**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Vista Health Care Center,
(CCN: 55-5723),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-12-175

Decision No. CR3000

Date: November 20, 2013

# DECISION

I sustain the determination of the Centers for Medicare & Medicaid Services (CMS) to impose a per-instance civil money penalty (PICMP) of $10,000 against Vista Health Care Center (Petitioner or facility). In addition, the state agency was required to withdraw approval from Petitioner to conduct a nurse aid training and competency evaluation program (NATCEP).

## I. Background

Petitioner is a skilled nursing facility (SNF) located in Southern California. On August 16, 2011, the California Department of Public Health (CDPH) conducted a complaint survey. CDPH determined that Petitioner was not in substantial compliance with the Medicare participation requirement found at 42 C.F.R. § 483.25(h) at a level constituting immediate jeopardy.

By letter dated October 11, 2011, CMS notified Petitioner that it agreed with the CDPH finding that Petitioner provided substandard quality of care and imposed a PICMP in the amount of $10,000 for noncompliance with 42 C.F.R. § 483.25(h), tag F323 (Accidents) at an immediate jeopardy level. Further, CMS notified Petitioner that CMS was

imposing a denial of payment for new admission (DPNA), effective October 26, 2011, and would terminate Petitioner's program participation by February 16, 2012, if Petitioner had not returned to substantial compliance before that date. CMS Exhibit (Ex.) 19. A revisit survey was conducted on October 20, 2011. Petitioner was found to have returned to substantial compliance during the revisit survey. Consequently the DPNA and termination did not go into effect. CMS Ex. 20, at 2. The PICMP and the loss of Petitioner's NATCEP remain before me.

By letter dated December 6, 2011, Petitioner requested a hearing. An Acknowledgment and Docketing Order was issued on December 8, 2011. I convened a video teleconference hearing from San Diego, California on January 7, 2013. During the hearing, CMS Exs. 1-21 and Petitioner's (P.) Exs. 1-33 were admitted into evidence. Following the conclusion of the hearing, the parties agreed to submit one round of briefing. CMS submitted its brief (CMS Br.) on April 24, 2013. Petitioner also submitted its brief (P. Br.) on April 24, 2013.

## II. Applicable Law

The statutory and regulatory requirements for participation of a SNF in Medicare are at section 1819 of the Social Security Act (Act) and 42 C.F.R. pt. 483. Section 1819(h)(2) of the Act authorizes the Secretary of Health and Human Services (Secretary) to impose enforcement remedies against a SNF for failure to comply substantially with the federal participation requirements established by sections 1819(b), (c), and (d) of the Act.[1] The Act requires that the Secretary terminate the Medicare participation of any SNF that does not return to substantial compliance with participation requirements within six months of being found not to be in substantial compliance. Act § 1819(h)(2)(C). The Act also requires that the Secretary deny payment of Medicare benefits for any beneficiary admitted to a SNF, if the SNF fails to return to substantial compliance with program participation requirements within three months of being found not to be in substantial compliance – commonly referred to as the mandatory or statutory denial of payments for new admissions (DPNA). Act § 1819(h)(2)(D). The Act grants the Secretary discretionary authority to terminate a noncompliant SNF's participation in Medicare, even if there has been less than 180 days of noncompliance. The Act also grants the Secretary authority to impose other enforcement remedies, including a discretionary DPNA, CMPs, appointment of temporary management, and other remedies such as a directed plan of correction. Act § 1819(h)(2)(B).

[1] Participation of a NF in Medicaid is governed by section 1919 of the Act. Section 1919(h)(2) of the Act gives enforcement authority to the states to ensure that NFs comply with their participation requirements established by sections 1919(b), (c), and (d) of 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. "*Substantial compliance* means 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 (emphasis in original). A deficiency is a violation of a participation requirement established by sections 1819(b), (c), and (d) of the Act or the Secretary's regulations at 42 C.F.R. pt. 483, subpt. B. Noncompliance refers to any deficiency that causes a facility not to be in substantial compliance. 42 C.F.R. § 488.301. State survey agencies survey facilities that participate in Medicare on behalf of CMS to determine whether the facilities are complying with federal participation requirements. 42 C.F.R. §§ 488.10-.28, 488.300-.335. The regulations specify the enforcement remedies that CMS may impose if a facility is not in substantial compliance with Medicare requirements. 42 C.F.R. § 488.406.

CMS is authorized to impose a CMP for the number of days of noncompliance – a per day CMP – or for each instance of noncompliance – a PICMP. 42 C.F.R. § 488.430. The regulations specify that a CMP that is imposed against a facility on a per day basis will fall into one of two ranges of penalties. 42 C.F.R. §§ 488.408, 488.438. The upper range of CMPs, $3,050 per day to $10,000 per day, is reserved for deficiencies that pose immediate jeopardy to a facility's residents and, in some circumstances, for repeated deficiencies. 42 C.F.R. § 488.438(a)(1)(i), (d)(2). "*Immediate jeopardy* means 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 (emphasis in original). The lower range of CMPs, $50 per day to $3,000 per day, is reserved for deficiencies that do not pose immediate jeopardy, but either cause actual harm to residents, or cause no actual harm but have the potential for causing more than minimal harm. 42 C.F.R. § 488.438(a)(1)(ii). The only range for a PICMP is $1,000 to $10,000. 42 C.F.R. §§ 488.408, 488(a)(2).

Petitioner was notified that it was ineligible to conduct a NATCEP. Pursuant to sections 1819(b)(5) and 1919(b)(5) of the Act, SNFs and NFs may only use nurse aides who have completed a training and competency evaluation program. Pursuant to sections 1819(f)(2) and 1919(f)(2) of the Act, the Secretary was tasked to develop requirements for approval of NATCEPs and the process for review of those programs. Sections 1819(e) and 1919(e) of the Act impose upon the states the requirement to specify what NATCEPs they will approve that meet the requirements that the Secretary established and a process for reviewing and re-approving those programs using criteria the Secretary set. The Secretary promulgated regulations at 42 C.F.R. pt. 483, subpt. D. Pursuant to 42 C.F.R. § 483.151(b)(2) and (f), a state may not approve and must withdraw any prior approval of a NATCEP offered by a skilled nursing or nursing facility that has been: (1) subject to an extended or partial extended survey under sections 1819(g)(2)(B)(i) or 1919(g)(2)(B)(i) of the Act; (2) assessed a CMP of not less than $5,000; or (3) subject to

termination of its participation agreement, a DPNA, or the appointment of temporary management. Extended and partial extended surveys are triggered by a finding of "substandard quality of care" during a standard or abbreviated standard survey and involve evaluating additional participation requirements. "Substandard quality of care" is identified by the situation where surveyors identify one or more deficiencies related to participation requirements established by 42 C.F.R. § 483.13 (Resident Behavior and Facility Practices), § 483.15 (Quality of Life), or § 483.25 (Quality of Care) that are found to constitute either immediate jeopardy, a pattern of or widespread actual harm that does not amount to immediate jeopardy, or a widespread potential for more than minimal harm that does not amount to immediate jeopardy and there is no actual harm. 42 C.F.R. § 488.301.

The Act and regulations make a hearing before an Administrative Law Judge (ALJ) available to a long-term care facility against which CMS has determined to impose an enforcement remedy. Act §§ 1128A(c)(2), 1866(h); 42 C.F.R. §§ 488.408(g), 498.3(b)(13). The hearing before an ALJ is a de novo proceeding. *The Residence at Salem Woods*, DAB No. 2052 (2006); *Cal Turner Extended Care*, DAB No. 2030 (2006); *Beechwood Sanitarium*, DAB No. 1906 (2004); *Emerald Oaks*, DAB No. 1800, at 11 (2001); *Anesthesiologists Affiliated*, 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), 488.330(e), 498.3. However, the choice of remedies, 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 determined by CMS, if a successful challenge would affect the range of the CMP that may be imposed or impact the facility's authority to conduct a NATCEP. 42 C.F.R. § 498.3(b)(14), (d)(10)(i). The CMS determination as to the level of noncompliance, including the finding of immediate jeopardy, "must be upheld unless it is clearly erroneous." 42 C.F.R. § 498.60(c)(2); *Woodstock Care Center*, DAB No. 1726, at 9, 38 (2000), *aff'd*, 363 F.3d 583 (6th Cir. 2003). The Departmental Appeals Board (the Board) has long held that the net effect of the regulations is that a provider has no right to challenge the scope and severity level assigned to a noncompliance finding, except in the situation where that finding was the basis for an immediate jeopardy determination. *See, e.g., Ridge Terrace*, DAB No. 1834 (2002); *Koester Pavilion*, DAB No. 1750 (2000). ALJ review of a CMP is subject to 42 C.F.R. § 488.438(e).[2]

[2] Although recognizing that the "prevailing interpretation of the regulations" precludes its challenging the immediate jeopardy determination where a PICMP has been imposed, Petitioner argues forcefully that it should be permitted to challenge the immediate jeopardy finding and thus the scope and severity assigned to the deficiency. P. Br. at 13-17. Insofar as Petitioner asserts that it has a constitutional due process right to do so, I am without the authority to hear those arguments. However, its due process argument is preserved for appeal. Where Petitioner argues that it should be allowed to address the

The hearing before an ALJ is a *de novo* proceeding, i.e., "a fresh look by a neutral decision-maker at the legal and factual basis for the deficiency findings underlying the remedies." *Life Care Center of Bardstown*, DAB No. 2479, at 32 (2012) (citation omitted). The standard of proof, or quantum of evidence required, is a preponderance of the evidence. CMS has the burden of coming forward with the evidence and making a prima facie showing of a basis for imposition of an enforcement remedy. Petitioner bears the burden of persuasion to show by a preponderance of the evidence that it was in substantial compliance with participation requirements or any affirmative defense. *Batavia Nursing & Convalescent Inn*, DAB No. 1911 (2004); *Batavia Nursing & Convalescent Center*, DAB No. 1904 (2004), *aff'd*, 129 F. App'x 181 (6th Cir. 2005); *Emerald Oaks*, DAB No. 1800; *Cross Creek Health Care Center*, DAB No. 1665 (1998); *Hillman Rehab. Center*, DAB No. 1611 (1997)(*remand)*, DAB No. 1663 (1998) (*aft. remand*), *aff'd*, *Hillman Rehab. Center v. United States*, No. 98-3789 (GEB), 1999 WL 34813783 (D.N.J. May 13, 1999).

## III. Issues

1. Whether there is a basis for the imposition of an enforcement remedy; and

2. Whether the PICMP imposed is reasonable.

## IV. Discussion[3]

### 1. Petitioner failed to comply substantially with the participation requirement at 42 C.F.R. § 483.25(h) (Tag F-323).

On August 4, 2011, Resident 1, a 75-year old woman, fell to the floor when two hospice certified nurse assistants (HCNAs)[4] attempted to transfer her from a shower gurney to her

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immediate jeopardy determination in challenging the reasonableness of the PICMP, as noted above, my review of the CMP is governed by 42 C.F.R. § 488.438(e) and it is under that standard that I evaluate the reasonableness of the PICMP.

[3] I have reviewed the entire record, including all the exhibits and testimony. Because the Federal Rules of Evidence do not control the admission of evidence in proceedings of this kind (*see* 42 C.F.R. § 498.61), I may admit evidence and determine later, upon a review of the record as a whole, what weight, if any, I should accord that evidence or testimony. To the extent that any contention, evidence, or testimony is not explicitly addressed or mentioned, it is not because I have not considered the contentions. Rather, it is because I find that the contentions are not supported by the weight of the evidence or by credible evidence or testimony.

[4] The HCNAs are provided to Petitioner from Apreva Hospice Services (Apreva) by a contractual agreement. P. Ex. 3. Pursuant to the agreement between Petitioner and

bed using Petitioner's Viking M lift. Tr. at 27-28, 105-107; CMS Ex. 1, at 1; CMS Ex. 6, at 1; CMS Ex. 9, at 1-2; CMS Ex. 10, at 1-4. The Viking M lift, product number 2040005, is manufactured by Liko, a wholly owned subsidiary of Hill-Rom, Inc.[5] CMS Ex. 10, at 1; CMS Ex. 11; CMS Ex. 21, at 11, 19. As a result of the fall, Resident 1, who was receiving hospice care in Petitioner's facility, suffered a broken left hip. Tr. at 27; CMS Exs. 6, 9.

According to the HCNAs who were attempting to transfer Resident 1 in the Viking M lift, the upper left half of the sling "snapped" off the sling bar during the transfer, causing the fall. P. Ex. 2, at 2; Tr. at 30-31, 106-07.

Petitioner's Director of Rehabilitation, John Clewis, and Petitioner's DON, Diana Klarenbach, examined the sling and sling bar hooks immediately after Resident 1's fall and found them to be intact with no damage. They also did not find any indication that the lift had failed in any way. Tr. at 30-31, 106-07; P. Ex. 2, at 2; CMS Ex. 10, at 2. Immediately after the examination, the sling used with Resident 1 was sealed in a bag and retained. Petitioner submitted a report of an "unusual occurrence" to CDPH.

During a complaint survey the following day on August 5, 2011, Ward Wagenseller, who is a surveyor, registered nurse, and a Health Facilities Evaluator Nurse (HFEN) at CDPH, examined the Viking M lift and found the sling intact and initially thought the entire lift was intact. Tr. at 29. Mr. Wagenseller was told that the lift was still being used and took photographs of the Viking M lift. Tr. at 33; CMS Ex. 11. Sometime after leaving on August 5, 2011, Mr. Wagenseller located the lift's operator manual on the Internet, consulted it, and found that safety clips were part of the lift according to the manufacturer's instructions. He was able to determine while looking at the photographs of Petitioner's lift that the safety clips at the end of the lift crossbar were missing. Mr. Wagenseller could see a "pinhole deeply positioned at the end of each of the hooks" on the lift crossbar that indicated that a clip-type device should be used in that pinhole "to restrain the sling from inadvertently escaping the clip." Tr. at 38, 39. Mr. Wagenseller and Lisa Mosel, a HFEN supervisor from CDPH, returned to the facility on August 16, 2011 to determine if the Viking M lift was being used on residents without the safety clips required by the manufacturer.

When Mr. Wagenseller and Ms. Mosel returned to the facility, they were told that the Viking M lift was being used by Petitioner on 25 residents between one to three times

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Apreva, Petitioner was responsible for maintaining "adequate facilities and equipment." P. Ex. 3, at 3. Diana Klarenbach, Petitioner's Director of Nursing (DON) testified that the term "equipment" includes the Viking M lift. Tr. at 115.

[5] The Viking M lift was used often because it had a scale attached and residents can be weighted easily. Tr. at 32.

daily, 25 to 75 uses per day. Tr. at 42, 78. No one at the facility, not even the maintenance personnel, had an owner's manual for the Viking M lift at the time of the August 5, 2011 complaint survey. Tr. at 36, 45-46. The maintenance personnel performed no maintenance on the lift except for calibrating the scale. There was no maintenance log for the lift. Tr. at 46. Ms. Mosel testified that Brian Pauleson, the maintenance supervisor, did not have the manufacturer's instructions until one week before the August 16, 2011 return visit and was unaware that the lift required maintenance beyond the need to calibrate the scale. Tr. at 79. The surveyors were told that the Viking M lift was purchased in 2007 and had been used continuously since that time. The Viking M lift was even being used on the date of the return visit. Upon examining the Viking M lift on August 16, 2013, Ms. Mosel testified that there were no safety clips on the lift. Tr. at 77.

Mr. Wagenseller testified that he talked with Harriet Nakyeyune, one of the HCNAs present at the time of Resident 1's fall. Ms. Nakeyune told Mr. Wagenseller that at the time of Resident 1's fall she noticed that the Viking M lift did not have safety latches[6] and that other Viking M lifts in other facilities in which she had worked did have safety latches. Tr. at 64-65. Ms. Nakeyune told Mr. Wagenseller that during Resident 1's transfer, Ms. Nakeyune was providing some degree of support to Resident 1's body, thus relieving the tension on the lift straps and causing the straps to slip out of the hooks, in turn causing the fall. Tr. at 63-64; CMS Ex. 10, at 14. According to the service representative from Hill-Rom with whom Mr. Wagenseller talked, the function of the safety latches was to prevent any such release of tension on the straps from allowing the sling to slip out and over the hooks. Tr. at 64.

On August 16, 2011 at 11:30 a.m., Mr. Wagenseller called Hill-Rom's customer service number. Mr. Wagenseller testified that "[w]hen I asked the product technician if they would ever recommend or saw any cause or reason to operate the device without safety latches at the end of the crossbar, he said he wouldn't ever use the device without safety latches. The sling could become loose from the bar and the patient could fall. They . . . indicated that the user's guide instructs the user to check the safety latch operation before each use." Tr. at 47. Mr. Wagenseller and Ms. Mosel "called" immediate jeopardy on August 16, 2011. Immediate jeopardy was abated 15 minutes after it was called when Petitioner removed the Viking M lift from service.

The general quality of care regulation, 42 C.F.R. § 483.25, requires that a facility ensure each resident receives necessary care and services to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being, in accordance with the resident's comprehensive assessment and plan of care. The quality of care regulations

[6] At various times during the hearing the term "safety clips" and "safety latches" were used interchangeably. I do so here as well.

impose specific obligations upon a facility related to accident hazards and accidents. The applicable regulatory provision states:

> The facility must ensure that –
>
> > (1) The resident environment remains as free of accident hazards as is possible; and
> >
> > (2) Each resident receives adequate supervision and assistance devices to prevent accidents

42 C.F.R. § 483.25(h). CMS instructs its surveyors that the intent of 42 C.F.R. § 483.25(h)(1) and (2) is "to ensure the facility provides an environment that is free from accident hazards over which the facility has control and provides supervision and assistive devices to each resident to prevent avoidable accidents." The facility is expected to: identify, evaluate, and analyze hazards and risks; implement interventions to reduce hazards and risks; and monitor the effectiveness of interventions and modify them when necessary. State Operations Manual (SOM), CMS Pub. 100-07, app. PP, Guidance to Surveyors Long Term Care Facilities, F323 (Rev. 27; eff. Aug. 17, 2007).[7]

The Board has provided interpretative guidance for adjudicating alleged violations of 42 C.F.R. § 483.25(h)(1):

> The standard in section 483.25(h)(1) itself -- that a facility "ensure that the environment is as free of accident hazards as possible" in order to meet the quality of care goal in section 483.25 -- places a continuum of affirmative duties on a facility. A facility must determine whether any condition exists in the environment that could endanger a resident's safety. If so, the facility must remove that condition if possible, and, when not possible, it must take action to protect residents from the danger posed by that condition. [Footnote omitted.] If a facility has identified and planned for a hazard and then failed to follow its own plan, that may be sufficient to show a lack of

[7] The SOM does not have the force and effect of law. However, the provisions of the Act and regulations interpreted by the SOM clearly do have such force and effect. *Indiana Department of Public Welfare v. Sullivan*, 934 F.2d 853 (7th Cir. 1991); *Northwest Tissue Center v. Shalala*, 1 F.3d 522 (7th Cir. 1993). Thus, while the Secretary may not seek to enforce the provisions of the SOM, she may seek to enforce the provisions of the Act or regulations as interpreted by the SOM.

> compliance with [the] regulatory requirement. In other cases, an ALJ may need to consider the actions the facility took to identify, remove, or protect residents from the hazard. **Where a facility alleges (or shows) that it did not know that a hazard existed, the facility cannot prevail if it could have reasonably foreseen that an endangering condition existed either generally or for a particular resident or residents.**

*Maine Veterans' Home – Scarborough*, DAB No. 1975, at 6-7 (2005) (emphasis added).

The Board has also explained the requirements of 42 C.F.R. § 483.25(h)(2) in numerous decisions. *Golden Living Center – Riverchase*, DAB No. 2314, at 6-7 (2010); *Eastwood Convalescent Center*, DAB No. 2088 (2007); *Century Care of Crystal Coast*, DAB No. 2076 (2007*), aff'd*, 281 F. App'x 180 (4th Cir. 2008); *Liberty Commons Nursing and Rehabilitation - Alamance*, DAB No. 2070 (2007); *Golden Age Skilled Nursing & Rehabilitation Center*, DAB No. 2026 (2006); *Estes Nursing Facility Civic Center*, DAB No. 2000 (2005); *Northeastern Ohio Alzheimer's Research Center*, DAB No. 1935 (2004); *Woodstock Care Center*, DAB No. 1726 (2000), *aff'd*, *Woodstock Care Center v. Thompson*, 363 F.3d 583 (6th Cir. 2003). The regulation does not make a facility strictly liable for accidents that occur, but it does require that a facility take all reasonable steps to ensure that a resident receives supervision and assistance devices that meet his or her assessed needs and mitigates foreseeable risks of harm from accidents. *Woodstock Care Center v. Thompson*, 363 F.3d at 589 (noting a SNF must take "all reasonable precautions against residents' accidents"). A facility is permitted the flexibility to choose the methods of supervision it uses to prevent accidents, but the chosen methods must be adequate under the circumstances. Whether supervision is "adequate" depends in part upon the ability of the resident to protect himself or herself from harm. *Id*. Based on the regulation and the cases in this area, CMS meets its burden to show a prima facie case if the evidence demonstrates that the facility failed to provide adequate supervision and assistance devices to prevent accidents, given what was reasonably foreseeable. *Alden Town Manor Rehabilitation & HCC*, DAB No. 2054, at 5-6, 7-12 (2006). An "accident" is an unexpected, unintended event that can cause a resident bodily injury, excluding adverse outcomes associated as a direct consequence of treatment or care (e.g., drug side effects or reactions). SOM, app. PP, Tag F323; *Woodstock Care Center*, DAB No. 1726, at 4.

The regulation gives Petitioner notice of the criteria or elements it must meet to comply with the program participation requirement established by the regulation. 5 U.S.C. §§ 551(4), 552(a)(1). Therefore, in order to make a *prima facie* showing of noncompliance, CMS must show that: (1) Petitioner violated the regulation by not complying with one or more of the requirements or elements of the regulation, which is a deficiency; and (2) the deficiency amounted to "noncompliance," i.e., that Petitioner was

not in substantial compliance because the deficiency posed a risk for more than minimal harm.

In this case, the elements required of the CMS *prima facie* case to establish non-compliance with 42 C.F.R. § 483.25(h) are: (1) an accident hazard existed within the resident's environment; (2) Petitioner failed to eliminate or mitigate the accident hazard to the extent possible; and (3) Petitioner failed to ensure a resident received supervision and assistive devices necessary to prevent accidents. For noncompliance,[8] CMS must also establish that the violation of 42 C.F.R. § 483.25(h) posed a risk for more than minimal harm. The regulations do not require that CMS show that an accident was foreseeable or that an accident actually occurred. The regulation establishes impossibility as a possible defense, i.e., Petitioner did all that was reasonably possible to mitigate or eliminate the risk but an accident occurred despite the steps taken. Board decisions also recognize a possible defense by providing that a facility is only responsible to eliminate or mitigate reasonably foreseeable risks for accidental injury. *Maine Veterans' Home – Scarborough*, DAB No. 1975, at 6-7.

At the hearing, Surveyor Wagenseller testified concerning: his discovery of the failure of Petitioner to use the Viking M lift with the safety clips; his discovery that no one at the facility had the manufacturer's instructions for the Viking M lift; the lack of maintenance performed on the Viking M lift other than calibrating the scale; and that no safety clips were on the Viking M lift on the day of the return visit, August 16, 2011. Surveyor Wagenseller also testified to his conversation with Ms. Nakyeyune, a HCNA present at the time of Resident 1's fall. Further, Surveyor Wagenseller testified to the conversation he had with the service representative from Hill-Rom about the function of safety clips and the conversation he had with the product technician from Hill-Rom's customer service department and the manufacturer's user's guide instructions.

CMS provided a transcript of an oral deposition of Dennis Detmer as CMS Ex. 21. Mr. Detmer is a Technical Product Manager at Hill-Rom, the parent company of Liko, the manufacturer of the Viking M lift. Mr. Detmer is considered an expert regarding lifts at Hill-Rom. CMS Ex. 21, at 24-25. Mr. Detmer confirmed that, per the instruction guide, all sling bars for the Viking M lift come with safety latches and that the safety latch function should be checked each day prior to use. CMS Ex. 21, at 33, 40-41; CMS Ex. 16, at 12. The lift instruction guide states that the standard care and maintenance of the lift includes checking the safety latch function daily to ensure the safety of those being lifted. CMS Ex. 21, 40-41; CMS Ex. 16, at 12. Mr. Detmer was asked:

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[8] Noncompliance is "any deficiency that causes a facility to not be in substantial compliance," which is "a level of compliance . . . such that any indentified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm." 42 C.F.R. § 488.301.

> Q: Would a Viking M lift that does not have safety latches be considered safe for use in a nursing home or hospital?
>
> A: It would not be considered safe for use in any facility, or any, in lifting point. [sic]
>
> Q: And why do you say that?
>
> A: Without the safety latch in place there's a possibility that the loop on the sling could become disengaged, which would then put the patient at risk.
>
> Q: And by risk, what do you mean?
>
> A: In a position that could possibly lead to a fall.

CMS Ex. 21, at 43-44. At another point in his deposition, Mr. Deter stated that "[w]ithout the safety latch there it's **very possible** for the loop to come out of the hook and then you could cause an accident." CMS Ex. 21, at 48 (emphasis added).

CMS argues that the absence of safety latches from Petitioner's Viking M lift renders the lift unsafe. It is undisputed that the Viking M lift did not have safety latches at the time of Resident 1's fall or at any time since it was purchased. Tr. at 38, 48, 64-65, 93, 102; CMS Ex. 1, at 3-5; CMS Ex. 11. The manufacturer's instructions require safety latches for the safe use of the lift. Tr. at 47; CMS Ex. 11, at 4-5; CMS Ex. 16; CMS Ex. 21, at 43-44. Petitioner did not have an instruction manual for the Viking M lift at the time of the accident. No one at Petitioner's facility testified that the facility had the instruction manual for the Viking M lift at any time since the lift was purchased in 2007. It is also undisputed that Petitioner did not have required annual inspections of the lift from the manufacturer or daily inspections by the user of the safety latch function prior to each use. Tr. at 36, 45-46, 79, 110-13; CMS Ex. 21, at 12. CMS argues that a facility has a duty to properly use and maintain equipment that could be the cause of falls, such as a lift. CMS asserts that the lack of safety latches on the lift and the resulting unsafe conditions for transferring all the residents — and not just Resident 1's fall — support the citation of the deficiency at issue. The foreseeability of Resident 1's accident is plainly established by the instruction manual's warning to use safety clips and to check the function of the safety clips each day prior to use.

CMS has presented sufficient evidence to establish noncompliance, absent effective rebuttal. Operating a significant piece of equipment, like a lift, without access to the manufacturer's instructions and without safety clips designed to prevent the sling from becoming loose from the sling bar — lapses that could and did result in a resident's fall — was quite simply waiting for the accident that eventually happened. Petitioner did not

check the safety clips daily as instructed by the manufacturer, did not perform maintenance on the lift, and did not have annual maintenance performed by a manufacturer's representative. Use of the Viking M lift without safety clips posed a risk for an accident that could result in a fall.[9] Falls in any population, and particularly in a nursing home filled with elderly fragile individuals, poses a risk of more than minimal harm.

Petitioner presented only one witness, Diana Klarenbach, Petitioner's DON. She testified that: she herself had never actually used a lift but had observed a lift being used; she never saw or knew about safety clips or latches for this lift; and that she believed that the clips had no function once a resident is lifted because of the effect of gravity. Tr. at 106. Ms. Klarenbach admitted that safety clips were missing from the Viking M lift. Tr. at 110-111. Ms. Klarenbach admitted that without reference to the instruction manual she would not know the function of safety clips for the Viking M lift. Tr. at 111-113; 103-104. She admitted that the Viking M lift was used for approximately 25 residents, one to three times per day. CMS Ex. 1, at 3, 5; Tr. 43, 78-79. In Ms. Klarenbach's opinion, caregivers shouldn't provide upward support during the use of the lift. Tr. at 125.

I place little reliance on Ms. Klarenbach's opinion since she never actually used a lift herself and had no knowledge that safety clips were required by the manufacturer for safe use of the lift.

Petitioner puts forth two main arguments. First, Petitioner argues that it used the Viking M lift for approximately seven years without any previous resident falls. Petitioner asserts that since Resident 1's fall was the only fall that happened as a result of using the Viking M lift, the failure to use the safely clips could not have been significant. The fact the Petitioner's residents had never previously fallen as a result of using the Viking M lift without safety clips is simply fortuitous and not a persuasive argument. CMS aptly draws an analogy to driving in a car without seatbelts. Merely because the car was never in an accident does not make it safe to drive in a car without seatbelts.

Second, Petitioner argues that the HCNAs involved in Resident 1's fall were employees of Apreva and were not Petitioner's employees. Petitioner asserts that it should not be held responsible for the training of HCNAs. The issue, however, is not who employed the HCNAs involved in this fall but whether Petitioner was routinely using a Viking M

[9] While the "accident" itself in this case is not a basis for finding Petitioner was not in substantial compliance, the occurrence of the accident identifies the accident hazard, and the facts and circumstances of the accident are evidence of noncompliance. *Lake Park Nursing & Rehab. Center*, DAB No. 2035, at 8 (2006) (citing *St. Catherine's Care Center of Findlay, Inc.*, DAB No. 1964 (2005)).

lift that was not safe to use.[10] The testimony clearly shows that the Viking M lift was not intact and did not have required safety clips. Safety clips are safety equipment intended by the manufacturer to ensure safe transfer of patients and residents.

Petitioner makes several other arguments, none of which I find persuasive. Petitioner asserts that the presence of safety latches on the Viking M lift was irrelevant to the operation of the lift because once the resident was lifted, the resident's weight prevents the sling from disengaging from the sling bar. CMS Ex. 21, at 55-56; Tr. at 103. Petitioner claims that Resident 1 suffered a fall towards the end of the lifting operation, after Resident 1 had been in the lift for a few minutes. P. Ex. 5, at 6. Tr. at 61-62. Again, Petitioner misses the basis of the deficiency: it is not just Resident1's fall that is the basis of the deficiency but the absence of safety latches from Petitioner's Viking M lift that *rendered the lift unsafe for every resident that used it each time it was used*. It is well established that a violation of a deficiency can exist in the absence of any accident resulting in an injury or other harm to a resident. *Buena Vista Care Center*, DAB No. 2498, at 6 (2013).

Petitioner claims that it followed manufacturer's safety instructions. In fact, Petitioner claims that instruction manual does not mention safety latches. P. Br. at 13. Petitioner is mistaken. On page 9 of the owner's manual there is a diagram of the Viking M lift with parts of the lift labeled. The diagram labels the fourth part as "4. Sling bar with safety latches." P. Ex. 32, at 9. The owner's manual also clearly states, "to ensure trouble free operation, certain components should be checked each day the lift system is used . . . check safety latch function." P. Ex. 32, at 20. The fact that the owner's manual does not specify that checking the safety latch function is a safety function is irrelevant. It is clear that Petitioner did not follow the owner's manual. In fact, prior to the complaint survey, Petitioner did not even have a copy of the owner's manual. It is also clear that the part missing from Petitioner's Viking M lift is called a "safety latch" which would imply to a reasonable reader some safety-related function in the part in question.

Petitioner argues that if I conclude that Petitioner was not in substantial compliance with program participation requirements, the deficiency did not pose immediate jeopardy. P. Br. at 13-15. Whether the declaration of immediate jeopardy was clearly erroneous is not an issue in this case as neither the PICMP nor the loss of NATCEP authority would be affected by a decision that the declaration of immediate jeopardy was clearly erroneous. 42 C.F.R. § 498.3(b)(14), (d)(10)(i); *Fort Madison Health Center*,

[10] As mentioned previously, according to the agreement between Petitioner and Apreva, Petitioner was responsible for maintaining "adequate facilities and equipment" and the term "equipment" includes the Viking M lift. P. Ex. 3, at 3; Tr. at 115.

DAB No. 2403, at 12-13 (2011) (recognizing that substantive review of an immediate jeopardy determination is not available if CMS proposes only a PICMP).

The evidence clearly shows that Petitioner used the Viking M lift daily for many residents, up to 75 uses per day, for several years. Petitioner used this lift without the benefit of safety latches, without following manufacturer's instructions and guidelines, and without performing necessary maintenance or performing any inspections. Petitioner was not even aware that safety latches should be on the sling bar. Using the lift in an unsafe manner put any resident being lifted at risk of an accident at any time. The unsafe conditions at Petitioner's facility caused serious injury and harm to Resident 1 and was likely to cause serious injury, harm, impairment or death to the approximately 24 other residents who used the Viking M lift daily. Consequently, I conclude that Petitioner was not in compliance with the regulation at 42 C.F.R. § 483.25(h) posing a risk of more than minimal harm.

**2. The proposed enforcement remedy of a $10,000 PICMP is reasonable.**

**3. Petitioner's ineligibility to conduct a NATCEP is mandatory.**

I have concluded that Petitioner was not in substantial compliance with program participation requirements due to a violation of 42 C.F.R. § 483.25(h) that posed a risk for more than minimal harm. If a facility is not in substantial compliance with program requirements, CMS has the authority to impose one or more of the enforcement remedies listed in 42 C.F.R. § 488.406, including a CMP. CMS may impose a per-day CMP for the number of days that the facility is not in compliance or a PICMP for each instance that a facility is not in substantial compliance, regardless of whether the deficiencies pose immediate jeopardy. 42 C.F.R. § 488.430(a). Here, CMS proposes to impose a PICMP of $10,000 for the instance of noncompliance on August 4, 2011. Petitioner's noncompliance provides a basis for the imposition of an enforcement remedy. The CMP that CMS proposes is the maximum permissible in the range of authorized PICMPs. 42 C.F.R. §§ 488.408, 488.438.

When I conclude, as I have in this case, that there is a basis for the imposition of an enforcement remedy and the remedy proposed is a CMP, my authority to review the reasonableness of the CMP is limited by 42 C.F.R. § 488.438(e). The limitations include: (1) I may not set the CMP at zero or reduce it to zero; (2) I may not review the exercise of discretion by CMS in selecting to impose a CMP; and (3) I may only consider the factors specified by 42 C.F.R. § 488.438(f) when determining the reasonableness of the CMP amount. In determining whether the amount of a CMP is reasonable, the following factors specified at 42 C.F.R. § 488.438(f) must be considered: (1) the facility's history of noncompliance, including repeated deficiencies; (2) the facility's financial condition; (3) the seriousness of the deficiencies as set forth at 42 C.F.R. § 488.404(b), the same

factors CMS and/or the state were to consider when setting the CMP amount; and (4) the facility's degree of culpability, including but not limited to the facility's neglect, indifference, or disregard for resident care, comfort, and safety. The absence of culpability is not a mitigating factor. The factors that CMS and the state were required to consider when setting the CMP amount and that I am required to consider when assessing the reasonableness of the amount are set forth in 42 C.F.R. § 488.404(b): (1) whether the deficiencies caused no actual harm but had the potential for minimal harm, no actual harm with the potential for more than minimal harm, but not immediate jeopardy, actual harm that is not immediate jeopardy, or immediate jeopardy to resident health and safety; and (2) whether the deficiencies are isolated, constitute a pattern, or are widespread. My review of the reasonableness of the CMP is de novo and based upon the evidence in the record before me. I am not bound to defer to the CMS determination of the reasonable amount of the CMP to impose but my authority is limited by regulation as already explained. I am to determine whether the amount of any CMP proposed is within reasonable bounds considering the purpose of the Act and regulations. *Emerald Oaks*, DAB No. 1800, at 10; *CarePlex of Silver Spring*, DAB No. 1683, at 14-16 (1999); *Capitol Hill Cmty. Rehab. & Specialty Care Center*, DAB No. 1629 (1997).

The evidence documents that Petitioner was cited for a violation the same regulatory deficiency at a D level in two successive prior cycles, May 2009 and May 2010. CMS Ex. 18, at 1.

With respect to its financial condition, it was Petitioner's responsibility to produce evidence showing that it cannot pay the CMP. Petitioner was free to call any witnesses to testify to its financial condition or to submit any documentary evidence regarding its financial condition. However, Petitioner provided no evidence, either before or at the hearing, to show that its financial condition hinders it from paying the proposed CMP.

The seriousness of the deficiency was high and had the potential of causing at least minimum harm to Resident 1. It is undisputed that Resident 1's fall resulted in her broken hip. Petitioner never took any steps to identify or mitigate an accident hazard. It never attempted to obtain a manufacturer's instruction manual before the August 5, 2011 survey. It never performed necessary maintenance of the Viking M lift. It used an unsafe lift to transfer many residents on a daily basis for multiple transfers per day for an extended period of time. Petitioner, therefore, demonstrated a very high level of culpability for the serious harm that Resident 1 suffered and the serious harm that could have occurred to any of its other residents using this lift. Petitioner never availed itself of the basic steps of obtaining and reading the instruction manual, and of performing needed maintenance or inspections. Petitioner ignored the obvious accident hazard posed by its failure to use safety latches, which it could have easily remedied. The regulation defines "culpability" as "neglect, indifference, or disregard for resident care, comfort, and safety." 42 C.F.R. § 488.438(f)(4). Petitioner is culpable because it failed to use the safety clips that the manufacturer clearly required for the safe transfer of residents.

Petitioner not only ignored the safety manual's instruction to check the function of the safety clips each day but it did not even have a copy of the safety manual. I conclude that Petitioner's failure to use safety clips reflects a high level of neglect, indifference, or disregard for its residents' safety.

It is not disputed that Resident 1 suffered a broken left hip as a result of the fall she sustained when she was being transferred using the Viking M lift. When a facility's deficient conduct results in actual harm to a resident, the seriousness of its noncompliance is arguably severe. Here, Petitioner did not follow manufacturer's instructions to ensure the safe use of a lift that is used up to 75 times each day. There was a potential that residents would suffer more than minimal harm during each of those 75 daily uses.

Given the history of noncompliance, the seriousness of the deficiency, and the culpability of the facility, the CMP is reasonable. CMS imposed a penalty of a $10,000 per-instance CMP, which although at the higher range for a per-instance CMP ($1,000-$10,000), is modest considering what CMS might have imposed considering the evidence of multiple uses over a period of years of an unsafe lift. *See Plum City Care Center*, DAB No. 2272, at 18-19 (2009) (observing that even a $10,000 per-instance CMP can be "a modest penalty" when compared to what CMS might have imposed.)

Petitioner was notified in this case that it was ineligible to be approved to conduct a NATCEP for two years. I have concluded that a CMP of more than $5,000 is reasonable. Thus, Petitioner is ineligible to conduct a NATCEP for two years as a matter of law. 42 C.F.R. § 483.151(b)(2) and (f).

## V. Conclusion

For the foregoing reasons, I conclude that Petitioner was not in substantial compliance with program participation requirements; that a $10,000 PICMP is reasonable; and that Petitioner was ineligible to be approved to conduct a NATCEP for two years.

/s/
Richard J. Smith
Administrative Law Judge