Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Buena Vista Care Center
Docket No. A-12-80
Decision No. 2498
February 27, 2013

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Buena Vista Care Center (Buena Vista), a California long-term care facility, requests review of the March 22, 2012 decision of Administrative Law Judge (ALJ) Richard J. Smith, *Buena Vista Care Center*, DAB CR2518 (2012) (ALJ Decision). The ALJ upheld a determination by the Centers for Medicare & Medicaid Services (CMS) imposing a $7,100 per-instance civil money penalty (CMP) on the ground that Buena Vista was not in substantial compliance with several Medicare participation requirements. The ALJ concluded that Buena Vista failed to comply substantially with 42 C.F.R. § 483.25(h) (accident prevention), the only alleged noncompliance Buena Vista contested, and that the $7,100 per-instance CMP was reasonable.

For the reasons discussed below, we sustain the ALJ Decision.

Case Background[1]

Based on a survey completed by the California Department of Public Health on May 20, 2010, CMS found Buena Vista out of substantial compliance with 19 participation requirements, including section 483.25(h). ALJ Decision at 1. The introductory language in section 483.25 states:

> Each 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.

[1] This background information is drawn from the undisputed facts in the ALJ Decision and the record before the ALJ and is not intended to substitute for his findings. The general legal background for this case is set out on pages 3-5 of the ALJ Decision.

Subsection (h) of 483.25 states:

> *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.

The statement of deficiencies (SOD) prepared by the surveyors identified the level of noncompliance with section 483.25(h) as "K," denoting a pattern of deficiencies that poses immediate jeopardy to resident health and safety.[2] CMS Ex. 1, at 27. The surveyors specifically determined that unsafe side rails posed immediate jeopardy. *Id*. at 34. Based on the deficiency findings in the SOD, CMS imposed a denial of payment for new admissions (DPNA) (which it later rescinded) as well as a $7,100 per-instance CMP and notified Buena Vista that, as a result of the DPNA and the amount of the CMP, the withdrawal of approval of its nurse aide training program was required. CMS letter dated 6/18/10, at 1-3. Buena Vista requested a hearing but agreed not to contest CMS's findings of noncompliance with regard to the participation requirements other than section 483.25(h). ALJ Decision at 2.

In his decision, issued after an in-person hearing, the ALJ stated that he was addressing five of six violations of section 483.25(h) identified in the SOD, noting that CMS did not address the remaining violation in its post-hearing brief and that it was not necessary for him to address that violation in order to support the CMP imposed. ALJ Decision at 8. The ALJ Decision sets out the following findings and conclusions:

> 1. Petitioner failed to comply substantially with the participation requirement at 42 C.F.R. § 483.25(h) (Tag F-323).
>
> A. Petitioner failed to develop an effective system to identify and replace unsafe side rails.
> B. Petitioner failed to provide an adequate level of supervision to protect Resident 20, assessed as a fall risk, from unassisted transfers and potential falls.
> C. Petitioner failed to provide an assistive anti-tip device as required by Resident 3's care plan.
> D. Petitioner failed to develop an individualized care plan to reduce Resident 14's risk of injury from seizures.
> E. Resident 19's bed alarm did not alert staff when she tried to get out of bed without assistance.

[2] Section 488.301 of 42 C.F.R. defines "immediate jeopardy" as "a situation in which the provider's noncompliance … has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident."

2. The remedy imposed for the noncompliance, a [per-instance CMP] of $7,100, is reasonable.

ALJ Decision at 6, 8, 14, 17, 18, 19, 21.

Buena Vista timely filed a request for review with the Board, challenging all of the findings and conclusions identified above and raising due process arguments. CMS then filed a response to the request for review. Buena Vista did not file a reply to CMS's response brief, although it had an opportunity under the Board's guidelines to do so. *See 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 *(Guidelines);* Board acknowledgment letter dated 6/4/12.

Analysis

On appeal, Buena Vista disputes all five findings on which the ALJ based his conclusion that Buena Vista failed to comply substantially with section 483.25(h). In addition, Buena Vista disputes the ALJ's conclusion that the $7,100 per-instance CMP imposed by CMS for this noncompliance was reasonable. Below, we first explain why we conclude that the five findings are supported by substantial evidence on the whole record and that the ALJ did not err in concluding, based on those findings, that Buena Vista failed to comply substantially with section 483.25(h). We then explain why we conclude that the ALJ did not err in upholding the $7,100 per-instance CMP. Finally, we address Buena Vista's argument that it was denied due process because it was prohibited by regulation from directly challenging CMS's immediate jeopardy determination and Buena Vista's request for a declaration by the Board that other "rules" concerning the appeals process violate due process.

1. The ALJ's conclusion that Buena Vista failed to comply substantially with section 483.25(h) is supported by substantial evidence and free of legal error.

A. Buena Vista failed to develop an effective system to identify and replace unsafe side rails.

For 17 residents, Buena Vista utilized full length metal side rails that bordered the sides of the mattress on the resident's bed. The residents used the side rails for bed mobility. ALJ Decision at 8. The surveyors observed that five residents (Residents 36, 37, 38,

42, and 44) had side rails with a gap in the middle of the upper or lower horizontal rail.[3] Each horizontal rail consisted of two metal tubes that were designed to be connected by a metal spacer, which was missing. The purpose of the spacer was to allow the side rails to lengthen when lowered and shorten when raised. According to the surveyors, the edges of the tubes where the spacer was missing were sharp and the side rails wobbled and leaned outward when a resident pushed on them. One surveyor observed the side rails on Resident 38's bed completely collapse when a maintenance worker attempted to reconnect the rail with the spacer, which he had retrieved from inside one of the tubes. *Id*. at 9; CMS Ex. 1, at 30-34; Tr. at 344-388.

The SOD cited the surveyors' findings with respect to the side rails as evidence of a violation of section 483.25(h), stating:

> The facility failed to ensure these metal spacers were maintained in a manner to prevent separation causing exposed sharp metal edges, instability, and collapse without warning of the side rail. The separated metal side rails were wobbly, and were observed to collapse.
>
> The separation and instability of the side rails resulted in the potential for residents to injure themselves, causing lacerations from the sharp metal edges, entrapment between the mattress and the side rail, as well as between the horizontal rails, and side-rail collapse.

CMS Ex. 1, at 28-29. The ALJ concluded that Buena Vista was not in substantial compliance with section 483.25(h) because Buena Vista lacked an effective system to identify and reduce the accident hazard presented by the side rails, which he indicated were also inadequate as an assistance device. ALJ Decision at 13. The ALJ stated in part as follows:

> I do not agree with [Buena Vista]'s argument that the spacer issue was only a minor maintenance issue. While I cannot determine . . . precisely how sharp the ends of the rails might have been, I need not reference the exact sharpness of the tube ends or whether the rails were likely to collapse to find noncompliance. I need only credit the observations of the surveyors who testified at the hearing that the side rails were wobbly and leaned outwards, to agree with CMS that a wobbly and/or outwardly leaning side rail presents a hazard to a nursing home resident

[3] Except in the case of Resident 44, only the side rails on one side of the bed were affected. CMS Ex. 1, at 30-33.

> using the rails for purposes of bed mobility. Expert testimony is not necessary in this regard. Moreover, ...the photograph at CMS Ex. 13, at 3, depicts an obvious gap in the upper rail. It is evident that a resident exiting the bed could get caught in that gap when the rail is in a lowered position.

Id. at 14.

Thus, in the ALJ's view, the surveyors' testimony that the side rails with missing spacers were wobbly and leaned outwards when used by a resident for bed mobility was sufficient to establish noncompliance with section 483.25(h), although he also found that there is an accident hazard when side rails with a missing spacer on the upper rail have been lowered to allow a resident to exit the bed.

On appeal, Buena Vista does not dispute, or even mention, the ALJ's finding that the lowered side rails were an accident hazard. In addition, notwithstanding Buena Vista's arguments to the contrary, we conclude that substantial evidence supports the ALJ's findings that the side rails with missing spacers were wobbly and leaned outward and that this was an accident hazard for residents using side rails for bed mobility.

Buena Vista disputes the ALJ's finding that the side rails with missing spacers were wobbly and leaned outwards by pointing to the testimony of its Director of Nursing (DON) that she had not observed a wobbly side rail. RR at 11-12, citing Tr. at 394. Buena Vista fails to mention that the DON also stated that the side rails "would move a little bit" (Tr. at 394). In any event, the ALJ clearly found more credible the testimony of Surveyor Coombs that she observed that the side rails on Resident 44's bed leaned outward when the resident put pressure on them and the testimony of Captain Gessay that she had observed that when a resident went to reach the side rails without a spacer, the side rails were wobbly and leaned outward. Tr. at 86, 280. "As an appellate body, we do not disturb an ALJ's assessment about the relative credibility of testimony by witnesses who appear in person at the hearing absent a compelling reason to do so." *Koester Pavilion*, DAB No. 1750, at 15 (2000). Buena Vista has given us no compelling reason to disturb the ALJ's credibility finding here.[4] Accordingly, we conclude that substantial evidence supports the ALJ's finding that the side rails with missing spacers were wobbly and leaned outwards.

[4] Buena Vista misreads Captain Gessay's testimony when it asserts that Captain Gessay disagreed with Surveyor Coombs that the missing spacers caused the side rails to wobble when Captain Gessay stated that the "side rail was wobbly and that was of concern unrelated to the spacer." RR at 6, quoting Tr. at 278. In light of her further testimony on this matter, it is clear that Captain Gessay meant by the latter phrase only that the wobbly side rails posed additional accident hazards, such as entrapment, apart from the accident hazard directly attributable to the missing spacers. *See* Tr. at 278-280.

Buena Vista also disputes the ALJ's finding that the wobbly and outwardly-leaning side rails were an accident hazard, asserting that its evidence "established that the side rails in its facility were not 'wobbly' to the point of presenting a safety issue." RR at 11. According to Buena Vista—

> [Nurse Supervisor] Schweitzer testified that the rails were not dangerously wobbly for residents, and that she was never concerned for resident safety because of a wobbly side rail, despite observing residents use the rails many, many times over the years …. [Nurse Consultant] Bermudes testified that he had never seen an incident report involving resident harm caused by side rail maintenance issues in four years as a Regional Director of Clinical Operations for Buena Vista's parent company, meaning that side rail 'wobbliness' had never caused a resident injury….

Id. (citations to transcript omitted). This testimony does not advance Buena Vista's case. It is well-established that a facility may violate section 483.25(h) even in the absence of an accident resulting in injury or other harm to a resident. *See, e.g., Clermont Nursing & Convalescent Ctr.*, DAB No. 1923, at 21-22 (2004), *aff'd, Clermont Nursing & Convalescent Ctr. v. Leavitt*, 142 F. App`x 900 (6th Cir. 2005). Accordingly, that no actual harm (such as a fall or an injury) had yet resulted from the wobbly side rails does not undercut the ALJ's finding that they were an accident hazard.

Buena Vista also asserts, as it did before the ALJ, that the side rails with missing spacers were "a maintenance issue, not a resident safety issue" noting that maintenance staff explained to Surveyor Coombs that "[t]hey have to be able to move the spacer—so when you raise & lower the full [side rail] it moves in & out." RR at 13; CMS Ex. 7, at 13. The ALJ disagreed "that the spacer issue was only a minor maintenance issue," quoting the Board's statement in *Meadow Wood Nursing Home*, DAB No. 1841, at 18 (2002) that "poorly maintained equipment is precisely the sort of preventable accident hazard that a facility can practicably be expected to address." ALJ Decision at 13-14. That Buena Vista's staff might have identified the side rails with missing spacers as a maintenance issue does not mean that the side rails were not also an accident hazard.

We therefore conclude that Buena Vista has not shown any basis for reversing the ALJ's finding that the side rails with missing spacers were an accident hazard because they were wobbly and leaned outward when used by residents for bed mobility as well as because of the danger posed to residents exiting the bed by lowered side rails that had a missing spacer in the upper rail.

Buena Vista also argues on appeal that the side rails with a missing spacer were not an accident hazard because they were not at risk of collapsing when used by a resident for bed mobility, as CMS had alleged. RR at 9-10. As we have discussed, Buena Vista has not shown that the ALJ incorrectly concluded that the side rails with a missing spacer

were an accident hazard regardless of whether they were likely to collapse (or of the exact sharpness of the tube ends where the spacer was missing). In any event, CMS's position that the side rails could collapse is supported by the record. Surveyor Coombs testified that these side rails were "unstable" and could collapse when pushed or pulled by a resident, creating a risk that a resident could fall out of bed or even be "impaled" by the side rails. Tr. at 86. CMS's position is also supported by evidence that the side rails on Resident 38's bed did collapse while being repaired by a maintenance worker during the resident's absence from bed. Surveyor Chereme testified that the maintenance worker first used pliers to retrieve the spacer from inside one of the tubes comprising the lower side rail and then attempted to reconnect the two tubes with the spacer. According to Surveyor Chereme, at that point, the spacer slid off the upper side rail, and the side rails collapsed to the ground in the middle while still attached at either end. *See* Tr. at 344-348. Surveyor Coombs testified that the collapse was relevant to the issue of whether the side rails presented an accident hazard because, while manipulating the side rails, the maintenance worker was pushing and pulling, "the same type of activity that a resident in bed would be doing." Tr. at 188; *see also* Tr. at 189 ("The pushing and pulling would be very similar.").

Buena Vista argues that the collapse of the side rails on Resident 38's bed "was a one-time event" and it was "untrue" that, as Surveyor Coombs testified, "the maintenance worker, while attempting to realign the side rail *from the outside of the bed*, was engaged in the 'same type of activity that a resident *in bed* would be doing.'" RR at 9 (quoting Tr. at 188) (italics added by Buena Vista). However, Buena Vista does not explain why CMS could not reasonably infer from the circumstances under which the side rails on Resident 38's bed collapsed that a resident using the disconnected side rails for bed mobility could also cause them to collapse. According to Surveyor Coombs, the middle of the side rails where the spacers are designed to be located is the area of the side rails most often used by residents for mobility purposes. CMS Ex. 21 (Coombs declaration) at 4, n.1. This is the same area where the maintenance worker held the side rails when reconnecting the side rails with the spacer. Moreover, Buena Vista presented no evidence that the maintenance worker applied more force to the side rails than would be applied by a resident using the side rails for bed mobility. Indeed, Surveyor Chereme testified that the maintenance worker "was as gentle as possible trying to . . . connect the lower portion of the rails together" and did not bang on the side rails or jerk or shake them. Tr. at 346-347. Furthermore, Buena Vista does not point to any evidentiary support for its position that a risk of collapse existed when the side rails were pushed or pulled from the outside of the bed, as when the maintenance worker was attempting to repair Resident 38's side rails, but not when pushed or pulled from the inside of the bed by a resident.

Contrary to what Buena Vista argues on appeal (RR at 11-12), the record also supports CMS's allegation that the side rails with missing spacers were an accident hazard due to the risk of a resident becoming entrapped in the space between the side rails and the mattress. Captain Gessay testified that there was a potential for such entrapment because the side rails with missing spacers were wobbly and leaned outwards. Tr. at 278-280. In addition, Surveyor Coombs testified that when Resident 44 put pressure on the side rail with a missing spacer, the side rail leaned outward, widening the space between the mattress and the side rail, and that she was concerned that the resident could get trapped in that space. Tr. at 86. Surveyor Coombs also stated in her declaration that during the survey she took a photograph (CMS Exhibit 13, at 5) showing a five-inch gap between an "intact side rail" and a mattress and that this gap presented a risk of entrapment. CMS Ex. 21 (Coombs declaration), at 7; Tr. at 86. Under Food and Drug Administration guidelines cited by Surveyor Coombs, a gap exceeding 4¾ inches presents a risk of entrapment. CMS Ex. 19, at 17. Buena Vista disputes that there was a potential for entrapment, pointing to the DON's testimony that the gap was "maybe an inch or less." RR at 12, quoting Tr. at 394. Buena Vista's Nurse Supervisor similarly testified that the gap was "about an inch." Tr. at 538. However, unlike the testimony of the CMS surveyors, this testimony is not corroborated by any photographic evidence. The DON and Nurse Supervisor also testified that no resident had ever become entrapped. Tr. at 394, 538. As already discussed, the lack of an accident or injury does not establish that the resident environment was as free of accident hazards as possible.

To comply with the requirement in section 483.25(h) to ensure that the "resident environment remains as free of accident hazards as is possible," a facility must "eliminate or reduce the risk of accident to the greatest degree practicable." *See Clermont*, 142 F. App'x 900, 904 (quoting DAB No. 1923 with approval). Buena Vista disputes the ALJ's conclusion that it did not have an effective system to identify and reduce accident hazards from side rails, arguing, as it did before the ALJ, that "the record demonstrates that Buena Vista had a comprehensive safety system that ensured side rail safety." RR at 12. Buena Vista points to its witness testimony that: 1) it had a safety committee that conducted room rounds on a daily basis and checked equipment safety, 2) the safety committee made weekly room checks which included inspecting bed rails to make sure they were in good working order, 3) any equipment issues identified by the safety committee or employees conducting room rounds were brought up at the standup meeting of department heads which took place every weekday morning, and 4) every 30 to 45 days all equipment a resident used was inspected during walking rounds by the resident's interdisciplinary team and others. *Id*. at 13-15.

We agree with the ALJ that the mere existence of such a system is insufficient to establish that Buena Vista eliminated or reduced the risk of accidents from side rails to the greatest degree practicable. As the ALJ noted, Buena Vista does not dispute that, "despite [its] system of daily and weekly rounds and monthly interdisciplinary team

walking rounds, no one at the facility was aware, when in May 2010 the surveyors entered the facility, that fully one quarter of its full-length side rails had observable gaps in the middle of the railings caused by the missing spacers until the surveyors brought the problem to the facility's attention." ALJ Decision at 14. Buena Vista can hardly claim that it had taken all practicable steps to eliminate or reduce the risk posed by these side rails when it had not even identified any of these side rails as needing repair. In addition, there is no indication in the record that Buena Vista's safety committee checked the size of the gap between the side rails and the mattress on residents' beds.

Buena Vista argues further that it complied with section 483.25(h) because its "safety system" "proved 100% successful in preventing injuries caused by faulty side rails." RR at 15. This argument stands on its head the requirement to keep the resident environment free of accident hazards. Given the evidence of the problems with the side rails, the absence of any injuries due to side rails with missing spacers was simply fortuitous, and the ALJ could reasonably decline to infer from that absence that Buena Vista was in substantial compliance with section 483.25(h). Contrary to what Buena Vista suggests (at RR at 12), nothing in *St. Catherine's Care Center of Findlay, Inc.*, DAB No. 1964 (2005) supports a conclusion that the absence of an injury is sufficient to rebut CMS's prima facie case that the facility has not eliminated or reduced the risk of accident to the greatest degree practicable.

We therefore conclude that substantial evidence supports the ALJ's finding that Buena Vista failed to develop an effective system to identify and replace unsafe side rails. We further conclude that the ALJ did not err in relying on this finding as one of the bases for finding that Buena Vista was not in substantial compliance with section 483.25(h).

B. Buena Vista failed to provide an adequate level of supervision to protect Resident 20 from unassisted transfers and potential falls.

Resident 20, who was admitted to Buena Vista on April 19, 2010, was assessed on admission as at high risk for falls due to intermittent confusion, gait problems, and a history of falls that included recent falls while attempting to get out of bed unassisted. ALJ Decision at 14. He was also assessed at that time as needing a one person physical assist for bed mobility, transfers, and walking. CMS Ex. 12, at 39. Buena Vista had a plan of care for fall prevention for Resident 20 on the date of admission that specified as interventions "tab alarm," "mattress on floor," and "keep floors free of spills and Clutter."[5] *Id*. at 25. Nursing notes for this resident dated April 19 state, "Tab

[5] The intervention "mattress on floor" appears to refer to a mat on the floor on one or both sides of the bed. *See, e.g.*, CMS Ex. 12, at 43 ("floor mattress next to bed"). The DON testified that Resident 20 was also given a low bed when he was admitted (Tr. at 415).

alarm placed since daughter states [resident] may get confused [at] night & try to get up [without] assist." P. Ex. 7, at 1. A tab alarm is "an alarm attached to a resident and the resident's bed that sounds if the resident attempts to get out of bed unassisted[.]" ALJ Decision at 15.

On April 21 at 4:30 p.m., a nurse responded to Resident 20's call light and found him lying on the floor next to his bed. CMS Ex. 12, at 48. The resident reported that he was looking for the telephone and slid off the bed. ALJ Decision at 15**.** The tab alarm did not activate, and the DON told a surveyor that at the time of the fall the tab alarm was "not working" but the problem was not the battery. CMS Ex. 12, at 3 (Surveyor Chereme's interview notes signed by DON). After the fall, Buena Vista replaced the resident's tab alarm with a new tab alarm. P. Ex. 7, at 13; Tr. at 413. The nursing staff also conducted frequent neurological checks of the resident until 12:45 a.m. on April 22 (presumably because the resident, who sustained a skin tear in the fall, said he may have also bumped his head). ALJ Decision at 15; *see also* P. Ex. 7, at 8 (Neurologic Assessment Flow Sheet). In addition, Buena Vista updated the resident's care plan on April 21 to require that staff "check placement of tab alarm before, during & after [change] of shift." CMS Ex. 12, at 9. The incident report on the fall included as a follow-up action "staff to check …battery is working before leaving resident in bed," although this was not added to the care plan. CMS Ex. 12, at 48.

Resident 20 fell again on April 22, at about 3:00 a.m., about 20 minutes after being toileted, and fractured his hip. A certified nurse aide heard the resident cry for help and found him on the floor, away from his mattress, with the tab alarm attached only to the bed. ALJ Decision at 15; CMS Ex. 12, at 3. The DON testified that she concluded that before he fell, Resident 20 must have removed the tab alarm where it was clipped on him because the aide who toileted him had checked that the tab alarm was clipped on him after returning him to bed. Tr. at 414; *see also* P. Ex. 7 (incident report signed by DON on 4/22/10 stating that the aide checked that the tab alarm was "attached to resident's shirt" and that after the fall "his tab alarm was unclipped from his shirt"). The resident said after the fall that he was trying to reach the phone. P. Ex. 7, at 2.

The SOD cited the surveyor's findings with respect to Resident 20 as evidence of a violation of section 483.25(h), stating that after the first fall, "[t]here were no documented interventions implemented to increase the supervision of Resident 20 after initial neurological checks . . . or to move Resident 20 closer to the nurse's station, utilize a different alarm, or provide a telephone which was easily accessible to him in bed." CMS Ex. 1, at 36. The SOD also stated that after Resident 20 returned to the facility from the hospital where his hip fracture was treated, Buena Vista "continued interventions which had proven to be ineffective for Resident 20 and placed him at risk for a further fall," noting that on May 10, he "was observed in a bed lowered to the floor with one side against a wall, a tab alarm attached to the back of his hospital gown, and a blue foam pad on the right side of the bed." *Id*. at 37.

The ALJ stated that the issue before him was limited to "whether the supervision and interventions that [Buena Vista] was utilizing on April 22, 2010, after the first fall, provided an adequate level of supervision for Resident 20."[6] ALJ Decision at 17. The ALJ noted Buena Vista's assertion that Resident 20 removed the tab alarm from his clothing shortly before the second fall and Buena Vista's argument that "the use of the tab alarm was still a reasonable intervention after the first fall" because staff could not have foreseen that Resident 20 would remove the tab alarm. *Id*. at 16. The ALJ also noted Buena Vista's assertion that "a resident has the right to remove a tab alarm." *Id*. at 17. However, the ALJ went on to state:

> Given Resident 20's obvious propensity for falls, [Buena Vista] should have re-evaluated its interventions and, as CMS notes, have considered other possibilities, including the use of a bed alarm.[7] I find disturbing [Buena Vista]'s argument that it takes time to determine what interventions are the most effective approach to deal with a resident. Given that [Buena Vista] knew the resident was a fall risk, [Buena Vista] should, in the interim, have provided the most comprehensive interventions possible to assure that the resident was actually supervised, provided appropriate assistive devices, and protected from accidental falls.

Id.

On appeal, Buena Vista continues to argue that it was reasonable to simply replace the tab alarm with another tab alarm after the resident's first fall. Buena Vista asserts that it could not have foreseen that the second tab alarm would fail to activate inasmuch as the original tab alarm and the second tab alarm failed to activate for different reasons: the original tab alarm due to a mechanical reason and the second tab alarm due to the resident's having removed the tab alarm from his clothing. *See* RR at 17. This argument is not persuasive. There is no indication in the record that Buena Vista had a clear understanding of why the original tab alarm failed to activate. Without such an understanding, Buena Vista could not reasonably conclude that replacing the original tab alarm with another tab alarm of the same type (which might be similarly flawed) was an adequate intervention. The DON never explained what mechanism was involved or what assessment, if any, was done to determine why the original tab alarm failed to activate.

[6] The ALJ did not rely on the finding in the SOD that Buena Vista continued its ineffective interventions after Resident 20 returned from the hospital after the second fall. The ALJ stated that he could not find a deficiency based on the surveyor's observation of Resident 20 with a tab alarm "given the other interventions in place which apparently included a bed alarm." ALJ Decision at 16.

[7] "A bed alarm is a type of safety alarm with a pressure-release pad that activates when a resident rises off a bed, as opposed to a tab alarm, which is attached to a resident and is activated when a resident attempts to get up." ALJ Decision at 15, n.8, citing CMS Ex. 1, at 29.

She stated that the original tab alarm was "not working" but also said the battery was not the problem. Thus, neither checking the battery in the second tab alarm when providing care to the resident nor checking the placement of the second tab alarm when providing such care (interventions specified in the incident report and in the updated care plan, respectively) was an adequate intervention.

In addition, Buena Vista should have known that the other interventions it had in place (keeping a mattress on the floor and the floor free from spills and clutter) might not protect Resident 20 from injury should the second tab alarm fail—whether for mechanical reasons or because Resident 20 removed it—since the resident injured himself when he fell the first time despite these interventions. Yet, Buena Vista presented no evidence indicating that it reassessed whether those other interventions were adequate in light of the alarm failure and the resident's fall. As the SOD indicated, Buena Vista could have considered interventions such as increased supervision, a different type of alarm, or making a telephone accessible to the resident in bed, the last of which would have addressed the resident's stated reason for attempting to get out of bed. Accordingly, during the period at issue, Buena Vista did not meet the requirements of section 483.25(h) with respect to Resident 20 because it did not take "all reasonable steps to ensure that a resident receives supervision and assistance devices that meet his or her assessed needs and mitigate foreseeable risks of harm from accidents." *Briarwood Nursing Ctr.*, DAB No. 2115, at 11 (2007), citing *Woodstock Care Ctr. v. Thompson*, 363 F.3d 583 (6th Cir. 2003).

Buena Vista asserts that in addition to providing the interventions the ALJ found inadequate, it conducted visual checks of Resident 20 every 30 minutes after the first fall. RR at 16-17. However, the evidence relating to the alleged visual checks consists only of testimony by the DON responding in the affirmative to the question whether visual checks were done every 30 minutes (Tr. at 412) and a nurse's note dated 4/22/10 stating "Visual checking [every] 30 mins & PRN" (CMS Ex. 12, at 43). Buena Vista presented no evidence recording actual visual checks after the neurological checks ended at 12:45 a.m. on April 22. Even assuming the visual checks were actually done, Buena Vista can hardly claim they were an adequate intervention since they neither prevented the resident from falling a second time nor mitigated the effects of that fall. Buena Vista also asserts that it "ultimately implemented additional and differen[t] interventions, such as a bed alarm" and argues that the ALJ "ignored these interventions—particularly the implementation of a bed alarm[.]" RR at 17. However, the record shows that the bed alarm was not added until after the second fall, and Buena Vista did not assert otherwise. *See, e.g.*, P. Ex. 7, at 9, 12; Tr. at 415. The addition of a bed alarm at that time has no bearing on the adequacy of Buena Vista's interventions between the first and second falls which, as the ALJ stated, is the material issue.

We therefore conclude that substantial evidence supports the ALJ's finding that Buena Vista failed to implement adequate interventions after Resident 20's first fall. We further conclude that the ALJ did not err in relying on this finding as one of the bases for concluding that Buena Vista was not in substantial compliance with section 483.25(h).

C. Buena Vista failed to provide an assistive anti-tip device as required by Resident 3's care plan.

A Fall Risk Assessment dated August 31, 2009 showed that Resident 3 required the use of a wheelchair and was at high risk for falls. CMS Ex. 9, at 10. On September 24, Resident 3 was found by Buena Vista's staff to have fallen from his wheelchair onto a cement patio. The resident reported that when he was trying to cross from the patio to the dining room, his wheelchair tipped backward and he fell, hitting his head. CMS Ex. 9, at 3; Tr. at 325. Resident 3's Fall Risk Care Plan dated August 31 was amended on September 25 to add as an intervention "Apply anti-tip device to [wheelchair]." CMS Ex. 9, at 14; *see also id.* at 13 (Episodic Care Plan: Post Fall, showing the same intervention under the heading "Additional Intervention Initiated"). Buena Vista's report on its investigation of the fall included as "Follow-Up Actions" applying an anti-tip device to the resident's wheelchair and rehabilitation department "will cont. to address safety measures." CMS Ex. 9, at 3. The purpose of an anti-tip device, which is attached to the bottom frame of a wheelchair, is to prevent a wheelchair from tipping backward. ALJ Decision at 17, n.9.

On May 12, 2010, Surveyor Chereme observed Resident 3 propelling himself in his wheelchair, which had no anti-tip device attached. Buena Vista's staff confirmed in interviews with the surveyor that the resident did not receive an anti-tip device. ALJ Decision at 17; CMS Ex. 9, at 4, 6. The SOD states that Buena Vista failed to "[p]rovide a post-fall rehabilitation assessment and install wheelchair anti-tip bars for Resident 3 after identifying through their post-fall investigation [that] the anti-tip bars were necessary to prevent another backward fall from the wheelchair" and that "[t]his failure placed Resident 3 at risk for fall and probability of injury." CMS Ex. 1, at 29. The ALJ determined that Buena Vista's failure to equip Resident 3's wheelchair with an anti-tip device was evidence of Buena Vista's noncompliance with section 483.25(h), stating in part, "Given that Resident 3 fell backwards, the anti-tip device was a reasonable accommodation to protect the resident[.]" ALJ Decision at 18.

We agree with the ALJ that Buena Vista violated section 483.25(h) by not providing an anti-tip device to Resident 3. Buena Vista itself made the judgment that this device was necessary in order for Resident 3 to safely use his wheelchair when it added the device to the resident's care plan after his fall on September 24, 2009. The same care plan was still in effect when the surveyor observed Resident 3 on May 12, 2010. As noted above, the introductory language in section 483.25 requires that a facility provide each resident 'the necessary care or services to attain or maintain the highest practicable physical, mental,

and psychosocial well-being, *in accordance with the comprehensive assessment and plan of care.*'" (emphasis added). Buena Vista's undisputed failure to equip Resident 3's wheelchair with the anti-tip device expressly required by his care plan was a clear violation of section 483.25(h)(2).

On appeal, Buena Vista argues that it "provided other measures, among other things a lap belt, that constituted adequate assistance devices to prevent accidents, and that those measures were effective in preventing further falls." RR at 18. Buena Vista cites to progress notes signed by Resident 3's interdisciplinary team on October 15 and on November 13, 2009, both of which state "safety belt is still appropriate for resident's safety." *Id.* citing CMS Ex. 9, at 83. Buena Vista's argument has no merit because, as the ALJ stated in addressing the same argument below, the "other interventions that [Buena Vista] asserts it provided were not specific to preventing a backwards fall." ALJ Decision at 18. The interdisciplinary team progress notes indicate that a seat belt was appropriate because Resident 3 was unable to call for assistance before getting up from the wheelchair due to impaired cognition and it was unsafe for him to get up and ambulate independently as he was unsteady on his feet. Thus, the purpose of the seat belt was to restrain the resident, whereas the purpose of the anti-tip device was to prevent the wheelchair from tipping backward. Buena Vista's argument is also undercut by the fact that the anti-tip device was not deleted from Resident 3's care plan after the interdisciplinary team decided he needed a seat belt.

Buena Vista also argues that the fact that Resident 3 experienced no further falls between September 24 and the time of the survey "demonstrates the effectiveness of the safety precautions that Buena Vista implemented and its substantial compliance with [section 483.25(h)]." RR at 18. The ALJ addressed the same argument below, stating, "That Resident 3 did not fall backwards again is providential, but it is not evidence that [Buena Vista] was in compliance with participation requirements." ALJ Decision at 18. We agree. As we indicated above, the absence of an accident resulting in injury to a resident does not show that a facility met the requirements of section 483.25(h).

We therefore conclude that substantial evidence supports the ALJ's finding that Buena Vista failed to provide an anti-tip for Resident 3's wheelchair as required by his care plan. We further conclude that the ALJ did not err in relying on this failure as one of the bases for his conclusion that Buena Vista was not in substantial compliance with section 483.25(h).

D. Buena Vista failed to develop an individualized care plan to reduce Resident 14's risk of injury from seizures.

On October 29, 2009, Resident 14 suffered a full body seizure lasting about one and one-half minutes during which she was seen to drool and lose consciousness. ALJ Decision at 18; CMS Ex. 1, at 39. On November 16, 2009, the resident had a consultation with a

neurologist, who found that the seizure was "isolated" but ordered medication to control seizures, with the dosage to be adjusted if the resident was excessively sleepy or had "breakthrough seizures." CMS Ex. 10, at 10-13. On the resident's pre-printed "Seizure Disorder" care plan listing various approaches that could be used to control seizures and prevent injury, the boxes next to each approach are unchecked, although the name of the anti-seizure medication prescribed by the neurologist is handwritten to the left of the approach "Medication as ordered by physician" and the date April 20, 2010 is handwritten to the right of this approach under the column "Reeval Date." CMS Exs. 1, at 40 and 10, at 18.

On May 12, 2010, a surveyor observed Resident 14 sleeping on a standard bed without side rails. CMS Ex. 1, at 41. The SOD states that Buena Vista failed to "[p]ad Resident 14's headboard and side-rails as per facility policy, or develop and implement seizure precautions as part of an individualized plan of care" and that "[t]his failure placed Resident 14 in an unsafe environment with the probability of sustaining an injury related to a seizure." CMS Ex. 1, at 29. Buena Vista had a policy for "nursing management" of seizures which included "Support resident and protect from injury by padding side rails and head of bed" under the heading "Procedure." CMS Ex. 10, at 6.

The ALJ determined that the facility policy cited in the SOD did not require that a resident at risk for seizures have padding on the headboard and side rails when the resident is not actually experiencing a seizure. The ALJ nevertheless found a violation of section 483.25(h) on the ground that "the care plan [Buena Vista] devised for Resident 14 was not adequate to ensure that her environment remained as free of accident hazards as possible or that she received adequate supervision and assistance devices to prevent her accidentally injuring herself during future seizures." ALJ Decision at 19.

On appeal, Buena Vista takes the position that section 483.25(h) "does not address care planning," so that the ALJ erred in concluding that Buena Vista violated section 483.25(h) on the ground that it "did not adequately care plan for Resident 14's seizures." RR at 19. Buena Vista also argues that the "record demonstrates that Buena Vista substantially complied with [section 483.25(h)] in regards to Resident 14 by following her physician's orders for administering seizure medication and monitoring her for 'breakthrough seizures.'" *Id*. at 20. The ALJ rejected similar arguments below, stating that the "fact is that here [Buena Vista]'s failure to care plan for active seizures placed Resident 14 at risk of accident" and that following her physician's orders does "not take the place of a facility care plan to ensure that the resident was adequately protected from risk of accident in the event of a future seizure." ALJ Decision at 19.

We see no error in the ALJ's findings, which we conclude are supported by substantial evidence. As noted, the neurologist indicated in prescribing anti-seizure medication for Resident 14 that the resident could experience "breakthrough seizures" while on the medication. Buena Vista stated in its March 8, 2010 comprehensive assessment that

Resident 14 was "prone to seizure." CMS Ex. 10, at 61 (RAP Narrative Report identifying this as a reason resident was at risk of falling). Yet Buena Vista points to nothing in the record to show that the facility put in place any interventions to address the risk that the resident might injure herself while having a seizure. The ALJ reasonably relied on the fact that none of the interventions on the resident's seizure care plan were checked and that, apart from noting the ordered medication, the seizure care plan did not otherwise identify any interventions addressing how to protect this seizure-prone resident. (We also note that Buena Vista did not point to any other part of the care plan that would provide adequate protection.) As the Board has previously stated, section 483.25 "effectively incorporates" the more specific regulatory requirements for assessments and individualized care plans "by requiring in its introductory language that a facility provide each resident 'the necessary care or services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, *in accordance with the comprehensive assessment and plan of care.*'" *Azalea Court*, DAB No. 2352, at 12 (2010), *aff'd, Azalea Court v. U.S. Dep`t of Health & Human Servs., Ctrs. for Medicare & Medicaid Servs.*, 482 F. App'x 460 (11th Cir. 2012) (emphasis added in DAB No. 2352). In addition, there is no evidence that, despite the absence of any interventions in the care plan other than the medication, Buena Vista nevertheless implemented interventions to protect the resident from the risk of injury from seizures. Buena Vista points out that, as of the time of the survey, the October 29, 2009 seizure "was the only seizure that Resident 14 ever experienced." RR at 20-21. The lack of any other seizures did not excuse Buena Vista's failure to address a risk to the resident that Buena Vista itself identified as still present in its March 8, 2010 comprehensive assessment.

We therefore conclude that substantial evidence supports the ALJ's finding that Buena Vista failed to provide adequate interventions to protect Resident 14 from falls in the event of a seizure. We further conclude that the ALJ did not err in relying on this finding as one of the bases for his conclusion that Buena Vista failed to comply substantially with section 483.25(h).

E. Resident 19's bed alarm did not alert staff when she tried to get out of bed without assistance.

Resident 19, an 83-year-old woman with diagnoses including rheumatoid arthritis and dementia, was assessed upon admission on March 18, 2010 as needing a two-person assist for both transfers and locomotion and as dependent upon a walker for locomotion. CMS Ex. 32, at 38. A fall risk assessment dated March 18 identified the resident as at high risk for falls. *Id*. at 41. The interventions to address that risk were keeping her call light within reach and encouraging its use and keeping her walker and wheelchair at easy reach. *Id*. at 20. The resident's "continence care plan" dated March 18 called for prompted toileting every two hours. *Id*. at 22.

On March 23, 2010, Resident 19 was found on the floor in front of the bathroom. CMS Ex. 32, at 48. She had gotten up from bed without assistance to go to the bathroom and slipped on her way back to bed. *Id*. at 48, 52. Buena Vista then added as interventions to address the resident's risk of falls placing her bed against the wall in the lowest position, placing a floor mattress next to her bed, and applying a bed alarm. *Id*. at 48-49. Buena Vista also "[p]rovided [s]afety [r]e-education" and "[r]einforced using call light for assistance." *Id*. at 52.

On April 10, 2010, Resident 19 was found on the floor mattress next to her bed and reported that she slid down to the floor when she got up from bed. CMS 32, at 54. When she fell, her bed alarm was activated. *Id*. at 27, 29, 54. Buena Vista then added as an intervention "Reinforce safe practices such as calling for [assistance] before getting up from bed and waiting for [assistance]." *Id*. at 24.

On May 16, 2010, Resident 19 was identified as having diarrhea. CMS Ex. 32, at 36. The next day, Surveyor Coombs observed Resident 19 in her bed "with brown substance on her sock and a brief on the floor of the bathroom with what appeared to be stool on it. A brown substance was also smeared on the floor." ALJ Decision at 20, citing Tr. at 101 and CMS Ex. 32, at 86. Surveyor Coombs also observed that no alarm was "going off" and that the bed alarm should have "still be[en] alarming" at that time given the condition of the room and the resident. CMS Ex. 32, at 5; Tr. at 102. One of Buena Vista's nurses told the surveyor that the bed alarm did not sound when Resident 19 got out of bed unassisted because the on-off switch had been turned off. CMS Ex. 1, at 44-45. The nurse also told the surveyor that she thought staff turned the switch off to silence the alarm when they got the resident up from bed earlier in the morning and had forgotten to turn it back on. *Id*. at 45; CMS Ex. 32, at 5.

The SOD stated that Buena Vista failed to "[t]urn on the bed alarm to alert staff when Resident 19 was attempting to get out of bed and needed assistance to use the bathroom." CMS Ex. 1, at 30. The SOD continued: "Resident 19 was a fall risk, needed assistance in ambulating, and ambulated to the bathroom without assistance while incontinent of stool and back to bed again creating a greater risk for injury." *Id*. The ALJ found that the alarm had not sounded on May 16 when Resident 19 got out of bed unassisted to go to the bathroom because a staff member had turned off the alarm. ALJ Decision at 21. The ALJ further found that it was "foreseeable that in this instance the resident would be likely to get up and go to the bathroom[.]" *Id*.

On appeal, Buena Vista disputes the ALJ's finding that Buena Vista's staff rather than Resident 19 turned off the bed alarm. According to Buena Vista, the nurse on whose statement this finding was based "was clearly guessing about an occurrence about which she had absolutely no firsthand information." RR at 22, citing Tr. at 205-206. Buena Vista asserts that the "best-founded evidence in the record is that Resident 19's bed alarm was in working order, because Buena Vista checked it every weekday during room

rounds and on a weekly basis by the safety committee" and that "it is more likely that Resident 19 turned the bed alarm off herself," especially in light of the fact that "two Buena Vista staff members told Ms. Coombs that Resident 19 had in fact turned off her own alarm on other occasions." RR at 22-23.[8]

We conclude that substantial evidence supports the ALJ's finding that Buena Vista's staff turned Resident 19's bed alarm off before the surveyor observed the resident on May 17. Buena Vista does not specifically deny that its staff assisted the resident earlier that day, that staff could have turned the bed alarm switch off while doing so, or that staff could have forgotten to turn the switch back on before leaving the resident in bed. While Buena Vista's nurse might not have known what actually occurred, her supposition that staff turned the bed alarm switch off while providing care and then forgot to turn it back on presumably was based on her experience and knowledge of facility practices. Buena Vista also does not assert that any of the daily room rounds or weekly safety checks it claims staff performed occurred between the time staff last assisted Resident 19 and the time she got out of bed unassisted. Accordingly, having these monitoring measures in place did not ensure that the bed alarm switch was on at the critical time here. Furthermore, it is undisputed that on May 18, the resident was unable to demonstrate to Surveyor Coombs how to turn the bed alarm switch off. CMS Ex. 32, at 5; Tr. at 108. Thus, even if Resident 19 had turned her bed alarm switch off on prior occasions, that does not necessarily mean she was still able to do so on May 17.

We therefore conclude that substantial evidence supports the ALJ's finding that Buena Vista failed to ensure that Resident 19's bed alarm was on at a time when Buena Vista could have foreseen that the resident might attempt to get out of bed unassisted. We further conclude that the ALJ did not err in relying on this finding as one of the bases for his conclusion that Buena Vista failed to comply substantially with section 483.25(h).

2. The ALJ's conclusion that a $7,100 per-instance CMP is reasonable is supported by substantial evidence and free of legal error.

When CMS elects to impose a per-instance CMP, the penalty amount must be in the range of $1,000 to $10,000 per instance. 42 C.F.R. § 488.438(a)(2), 488.408(d)(1)(iv). In deciding whether a CMS-imposed penalty amount is reasonable, an ALJ (or the Board) may consider only those factors specified in section 488.438(f): (1) the facility's history of noncompliance; (2) the facility's financial condition; (3) factors specified in 42 C.F.R. § 488.404, including the "seriousness of deficiencies" (i.e., their severity and scope) and

[8] Buena Vista also argues that the ALJ "found that Buena Vista should have toileted Resident 19 more than every two hours when she had diarrhea" and that this finding is not supported by any evidence in the record. RR at 23. However, the ALJ made no such finding. Instead, he merely noted that "it did not occur to [Buena Vista] to toilet the resident more often than every two hours when she had diarrhea." ALJ Decision at 21. In context, it appears that the fact that the facility knew the resident had diarrhea was simply part of the ALJ's rationale for finding it foreseeable that the resident would attempt to get out of bed unassisted. *Id*.

"the relationship of the one deficiency to other deficiencies resulting in noncompliance;" and (4) the facility's degree of culpability. Section 488.483(e)(3), (f). Section 488.404(b) provides that CMS considers the following factors to determine the seriousness of the deficiency:

> (1) Whether a facility's deficiencies constitute—
> (i) No actual harm with a potential for minimal harm;
> (ii) No actual harm with a potential for more than minimal harm, but not immediate jeopardy;
> (iii) Actual harm that is not immediate jeopardy; or
> (iv) Immediate jeopardy to resident health or safety.
> (2) Whether the deficiencies—
> (i) Are isolated;
> (ii) Constitute a pattern; or
> (iii) Are widespread.

The ALJ found that Buena Vista had a history of noncompliance with section 483.25(h), that it was culpable for its failure to take all reasonable steps to eliminate foreseeable risks from the accident hazards presented by the side rails, and that its failure to provide adequate supervision and assistance devices and reduce accident hazards for Residents 20, 3, 14, and 19 placed them at risk of more than minimal harm. ALJ Decision at 21. The ALJ concluded, "given that I have found several instances of a deficiency involving [section 483.25(h)], involving different failures on [Buena Vista's] part, the amount of [per-instance CMP] imposed is reasonable and could even be considered de minimis." *Id*. at 22.

On appeal, Buena Vista disputes the ALJ's conclusion that the $7,100 per-instance CMP is reasonable. Buena Vista maintains that CMS erred in determining that the side rails posed immediate jeopardy because, according to Buena Vista, the "side rails were not likely to cause any harm[.]" RR at 25. Buena Vista continues:

> Because the scope and severity of the deficiency is a factor that must be considered in reviewing the reasonableness of the CMP, because it was clearly erroneous to assess a level "K" scope and severity to the [section 483.25(h)] deficiency, and because Judge Smith did not consider the proper scope and severity of the alleged violation, the $7,100 CMP was unreasonable.

RR at 26.

Buena Vista is trying to do indirectly what it acknowledges it is prohibited from doing directly, obtaining review of CMS's immediate jeopardy determination. *See* RR at 27-28. As the ALJ correctly noted, and Buena Vista does not dispute, the issue of whether CMS clearly erred in citing immediate jeopardy may not be reviewed on appeal where, as

here, CMS imposes a per-instance CMP because CMS's determination regarding the level of noncompliance, i.e., its scope and severity, is appealable "only if a successful challenge on this issue would affect—(i) The range of civil money penalty amounts that CMS could collect…; or (ii) A finding of substandard quality of care that results in the loss of approval for a SNF [skilled nursing facility] or NF [nursing facility] of its nurse aide training program [NATCEP]."[9] 42 C.F.R. § 498.3(b)(14). A per-instance CMP (as opposed to a per-day CMP) has only one range. *Compare* 42 C.F.R. § 488.438(a)(1) and (a)(2). In addition, under section 483.151(b)(2)(iv) and (f)(1), the imposition of a CMP of $5,000 or more automatically results in the loss of NATCEP; thus, the fact that there was a finding of substandard quality of care in this case would not provide a basis for appealing the immediate jeopardy determination.[10] Because CMS's determination regarding the level of noncompliance was not reviewable as a matter of law, it was final and the ALJ could properly consider the scope and severity reflected by that determination when assessing whether the CMP amount is reasonable. *See* 42 C.F.R. § 488.404(b), incorporated by reference in 488.438(f).

In any event, the ALJ Decision does not reflect any specific reliance on the immediate jeopardy determination. Instead, as indicated above, in determining that the CMP amount was reasonable, the ALJ merely found, in pertinent part, that Buena Vista's noncompliance involved several different instances of a deficiency and that the noncompliance with respect to Residents 20, 3, 14, and 19 "placed the residents at risk of more than minimal harm." ALJ Decision at 21-22. Buena Vista does not dispute that finding or the ALJ's findings that Buena Vista had a history of noncompliance with section 483.25(h) and that Buena Vista was culpable for the noncompliance found by the ALJ with respect to the side rails. Nor does Buena Vista argue that these findings are insufficient to support a per-instance CMP of $7,100. Accordingly, we agree with the ALJ that the $7,100 per-instance CMP is reasonable.

3. Buena Vista's due process arguments are not properly before us.

Before the ALJ, Buena Vista argued that it had a constitutional due process right to challenge CMS's immediate jeopardy determination independent of the issue of whether the ALJ or Board could review that determination when considering the reasonableness of the CMP amount. The ALJ found that he was "without the authority" to consider Buena Vista's due process argument but that it "is preserved for appeal." ALJ Decision at 5, n.4.

[9] Under section 488.301, substandard quality of care includes a deficiency related to participation requirements under section 483.25 which constitutes immediate jeopardy to resident health or safety.

[10] In any event, Buena Vista did not challenge the loss of its NATCEP.

Buena Vista argues before us that prohibiting it "from directly challenging immediate jeopardy determinations violates its procedural due process rights." RR at 27. Buena Vista asserts:

> Making an immediate jeopardy finding, as CMS did here, carries substantial repercussions. For instance, it affects insurance coverage, can result in licensure and certification issues, and may carry other penalties. It is, in short, a significant deprivation to make an immediate jeopardy finding.

RR at 27. According to Buena Vista, "Where government action results in a significant deprivation, procedural process mandates that the person subject to the government action have an opportunity to be heard." *Id*., citing *Mathews v. Eldridge*, 424 U.S. 319, 335 (1976).

This argument challenges the constitutionality of the Secretary's duly promulgated regulations since, as Buena Vista acknowledges, it is not entitled to review of CMS's immediate jeopardy determination under those regulations. The Board has no authority to declare regulations invalid on the ground that they are unconstitutional. *See, e.g., Northern Montana Care Ctr.*, DAB No. 1930, at 10 (2004), citing *Sentinel Medical Laboratories, Inc.*, DAB No. 1762, at 9 (2001), *aff'd sub nom., Teitelbaum v. Health Care Financing Admin.*, No. 01-70236 (9th Cir. Mar. 15, 2002), *reh'g denied*, No. 01-70236 (9th Cir. May 22, 2002).

Buena Vista also requests that the Board "declare" certain "rules concerning this appeals process to be unconstitutional due process violations[.]"[11] RR at 29. Buena Vista cites regulations that: (1) preclude an appeal where CMS imposes no remedy, (2) preclude review of CMS's choice of remedy or the factors CMS considers when choosing remedies, and (3) require the application of a "clearly erroneous" standard where a SNF is permitted to challenge an immediate jeopardy determination. *Id*., citing 42 C.F.R. § 488.408(g)(1), 488.430(e), 498.2, 488.408(g)(2), and 498.60(c)(2). Buena Vista also cites the "rule forcing SNFs to bear the burden of proving substantial compliance by a preponderance of the evidence." RR at 29.

This is not a case where CMS imposed no remedy, and Buena Vista does not specifically dispute CMS's choice of a per-instance CMP. Thus, whether the regulations regarding these matters are constitutional has no bearing on this appeal. In addition, to the extent that Buena Vista's request challenges the constitutionality of the Secretary's duly promulgated regulations, as already indicated, the Board lacks authority to entertain this challenge.

[11] Buena Vista did not challenge before the ALJ any of the "rules" it identifies here.

Moreover, Buena Vista has shown no basis for concluding that the Board's "rule" for allocating evidentiary burdens in a proceeding requested by a long-term care facility under 42 C.F.R. Part 498—that the facility must demonstrate substantial compliance by a preponderance of evidence—is unconstitutional. In the first place, Buena Vista's use of the word "rule" to describe the Board's and the ALJs' allocation of the burden of proof implies that it is a rulemaking within the meaning of the Administrative Procedure Act, whereas the Board has held that it is not. *See, e.g., Owensboro Place & Rehab. Ctr.*, DAB No. 2397, at 9 (2011) (stating that the burden of proof the Board applies "is not a 'rule' under the APA but is, instead, 'in the nature of an order setting forth a rationale, based on the statute and regulations, that establishes precedent for ALJ hearings in these cases.'" (citations omitted)). Secondly, in *Hillman Rehab. Ctr.*, DAB No. 1611, at 20-25 (1997), *aff'd, Hillman Rehab. Ctr. v. U.S.*, No. 98-3789 (GEB)(D.N.J. May 13, 1999), the Board rejected the argument that putting on a Medicare provider the ultimate burden of proving compliance by a preponderance of the evidence was inconsistent with due process. *Accord, Batavia Nursing & Convalescent Ctr.*, DAB No. 1911, at 11(2004) (extending the reasoning in *Hillman* to long-term care facilities), *aff'd, Batavia Nursing & Convalescent Ctr. v. Thompson*, 143 F. App'x 664 (6th Cir. 2005). Buena Vista does not cite any authority that supports its assertion that placing the ultimate burden of persuasion on the provider violates due process. In any event, the ultimate burden of persuasion is relevant only if the weight of all the competing evidence is in equipoise. *See, e.g., Azalea Court* at 16. As indicated by the foregoing discussion of Buena Vista's noncompliance with section 483.25(h), that was not the case here.

Accordingly, we deny Buena Vista's request that we review its constitutional claims.

Conclusion

For the reasons explained above, we sustain the ALJ Decision.

/s/
Judith A. Ballard

/s/
Constance B. Tobias

/s/
Sheila Ann Hegy
Presiding Board Member