Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Meadowwood Nursing Center
Docket No. A-13-91
Decision No. 2541
November 18, 2013

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Meadowwood Nursing Center (Meadowwood), a North Carolina skilled nursing facility (SNF), appeals the June 17, 2013 decision of an Administrative Law Judge (ALJ), *Meadowwood Nursing Center*, DAB CR2829 (2013) (ALJ Decision). The ALJ concluded that Meadowwood was not in substantial compliance with the Medicare participation requirement at 42 C.F.R. § 483.25(h) and sustained a civil money penalty (CMP) of $3,550 per day for the period March 7 through July 7, 2011.

As discussed below, we conclude that Meadowwood was in substantial compliance with section 483.25(h) through March 31 and that the noncompliance that began on April 1 continued through July 7. According, we reverse the ALJ Decision sustaining the CMP for the period March 7 through March 31, 2011 and uphold the ALJ Decision sustaining the CMP for the period April 1 through July 7, 2011.

Legal Background

To participate in Medicare, a SNF must at all times be in "substantial compliance" with the requirements in 42 C.F.R. Part 483. The Secretary contracts with state survey agencies to conduct periodic onsite surveys to assess compliance with those requirements. Social Security Act §§ 1819(g), 1864(a); 42 C.F.R. Part 488, subpart E. Survey findings are reported in a Statement of Deficiencies (SOD). A "deficiency" is a "failure to meet a participation requirement specified in the Act or [42 C.F.R. Part 483]." 42 C.F.R. § 488.301. "Substantial compliance" is "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." *Id.* "Noncompliance" is "any deficiency that causes a facility to not be in substantial compliance." *Id.* "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." *Id.*

CMS may impose various remedies on a facility that is found not to comply substantially with the participation requirements, including a per-day CMP for the number of days that the facility is not in substantial compliance. 42 C.F.R. § 488.408(d). For noncompliance determined to pose immediate jeopardy, CMS may impose per-day CMPs in amounts ranging from $3,050 to $10,000 per day. 42 C.F.R. § 488.438(a)(1)(i).

The quality of care regulations in 42 C.F.R. § 483.25 contain the overarching requirement that—

> [e]ach resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.

The Medicare participation requirement at issue here is 42 C.F.R. § 483.25(h), which provides:

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

It is well-established that the provisions of section 483.25(h) "come into play when there are conditions in a facility that pose a known or foreseeable risk of accidental harm." *Meridian Nursing Ctr.*, DAB No. 2265, at 9 (2009), *aff'd, Fal-Meridian, Inc. v. U.S. Dep`t of Health & Human Servs.*, 604 F.3d 445 (7th Cir. 2010). The Board has held that section 483.25(h)(1) requires that a facility address foreseeable risks of harm from accidents "by identifying and removing hazards, where possible, or where the hazard is unavoidable because of other resident needs, managing the hazard by reducing the risk of accident to the extent possible." *Maine Veterans' Home - Scarborough*, DAB No. 1975, at 10 (2005); *see also Clermont Nursing & Convalescent Ctr.*, DAB No. 1923, at 21 (2004) (to comply with section 483.25(h)(1), a facility must "eliminate or reduce the risk of accident to the greatest degree practicable" (emphasis in original)), *aff'd, Clermont Nursing & Convalescent Ctr. v. Leavitt*, 142 F. App`x 900 (6th Cir. 2005). Further, section 483.25(h)(1) "places a continuum of affirmative duties on a facility" to identify, remove, and protect residents from hazards. *Maine Veterans' Home* at 6-7. "[W]here a facility takes action to remove a hazard but then has reason to know that those measures are substantially ineffective, the facility must, if possible, implement more effective measures." *Estes Nursing Facility Civic Ctr.*, DAB No. 2000, at 7 (2005).

The Board has also stated that section 483.25(h)(2) requires that a facility take "all reasonable steps to ensure that a resident receives supervision and assistance devices that meet his or her assessed needs and mitigate foreseeable risks of harm from accidents. *Woodstock* [*Care Ctr. v. Thompson*,] 363 F.3d [583,] at 590 [(6th Cir. 2003)] (facility must take 'all reasonable precautions against residents' accidents')." *Briarwood Nursing Ctr.*, DAB No. 2115, at 11 (2007). "[I]f a facility implements accident prevention measures for a resident but has reason to know that those measures are substantially ineffective in reducing the risk of accidents, it must act to determine the reasons for the ineffectiveness and to consider -- and, if practicable, implement -- more effective measures. *Woodstock* [*Care Ctr.*, DAB No. 1726,] at 28 [(2000)] (affirming CMP based on evidence that facility failed to change its practices after it became clear those practices were ineffective)." *Residence at Kensington Place*, DAB No. 1963, at 9 (2005).

The regulations permit facilities "the flexibility to choose the methods" they use to provide supervision or assistive devices to prevent accidents, so long as the chosen methods constitute an adequate level of supervision for a particular resident's needs. *Windsor Health Care Ctr.*, DAB No. 1902, at 5 (2003), *aff'd, Windsor Health Care Ctr. v. Leavitt*, 127 F. App'x 843 (6th Cir. 2005). "The regulation speaks in terms of ensuring that what is 'practicable' and 'possible' to do is done. What is thus required of facilities is not prescience but reason and professional judgment in assessing what can be done to make residents (given their special needs) safe, through removing accident hazards, providing appropriate devices, and ensuring adequate supervision." *Josephine Sunset Home,* DAB No. 1908, at 15 (2004).

The "mere fact that an accident occurred does not, in itself, prove that the supervision or devices provided must have been inadequate to prevent it." *Josephine Sunset Home* at 14. The occurrence of an accident is relevant to the extent the surrounding circumstances shed light on the nature of the supervision being provided and its adequacy for the resident's condition. *St. Catherine's Care Ctr. of Findlay, Inc.*, DAB No. 1964, at 12-14 (2005) (accident circumstances may support an inference that the facility's supervision of a resident was inadequate). It is not a prerequisite to finding noncompliance under section 483.25(h)(2) that any actual accident have occurred or be caused by the inadequate supervision. *Woodstock Care Ctr.*, DAB No. 1726, at 17 ("observations and the occurrence of events other than accidents may suffice to expose the absence of supervision adequate to prevent accidents"), 36.

CMS's State Operations Manual (SOM) states that side rails are assistive devices that can assist with transfers and positioning, but also recognizes that side rails "can increase resident safety risk." SOM, Appendix PP, F323.[1] The SOM indicates that side rails "that are defective; not used properly or according to manufacturer's specifications; . . . and/or

[1] Appendix PP of the SOM is at https;//cms.hhs.gov/Regulations_and_Guidance/Guidance/Manuals/downloads/som107ap_pp_guidelines_ltcf.pdf.

used without adequate supervision, in relation to the facility's assessment of the resident" can constitute accident hazards. *Id*. The SOM also notes that the Food and Drug Administration (FDA) issued a safety alert in 1995 regarding the risk of entrapment posed by side rails. *Id*. The most recent FDA guidance on side rail entrapment is the March 10, 2006 *Guidance for Industry and FDA Staff: Hospital Bed System Dimensional and Assessment Guidance to Reduce Entrapment* (CMS Ex. 28). The ALJ noted that the "FDA recommends a dimensional limit of less than 4.75 inches for the area . . . between the rail and the mattress." ALJ Decision at 5, citing CMS Ex. 28, at 18-20. Meadowwood acknowledges that this guidance is part of "the clinical standards of care that govern or influence the use of side rails[.]" P. Reply Br. at 6.

Case Background

The following facts are undisputed. Surveyors from the State agency conducted a complaint investigation, recertification, and revisit survey of Meadowwood, a 50-bed SNF, from July 5-8, 2011. CMS Ex. 3, at 1; ALJ Decision at 2. The SOD stated that "[b]ased on observation, record review and staff interviews the facility failed to position mattresses and side rails in such a manner to maintain the safety" of R2 and R8, two of 10 sampled residents who used side rails. CMS Ex. 4, at 1. According to the SOD, immediate jeopardy began on March 7 and was removed on July 8 when Meadowwood provided and implemented a credible allegation of compliance. *Id*.

R2 was admitted to Meadowwood in 2005 with diagnoses including stroke, left sided paralysis, aphasia, abnormal posture, and dementia. CMS Ex. 4, at 2. The Minimum Data Set used to assess her abilities and needs indicated that she required extensive assistance to turn from side to side and position her body in bed. *Id.* A Siderail Utilization Assessment for R2 dated December 21, 2010 stated that side rails were indicated and served as an enabler to promote independence in position and bed mobility. *Id*.; CMS Ex. 11, at 123. On March 7, 2011, a nurse aide found R2 in bed "with her head under the side rail and the rail resting on her neck." CMS Ex. 4, at 1, 4. R2's bed had full side rails and the head of the bed was raised approximately 20 to 30 degrees, creating the gap between the mattress and the full side rail in which R2 was entrapped. *Id*. at 1, 5; *see also* Tr. at 41 (surveyor's testimony that the mattress bends midway down the bed when the head of the bed is raised). A nurse whom the nurse aide asked for help lifted the rail off of R2's neck. CMS Ex. 4, at 4; CMS Ex. 11, at 11. The nurse prepared an incident report that evening (which neither party submitted) and also stated in nurse's notes on March 8 that "at approximately 11:10 p.m. last night this nurse was informed that resident had somehow gotten head under left bedrail and it was resting on . . . right side of neck with substantial pressure. No apparent injury found . . . ." CMS Ex. 4, at 3; CMS Ex. 11, at 14, 32. The March 8 nurse's notes also state that the incident was reported to the State agency. CMS Ex. 11, at 32. At 10:48 a.m. on March 8,

Meadowwood's Director of Nursing (DON) e-mailed its administrator stating that she had received an incident report that R2 "was found with her head under the side rail with the rail pressing down on [her] neck." P. Ex. 6. The e-mail continued: "The steps that we have already implemented were [sic] removal of the side rails and an alarm while patient in or out of bed. It is my recommendation that we conduct a safety audit on all residents in use of side rails and look into other options due to the high risk of injury related to using full side rails." *Id*.

R8 was admitted to Meadowwood in 2007 with diagnoses including obesity, altered mental state, and lumbar spine degeneration. CMS Ex. 4, at 6; CMS Ex. 33, at 3. Her Minimum Data Set indicated that she required extensive staff assistance for transfers and had impaired mobility of both lower extremities. CMS Ex. 4, at 7. R8 had a Siderail Utilization Assessment dated April 19, 2011 and used side rails to enable positioning or support. *Id*. On July 5, 2011 at 11:58 a.m., a surveyor observed R8 lying in her bed on her back with her head and shoulders positioned in the middle of the mattress. *Id*. The two full side rails were up, but the "right side rail was splayed outward at the head of the bed with the mattress shifted against that portion of the side rail. This exposed the bed frame on the left side leaving a gap" of at least five inches at the head of the bed between the rail and the mattress.[2] *Id*.; ALJ Decision at 11; Tr. at 79. The surveyor made the same observation at 3:15 p.m. CMS Ex. 4, at 8. At 5:27 p.m., the surveyor observed R8 in bed with the head of the bed in the up position eating her supper without assistance. *Id*. The side rails were in the same position as previously observed and the "bed frame continued to be exposed at the head of the bed on the left side" as previously observed. *Id*. After the surveyor pointed out the gap to the maintenance director, he determined that the latch on the "splayed out" side rail "had become disengaged from the bed frame at the head of the bed[.]" *Id*.

We identify other undisputed facts as relevant below.

The ALJ Decision

The ALJ Decision specifically identifies the following as findings of fact and conclusions of law (FFCLs):

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

[2] According to Meadowwood, the gap was narrower in the center of the bed than at the top. P. Reply Br. at 13 ("simple math shows that if the gap was eight inches at the top, it must have been only four inches in the center").

1. Petitioner was placed on notice of a foreseeable risk of harm when Resident 2's neck became entrapped in her bed's side rails.
2. Petitioner took some reasonable steps to eliminate the foreseeable risk of accidents involving bed side rail entrapment.
3. Petitioner did not reasonably address all foreseeable risks of accidents involving bed side rail entrapment because Petitioner did not correct a gap between the mattress and the side rail in Resident 8's bed.

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

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

ALJ Decision at 4, 5, 8, 9, 13, 15.

Standard of Review

We review a disputed finding of fact to determine whether the finding is supported by substantial evidence in the record as a whole, and a disputed conclusion of law to determine whether it is erroneous. *Departmental Appeals Board, Guidelines --Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's Participation in the Medicare and Medicaid Programs,* http://www.hhs.gov/dab/divisions/appellate/guidelines/prov.html.

Meadowwood's Arguments

Meadowwood disputes both the ALJ's finding that it was not in substantial compliance as of March 7 (the date R2 was found entrapped) and his finding that the noncompliance continued through July 7. In particular, Meadowwood argues that "neither the Statement of Deficiencies nor CMS' witnesses ever alleged that Petitioner had done something wrong in the case of Resident #2." Request for Review (RR) at 12; *see also, e.g.*, RR at 13 ("there is nothing in the record to show that some act or omission *by Petitioner's staff* caused or exacerbated a dangerous situation" (italics in original)); P. Reply Br. at 1, 4. Meadowwood also asserts that it had systems for assessing residents for side rail use (pursuant to which it determined that the benefits of side rail use outweighed the risk in the case of all residents using side rails) and for preventive maintenance of beds with side rails and that it was undisputed that these systems met the standard of care. RR at 11-12, 33; P. Reply Br. at 1-2, 16-17.

According to Meadowwood, the ALJ correctly recognized that "there is *some* unavoidable risk associated with side rails, even if used properly," but impermissibly interpreted the regulation to impose "'per se' or 'strict' regulatory liability for any accident[.]" RR at 32 (italics in original), citing ALJ Decision at 4; RR at 2; *see also* RR

at 3-4 (the ALJ "held that *occurrence of the accident itself* triggered a lengthy period of 'immediate jeopardy' noncompliance simply *because of the existence of risk* associated with side rail use" (italics in original)). Meadowwood notes that in *Spring Meadows Health Care Ctr.*, DAB No. 1966 (2005), the Board stated that "[b]ecause the definition of 'immediate jeopardy' requires that there be some *causal connection* between the facility's noncompliance and the existence of serious injury or a threat of injury, the nature and circumstances of a facility's noncompliance are of obvious importance to the evaluation." RR at 25-26 (italics added by Meadowwood). Meadowwood also takes the position that, even if noncompliance existed in this case, it was "resolved completely" the day after R2's entrapment, when Meadowwood's staff removed the side rails on her bed. P. Reply Br. at 2.

Meadowwood argues further that any noncompliance was not at the immediate jeopardy level and that its financial condition warranted a reduction in the CMP amount. RR at 6-7, 37-39.

Analysis

As discussed in detail below, we conclude that the ALJ erred in determining that Meadowwood was not in substantial compliance with section 483.25(h) as of March 7, when Meadowwood found R2 with her head entrapped under a side rail. We further conclude, however, that Meadowwood failed to comply substantially with section 483.25(h) beginning April 1, when a side rail audit found six beds with gaps between the mattress and side rails that posed a risk of entrapment. At that point, Meadowwood was on notice that its existing system for identifying and fixing side rail problems was ineffective in preventing dangerous gaps. Yet, Meadowwood took no further steps to investigate how the gaps were being created or why its system was not working to prevent dangerous gaps . We therefore affirm the ALJ's conclusion that Meadowwood did not return to substantial compliance until July 8, the date determined by CMS.

In addition, as also discussed below, we affirm the ALJ's conclusions that CMS's immediate jeopardy determination was not clearly erroneous and that the $3,550 per-day CMP imposed by CMS is reasonable in amount.

I. We reverse the ALJ Decision to the extent it concludes that Meadowwood was not in substantial compliance with section 483.25(h) from March 7 through March 31, 2011.

We note preliminarily that the ALJ Decision discusses at some length the manufacturer's instructions for the beds with full side rails used by Meadowwood. Those instructions state that there will be a gap between the mattress and a side rail when the head of the bed is raised to the "semi-fowler position" and the side rail is not in the "MID" position. CMS Ex. 26, at 4. The ALJ appeared to find that R2's bed and side rail were positioned

in this manner when R2 was entrapped. *See* ALJ Decision at 6-7. Meadowwood challenges that finding on the ground that the head of a bed that is raised 20 to 30 degrees, as R2's was, is not in the "semi-fowler position," relying on the surveyor's testimony that in this position, the head of the bed is "typically [at] a 45 degree angle." *See* P. Reply Br. at 11, citing Tr. at 69-70. However, we need not reach this issue because the ALJ did not find that Meadowwood was out of compliance prior to R2's entrapment on March 7 but instead found it out of compliance beginning March 7 based on Meadowwood's inadequate response to this accident.[3]

Moreover, the ALJ made no finding that R2's entrapment was in any other way attributable to an act or omission on Meadowwood's part. Instead, the ALJ found that Meadowwood "was on specific notice of a foreseeable risk of harm" only after facility staff found R2 entrapped in a gap between her mattress and side rail on March 7. ALJ Decision at 8. Thus, the issue in this case is limited to whether Meadowwood removed or mitigated the accident hazard that was foreseeable once R2 was found entrapped. *Cf. Buena Vista Care Ctr.*, DAB No. 2498, at 11 (2013) (where a resident's first fall from bed was unforeseeable, the issue was limited to whether the supervision and interventions the facility was utilizing after that fall provided an adequate level of supervision for the resident).

The ALJ concluded that Meadowwood was not in substantial compliance with section 483.25(h) as of March 7, finding that in the days after R2's entrapment Meadowwood took only "some reasonable steps to eliminate the foreseeable risk of side rail entrapment." ALJ Decision at 8. As explained below, we conclude that this finding is not supported by substantial evidence in the record as a whole. Meadowwood promptly removed the side rails from R2's bed and took other steps based on which it could reasonably determine that no other beds had gaps posing a risk of entrapment and that its system for preventing gaps was effective.

The ALJ's discussion of his finding states that in a March 8 e-mail to the administrator, the DON noted that Meadowwood "had already removed side rails from Resident 2's bed and outfitted her with an alarm." *Id.* In addition, the ALJ Decision states: "[Meadowwood] conducted two side rail audits. A side rail audit on March 8, 2011 found

[3] CMS initially alleged that Meadowwood was not in substantial compliance with section 483.25(h) because "Resident #2 did not receive the level of supervision necessary for someone in her physical condition who also had lowered safety awareness." CMS Pre-Hearing Br. at 5. CMS appeared to rely on the length of time that elapsed between when R2 was last checked by facility staff and when she was found entrapped. However, the surveyor testified at hearing that the standard for doing routine rounds at a nursing facility is typically every two hours. Tr. at 25. CMS ultimately conceded that R2 was entrapped no more than two hours and ten minutes from the time she was last checked until she was found by facility staff (CMS Post-Hearing Br. at 6), and the ALJ did not address this issue.

broken, bent and improperly fitting side rails. CMS Ex. 24, at 1. However, a March 10, 2011 "Audit" note stated that no gaps of more than 4" were found. P. Ex. 7. . . . ." ALJ Decision at 8.

The ALJ Decision also describes the testimony of Meadowwood's maintenance director regarding the facility's system of preventive maintenance. ALJ Decision at 8, citing P. Ex. 38 and Tr. at 164, 168-169. According to the maintenance director, since he first became employed by Meadowwood three years earlier, he "check[ed] every side rail that is used every week to determine whether it is damaged or otherwise needs repair or replacement" and also checked weekly that "the beds are in working order[.]" P. Ex. 28, at 1-2; Tr. at 164. The maintenance director further testified:

> I keep a "maintenance book" at the nursing station where nurses write down anything that needs my attention, from a burned out light bulb to major repairs, and I check the book several times a day every time I walk by the nursing station . . . . I always show new nurses how to use the maintenance book, and tell them to inform me if any side rail (or anything else) is broken or needs to be replaced. I keep a supply of extra side rails on hand, so when a nurse notifies me that a side rail is broken, or I see that for myself, I change it immediately.

P. Ex. 28, at 2.[4]

Neither CMS nor the ALJ explained why the removal of R2's side rails on March 8 and the side rail audit concluded on March 10, together with the preventive maintenance system Meadowwood already had in place, were an insufficient response to R2's entrapment. As noted above, Meadowwood did not find R2 entrapped until 11:10 p.m. on March 7. Meadowwood removed the side rails from R2's bed sometime before 10:48 a.m. the next morning. On its face, this action eliminated the risk to R2 of side rail entrapment. In addition, after removing the side rails, Meadowwood lowered R2's bed and placed a protective mat on the floor next to the side of the bed that was not against the wall (CMS Ex. 4, at 4), thus mitigating the foreseeable risk to R2 of falls.

Meadowwood also took steps to ascertain whether R2's entrapment, the cause of which Meadowwood says it was unable to determine (*see, e.g.*, P. Ex. 26, at 5), was part of a broader problem. In the March 10 side rail audit to which the ALJ Decision refers, Meadowwood measured "all the gaps and spaces between mattresses and side rails[.]" Tr. at 166-167 (testimony of maintenance director). The March 10 audit note includes the comment "this shows 4 [inches] did not exist anywhere on any bed." P. Ex. 7.

[4] Although the maintenance director's testimony does not specify when he began using the "maintenance book," the record shows that it was part of his preventive maintenance system before R2 became entrapped. *See* CMS Ex. 4, at 3 (statement in SOD that when R2 was found entrapped, a "note was left in the maintenance request book to look at bed rail").

Moreover, of the 40 beds with side rails listed on the audit note, none had a gap that measured more than two and one half inches. *Id.* Thus, all of the gaps found in this audit were far smaller than the 4.75-inch gap the FDA guidance says poses a risk of entrapment. There is no definitive evidence in the record addressing whether in the case of each bed the gap was measured with the head of the bed raised, as R2's was at the time of her entrapment. However, even if the gaps were measured with the heads of the beds down, CMS made no finding as a result of the survey (and the ALJ did not address) whether raising the head of a bed would have automatically created a gap exceeding the dimensional limit specified by FDA, and an audit done during the survey with the heads of the beds up found no such gap (CMS Ex. 4, at 11-12).[5] Thus, the March 10 audit found that none of Meadowwood's residents were in beds with side rail gaps that posed a risk of entrapment.

The ALJ Decision indicates that other problems with side rails were identified in the March 8 audit, which the ALJ said found "broken, bent or improperly fitting side rails." ALJ Decision at 8. However, the surveyor testified only that the March 8 audit showed that "[t]here were still some residents who had gaps and loose bed rails."[6] Tr. at 51. Since the March 10 audit did not find any gaps larger than two and one-half inches, either any gaps identified on March 8 were not that large or they were fixed by March 10. Accordingly, Meadowwood could have reasonably determined once the March 10 audit was done that its system of preventive maintenance was adequately protecting residents in beds with side rails from the risk of entrapment presented by gaps exceeding the FDA guidance's dimensional limit of 4.75 inches.

We therefore find that as of March 10, Meadowwood had taken all reasonable steps to mitigate the risk of side rail entrapment that was foreseeable as of the night of March 7. Meadowwood eliminated the foreseeable risk to R2 less than 12 hours after Meadowwood found her entrapped under the side rail. Also, on only the third day after Meadowwood found R2 entrapped, Meadowwood completed an audit of all resident beds with side rails that did not identify any resident beds with gaps posing a risk of entrapment. Neither CMS nor the ALJ explained why these measures were not timely or adequate to address the foreseeable risks. We therefore find that substantial evidence in the record does not support a conclusion that Meadowwood failed to comply substantially with the requirements of section 483.25(h) from March 7 through March 31, 2011.

[5] The ALJ did not make any finding regarding the size of the gap on R2's bed, stating, "The fact remains that the gap was large enough, possibly in conjunction with the flexibility of the mattress, for Resident 2 to become entrapped[.]" ALJ Decision at 7.

[6] The March 8 audit document in the record at CMS Exhibit 24, at 1, is partially obscured, and the SOD does not mention a March 8 audit.

Accordingly, we reverse the ALJ Decision to the extent it upholds the CMP imposed for the period March 7 through March 31, 2011 based on the ALJ's conclusion that Meadowwood was not in substantial compliance with section 483.25(h) during that period.

II. We sustain the ALJ Decision to the extent it concludes that Meadowwood was not in substantial compliance with section 483.25(h) during the period April 1 through July 7, 2011.

Although Meadowwood's March 10 side rail audit found that no beds had gaps posing a risk of entrapment, another side rail audit on April 1 demonstrated otherwise. The nurse who conducted the April 1 audit found a "space" between the mattress and side rail on six resident beds on which the head of the bed was raised and identified four of these spaces as a "large space." CMS Ex. 24, at 2. The nurse told the surveyor during the July survey that all six gaps were "too large." CMS Ex. 4, at 6. Although the nurse did not identify the dimensions of the gaps or expressly state that they posed a risk of entrapment, the ALJ could reasonably infer from her description of the gaps as "too large" that she meant they posed a risk of entrapment.[7] Thus, the April 1 audit put Meadowwood on notice that there were several gaps posing a risk of entrapment to residents other than R2 (as to whom the risk had been eliminated) notwithstanding the system of preventive maintenance that was in place. For the following reasons, we conclude that Meadowwood did not show it took steps that adequately addressed the risk of entrapment that was foreseeable as of April 1 prior to July 8, the date determined by CMS. We therefore conclude that Meadowwood was not in substantial compliance with section 483.25(h) from April 1 through July 7.

Meadowwood points to the fact that on April 1, it was in the process of replacing full side rails such as those on R2's bed with half side rails. RR at 21, 35. However, Meadowwood's maintenance director testified that Meadowwood did not replace all full rails with half rails until July 7. Tr. at 170. Meadowwood did not allege that it immediately replaced any full rails on the six beds identified in the April 1 audit as having gaps or that none of the residents who still had full side rails after April 1 were at risk of being entrapped (e.g., due to personal characteristics). Nor did Meadowwood point to any evidence that it had investigated why, despite the system it had in place for maintaining beds with side rails, dangerous gaps were still being discovered, or even allege that it had reminded staff to report any maintenance problems that might cause such gaps. Indeed, Meadowwood does not deny that the nurse who conducted the April 1 audit told the surveyor during the July audit that she had given the audit results to the DON (presumably upon completion of the audit) but did not know what the DON did

[7] Meadowwood did not deny that the nurse made this statement to the surveyor or submit any testimony from her that would undercut the inference the ALJ drew from her statement.

with them. CMS Ex. 16, at 7. If any steps had been taken to address the systemic problem she had reported, one would reasonably expect the nurse to have been aware of them. Moreover, Meadowwood does not point to any evidence that the DON took any action in response to the April 1 audit. Nor does Meadowwood allege that any other staff members took steps to prevent the large gaps identified in the April 1 audit prior to July 7, when Meadowwood submitted its plan of correction and credible allegation of compliance.[8] That there were other reasonable steps Meadowwood could have taken is clear from the plan of correction. *See* CMS Ex. 7; *see also* CMS Ex. 4, at 9-14.

Meadowwood instead relies on its repeated assertion that CMS does not dispute either that all residents using side rails were properly assessed as needing to use side rails or that Meadowwood's system of preventive maintenance met the standard of care. However, the record does not support Meadowwood's assertion that CMS conceded that its preventive maintenance system met the standard of care "at all pertinent times." RR at 11-12, citing Tr. at 34-38.[9] Moreover, Meadowwood does not contend that the assessments meant it did not need to take all reasonable steps to reduce the risk of entrapment from gaps.

Furthermore, as the ALJ found, the record shows that residents were still at risk of entrapment as late as July 5, when a surveyor observed a gap larger than the dimensional limit of 4.75 inches in the FDA guidance between the mattress and an unlatched side rail on R8's bed three times in one afternoon. According to the ALJ, the fact that Meadowwood's "staff did not recognize" this gap until the surveyor pointed it out "confirmed a lack of facility vigilance[.]" ALJ Decision at 16; *see also id*. at 10.[10]

Meadowwood argues that the ALJ erred in relying on the surveyor's observation because R8 was not in fact at risk of entrapment. According to Meadowwood, it was impossible for R8 to become entrapped in the gap given her large size (close to 300 pounds) and limited bed mobility. RR at 5, 22-23. Meadowwood also claims that the FDA guidance does not apply to "bariatric (obese) patients such as Resident #8[.]" RR at 16. The ALJ

[8] Meadowwood says its staff "consulted with various clinical and operational experts," noting that "a draft internal Quality Assurance report [was] prepared by Petitioner's outside risk management consultant several months following Resident #2's accident that contained candid assessments of various facility policies and events, including side rail use." RR at 3, and *id*. n.1. However, Meadowwood does not allege that it took any actions based on this report (which is the same document Meadowwood sought to exclude from the record, as indicated in a later note).

[9] In the cited testimony, the surveyor merely stated that she saw nothing about the facility's system for assessing and deciding to use side rails that was beneath an applicable standard of care. Tr. at 38.

[10] In support of his conclusion that Meadowwood had not taken all reasonable steps to address the foreseeable risk of entrapment, the ALJ also relied on a May 11, 2011 "Community Performance Improvement Plan" that recommended "corrective action" to address the risk of side rail entrapment. ALJ Decision at 9, citing CMS Ex. 23. Meadowwood argues that the ALJ erred in denying its motion to strike this document. RR at 3, n.1, 26-31. We need not address this argument because we conclude, without relying on this document, that substantial evidence in the record supports the ALJ's conclusion with respect to the period April 1 through July 7, 2011.

rejected the same arguments. ALJ Decision at 11-12. As the ALJ correctly pointed out, the FDA guidance specifically excludes "bariatric beds" (not bariatric patients) from the recommended dimensional limits, but nonetheless suggests that "users identify and address areas of potential entrapment for each patient or resident through a comprehensive bed safety program." CMS Ex. 28, at 11.[11] We conclude, moreover, that the "lack of facility vigilance" showed that other residents were at risk of entrapment from gaps even if R8 was not.

It is undisputed that Meadowwood's maintenance director, administrator, and administrative manager told the surveyor that R8's caregivers should have reported the gap on her bed. CMS Ex. 33, at 5; Tr. at 111. The ALJ could reasonably infer from this, as well as from the maintenance director's testimony that he explained to all new staff how to use the maintenance book, that Meadowwood expected its staff to check for gaps when they provided care. However, it is undisputed that R8's caregivers told the surveyor they did not notice the gap on R8's bed (*see* CMS Ex. 4, at 9; Tr. at 87-88; CMS Ex. 16, at 7), and the ALJ could reasonably conclude from the size of the gap that it was noticeable. Thus, even if R8 was not at risk of entrapment, residents other than R8 were at risk of entrapment from gaps that might have gone unnoticed by those residents' caregivers.

Meadowwood asserts that "[a]ll that the surveyor saw was a mechanical malfunction that is inherent in using side rails," that the gap could have been caused "by a nurse leaning against [the side rail] while providing care," that its nurses "routinely report such matters to [Meadowwood's] Maintenance Director, and that the response is simply to relatch the rail – which is exactly what happened here." RR at 36; P. Reply Br. at 12. Meadowwood ignores the fact that the surveyor's observations of R8 showed that nurses did <u>not</u> report the gap and that the rail was <u>not</u> relatched until after the surveyor alerted facility staff that there was a gap. Moreover, if the side rail became unlatched because a nurse (or other caregiver) leaned against the side rail, the nurse should have been aware of the problem and reported it. Thus, Meadowwood's assertions do not undercut the ALJ's finding that facility staff should have been expected to notice and report the gap between R8's mattress and side rail at some point during the period of more than five hours over which the surveyor observed the gap.

[11] The ALJ observed that there is no evidence that R8 was in a bariatric bed and that the surveyor testified that R8 "was in what appeared to be a normal, not a bariatric bed." ALJ Decision at 12, citing Tr. at 80. Meadowwood does not argue on appeal that R8 was in a bariatric bed. In any case, it is irrelevant whether the FDA guidance excludes obese patients as well as bariatric beds from its recommendations because Meadowwood does not argue that it had a policy that staff need not identify and report large gaps in beds occupied by residents who are obese.

Meadowwood also argues that the surveyor's observation of this gap is not evidence that the facility had failed to take all reasonable steps to mitigate the risk of entrapment foreseeable from R2's accident because R2 and R8 had nothing in common other than that they were both in beds with side rails. RR at 5, 37. It is true that the gap between R2's mattress and side rail differed from the gap between R8's mattress and side rail with respect to its cause and location, and that R2 and R8 differed with respect to their mobility and other characteristics. These differences are immaterial under our analysis, however. That analysis focuses on the inadequacy of the steps Meadowwood took after the April 1 side rail audit identified six beds with large gaps between the mattress and side rail and put Meadowwood on notice that its systems were ineffective to ensure that the facility was as free of accident hazards as possible. After the April 1 audit, Meadowwood, at the very least, should have recognized that R2's entrapment may have resulted from a systemic problem that allowed the creation of large gaps, rather than being attributable to her personal characteristics. Meadowwood's failure, at that point, to adequately address the problem is particularly troublesome, given that R2's entrapment should have heightened Meadowwood's awareness of the importance of being alert to the potential hazards from side rails.

Accordingly, we conclude that there is substantial evidence in the record to support the ALJ's decision sustaining the imposition of a CMP for the period April 1 through July 7, 2011 on the ground that Meadowwood was not in substantial compliance with section 483.25(h).[12]

III. We sustain the ALJ's conclusion that CMS's immediate jeopardy determination was not clearly erroneous.

As noted, "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." 42 C.F.R. § 488.301. CMS's immediate jeopardy finding "must be upheld unless it is clearly erroneous." 42 C.F.R. § 498.60(c)(2). "The 'clearly erroneous' standard ... is highly deferential and places a heavy burden on the facility to upset CMS's finding regarding the level of noncompliance." *Yakima Valley School*, DAB No. 2422, at 8 (2011) (citing cases).

[12] Meadowwood notes that a survey in May 2011 did not cite any noncompliance with section 483.25(h) and asserts that "CMS never explained how Petitioner's staff could have been on notice that any noncompliance relating to side rails extended back to" an earlier date. RR at 7, n.2, 36. However, Meadowwood acknowledges that 42 C.F.R. § 488.430(b), which precludes the imposition of a CMP for past noncompliance before the last standard survey, does not apply to this case because the May 2011 survey was a complaint survey. *Id*., n.2. Meadowwood also suggests that the fact the May 2011 survey cited no noncompliance calls into question the findings of the July 2011 survey. P. Reply Br. at 18-19. However, the Board has held that a state agency's "previous failure to detect a deficiency does not invalidate an adequately documented deficiency." *Maine Veterans' Home* at 21.

As discussed above, as of April 1, Meadowwood was not in substantial compliance with section 483.25(h) because it was not taking all reasonable steps to address the foreseeable risk of entrapment in side rail gaps. The ALJ upheld CMS's determination that this noncompliance posed immediate jeopardy based on evidence in the record "that entrapments are likely to lead to serious injury or death to a resident." ALJ Decision at 13. The ALJ pointed out that, according to the FDA guidance, of the 691 people for whom FDA received entrapment reports from 1985 to 2006, "413 people died, 120 were injured, and 158 were near-miss events with no serious injury as a result of intervention." *Id*. at 14, quoting CMS Ex. 28, at 6. The ALJ also stated that one surveyor "credibly opined that Resident 2's entrapment could have seriously injured or killed her"; another surveyor "credibly testified" that the gap on R8's bed "was likely to cause a serious injury, such as Resident 8's head getting caught in the gap"; and that Meadowwood's interim administrator "acknowledged that entrapment could cause a loss of breathing." *Id*., citing CMS Ex. 34, at 6; CMS Ex. 33, at 4-5; Tr. at 86-88; and P. Ex. 25, at 3.

Meadowwood takes the position that CMS's immediate jeopardy determination was clearly erroneous, arguing that the surveyors found immediate jeopardy based on the erroneous belief that "the regulation allowed them to cite an 'immediate jeopardy' deficiency simply because Resident #2 suffered an accident, whether or not [Mreadowwood] was responsible for that accident." P. Reply Br. at 19; *see also* RR at 37-38. This argument lacks merit. The ALJ relied on the surveyors' opinions regarding the likelihood of serious harm to R2 and R8, not on their opinions as to whether, as a matter of law, the noncompliance posed immediate jeopardy. Moreover, Meadowwood's argument is, in effect, that there was no basis for finding immediate jeopardy because there was no basis for finding noncompliance in the first instance. As we have concluded above, however, substantial evidence supports the ALJ's conclusion that Meadowwood was not in substantial compliance for the period April 1 through July 7, 2011.

Meadowwood also argues that any noncompliance did not pose immediate jeopardy because "'immediate jeopardy' noncompliance – that is, the 'likelihood' of death or serious harm – ought not to be hypothetical, conjectural or remote." RR at 38. According to Meadowwood, both FDA and the Consumer Product Safety Commission (CPSC) have noted that "the rate of serious injury or death associated with use [of side rails] is actually very low." *Id*. In Meadowwood's view, "[i]t makes no sense to impose huge sanctions simply because it is *possible* for a device – *even if properly used* – to cause harm." *Id*. (italics in original).

Meadowwood's reliance on the data in the FDA guidance is misplaced. FDA did not offer the data to show the statistical likelihood that an individual in a bed with side rails will be seriously injured or die as a result of being entrapped in the side rails. Instead,

FDA identified "several limitations of these adverse event report data," and stated that "[d]espite these limitations, adverse event reports can suggest a profile of the areas or locations on a hospital bed that present a risk of entrapment, as well as the parts of the body that are at risk of entrapment." CMS Ex. 28, at 6, n.9.

The ALJ did not admit the October 11, 2012 CPSC memorandum on which Meadowwood relies, finding no good cause for permitting Meadowwood to supplement its evidentiary exchange with this document after the hearing and post-hearing briefing periods concluded. ALJ Decision at 14. In any event, as the ALJ noted, this document undercuts Meadowwood's position because it shows that 145 of the 160 incidents reported to the CPSC involved side rail entrapments, and of those, 143 resulted in fatalities. *Id*.

Moreover, Meadowwood does not dispute the surveyor's testimony that R2's entrapment could have seriously injured or killed her. Meadowwood can hardly argue that R2's situation was unique after admitting that it was unable to determine how R2 became entrapped and points to no evidence distinguishing R2 from the six residents whose beds were identified in the April 1 audit as having a gap between the mattress and side rail that posed a risk of entrapment. Thus, the ALJ could reasonably infer that it was likely that those residents could become entrapped in the gap and be seriously injured or die.

Accordingly, we find no basis for overturning the ALJ's conclusion that CMS's immediate jeopardy determination was not clearly erroneous.

IV. We uphold the ALJ's conclusion that the $3,550 per-day CMP imposed by CMS is reasonable in amount.

An ALJ (or the Board) determines de novo whether a CMP is reasonable based on the factors specified in section 488.438. *See* 42 C.F.R. § 488.438(e), (t). Those factors are: (1) the facility's history of noncompliance; (2) its financial condition -that is, its ability to pay a CMP; (3) the severity and scope of the noncompliance, and "the relationship of the one deficiency to other deficiencies resulting in noncompliance"; and (4) the facility's degree of culpability, which includes neglect, indifference, or disregard for resident care, comfort or safety. 42 C.F.R. §§ 488.438(f), 488.404(b), (c)(l).

The ALJ noted that the $3,550 per-day CMP imposed by CMS "is in the very low range for immediate jeopardy level noncompliance." ALJ Decision at 15. The ALJ found that Meadowwood's "history of noncompliance fully supports the relatively low CMP[.]" *Id*. The ALJ also relied on two other regulatory factors, stating, "[Meadowwood's] deficiency is also serious (constituting immediate jeopardy to its residents) and [Meadowwood] is culpable for identifying risks but not reasonably addressing those foreseeable risks of entrapment." *Id*. at 16. As indicated above, the ALJ also found that

Meadowwood's noncompliance was at the immediate jeopardy level. Moreover, Meadowwood's failure to take steps in response to the April 1 audit shows at the very least sufficient indifference to resident safety to justify setting the per-day CMP amount at $500 above the minimum for immediate-jeopardy level noncompliance.

The ALJ rejected Meadowwood's argument "that its financial condition should be considered in mitigation of the CMP" because "the CMP imposed is greater than its annual operating budget[.]" ALJ Decision at 16. The ALJ found that Meadowwood had not met its "burden of proving that payment of the CMP would result in closure of its facility or compromise in resident health and safety." *Id*., citing *Oceanside Nursing & Rehab. Ctr*., DAB No. 2382, at 22-23 (2011) ("The Board has long held, based on the preamble to the regulation stating the relevant factors in setting a CMP, that the correct inquiry in considering a facility's financial condition is whether the facility can show that it lacks "adequate assets to pay the CMP without having to go out of business or compromise resident health and safety.").

In particular, the ALJ stated that he was "unable to assess [Meadowwood's] actual financial condition based on" the unsupported testimony of the Vice President of Operations for Sterling Health Care, who was also Meadowwood's interim administrator immediately before and during the July 8 survey. ALJ Decision at 16. That individual testified that the CMP "represents about the entire annual costs for payroll, benefits, food, supplies and medicine combined, and would be devastating to the facility." P. Ex. 25, at 2 (cited at ALJ Decision at 16).

Before the Board, Meadowwood points out that CMS never disputed this testimony "from one of [Meadowwood's] senior managers." P. Reply Br. at 20; *see also* RR at 7, 38. Meadowwood also asserts that one need not be an accountant or financial expert "to recognize that a small 50-bed facility does not have the financial resources to pay a CMP in the same amount as the facility's total annual operating costs." *Id*.

Since we reverse the ALJ Decision to the extent that the ALJ concluded that Meadowwood was not in substantial compliance for the period March 7 through March 31, 2011, the total amount of the CMP is now $88,750 less than the total amount imposed by CMS. We presume that Meadowwood would maintain that its financial condition precluded it from paying even the lower amount. However, we conclude that the ALJ did not err in determining that Meadowwood did not meet its burden of proving that its financial condition should have been taken into account in determining the reasonableness of the CMP amount.

Contrary to what Meadowwood suggests, the fact that CMS did not dispute the interim administrator's testimony that the CMP amount equaled Meadowwood's annual operating costs does not relieve Meadowwood of the burden to prove its financial condition. The ALJ assigned the testimony "little weight" because Meadowwood failed

to provide "any sort of easily accessible financial information . . . such as tax returns, balance sheets, income statements, or cash flow statements" to support the testimony. ALJ Decision at 16. Even if Meadowwood had provided documentation to support the interim administrator's testimony, the testimony would not establish that the CMP amount should be reduced because the testimony is not probative of the relevant issue: that is, whether Meadowwood lacked the ability to pay the CMP without going out of business or jeopardizing resident health and safety. The Board has explained repeatedly that partial information, such as information about a facility's "annual profits or losses, may not be an accurate reflection of a facility's financial health or ability to pay, and must be considered in the light of such other indicators as the facility's financial reserves, assets, credit-worthiness, and 'other longterm indicia of its survivability."' *Guardian Care Nursing & Rehab. Ctr.*, DAB No. 2260, at 8 (2009), citing *Kenton Healthcare, LLC*, DAB No. 2186 (2008) (all indicia of financial situation, as well as financing options, not merely cash flow, considered for this factor) and *Windsor Health Care*, DAB No. 1902 (2003) (adequacy of assets, not profits, the relevant inquiry). The interim administrator did not represent that Meadowwood did not have sufficient assets to pay the CMP. The only information he provided was that the total CMP amount was equal to Meadowwood's annual operating costs. This information on its face is insufficient to establish that payment of the CMP would put Meadowwood out of business or compromise resident health and safety.

Moreover, Meadowwood's long term care facility application for Medicare and Medicaid for the fiscal year ending October 31, 2011 shows that Meadowwood was owned or leased by a multi-facility organization (Sterling Health Care). CMS Ex. 1, at 1. Thus, even if Meadowwood itself did not have sufficient assets to pay the CMP, it does not necessarily follow that Meadowwood would have had to go out of business or compromise its residents' health and safety in order to pay the CMP. *Cf. Oceanside Nursing & Rehab. Ctr.* at 23 (Oceanside's "common ownership with other facilities" with large gross revenues cannot be ignored in determining Oceanside's financial condition).

Accordingly, we conclude that a per-day CMP amount of $3,550 is reasonable in light of the seriousness of Meadowwood's noncompliance and Meadowwood's culpability.

Conclusion

We reverse the ALJ Decision to the extent it concludes that Meadowwood was not in substantial compliance with section 483.25(h) for the period March 7 through March 31, 2011 and upholds the $3,550 per-day CMP imposed by CMS for that period. We uphold the ALJ Decision to the extent it concludes that Meadowwood was not in substantial compliance with section 483.25(h) for the period April 1 through July 7, 2011 and that the $3,550 per-day CMP imposed for that period is reasonable.

/s/
Stephen M. Godek

/s/
Leslie A. Sussan

/s/
Judith A. Ballard
Presiding Board Member