Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Deltona Health Care
Docket No. A-13-28
Decision No. 2511
May 10, 2013

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Deltona Health Care (Deltona), a Florida long-term care facility, appeals the November 5, 2012 decision by an Administrative Law Judge (ALJ), *Deltona Health Care*, DAB CR2657 (2012) (ALJ Decision). The ALJ concluded that Deltona was noncompliant with Medicare participation requirements at 42 C.F.R. §§ 483.25(h), 483.25(i), and 483.20(d) from September 20, 2010 to February 14, 2011. The ALJ also upheld a finding by the Centers for Medicare & Medicaid Services (CMS) that Deltona's noncompliance was at the immediate jeopardy level from September 20, 2010 to January 19, 2011. Finally, the ALJ sustained the civil monetary penalties (CMPs) imposed by CMS based on CMS's determinations of noncompliance.

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

Case Background[1]

On January 4-6, 2011, the Florida Agency for Health Care Administration (state survey agency) conducted a Medicare compliance survey of Deltona triggered by the filing of a complaint. P. Ex. 1, at 1; CMS Ex. 7, at 1. Based on its investigation, which included a review of facility records and employee interviews, the state survey agency issued a Statement of Deficiencies (SOD) citing Deltona for noncompliance with five Medicare participation requirements, each identified with a unique survey F-tag number. P. Ex. 1, CMS Ex. 7, at 10. The state survey agency determined that each of the cited instances of noncompliance posed immediate jeopardy to resident health and safety. P. Ex. 1.

[1] Background information is drawn from 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 4-5 of the ALJ Decision.

CMS subsequently notified Deltona that it concurred with the state survey agency's findings. CMS Ex. 2, at 1-2. CMS notified Deltona that it considered the immediate jeopardy ongoing since July 20, 2010 and was imposing a CMP of $5,550 per day, effective July 20, 2010, until the immediate jeopardy was removed or Deltona's provider agreement was terminated. *Id.*

Based on a revisit survey conducted on January 26, 2011, CMS determined that the immediate jeopardy was removed as of January 20, 2011, but that Deltona remained out of substantial compliance with the Medicare participation requirements. CMS Ex. 3, at 1. CMS notified Deltona that the CMP would accrue at the rate of $5,550 per day from July 20, 2010 to January 19, 2011, and $100 per day from January 20, 2011 until Deltona achieved substantial compliance. *Id.* at 2. Based on a second revisit survey conducted on February 15, 2011, CMS determined that Deltona was in substantial compliance as of that date. CMS Ex. 4.

Deltona requested an ALJ hearing to challenge CMS's determinations and the remedies imposed. In its pre-hearing brief, CMS stated that it had revised the immediate jeopardy period to begin on September 20, 2010 and had reduced the total CMP amount accordingly, from $1,023,800 to $679,700. CMS Pre-Hear. Br. at 22. Following a hearing conducted via videoconference and the submission of post-hearing briefs, the ALJ issued his decision.

In his decision, the ALJ stated that he was addressing three of the five violations found by CMS and that it was not necessary for him to address the remaining two violations in order to uphold the CMP imposed. ALJ Decision at 3. The ALJ made the following findings and conclusions:

A. [Deltona] was not in substantial compliance with 42 C.F.R. § 483.25(i) (Tag F325) because it did not ensure that residents maintained acceptable parameters of nutritional status, as demonstrated by several residents' severe and unplanned weight loss.
    1. [Deltona] did not sufficiently rebut CMS's showing of inadequate nutrition regarding Resident 6's severe unplanned weight loss.
    2. [Deltona] did not sufficiently rebut CMS's showing of inadequate nutrition regarding Resident 7's severe unplanned weight loss.
    3. [Deltona] did not sufficiently rebut CMS's showing of severe weight loss in eight other residents.

B. [Deltona] was not in substantial compliance with 42 C.F.R. § 483.25(h) (Tag F323) because [Deltona] did not take all reasonable precautions to prevent falls and injuries to Residents 3 and 10.
    1. [Deltona] did not take all reasonable precautions to prevent foreseeable falls and injuries to Resident 3.

2. [Deltona] did not take all reasonable precautions to prevent foreseeable falls and injuries to Resident 10.

C. [Deltona] was not in substantial compliance with 42 C.F.R. § 483.20(d) (Tag F279) because [Deltona] did not adequately monitor and document its residents' conditions to ensure the sufficiency of their care plans.

D. CMS's determination that the facility's noncompliance posed immediate jeopardy to resident health and safety is not clearly erroneous.

E. The penalty CMS imposed is reasonable.

Id. at 5, 6, 9, 11, 12, 13, 16, 19, 22, 23.

Deltona filed a timely request for review with the Board, challenging all of the findings and conclusions identified above and contesting the burdens and standards of proof applied by the ALJ. Deltona also challenges the ALJ's denial of its motion to exclude evidence about the weight loss experienced by eight residents who were not identified in the SOD.

Standard of Review

We review a disputed finding of fact to determine whether the finding is supported by substantial evidence on the record as a whole, and a disputed conclusion of law to determine whether it is erroneous. *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.

Analysis

1. *The ALJ applied the correct burdens and standards of proof.*

The Board has held that, when a long-term care facility requests an ALJ hearing to contest a finding of noncompliance that has resulted in a CMP or other enforcement remedy, CMS has the burden of coming forward with evidence that, together with any undisputed facts, is legally sufficient to establish a prima facie case of noncompliance. *Azalea Court*, DAB No. 2352, at 2 (2010) (citations omitted). If CMS makes a prima facie showing, the facility then has the burden of persuasion to establish by a preponderance of the evidence that it was in substantial compliance. *Id.*

Deltona challenges the ALJ's use of this burden of proof, arguing that it violates section 7(c) of the Administrative Procedure Act (APA), 5 U.S.C. § 556(d), which provides that the burden of proof in an administrative proceeding lies with the proponent of a rule or order. According to Deltona, this provision places the burden of proof on CMS because it seeks to impose a CMP on Deltona. RR at 22. To the contrary, the Board has repeatedly held that "under the statutes and regulations governing nursing home

participation in the Medicare program, a facility is the proponent of an order finding it in substantial compliance" with the Medicare participation requirements. *Azalea Court*, DAB No. 2352, at 16; *see also Carrington Place of Muscatine*, DAB No. 2321, at 24 ("The Board has consistently held, based on analysis of the applicable statutory and regulatory provisions, that allocating the burden of persuasion to the [facility] does not violate APA procedural requirements."). This line of cases relies on the analysis in *Batavia Nursing and Convalescent Center*, in which the Board rejected a similar argument based on the APA. *See* DAB No. 1904 (2004), *aff'd, Batavia Nursing & Convalescent Ctr. v. Thompson*, 129 F. App'x 181 (6th Cir. 2005). We also note that the burden of proof is relevant only when the evidence is in equipoise. *Azalea Court*, DAB No. 2352, at 16; *see also Fairfax Nursing Home, Inc. v. U.S. Dep't of Health & Human Servs.*, 300 F.3d 835, at 840 n.4 (7th Cir. 2002), *aff'ing Fairfax Nursing Home, Inc.*, DAB No. 1794 (2001), *cert. denied*, 537 U.S. 1111 (2003). As evident from our discussion in the next sections, the evidence is not in equipoise here.

Deltona also challenges the standard and burden of proof used by the ALJ for determining Deltona's level of noncompliance. Under 42 C.F.R. § 498.60(c), "CMS's determination as to the level of noncompliance of [a long-term care facility] must be upheld unless it is clearly erroneous." Deltona maintains that this regulation violates both the APA and its constitutional right to due process. RR at 23. However, this regulation is clear, and the Board and ALJs have no authority to find duly promulgated regulations invalid. *See, e.g., Buena Vista Care Ctr.*, DAB No. 2398, at 21 (2013); *Sentinel Med. Labs., 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. 0170236 (9th Cir. May 22, 2002).

In any event, Deltona contends specifically that the regulation is inconsistent with 5 U.S.C. §§ 556(d) and 554(d). Its argument regarding section 556(d) is meritless for the reasons discussed above. Its argument regarding section 554(d) is equally meritless. Section 554(d) provides in relevant part that an "employee or agent engaged in the performance of investigative or prosecuting functions for an agency in a case may not, in that or a factually related case, participate or advise in the decision, recommended decision, or agency review . . . , except as witness or counsel in public proceedings." Deltona asserts that this section "limits investigative personnel to being witnesses, and prohibits treating them as if they were neutral fact-finders whose opinions are presumed correct." RR at 23. However, the fact that the regulations require an ALJ to uphold CMS's determination of the level of a facility's noncompliance unless the determination is clearly erroneous does not change the state surveyors who investigated Deltona from witnesses to participants or advisors in the ALJ Decision. One of the surveyors testified on behalf of CMS, but the ALJ independently evaluated all of the evidence, including the surveyor's testimony, before making a decision.

In addition, Deltona's due process argument appears to be based on the false premise that the CMP imposed was a quasi-criminal sanction. Deltona maintains that the "burden and standard of proof violate due process by making a facility prove its innocence." RR at 23. However, the CMP enforcement remedy imposed by CMS was remedial in nature, not punitive. As the Board explained in *Carrington Place*, where CMS imposed a CMP and denied payment for new admissions, "CMS imposed these remedies not to punish [the facility] but to motivate it to correct its deficiencies and maintain substantial compliance with Medicare participation requirements for the benefit and protection of its residents." DAB No. 2321, at 24, citing 42 C.F.R. § 488.402 (stating that the purpose of the remedies specified in section 488.406 is "to ensure prompt compliance with program requirements"); *Embassy Health Care Ctr.*, DAB No. 2299, at 11 (2010) ("the purpose of nursing home enforcement CMPs is to ensure compliance with program requirements, making them not punitive but remedial in nature").

2. *The ALJ's conclusion that Deltona failed to comply substantially with section 483.25(i) is supported by substantial evidence and free of legal error.*

Section 483.25(i) requires a facility to ensure that each resident maintains "acceptable parameters of nutritional status, such as body weight and protein levels, unless the resident's clinical condition demonstrates that this is not possible," and that each resident receives "a therapeutic diet when there is a nutritional problem." As the ALJ stated in his decision, the Board has held that unplanned weight loss may raise an inference of inadequate nutrition sufficient to establish a prima facie case of noncompliance with section 483.25(i). ALJ Decision at 6, citing *Carehouse Convalescent Hosp.*, DAB No. 1799, at 21-22 (2001). A facility may then rebut that showing by presenting evidence that the resident received adequate nutrition or that the weight loss "is due to non-nutritive factors, such as a clinical condition." *Id.*, quoting *Carrington Place*, DAB No. 2321, at 5. However, as the ALJ noted, the clinical condition exception "applies only when a facility demonstrates that it cannot provide nutrition adequate for the resident's overall needs so that weight loss is unavoidable." *Id.*, quoting *The Windsor House*, DAB No. 1942, at 8 (2004). CMS's State Operations Manual (SOM) suggests parameters for evaluating the significance of unplanned weight loss. *Id.* According to the SOM, a loss of more than 5% of body weight in a one-month period, for example, is considered to be "severe loss." *Id.*

The ALJ concluded that Deltona did not rebut CMS's showing that Deltona was noncompliant with section 483.25(i), as evidenced by the severe, unplanned weight loss of Resident 6, Resident 7, and eight other residents. Below, we explain why we uphold that conclusion.

Resident 6

Resident 6 was 94 years old at the time of the initial survey. ALJ Decision at 6, citing CMS Ex. 16, at 1. She was admitted to Deltona on November 22, 2010 following a hospital stay for a broken hip and arm. *Id.* The ALJ found that Resident 6 lost approximately 17% of her body weight between November 22, 2010 and January 3, 2011, and that this severe weight loss was unplanned and undesired. *Id.* at 7, 9. Deltona argued that any weight loss Resident 6 experienced was caused by new antidepressant medication, which suppressed her appetite, and by the removal of a plaster cast from her arm. *Id.* at 8; P. Pre-Hear. Br. at 9. The ALJ acknowledged that these factors "may have contributed to the weight loss," but found that Deltona's staff "did not even initially recognize that [Resident 6] was experiencing weight fluctuations" and did not "monitor [Resident 6]'s weight and nutritional status so that any weight loss could be identified and addressed to any extent that the weight loss was avoidable." *Id.* at 8-9.

On appeal, Deltona raises a number of challenges to the ALJ's conclusion. First, Deltona contests the ALJ's finding regarding the extent of Resident 6's weight loss, contending that Resident 6's "weight history fluctuated wildly and her usual body weight was unknown." RR at 3. The ALJ noted that Resident 6's usual body weight was unknown when she was admitted to Deltona. ALJ Decision at 7, citing CMS Ex. 16, at 4. However, Deltona did not dispute that shortly after her admission, on December 2, 2010, Resident 6 weighed 108 pounds and Deltona's dietician assessed her ideal body weight as 105 pounds, plus or minus 10%. *Id.* Deltona also did not dispute that a care plan for Resident 6 dated December 2 included the goal that she not experience any significant weight changes, yet on January 3, 2011 Resident 6 weighed 89.6 pounds, a loss of approximately 17% of her last measured body weight. *Id.*, citing CMS Ex. 16, at 6. Thus, despite the fact that Deltona did not know Resident 6's usual body weight on admission, it planned for her to maintain her most recent weight of 108 pounds, which was close to her ideal body weight as assessed by the dietician. Accordingly, as the ALJ concluded, the weight loss Resident 6 experienced was unplanned and severe.

Deltona also argues that the ALJ erroneously found that there was an "extended period" when its staff was unaware Resident 6 was losing weight. RR at 4. According to Deltona, this finding conflicts with the ALJ's acceptance of Deltona's assertion that the "first indication" its staff had that Resident 6 was losing weight was when staff received the residents' monthly weights on January 3, 2011. *Id.*; *see* ALJ Decision at 8, citing P. Pre-Hear. Br. at 11. Deltona's argument misses the ALJ's point: its staff should have noticed before January 3, 2011 that Resident 6 was losing weight. As the ALJ noted, Resident 6's December 2, 2010 care plan indicated that she should be weighed weekly for a month, but there is no evidence that Resident 6 was weighed at all between

December 2 and January 3, 2011. ALJ Decision at 7-9. We agree with the ALJ that had Deltona's "staff been monitoring [Resident 6]'s weight weekly as ordered under her care plan, they would have been alerted to the fact that her weight was on the decline, and they could then have modified her care plan with appropriate interventions." *Id.* at 8.

Deltona further argues that the ALJ erred in concluding that Deltona failed to show that Resident 6's weight loss was unavoidable. Deltona maintains that "there are facts which clearly indicate" that Resident 6's weight loss was unavoidable, "including an outbreak of gastrointestinal flu and the removal of a hard plaster cast from her arm." RR at 4. According to Deltona, the ALJ "substitute[d] his own clinical judgment for that of an experienced health care provider" in "find[ing] that the flu had no effect on [the] weight loss experienced" by Resident 6 "or any other resident." *Id.* at 3.

Contrary to Deltona's contention, the ALJ did not make the finding alleged. He made no determination about the impact of the flu on Resident 6's weight. This is not surprising since Deltona did not specifically contend in its briefs below that Resident 6 (or any other resident) had the flu and that the illness contributed to her weight loss; nor did Deltona cite the declaration in which its nurse consultant asserted that Resident 6 was one of several residents who had the flu in December 2010 and that the "effect of this flu outbreak on residents' weights cannot be discounted."[2] *See* P. Pre-Hear. Br.; P. Post-Hear. Br.; P. Ex. 28, at ¶ 67.

As noted above, the ALJ acknowledged that the removal of Resident 6's cast and the suppression of her appetite by a new medication "may have contributed" to her weight loss. ALJ Decision at 8. What guided the ALJ's conclusion about Deltona's noncompliance, however, is evidence that Deltona did not monitor Resident 6's weight and nutrition as it had planned to do in her care plan, and so did not take steps to address Resident 6's weight loss until after she had already experienced "severe loss." We agree that this evidence supports the ALJ's determination that Deltona failed to provide care and services in accordance with Resident 6's plan of care to ensure that she maintained acceptable parameters of nutritional status. Indeed, the Board "has repeatedly stated that a facility's failure to follow its care plan . . . may be grounds for concluding that the facility is not in substantial compliance with section 483.25 quality of care standards." *Venetian Gardens*, DAB No. 2286, at 5 (2009). The Board's conclusion is based on the

[2] We note that the ALJ did reject the idea that the flu might have contributed to Resident 7's weight loss (*see* ALJ Decision at 10-11), but Deltona never contended that Resident 7 had the flu, so Deltona cannot now contest the ALJ's conclusion. In any event, the ALJ's rationale for dismissing the effect of the flu on Resident 7's weight loss is sound and would apply equally to Resident 6. The ALJ concluded that the flu "may have accounted" for some of Resident 7's weight loss, but that considering the flu's 24 to 48-hour duration, he was persuaded by the surveyor's testimony that it was "not reasonable to expect [the flu] to have significantly contributed to the severe overall weight loss [Resident 7] experienced . . . ." ALJ Decision at 10, citing CMS Ex. 36, at 3. In reaching this conclusion, the ALJ relied on the testimony of the surveyor, who is a Registered Nurse and is certified as a Director of Nursing. *See* CMS Ex. 36, at 1.

introductory paragraph to section 483.25, which sets out the overarching standard for the quality of care regulation. Under the regulation, a facility must "provide the necessary care and services" for each resident to "attain or maintain the highest practicable physical, metal, and psychosocial well-being, in accordance with" the resident's "comprehensive assessment and plan of care."

We also note that after Deltona became aware of Resident 6's weight loss, its dietician increased her daily caloric intake and recommended increasing the quantity of her daily nutritional supplement. ALJ Decision at 8, citing CMS Ex. 16, at 5. Deltona argues that this shows it "moved quickly to implement new interventions" after the weight loss was discovered. RR at 4. However, the issue here is not what steps Deltona took after belatedly discovering Resident 6's weight loss, but instead whether it monitored her weight as frequently as her care plan required, which it did not do. In addition, the fact that Deltona took additional steps after it became aware of Resident 6's weight loss suggests that it could have adopted such measures earlier. Had it done so, Resident 6's weight loss might have been avoided or reduced.

Before Deltona became aware of Resident 6's weight loss, her care plan stated that she would receive 90 ml of a nutritional supplement called Med Pass three times a day. CMS Ex. 16, at 5. The ALJ found that Deltona did not dispute that Resident 6 did not receive the supplement daily as ordered, and concluded that it was "questionable" how frequently she received it. ALJ Decision at 7-8. Deltona argues that the record does not support the ALJ's conclusion, and points out that elsewhere in his decision the ALJ noted that Deltona's dietician had indicated on January 5, 2011, during the initial survey, that Resident 6 was "currently receiving" 90 ml of Med Pass and accepted and tolerated it well. RR at 3; ALJ Decision at 8, citing CMS Ex. 16, at 5.

Even if the ALJ erroneously concluded that it was <u>undisputed</u> that Resident 6 did not receive Med Pass as ordered, the ALJ's error is harmless. The record does not establish that Resident 6 received the supplement as often as ordered. Although medication records submitted by CMS show that on January 7-9, 2011 Resident 6 received the increased dosage of Med Pass recommended by the dietician (*see* CMS Ex. 16, at 12-13), Deltona did not submit records showing she received the increased dosage during any prior time periods. The dietician's note from January 5, 2011 also does not establish that Resident 6 had been regularly receiving 90 ml of Med Pass prior to that date. Moreover, even if Resident 6 was receiving the prescribed dosage of Med Pass three times a day prior to January 5, 2011, that does not mean she was receiving adequate nutrition, as Deltona appears to argue. RR at 3-4. She fell significantly below her assessed ideal body weight and Deltona has not pointed to any evidence in the record, beyond statements in the declaration of its nurse consultant, establishing that Resident 6 maintained acceptable parameters of nutritional status despite this severe weight loss. *Id.* at 4, citing P. Ex. 28, at ¶¶ 62-67. The consultant opined that Resident 6's weight loss was unforeseeable and

that the flu and removal of the cast from her arm contributed to her severe weight loss. P. Ex. 28, at ¶¶ 65-67. The consultant did not, however, state directly that Resident 6 had maintained acceptable parameters of nutrition, despite the weight loss, as Deltona suggests. Moreover, while the consultant testified that Resident 6 was "appropriately care planned for nutrition," she did not address the facility's failure to follow that care plan. *Id.* ¶ 64.

Accordingly, the ALJ's conclusion that Deltona failed to rebut CMS's showing that Deltona did not maintain acceptable parameters of nutritional status for Resident 6 is supported by substantial evidence and free of legal error.

Resident 7

Resident 7, who was 76 years old at the time of the initial survey, weighed 208 pounds when she was admitted to Deltona on October 3, 2010. CMS Ex. 17, at 8. Her diagnoses included dementia, hypothyroidism, and morbid obesity. *Id.* The ALJ found that Resident 7 lost approximately 13% of her body weight from December 2010 to January 2011, and approximately 17% of her body weight between October 2010 and January 2011. ALJ Decision at 9. As noted earlier, this is a severe weight loss under the SOM. The ALJ found that this severe weight loss was unplanned and rejected Deltona's arguments that the weight loss was both unavoidable and desirable. *Id.* at 10-11.

Deltona contends that it presented "substantial persuasive evidence" that the severe weight loss Resident 7 experienced – 25 pounds between December 2010 and January 2011 alone – is not usually caused "solely" by a decrease in caloric intake, and so must have been caused by "clinical reasons, unrelated to the provision of nutrition." RR at 5-6. Deltona asserts that the ALJ should have concluded that Resident 7's hypothyroidism, her dislike of many foods, and her medications made her weight loss unavoidable. *Id.* at 6.

We agree with the ALJ that "none of these reasons excuses" Deltona's failure to monitor Resident 7's weight and nutrition. ALJ Decision at 10. As the ALJ reasoned, if Resident 7's thyroid problem or her medications were causing weight loss, Deltona should have alerted her physician so that he could adjust her medications or her diet. *Id.* In addition, if Resident 7's dislike of many foods was contributing to her weight loss, Deltona should have offered her snacks, replacement meals, and nutritional supplements. *Id.* Deltona points out that it did take some of these steps after its staff became aware of Resident 7's severe weight loss on January 3, 2011. RR at 6. As with Resident 6, however, the evidence shows that if Deltona had monitored Resident 7's weight in accordance with her care plan, Deltona would have been aware of Resident 7's weight loss and could have implemented those interventions sooner. As the ALJ pointed out, Resident 7's care plan dated October 5, 2010 indicated that she would be weighed weekly for a month, but there

is no evidence that she was weighed as planned. ALJ Decision at 9. In addition, on December 28, 2010 Deltona's interdisciplinary care team assessed Resident 7 as "maintaining" in the area of nutrition, hydration, and weight, despite the fact that she had lost 20 pounds between October and December 2010. *Id.*, citing CMS Ex. 17, at 4. We agree with the ALJ that this evidence suggests Deltona's staff was "not properly monitoring" Resident 7's weight, or "documenting any steps to address a severe weight loss." *Id.* at 9-10.

Deltona also appears to argue that the ALJ should not have relied on Resident 7's weight loss as evidence of a deficiency under section 483.25(i) because, according to Deltona, Resident 7 was happy with the weight loss and needed to lose weight. RR at 7. In rejecting this argument, the ALJ reasoned that if the weight loss had been intentional, he would have expected weight loss to be part of Resident 7's care plan, but it was not. ALJ Decision at 10.

Deltona asserts that "[n]ot every clinical issue must be included on the care plan." RR at 7. Deltona's argument lacks merit. As the ALJ noted, Resident 7's care plan did address her weight, and stated that she would not experience any significant weight changes until the next care plan review. ALJ Decision at 10; *see* CMS Ex. 17, at 10. Thus, the record contradicts Deltona's contention that Resident 7's weight loss was a planned development. The ALJ's conclusion that Deltona failed to rebut CMS's showing that Deltona did not maintain acceptable parameters of nutritional status for Resident 7 is supported by substantial evidence and free of legal error.

Eight other residents not identified in the SOM

As part of its pre-hearing exchange, CMS submitted as proposed exhibits two weight charts that the surveyors had obtained from Deltona during the initial survey. The charts show that eight residents, in addition to Residents 6 and 7, also experienced weight loss that appears to be "severe." *See* CMS Exs. 23-24. In its briefing, CMS cited the weight loss experienced by the eight residents as further support for its contention that Deltona failed to comply substantially with section 483.25(i). CMS Pre-Hear. Br. at 4. Deltona moved to exclude any evidence related to the eight residents, arguing that, unlike Residents 6 and 7, they had not been identified in the SOD and so Deltona had not received adequate notice to refute CMS's contentions regarding those residents. Mot. in Lim. to Exclude Proposed Exs. 23 & 24. The ALJ denied Deltona's motion and later determined that the evidence "further support[ed]" his conclusion that Deltona had not been in substantial compliance with section 483.25(i). Ruling Denying P.'s Mots.; ALJ Decision at 11.

On appeal, Deltona contends that the ALJ erroneously denied its motion in limine. RR at 15-17. Deltona also challenges the ALJ's conclusion that it failed to rebut CMS's showing that the eight residents experienced severe, unplanned weight loss. *Id.* at 7-8; P. Reply at 4th page (unnumbered).

The ALJ did not err in denying Deltona's motion. Under section 498.61, an ALJ has "broad discretion to admit evidence." *Jennifer Matthews Nursing & Rehab. Ctr.*, DAB 2192, at 51 (2008). In addition, the Board has held that an ALJ may permit "issues to be raised during the hearing that were not clearly raised on the SOD provided the facility has notice and a meaningful opportunity to be heard on those issues." *Life Care Ctr. of Bardstown*, DAB No. 2479, at 7 (2012), citing *Livingston Care Ctr.*, DAB No. 1871 (2003), *aff'd, Livingston Care Ctr. v. U.S. Dep't of Health & Human Servs.*, 388 F.3d 168 (6th Cir. 2004). As the ALJ explained in his decision, "[n]otice of additional evidence . . . may be provided through prehearing record development without amending the SOD." ALJ Decision at 11. The ALJ did not err in reasoning that there was no notice problem because CMS included the weight charts in its proposed exhibits and timely argued in its pre-hearing brief, based on the charts, that ten residents lost more than five percent of their body weight in a single month.

In any event, we conclude that the evidence concerning Residents 6 and 7 amply supports the ALJ's determination that Deltona failed to comply substantially with section 483.25(i). Accordingly, there is no need for us to evaluate the ALJ's analysis regarding the other eight residents.

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

Under section 483.25(h), a facility must ensure that the "resident environment remains as free of accident hazards as possible" and that each resident receives "adequate supervision and assistance devices to prevent accidents." As the ALJ noted, the Board has interpreted this provision as requiring a facility to take "all reasonable steps to ensure that a resident receives supervision and assistance devices to meet his or her assessed needs and mitigate foreseeable risks of harm." ALJ Decision at 12, quoting *Briarwood Nursing Ctr.*, DAB No. 2115, at 11 (2007). The ALJ concluded that Deltona failed to satisfy this requirement for Residents 3 and 10. As we discuss below, substantial evidence supports the ALJ's conclusion and Deltona's objections lack merit.

Resident 3

Resident 3 was 88 years old at the time of the initial survey. ALJ Decision at 13, citing CMS Ex. 15, at 1. She fell four times between September 2009 and September 2010. CMS Ex. 6, at 4; CMS Ex. 7, at 6. After Resident 3 fell on June 17, 2010, a consultant

pharmacist noted that Resident 3 was receiving 5 mg of the sleep aid Ambien nightly at bedtime, "which could contribute to a fall due to excessive sedation." P. Ex. 2, at 12. The pharmacist recommended decreasing Resident 3's Ambien dosage to 2.5 mg at bedtime "as needed." *Id.* Resident 3's treating physician agreed, and ordered the change on June 26, 2010.[3] P. Ex. 2, at 10, 14. A care plan dated September 20, 2010 identified Resident 3 as a fall risk and listed several interventions for decreasing that risk. ALJ Decision at 13-14, citing CMS Ex. 15, at 3. On November 3, 2010 at approximately 7 a.m., Resident 3 was found on the floor calling for help. CMS Ex. 15, at 15. She had a prominent, painful bulge on her left hip. *Id.* Deltona staff members lifted Resident 3 off the floor and put her back in bed. An x-ray later revealed that Resident 3 had fractured her hip. Over five hours after she was found on the floor, Resident 3 was taken to the emergency room for treatment. *Id.* at 15-16.

The ALJ found that, although Deltona knew Resident 3 was a fall risk, it "did not implement adequate interventions to ensure" her safety. ALJ Decision at 13. The ALJ faulted Deltona for failing to update Resident 3's care plan to reflect that her physician had reduced her dosage of Ambien, and for continuing to administer the higher dosage. *Id.* The ALJ also determined that Deltona's staff failed to "act promptly to provide [Resident 3] with necessary care and treatment" when she exhibited signs of a possible hip fracture on November 3, 2010. *Id.* In addition, the ALJ concluded that there were "other reasonable precautions" Deltona's staff could have taken to safeguard Resident 3 from falls. *Id.* at 15.

Deltona asserts that the ALJ erred in finding that it should have updated Resident 3's care plan to reflect that her physician had changed her dosage of Ambien from 5 mg "routine" to 2.5 mg "as needed." Deltona does not dispute that it did not include information about Resident 3's Ambien dosage in her care plan, but argues that no regulation requires types or doses of medications to be put on care plans. RR at 9-10. The ALJ did not conclude, however, that Deltona's failure to note the change in Resident 3's Ambien dosage on her care plan itself constituted a violation of the regulations. Instead, the ALJ determined that Deltona's failure to note the updated dosage on the care plan – and, more importantly, Deltona's failure to comply with the new order – "increased the likelihood" that Resident 3 would suffer "serious harm from a fall resulting from oversedation." ALJ Decision at 15. Deltona has presented no evidence that it communicated the doctor's ordered dosage change to care staff in any fashion – whether by care plan or some other document routinely available to staff.

[3] The ALJ found that the physician ordered the change on June 25, 2010. *See* ALJ Decision at 14, 24. As we read the record, on June 25 the physician switched Resident 3's Ambien prescription to "as needed" but kept the dosage at 5 mg. The following day, June 26, the physician changed the prescription to 2.5 mg as needed. *See* P. Ex. 2, at 10, 12, 14. The exact date of the change does not impact the remedies imposed, however.

Deltona argues that Resident 3's Ambien dosage did not have any bearing on her fall on November 3, 2010. Deltona contends that Resident 3's physician increased the dosage back to its original level, and that Deltona's physician expert, its nurse consultant, and the surveyor "all agreed that Resident 3's Ambien would likely have worn off by the time she fell" on November 3. RR at 10.

Deltona does not say when the doctor allegedly increased Resident 3's Ambien dosage back to 5 mg, much less point to evidence that any increase occurred prior to November 3. The record contains a "Medication Regimen Review Sheet" documenting that on November 15, 2010 the consultant pharmacist recommended that "the routine order for Ambien 5 mg routine be discontinued and changed to Ambien 5 mg HS PRN [as needed]." P. Ex. 2, at 16. The document also shows that the physician signed off on this change at some later date (his signature is undated). *Id.* However, it is unclear what "order for Ambien 5 mg routine" means since there is no such order in the record. The only orders in the record related to Resident 3's Ambien prescription reflect the physician's reduction of her dosage on June 26, 2010 from 5 mg routine at bedtime to 2.5 mg as needed at bedtime. P. Ex. 2, at 10, 14. More specifically, there are no records showing that at some point between June 26, 2010 and November 15, 2010, Resident 3's physician switched her Ambien dosage back to 5 mg routine.[4]

In addition, although Deltona's physician expert and nurse consultant stated in their declarations that the Ambien Resident 3 took at bedtime on November 2, 2010 would have worn off by the time she fell on November 3 (P. Ex. 27, at ¶ 6; P. Ex. 28, at ¶ 41), the surveyor did not concur in this assessment. In response to a question about whether taking Ambien at bedtime would leave someone drowsy in the morning, the surveyor explained that after a certain number of hours the body starts to absorb and then excrete the medication. Tr. at 47. However, the surveyor further testified that it was "a possibility" that Resident 3's taking Ambien at bedtime on November 2 might have contributed to her fall on the morning of November 3, because "[p]eople react to medications differently." *Id.* at 48. In any event, the ALJ relied on the treating physician's opinion that reducing Resident 3's Ambien dosage would decrease her risk of falls. ALJ Decision at 15. Even though the physician did not testify, the ALJ could rely on the physician's orders as evidence of his judgment about what was best for Resident 3, especially since the dosage reduction was in response to the pharmacist's recommendation.

[4] The record does contain Resident 3's medication record for November 2010, which incorrectly indicates that an order dated June 26, 2010 prescribed Resident 3 a routine 5 mg dose of Ambien at bedtime, whereas the physician order on that date actually reduced the dosage. CMS Ex. 15, at 30. The fact that the resident's medication record contained such an error underscores the care deficits that led to this finding of noncompliance.

Moreover, it is "not a prerequisite" to finding noncompliance under section 483.25(h) "that any actual accident have occurred or be caused by" a facility's inadequate supervision and assistive devices. *Del Rosa Villa*, DAB No. 2458, at 18 (2012), quoting *Briarwood Nursing Ctr.*, DAB No. 2115, at 11. The "proper inquiry" is whether the facility took all reasonable steps to "meet assessed needs" and to mitigate "foreseeable risks of harm." *Id.* Deltona did not dispute the ALJ's finding that Resident 3's physician initially decreased her Ambien dosage and modified it to be given "as needed" rather than regularly in June 2010 because he determined that "a higher dosage could result in excessive sedation and a higher risk for falls." ALJ Decision at 14-15. Thus, Deltona had notice prior to the November 3 fall that Resident 3's physician believed the higher dosage would put Resident 3 at an increased risk of falling. Yet it is undisputed that Deltona's staff erroneously continued to give Resident 3 the higher Ambien dosage after the physician ordered it decreased, and, as noted above, although Deltona asserts the dosage was increased again, it has not provided any persuasive evidence that this was done before the date of her fall. *Id.*; *see* CMS Ex. 15, at 30. By continuing to give Resident 3 the higher dosage of Ambien, in contravention of the physician's order, Deltona failed to take all reasonable precautions to prevent Resident 3 from falling.

Deltona further argues that "appropriate interventions were in place" to reduce Resident 3's risk of falls and that the ALJ erred in concluding that "there could have been additional interventions in place." RR at 9, 11. The fall risk care plan in effect for Resident 3 prior to her fall on November 3, 2010 included the interventions "assist w/1," observe for medication side effects, and provide appropriate safety and enabler devices, specifically "1/2 side rails" and non-skid socks. CMS Ex. 15, at 3. The care plan form lists several potential interventions that staff can select by checking a box next to the intervention, and also has space for writing in unlisted interventions. *Id.* The listed interventions that Deltona chose not to implement for Resident 3 included utilizing a "low bed," assisting her with toileting at set periods, providing assistance for unsteady gait, and including her in Deltona's "Starlight" or "Falling Star" program, for residents who are at a high risk of falls and require frequent monitoring. *Id.*; *see* CMS Ex. 6, at 13. CMS argued before the ALJ that Deltona could reasonably have considered or implemented additional steps to limit Resident 3's risk of falls, such as including her in the "Falling Star" program so she would receive additional monitoring, moving her call button to an easier-to-reach spot, and installing a bed alarm. CMS Post-Hear. Br. at 11.

Deltona correctly points out that the regulations generally do not identify the specific interventions facilities are required to implement. RR at 11. Even though a facility is "permitted the flexibility to choose the methods it uses to prevent accidents and injuries," however, facilities must "take all 'practicable' measures" to mitigate foreseeable risks of harm from accidents, and the "chosen methods must be adequate under the circumstances." *Golden Oaks*, DAB No. 2470, at 5, citing *Josephine Sunset Home*, DAB No. 1908, at 14 (2004); *Guardian Health Care*, DAB No. 1943 (2004). Deltona has not shown that the interventions it had in place for Resident 3 on November 3, 2010 were

adequate and that it took all "practicable" measures to mitigate Resident 3's risk of falling. For example, Deltona did not document, nor has it attempted to explain, why it chose not to implement the additional interventions listed but not selected on Resident 3's care plan. Deltona also has not explained how it selected the interventions it did choose to implement, and has not shown that it ever evaluated the effectiveness of those interventions prior to Resident 3's fall on November 3. Contrary to Deltona's contention, the ALJ did not conclude that Deltona provided inadequate care because it failed to implement these specific measures. Instead, the ALJ determined more generally that Deltona "could have reasonably implemented additional safety interventions to address [Resident 3's] risk of falls." ALJ Decision at 15.

The Board has explained that under section 483.25(h) what is "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. Deltona failed to demonstrate that it exercised the requisite reason and professional judgment in assessing the interventions necessary to keep Resident 3 safe.

Finally, Deltona argues that the ALJ erred in considering the actions taken by its staff after Resident 3's fall on November 3, 2010 when determining whether it complied with section 483.25(h).[5] It maintains that the section "does not impose any requirement on facilities regarding their actions once an accident has occurred," and that in any event its staff did respond appropriately to Resident 3's fall. RR at 9. Since the other evidence we have discussed amply supports our decision to uphold the ALJ's determination that Deltona failed to comply substantially with section 483.25(h) in caring for Resident 3, we do not need to reach this issue.

Resident 10

Resident 10, who was 66 years old at the time of the initial survey, was admitted to Deltona on May 8, 2010. ALJ Decision at 16, citing CMS. Ex. 18, at 1. She was assessed as being at risk for falls at the time of admission, and Deltona created a care plan for reducing that risk. *Id.*, citing P. Ex. 5, at 2. On November 8, 2010, Resident 10 fell during the middle of the night, but she did not exhibit any sign of injury. *Id.* at 17, citing P. Ex. 5, at 24. On November 12, 2010, Resident 10 fell again and fractured her hip.

[5] The ALJ determined staff did not immediately call 911 when they found Resident 3 on the floor, and did not arrange for her to be transported to the hospital until more than five hours had passed. ALJ Decision at 13-14. The ALJ also determined that during the period after Resident 3 had fallen but was still at the facility, Deltona's Director of Nursing "did not appropriately intervene" to ensure that she "received appropriate treatment and services." *Id.* The ALJ made similar findings about staff's response to a fall by Resident 10, who we discuss below.

Deltona argued before the ALJ that Resident 10's falls and injury were unpreventable and unpredictable, and that she had an appropriate care plan in place and received appropriate care once her injury occurred. *Id.* at 16. The ALJ concluded that the fact that Resident 10 "fell twice in four days . . . and suffered a fractured hip suggests that [Deltona's] interventions to deal with her risk for falls were not adequate to prevent accidental injury." *Id.* at 17. The ALJ also determined that Deltona's staff did not respond appropriately after Resident 10's second fall, exacerbating her risk of serious injury. *Id.* at 18-19.

Deltona argues that the ALJ erred in concluding that it did not have adequate interventions in place to prevent Resident 10 from falling. Deltona again asserts that the regulations do not require facilities to implement specific interventions. RR at 12. Since we have addressed that argument above, we need not address it again.

Deltona also asserts that the ALJ inappropriately held it strictly liable for Resident 10's falls. RR at 12. The ALJ did not hold Deltona strictly liable for Resident 10's falls. He did not conclude that Deltona failed to comply substantially with section 483.25(h) based solely on the fact that Resident 10 fell twice between November 8 and 12, 2010. Instead, the ALJ concluded that the fact Resident 10 fell twice in such a short span of time suggested that Deltona did not have appropriate interventions in place to reduce her risk of falling. ALJ Decision at 17. Substantial evidence supports the ALJ's conclusion.

If 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." *Sunshine Haven Lordsburg*, DAB No. 2456, at 14 (2012). After Resident 10's fall on November 8, 2010, Deltona was on notice that the fall risk interventions it had in place for her might be inadequate. The ALJ noted that Deltona claimed it updated Resident 10's care plan after she fell, but he did not see any evidence that Deltona modified the interventions in place or implemented additional measures. ALJ Decision at 17. On appeal, Deltona contends that "there were additional interventions put in place after the November 8, 2010 fall" (RR at 12), but the record contradicts Deltona's assertion. A document titled "Fall Action Team: Fall Review," which is dated November 8, 2010, concerns Resident 10's fall on that date. *See* P. Ex. 5, at 24. A section of the document titled "Fall Action Team Response" contains the handwritten note "Educated pt R/T Safety," but the box next to "Care plan interventions updated" is not checked. *Id.* Deltona's nurse consultant also stated that after Resident 10's November 8 fall, although the Fall Action Team "re-educated the resident," it "determined that no additional interventions were necessary." P. Ex. 28, at ¶ 47.

As the ALJ noted, Deltona did eventually implement additional interventions for Resident 10, but only after her second fall on November 12, 2010. ALJ Decision at 17. The ALJ pointed out that in a "Post Event Evaluation" form completed by Deltona staff on November 12, 2010, the staff noted that Resident 10 did not have a low bed, a tab alarm, or a sensor pad. *Id.*, citing P. Ex. 5, at 1. On November 18, 2010, she received these assistive devices. *Id.*, citing CMS Ex. 18, at 4. Notably, Deltona does not claim that it considered but rejected providing Resident 10 with these devices after her first fall or otherwise attempt to explain why it did not provide Resident 10 with these devices or other interventions sooner.

Deltona also argues that the ALJ erroneously concluded that its staff did not respond appropriately to Resident 10's injury on November 12, 2010, and that even if its staff's response was inappropriate, "it would be irrelevant" in determining whether Deltona failed to comply substantially with section 483.25(h). RR at 12-13. We do not need to reach this issue for the same reason we stated with respect to Resident 3. Substantial evidence supports the ALJ's conclusion that Deltona failed to comply substantially with section 483.25(h) in caring for Resident 10.

4. *The ALJ's conclusion that Deltona failed to comply substantially with section 483.20(d) is supported by substantial evidence, but we modify the ALJ's analysis to include the requirements of section 483.20(k)(1) and to clarify the basis for finding noncompliance.*

Section 483.20(d) requires a facility to "maintain all resident assessments completed within the previous 15 months in the resident's active record" and to "use the results of the assessments to develop, review, and revise the resident's comprehensive plan of care." Section 483.20(k)(1) requires a facility to "develop a comprehensive care plan for each resident that includes measurable objectives and timetables to meet a resident's medical, nursing, and mental and psychosocial needs that are identified in the comprehensive assessment." The care plan must describe the "services that are to be furnished to attain or maintain the resident's highest practicable physical, mental and psychosocial well-being as required under § 483.25" and any services that "would otherwise be required under § 483.25 but are not provided due to the resident's exercise" of various rights, including "the right to refuse treatment." 42 C.F.R. § 483.20(k)(1)(i), (ii).

The surveyors cited Deltona for noncompliance with both section 483.20(d) and section 483.20(k)(1) in the SOD. P. Ex. 1, at 13. CMS likewise relied on both sections in the portions of its briefing alleging that Deltona was noncompliant with the regulations

because it failed to develop comprehensive care plans. CMS Pre-Hear. Br. at 20; CMS Post-Hear. Br. at 16-17. In concluding that Deltona's care plans failed to comply with the regulations, the ALJ referenced only section 483.20(d). ALJ Decision at 2, 19. Nonetheless, the substance of his analysis encompasses the requirements of both subsections. Accordingly, we affirm the ALJ's conclusion that Deltona did not sufficiently prepare and update its residents' care plans, but modify his analysis to specifically include a finding that Deltona was not in substantial compliance with section 483.20(k)(1) as well as section 483.20(d) and to clarify the basis for finding noncompliance.

In his analysis, the ALJ focused mainly on Resident 11, a 94-year-old resident who was severely cognitively impaired and required total assistance with all activities of daily living. ALJ Decision at 19, citing CMS Ex. 19, at 3. The SOD alleged that Deltona did not meet the care planning requirements because it did not update her plan when she returned from the hospital with a hard cast on her leg. P. Ex. 1, at 17. The ALJ found that Deltona's staff failed to monitor Resident 11's right leg for possible swelling and circulatory problems when the leg was in a hard cast, even though staff had added a note on Resident 11's care plan to monitor her circulation in the leg when she returned to Deltona with that cast. ALJ Decision at 20. The ALJ's analysis of Deltona's care plan for Resident 11 identified a problem with the staff's failure to <u>follow</u> the care plan, not a problem with the staff's development of the care plan.

However, we conclude that the care plan was deficient because it did not provide sufficient detail as to how staff were to monitor Resident 11's circulation. The Board has explained that a comprehensive care plan "functions as a roadmap for all of the resident's caregivers, including those unfamiliar with a resident or without professional training, to provide consistent care and services tailored to 'attain or maintain the [resident's] highest practicable physical, mental and psychosocial well-being.'" *Sheridan Health Care Ctr.*, DAB No. 2178, at 37 (2008), quoting 42 C.F.R. § 483.20(k). "Accordingly, the care plan must include sufficient guidance to ensure that the services provided promote the plan's specified objectives." *Id.* Deltona's medical expert opined that it is "very difficult to gain access to the pulses in the lower limbs" when someone has a hard cast, and both he and the surveyor described specific (albeit somewhat different) steps that should be used to evaluate circulation in that situation. P. Ex. 27, at ¶ 32; Tr. at 63-64. Yet, the note in Resident 11's care plan only instructed staff to "monitor circulation to rt. lower ext" and did not include directions about how to do this. CMS Ex. 19, at 16. Because the care

plan did not explain who was responsible for monitoring the circulation in Resident 11's leg, how to do the monitoring, or how often to do so, it did not provide adequate guidance to staff to ensure that Resident 11 received the requisite care.[6]

Moreover, the ALJ did not base his finding of noncompliance with section 483.20 only on Resident 11. He also determined that Deltona failed to develop effective care plans to meet the needs of several other residents, including Resident 10. ALJ Decision at 21-22. As discussed above, the record establishes that Deltona did not have sufficient interventions listed on the fall risk care plan for Resident 10 to reduce her risk of falls. Although Resident 10 fell on November 8, 2010, Deltona did not update the interventions in her care plan until she fell again four days later, and Deltona has not presented a persuasive explanation for why it did not add and implement the new interventions sooner. The ALJ could reasonably infer that, until it was updated, the care plan did not describe all of the services and interventions that were necessary to reduce the risk that Resident 10 would fall again, as she did on November 12.

The findings we uphold for Residents 11 and 10 are sufficient to uphold the ALJ's conclusion that Deltona was not in substantial compliance with section 483.20. Thus, we need not discuss the ALJ's findings regarding the other residents under this requirement.

5. *The ALJ did not err in concluding that CMS's immediate jeopardy determination was not clearly erroneous.*

Deltona challenges the ALJ's conclusion that CMS did not clearly err in determining that Deltona's noncompliance with the Medicare participation requirements posed immediate jeopardy to resident health and safety. RR at 19-21. As the ALJ noted, immediate jeopardy exists if a facility's noncompliance "has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." ALJ Decision at 22, quoting 42 C.F.R. § 488.301.

Deltona's challenge is based in part on its disagreement with the standard and burden of proof for determining a facility's level of noncompliance: CMS's determination must be upheld unless it is clearly erroneous. 42 C.F.R. § 498.60(c). However, as discussed above, we reject Deltona's arguments on that point.

Deltona also contends, without elaboration, that there "was no likelihood of serious injury, harm, impairment or death to any resident involved in the survey." RR at 21. The

[6] Deltona argues that its staff properly monitored Resident 11's leg when it was in a cast because staff monitored Resident 11's pain levels, which Deltona's medical expert opined is a better way to identify complications than circulation checks. RR at 14; *see* P. Ex. 27, at ¶¶ 32-33. Deltona's argument ignores the fact that it specifically identified monitoring the circulation in Resident 11's leg as a necessary intervention on her care plan. *See* CMS Ex. 19, at 16.

record refutes this assertion. As the ALJ noted, Residents 6 and 7 both suffered severe, unplanned weight loss because Deltona failed to appropriately monitor their weights. ALJ Decision at 22. The ALJ reasonably concluded that "[i]nadequate nutrition is a serious problem, especially for elderly individuals who require skilled nursing care" because "nutrients are critical to the body's metabolism and its healing process." *Id.*, citing CMS Ex. 36, at 2. In addition, Residents 3 and 10 fractured bones because Deltona did not have appropriate interventions in place to prevent accidents. *Id.* at 22-23. Thus, four of the five residents discussed in the ALJ Decision suffered actual, serious harm as a result of Deltona's noncompliance.

In addition, Deltona contests the ALJ's finding regarding the duration of the immediate jeopardy. RR at 20, 23-24. The ALJ upheld CMS's determination that Deltona's noncompliance was at the immediate jeopardy level from September 20, 2010 to January 19, 2011. According to Deltona, "[i]f there could be an argument made for an immediate jeopardy level violation, it could not have been before November 8, 2010 when Resident #10 fell for the first time." *Id.* at 23.

CMS determined that the immediate jeopardy began on September 20, 2010 because that is the date that Deltona implemented the fall risk care plan for Resident 3 that was in effect when she fell on November 3, 2010. *See* CMS Pre-Hear. Br. at 22. CMS maintains, and the ALJ agreed, that Deltona should have noted on the care plan that Resident 3's Ambien dosage had been reduced, and that the failure to document this change on the plan helped create a risk that Resident 3 would fall as a result of oversedation. *See id.*; CMS Post-Hear. Br. at 21-22; ALJ Decision at 15.

We do not need to reach the specific issue of whether or when Deltona needed to note the dosage change on Resident 3's care plan in order to uphold the start date for the immediate jeopardy period. As noted above, Resident 3's medication record for November 2010 incorrectly indicates that, per an order dated June 26, 2010, Resident 3 should regularly receive 5 mg of Ambien nightly at bedtime. *See* CMS Ex. 15, at 30. The November medication record also shows that Resident 3 received this dosage on November 1 and 2, 2010, in accordance with the erroneous information about the physician's order. *See id.*; P. Ex. 2 at 10, 14. Deltona did not submit medication records from earlier time periods showing what dosage Resident 3 had received on any other dates after the order was written on June 26, 2010. As discussed above, we agree with the ALJ that Deltona's failure to follow the physician's order and reduce her Ambien dosage created a risk that Resident 3 could fall and sustain injuries as a result of oversedation. Under section 488.440(a), a per-day CMP "may start accruing as early as the date that the facility was first out of compliance, as determined by CMS or the State."

Thus, CMS could have determined that Deltona was first out of compliance on June 26, 2010. CMS had discretion, however, to choose a later effective date. *See Regency Gardens Nursing Ctr.*, DAB No. 1858, at 10 (2002) ("From the provision that remedies may be imposed as early as the first day of noncompliance, it follows that CMS may choose to begin any remedy at a later date.") (emphasis in original). Accordingly, we find no error in the ALJ's decision to uphold CMS's determination to begin imposing remedies for noncompliance at the immediate jeopardy level on September 20, 2010.[7]

Once a facility has been found to be out of substantial compliance, it remains so until it affirmatively demonstrates that it has achieved substantial compliance again. *See* 42 C.F.R. § 488.454(a)(1); *see also Owensboro Place & Rehab. Ctr.*, DAB No. 2397, at 12 (2011) ("The Board has made it clear that the facility bears the burden of showing that it returned to substantial compliance on a date earlier than that determined by CMS and has rejected the idea that CMS must establish a lack of substantial compliance during each day in which a remedy remains in effect.") (citations omitted). Deltona has not pointed to any evidence that would establish earlier dates for the abatement of immediate jeopardy and the return to substantial compliance. Indeed, Deltona does not specifically contest the ALJ's conclusion regarding the date the immediate jeopardy was abated, or the dates for which it was found to continue to be out of substantial compliance at a level less than immediate jeopardy.

6. *The ALJ did not err in concluding that the CMPs amounts were reasonable.*

Deltona challenges the ALJ's conclusion that the CMPs imposed by CMS were reasonable. Section 488.438(f) sets out several factors that CMS must consider when determining the amount of a CMP, and that an ALJ must consider when evaluating de novo the reasonableness of the CMP imposed by CMS. Those factors are: (1) the facility's history of noncompliance; (2) the facility's financial condition, i.e., its ability to pay the CMP; (3) the severity and scope of the noncompliance, the "relationship of the one deficiency to other deficiencies resulting in noncompliance," and the facility's prior history of noncompliance; and (4) the facility's degree of culpability. 42 C.F.R. §§ 488.438(f), 488.404(b), (c).

Deltona asserts that the ALJ erroneously determined that the $679,700 total CMP amount was reasonable because it was lower than the $1,023,800 total CMP amount CMS had initially indicated it would impose. RR at 21. The ALJ did note that CMS had

[7] Although the ALJ did not articulate the same rationale as we rely on here for upholding the immediate jeopardy period, he indicated that CMS could have imposed a CMP beginning as early as June 25, 2010 on this basis. *See* ALJ Decision at 24 (stating "considering that I am finding [Deltona] responsible for not following [Resident 3's] physician's order starting June 25, 2010, CMS's shortening of the CMP duration is actually already quite favorable to [Deltona]").

"considerably decreased the original CMP duration" and that this shortening was "quite favorable" to Deltona. ALJ Decision at 24. However, we do not construe the ALJ's observations about the change in the total CMP amount to mean that he evaluated the reasonableness of the CMPs based on that change. Contrary to Deltona's assertion, the ALJ, as required, applied the factors in section 488.438(f) to determine the reasonableness of the per-day amount of the CMPs. *See* ALJ Decision at 23.

Deltona also contends that CMS and the ALJ failed to consider its history of compliance with the Medicare participation requirements. RR at 21. It emphasizes that it did not have any deficiencies above a "D" scope and severity level during surveys conducted from 2007 to 2010 and asserts that its "history of compliance does not warrant the amount of the CMP[s]." *Id.* The ALJ acknowledged Deltona's argument about its past compliance, but reasoned that Deltona's history of compliance was adequately factored into the CMP amounts because CMS could have imposed much higher CMPs. ALJ Decision at 24. The ALJ noted that the $5,500 per-day CMP that CMS imposed for September 20, 2010 to January 19, 2011 was "in the lower half of the CMP range for immediate jeopardy level deficiencies," since that range is $3,050 to $10,000 per day. *Id.*, citing 42 C.F.R. § 488.438(a)(1)(i). The ALJ likewise concluded that the $100 per-day CMP that CMS imposed for January 20, 2011 to February 14, 2011 was "at the very low end of the CMP range for non-immediate jeopardy level deficiencies," which is $50 to $3,000 per day. *Id.*, citing 42 C.F.R. § 488.438(a)(1)(ii). We see no error in the ALJ's reasoning.

Deltona further argues that CMS and the ALJ failed to consider, and that CMS failed to present evidence of, Deltona's financial condition and culpability. RR at 22. Deltona's argument is meritless. The Board has repeatedly held that "an ALJ or the Board properly presumes that CMS considered the regulatory factors and that those factors support the amount imposed." *Pinecrest Nursing & Rehab. Ctr.*, DAB No. 2446, at 23 (2012) (emphasis in original; citations omitted). Thus, CMS did not need to present evidence regarding each regulatory factor. Instead, the burden was on Deltona "'to demonstrate, through argument and the submission of evidence addressing the regulatory factors, that a reduction is necessary to make the CMP amount reasonable.'" *Id.*, quoting *Oaks of Mid City Nursing & Rehab. Ctr.*, DAB No. 2375, at 26-27 (2011). Moreover, the ALJ did discuss both financial condition and culpability in his decision. He determined that Deltona "provided no evidence to show that its financial condition hinders it from paying" the proposed CMPs. ALJ Decision at 24. Deltona's mere assertion on appeal that it is "common sense" that "few, if any, facilities would be able to afford" CMPs totaling "almost three quarters of a million dollars" (RR at 22), does not fill this evidentiary vacuum. The ALJ also concluded that the deficiencies in the case were "serious" and caused "actual harm" to Residents 3, 6, 7, and 10, and that Deltona was "highly culpable for the disregard for residents' care, comfort, and safety." *Id.* We agree with his analysis.

For all of these reasons, we affirm the ALJ's conclusion that the CMPs totaling $679,700 were reasonable.

Conclusion

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

/s/
Judith A. Ballard

/s/
Leslie A. Sussan

/s/
Sheila Ann Hegy
Presiding Board Member