehensive " assessment of a resident's needs; (2) designing and using an instrument that describes every conceivable permutation of care needed by the nursing home population is impracticable if not impossible, and (3) limiting comprehensive assessments to a specific instrument would subject residents to the risk of having care needs not assessed because they were not on the instrument.

Id. at 18.

Resident 1's side rail assessment, dated February 16, 2002, was not comprehensive because there was no reassessment done following her March 12, 2002 fall. No documentation exists in Resident 1's medical record to show that the use of side rails was ever reevaluated as to whether its benefits outweighed its risks and no documentation exists that alternatives to the use of side rails to prevent falls were considered. Tr. 46, 47. Resident 1 had two falls following the February 16, 2002 side rail assessment and prior to the entrapment incident that resulted in her death. One fall occurred on March 2, 2002, and the other one occurred on March 12, 2002. According to Surveyor Lapington, both falls related to Resident 1's bed and should have resulted in a new side rail assessment. Tr. 79, 85. In referring to the March 12, 2002 fall where Resident 1's neck became entrapped between her side rail and mattress, Dr. Blaise, Petitioner's Medical Director and Resident 1's treating physician, testified that Resident 1 could have bruised herself, suffered musculoskeletal injuries, or her airway could have become obstructed. Tr. 392, 394. Thus, Petitioner had notice that Resident 1 could become entrapped. Petitioner should have known that such entrapment could harm Resident 1. Thus, Petitioner, was obligated to at least reassess the risks of using side rails following the March 12, 2002 fall.

I note CMS's argument that even prior to the March 12, 2002 fall, the February 16, 2002 side rail assessment was not comprehensive because it did not show that there was an initial assessment to indicate that the benefits of using the side rails outweighed the risks of using the side rails. Tr. 44; CMS Ex. 17, at 1. No documents exist to show that the interdisciplinary team that made the recommendation for the use of side rails ever initially considered the risks of side rails or possible alternative interventions to the use of side rails. The assessment form merely indicated that the side rails were being used for safety concerns and to assist with bed transfers and bed mobility and that the side rails were not considered restraints. CMS Ex. 17. CMS also argues that the side rail assessment was not comprehensive because it failed to accurately reflect Resident 1's need for the side rails. The side rail assessment indicated that the rails were to be used at all times when Resident 1 was in bed. *Id.* However, Resident 1's care plan indicated that the side rails

were to be used on an as needed basis for transfers and bed mobility. CMS Ex. 16, at 1. I find that I need not address these arguments because it is clear that Petitioner had a duty to reassess Resident 1's use of side rails following the March 12, 2002 fall that resulted in her entrapment, and it did not do so.

Petitioner counters by claiming that the half side rails were needed all the time because Resident 1 was fed through a gastric tube which required that the head of the bed be elevated. A review of the evidence before me shows that neither the February 16, 2002 side rail assessment nor Resident 1's care plan corroborates this claim. CMS Exs. 16, 17.

When a significant change in the condition of a resident occurs, the regulations require that a revised MDS be completed. 42 C.F.R. § 483.20(b)(2). Petitioner argues that a reassessment was not required because Resident 1 did not experience a significant change in her condition after the March 12, 2002 fall. While Petitioner might be correct that Resident 1's condition did not change, the March 12, 2002 fall placed Petitioner on notice that a risk, possibly a lethal risk, existed as to use of side rails with Resident 1. As previously noted, there is no documentation to show that, after the March 12, 2002 incident where Resident 1's head was found wedged between the half side rail and the mattress, Petitioner's staff ever reconsidered or reweighed the benefits and risks of using side rails. As previously discussed, a resident who is weak, confused, and has Alzheimer's Disease or dementia, is at increased risk of being entrapped. Resident 1 was such a resident even before March 12, 2002. However, after the March 12, 2002 fall, Petitioner had actual notice that Resident 1 could be entrapped between her side rails and her mattress and a comprehensive assessment requires that such a risk be weighed against the benefits and alternatives.

In addition, Petitioner argues that the purpose of its side rail assessment was only to determine whether the side rails served as restraints and, therefore, a reassessment was not needed. This argument is unavailing. Whatever the reason for the use of side rails, whether as a restraint, a mobility device, or a fall prevention measure, the risks of side rails remains the same. In the matter before me, where Resident 1 had already experienced an entrapment episode, Petitioner had a duty to assess the risks and benefits of the continued use of side rails and consider alternatives. After the March 12, 2002 fall, Petitioner continued to assess Resident 1 to be at risk for falls on her care plan. Petitioner never modified its care plan after the March 12, 2002 fall to reflect any interventions that could prevent or decrease the risk of entrapment.

C. Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.25(h)(2).

The February 18, 2003 survey found that Petitioner was not in substantial compliance, at an immediate jeopardy level (level J), with the regulation at 42 C.F.R. § 483.25(h)(2) which provides:

> Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psycho social well-being, in accordance with the comprehensive assessment and plan of care.
>
> (h) *Accidents.* The facility must ensure that -
>
> . . . .
>
> (2) Each resident receives adequate supervision and assistance devices to prevent accidents.

This regulation does not require a facility to be free of all accidents; it does not impose strict liability on a facility for accidents that a resident may sustain. *See Koester Pavilion,* DAB No. 1750 (2000); *Heath Nursing and Convalescent Center,* DAB CR610 (1999); *Woodstock Care Center,* DAB No. 1726 (2000); *Carehouse Convalescent Hospital,* DAB CR729 (2001); *Price Hill Nursing Home,* DAB CR745 (2001); *Hermina Traeye Memorial Nursing Home,* DAB CR756 (2001). In other words, simply because an accident occurred does not necessarily mean that a facility failed to substantially comply with regulatory requirements. In cases concerning compliance with 42 C.F.R. § 483.25(h), the focus is on the language of the regulation; i.e., the facility **must ensure** each resident receives adequate supervision to prevent accidents according to a comprehensive assessment and a plan of care (emphasis added). The facility's duty, as stated in the regulation, is an affirmative duty.

The Board in *Koester Pavilion,* DAB No. 1750, at 24 (2000) stated that "a facility is not required to do the impossible or be a guarantor against unforeseeable occurrences, but is required to do everything in its power to prevent accidents." The facility's duty, pursuant to 42 C.F.R. §§ 483.25(h)(1) and (2), is expressed in a slightly different way in *Woodstock Care Center,* DAB No. 1726 (2000). In that case, the Board found that a facility is obligated to take measures that are designed, to the extent that is practicable, to assure that residents do not sustain accidents that are reasonably foreseeable. The fact that an accident actually occurred in a nursing home does tend to show that the facility's supervision was inadequate to prevent the occurrence; that is, the facility did not do

everything in its power to prevent its occurrence. This is particularly true if, as in the case before me, the facility has had notice of a prior occurrence so that the potential for a resident's accident is foreseeable.

The question here is whether Petitioner took measures, to the extent practicable, to assure that Resident 1 did not become entrapped, given that Resident 1 had a previous episode of entrapment on March 12, 2002.

Petitioner asserts that never in the history of the facility had such an unfortunate accident occurred, and never had a resident died in a manner like Resident 1. P. Br. at 3. Petitioner argues, and its Administrator, Merle Taylor, so testified, that there was no reason to believe such an incident of entrapment resulting in the death of a resident could occur. P. Br. at 3; Tr. 152. Petitioner's other witnesses also opined that the January 19, 2003 incident was unforeseeable.

Petitioner's argument that the entrapment episode that resulted in R1's death was an unforeseeable accident must fail because, given the entrapment episode of March 12, 2002, the January 19, 2003 entrapment episode was certainly reasonably foreseeable. As I discussed in Part IV.B. of this Decision, entrapment as a result of the use of side rails is a known risk for residents in nursing homes. Dr. Blaise, Petitioner's Medical Director and Resident 1's treating physician, testified that Resident 1 could have bruised herself, suffered musculoskeletal injuries, or her airway could have become obstructed as a result of the March 12, 2002 incident. Tr. 392, 394. Petitioner's staff members Merle Taylor, Stephanie Green, Laura Ticer, Vickie Holford, and Dr. Blaise, each testified that he or she was aware of the previous March 12, 2002 entrapment incident. Tr. 154-55, 182, 240-41, 298, 314, 375, 391-92. Further, Merle Taylor and Dr. Blaise both testified that they were aware of the risks side rails posed to nursing home residents. Tr. 154, 390, 392, 394. Since entrapment had happened once before, on March 12, 2002, involving the same resident, it is not unforeseeable that it could happen again. In fact, the position in which Resident 1 was found after both incidents was almost exactly the same. In both instances, Resident 1's neck was wedged between the mattress and the side rail. I do not find that for a risk to be foreseeable, it must have previously materialized. But where such a risk has previously materialized, Petitioner has a particularly heavy burden to show that an accident was unforeseeable. Petitioner has not met this burden.

Resident 1 was the type of resident who is most vulnerable to entrapment because she may move without regard to her own safety, was more likely to become entrapped, was weak and confused, and would be less able to extricate herself from a gap. First, Petitioner failed to identify the hazard of further entrapment after the March 12, 2002 entrapment episode. Thereafter, Petitioner did nothing to prevent another occurrence. Petitioner failed to change Resident 1's care plan, or reassess the use of side rails, or

consider alternatives to the use of side rails, as discussed in Part IV.B. of this Decision. Petitioner failed to provide adequate supervision or assistive devices to prevent another entrapment. Evidence was presented that Resident 1's room could not be seen from the nurses station. Tr. 237. Under section 483.25(h), a facility must identify and remove hazards, where possible, or, where the hazard is unavoidable because of other resident needs, a facility must manage the hazard by reducing the risk of accident to the extent possible. Ensuring that a gap between the mattress and the side rail was very small, by the use of padded side rails or by some other means, would have reduced the risk of entrapment.

As noted above, Petitioner's staff members Merle Taylor, Stephanie Green, Laura Ticer, Vickie Holford, and Dr. Blaise, each testified that he or she was aware of the March 12, 2002 entrapment incident. Tr. 154-55, 182, 240-41, 298, 314, 375, 391-92. Further, Merle Taylor and Dr. Blaise both testified that they were aware of the risks side rails posed to nursing home residents. Tr. 154, 390, 392, 394. There is no doubt that Petitioner had notice of the risk of entrapment for Resident 1 and that Resident 1 had been unable to free herself during the previous incident of entrapment.

Under section 483.25(h), Petitioner has a duty to take all reasonable steps that it could to prevent an accident. Petitioner could have implemented alternative interventions to prevent Resident 1 from becoming entrapped and still address Resident 1's risk of falling. Testimony was presented that possible alternative interventions included: removing the side rails entirely and placing Resident 1 in a low bed with padding around her bed; providing Resident 1 with a bed alarm; using a concave mattress; or padding the side rails with a bed bolster to eliminate the space between the side rails and the mattress. Tr. 43. Petitioner did not implement alternative interventions and presented no evidence that it even considered alternative interventions. In fact, the evidence shows that one intervention, the use of a sentinel alarm, was discontinued in October 2002. P. Br. at 17. Instead, Petitioner argues that it reinforced interventions already in place. Tr. 183, 315. However, the interventions already in place failed to prevent the March 12, 2002 entrapment incident and, therefore, were not sufficient.

Petitioner asserts that "[i]n assessing R1, Jackson County determined that this incident [of March 12, 2002] occurred because R1 would become agitated when incontinent, and would attempt to get out of bed in the morning hours to go to the bathroom." P. Br. at 16. As a result, Petitioner responded by continuing scheduled toileting in order to decrease agitation which would lead to attempts to self-transfer. P. Exs. 1, at 4; 10, at 1-21; Tr. 315-16, 395. Monitoring every 30 minutes was also continued. P. Ex. 4. A call light and a sentinel alarm were used to monitor Resident 1. *Id.* As noted above, however, the sentinel alarm was discontinued in October of 2002. P. Ex. 5, at 1. According to Petitioner, the sentinel alarm was discontinued because it was no longer needed. P. Br. at

17. I take note that Petitioner discontinued the use of the sentinel alarm, which was one of the possible interventions that CMS's surveyors testified was available for use with Resident 1.

Petitioner also claimed that the type of mattress was changed.[5] Tr. 345. Petitioner's Rehabilitation Nurse, Vickie Holford, testified that Petitioner changed the type of mattress that Resident 1 was using after the March 12, 2002 incident. Tr. 340-46. I give little weight to this testimony because this testimony is not supported by anything in the record before me. Petitioner's request for Informal Dispute Resolution (IDR) did not mention a change of mattress after March 12, 2002. P. Ex. 2. Resident 1's care plan does not mention a change of mattress. CMS Ex. 16. No documentation in evidence before me indicates a change of mattress. DON Green did testify that it was her "understanding" that Resident 1's mattress had been changed sometime between March 2002 and January 2003. Tr. 253. However, DON Green also admitted that there was no documentation to show that Resident 1's new mattress had been evaluated for appropriateness of use with her side rails. Tr. 253-54. Not all mattresses can be safely used with all side rails. *Good Samaritan Center*, DAB CR884 (2002). Therefore, even if I accept as true that Resident 1's mattress had been changed, it would be Petitioner's burden to show that the type of mattress used with the type of side rails in use on Resident 1's bed was a safe combination. Petitioner did not sustain this burden.

Petitioner argues that Resident 1 did not fall from her bed for a 10 month period from March 2002 until January 2003 and, therefore, it was providing Resident 1 with adequate supervision and assistance devices. I find Petitioner's reasoning to be unpersuasive. The absence of a fall or an entrapment does not necessarily lead to the conclusion that Resident 1 was being provided with adequate supervision and assistance devices. Therefore, I reject Petitioner's argument. Further, Petitioner claims that Resident 1 no longer attempted to transfer out of her bed during this 10-month period and, therefore, the incident of January 19, 2003 was unforeseeable. Even if I take this claim to be true, Petitioner's argument is unavailing. Petitioner's argument is undercut by the fact that it still assessed Resident 1 to be at risk for falls up to the time of Resident 1's entrapment that led to her death. CMS Ex. 16. Petitioner had still assessed Resident 1 to be at risk for falls in spite of the fact that there were no falls for a 10-month period, and in spite of its claim that Resident 1 no longer attempted to transfer from her bed.

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[5] Petitioner asserts that an air pressure mattress on Resident 1's bed was changed to an egg crate mattress. Tr. 345; P. Br. at 17.

Petitioner also argues that Dr. Blaise, Resident 1's physician, did not order that the side rails be discontinued, and that Resident 1's family did not request that the side rails be removed. This argument is also unavailing because under the regulations it is the facility's responsibility to ensure that the resident receives adequate supervision and assistance devises. Therefore, Petitioner's actions or inactions cannot be blamed on the Resident's physician or family.

Further, Petitioner argues that side rails were needed because the head of Resident 1's bed had to be elevated at least to a 35 degree angle because Resident 1 was being fed through a gastric tube. Tr. 369. Resident 1's care plan does not support this assertion. CMS Ex. 16. Surveyors Martin and Lapington, as well as Petitioner's DON, Stephanie Green, testified that the use of half side rails is not related to the use of a gastric tube. Tr. 44, 76-78, 238. Petitioner's Rehabilitation Nurse, Vickie Holford, testified that the use of half side rails was not part of Petitioner's protocol for gastric feeding, but then changed her testimony stating that she was unsure of the policy for gastric feeding. Tr. 339. Petitioner's argument is not supported by the evidence before me, but even if it was, Petitioner still had to assess the risks and benefits of using side rails for Resident 1 and consider alternative interventions that would reduce the risk of entrapment. Where the hazard, such as side rails, is unavoidable because of other resident needs, managing the hazard by reducing the risk of accident to the extent possible is a facility's responsibility.

D. CMS's determination that Petitioner's noncompliance with the regulation found at 42 C.F.R. § 483.25(h)(2) was at the immediate jeopardy level is not clearly erroneous.

In this case, CMS determined that the facility was not in substantial compliance with the regulation found at 42 C.F.R. § 483.25(h)(2) at an immediate jeopardy level. As noted above, CMS assessed a per-instance CMP of $3,050.

Appeal rights attach to certain initial determinations made by CMS as set forth in the regulations. The level of noncompliance, in this case immediate jeopardy, can be appealed but only if the *range* of CMP that would be collected could change or if the facility's nurse's aide training program would be affected due to a finding of substandard quality of care. 42 C.F.R. §§ 498.3(b)(14)(i), (ii) and 498.3(d)(10)(i), (ii).

A per-instance CMP can be from $1,000 to $10,000. There is no specifically defined range of per-instance penalty for findings of immediate jeopardy. 42 C.F.R. § 488.438(a)(2). Thus, a finding of immediate jeopardy can have no effect on the range of penalties. Nonetheless, CMS's determination of immediate jeopardy in this case is an

appealable initial determination pursuant to section 498.3(b)(14)(ii), because the deficiency cited resulted in a finding of substandard quality of care affecting the facility's NATCEP.

Immediate jeopardy is defined in the regulations as "a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301. In any case where immediate jeopardy is at issue, CMS has the burden of coming forward with sufficient prima facie evidence to show that immediate jeopardy was present. The burden on a facility to disprove a determination of immediate jeopardy that is supported by prima facie evidence is very heavy. A facility may overcome a prima facie case of immediate jeopardy only by proving that CMS's determination was clearly erroneous. 42 C.F.R. § 498.60(c)(2).

The evidence offered by CMS establishes a prima facie case that Petitioner's noncompliance, was at an immediate jeopardy level. Generally, to establish immediate jeopardy it is not necessary to show that a resident or residents sustained serious injury, harm, impairment, or died as a result of a deficiency. Immediate jeopardy exists also where there is no proof that a deficiency has actually harmed a resident but where the deficiency is *likely* to cause serious injury, harm, impairment, or death to a resident. 42 C.F.R. § 498.60(c)(2); *Innsbruck HealthCare Center*, DAB No. 1948 (2004). The evidence in the case before me shows a likelihood of serious injury, harm, impairment, or death to Resident 1 as a consequence of being entrapped. The risks of entrapment are well known in the nursing home industry and the January 19, 2003 entrapment of Resident 1 actually resulted in Resident 1's death. The death certificate listed the cause of death as asphyxiation-positional, extrinsic compression of the neck, and neck trapped under the bed rail. CMS Ex. 13. Therefore, CMS's determination that Petitioner's noncompliance was at the immediate jeopardy level is not clearly erroneous.

E. The amounts of the per-instance CMPs assessed against Petitioner are reasonable.

CMS imposed a $1,000 per-instance CMP for the deficiency cited under 42 C.F.R. § 483.20(b) and a $3,050 per-instance CMP for the deficiency cited under 42 C.F.R. § 483.25(h)(2). I find that both of the per-instance CMPs imposed against Petitioner are reasonable.

As noted above, a per-instance CMP can range from $1,000 to $10,000. In considering whether the amount of the $3,050 CMP imposed by CMS is reasonable, I applied the four factors listed in 42 C.F.R. § 488.438(f). The factors are: the facility's history of noncompliance; the facility's financial condition; the factors specified in 42 C.F.R.

§ 488.404; and the facility's degree of culpability which includes, but is not limited to, neglect, indifference, or disregard for resident care, comfort, or safety. The factors to be considered under 42 C.F.R. § 488.404 include the scope and severity of the deficiency and the facility's prior history of noncompliance with reference to the cited deficiency.

There is evidence that Petitioner's financial condition is such that it could pay the total per-instance CMP of $4,050. CMS presented evidence that Petitioner's general balance fund totaled $7,014,144. CMS Ex. 34, at 1. Petitioner's Administrator Merle Taylor testified that Petitioner was one of the largest employers in Jackson County, with an annual budget of approximately seven million dollars. Tr. 141. Although, Mr. Taylor stated that the facility was not profitable, Petitioner provided no evidence that paying a total per-instance CMP of $4,050 would put it out of business. When considering the reasonableness of a CMP, the relevant question is whether a CMP is so large that it would put the facility out of business. *Kelsey Memorial Hospital,* DAB CR583 (1999).

The parties made no argument concerning Petitioner's culpability or its prior enforcement history. The scope and severity of the deficiency was an isolated incident, but at the immediate jeopardy level. The facility ignored the need to apply measures to prevent entrapment in spite of the obvious risks posed in the case of Resident 1. Had CMS chosen to impose a per day CMP, the minimum amount of per day CMP that could be imposed for an immediate jeopardy deficiency is $3,050. Petitioner's financial condition and the scope and severity of the deficiency suggest that a per-instance CMP for the deficiency cited under 42 C.F.R. § 483.25(h)(2) of $3,050 is reasonable. The per-instance CMP for the deficiency cited under 42 C.F.R. § 483.20(b) is for the minimum amount of $1,000 and is reasonable as a matter of law. I conclude that the combined per-instance CMPs imposed against Petitioner are reasonable.

V. Conclusion

I sustain CMS's determination to impose two per-instance CMPs totaling $4,050 against Petitioner. I deny Petitioner's motion for a directed finding in its favor.

/s/
Alfonso J. Montano
Administrative Law Judge