Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Deltona Health Care,
(CCN: 10-5447),

Petitioner,

v.

Centers for Medicare and Medicaid Services.

Docket No. C-11-362

Decision No. CR2657

Date: November 5, 2012

DECISION

Petitioner, Deltona Health Care (Petitioner or facility), is a long-term care facility located in Deltona, Florida, that participates in the Medicare program. Based on a survey completed on January 6, 2011, the Centers for Medicare and Medicaid Services (CMS) determined that Petitioner was not in substantial compliance with Medicare participation requirements. CMS imposed against Petitioner a civil money penalty (CMP) of $5,550 per day from September 20, 2010 through January 19, 2011 (122 days at an immediate jeopardy level) and a CMP of $100 per day from January 20, 2011 through February 14, 2011 (26 days of substantial noncompliance that was not at an immediate jeopardy level).

I find Petitioner not to be in substantial compliance with 42 C.F.R. §§ 483.25(i), pertaining to Failure to Maintain Nutritional Status, 483.25(h), pertaining to Supervision and Prevention of Accidents, and 483.20(d) pertaining to Sufficiency of Resident Care Plans. I also find CMS's determinations relating to immediate jeopardy not clearly erroneous, and the CMP that CMS imposed is reasonable.

I. Background

The Florida Agency for Health Care Administration (state survey agency) conducted a complaint survey of the facility from January 4-6, 2011. The state survey agency determined that Petitioner was not in substantial compliance with the following five Medicare participation requirements: 42 C.F.R. § 483.13(c) (Tag F224); 42 C.F.R. § 483.20(d) (Tag F279), 42 C.F.R. § 483.25(h) (Tag F323); 42 C.F.R. § 483.25(i) (Tag F325), and 42 C.F.R § 483.75(o)(1) (Tag F520).

By letter dated January 24, 2011, CMS notified Petitioner that the survey found that the facility was not in substantial compliance with Medicare participation requirements and that the conditions constituted immediate jeopardy and substandard quality of care to the residents' health and safety. CMS stated that the immediate jeopardy was considered ongoing since July 20, 2010. CMS informed Petitioner that it was imposing the following remedies: a CMP of $5,550 per day, effective July 20, 2010, until the immediate jeopardy was removed or Petitioner's provider agreement was terminated; a denial of payment for new admissions (DPNA) effective January 26, 2011, if the facility was still out of compliance on that date; and termination of Petitioner's provider agreement on January 29, 2011, if the immediate jeopardy was not removed by that date.

By letter dated February 28, 2011, CMS notified Petitioner that a revisit survey on January 26, 2011, found that the immediate jeopardy was removed as of January 20, 2011, but that the facility remained out of substantial compliance. CMS advised Petitioner that the remedies imposed in the January 24, 2011 notice letter remained in effect, but the CMP would be decreased as a result of the revisit survey findings. CMS stated that, effective January 20, 2011, the CMP would accrue at the revised rate of: $5,550 per day effective July 20, 2010 through January 19, 2011,[1] and then $100 per day effective January 20, 2011, until substantial compliance was achieved. With respect to the continuing remedies, CMS stated that the DPNA remained in effect as of January 26, 2011, and that termination would now be effective July 6, 2011, if Petitioner had not achieved substantial compliance by that date.

In another letter dated February 28, 2011, CMS notified Petitioner that a second revisit survey conducted on February 15, 2011, found that Petitioner was in substantial compliance with Medicare participation requirements. CMS advised Petitioner that the DPNA would remain in effect from January 26, 2011 through February 14, 2011. CMS stated further that Petitioner's provider agreement would be continued.

Petitioner requested a hearing before an administrative law judge (ALJ) on March 25, 2011, and this case was assigned to me for hearing and decision on March 29, 2011.

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[1] In its prehearing briefing and at a prehearing conference, CMS confirmed that it revised the immediate jeopardy period to actually begin on September 20, 2010.

On December 12, 2011, I convened a video hearing from the offices of the Departmental Appeals Board in Washington, D.C. Counsel and CMS witness, Katherine D. Johnson, R.N., convened in Orlando, Florida. I have admitted into evidence CMS Exhibits (Exs.) 1-36 and Petitioner Exhibits (P. Exs.) 1-34. Order Following Prehearing Conference (November 4, 2011); Transcript (Tr.) at 7. At the hearing, I also admitted into evidence CMS Exs. 37-39. Tr. at 7.

In accordance with my prehearing order, Petitioner offered direct testimony in the form of declarations from Paul J. Maluso, M.D. (P. Ex. 27); Nurse Consultant Karen Robbins, R.N. (P. Exs. 28, 30); Richard Weber, R.N. (P. Ex. 29); Victoria DeJesus, L.P.N. (P. Ex. 31); Carmen Aponte, C.N.A. (P. Ex. 32), and Pearl Moyer, L.P.N. (P. Ex. 33). CMS chose not to cross-examine any of Petitioner's witnesses. The parties have filed pre-hearing briefs (CMS Pre-hrg. Br.; P. Pre-hrg. Br.) and post-hearing briefs (CMS Br.; P. Br.). CMS filed a post-hearing reply brief (CMS Reply).

II. Issues

Although CMS cited Petitioner for five deficiencies, I make findings of fact and conclusions of law for three of the five deficiencies cited: 42 C.F.R. § 483.25(i) (Tag F325) , 42 C.F.R. § 483.25(h) (Tag F323), and 42 C.F.R. § 483.20 (Tag F279), deficiencies which fully support the imposition of the CMP.[2]

Therefore, I consider here:

1) Whether, from September 20, 2010 through February 14, 2011, Petitioner was in substantial compliance with the requirements of 42 C.F.R. § 483.25(i), pertaining to Failure to Maintain Nutritional Status, and 42 C.F.R. § 483.25(h), Supervision and Prevention of Accidents;

2) If, from September 20 through January 19, 2011, Petitioner was not in substantial compliance with 42 C.F.R. § 483.25(h), 42 C.F.R. § 483.25(i), and 42 C.F.R. § 483.20, whether CMS's scope and severity determinations of immediate jeopardy to the health and safety of Petitioner's residents were clearly erroneous; and

3) Whether the CMP that CMS imposed was reasonable.

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[2] An ALJ need not review all survey findings of noncompliance if those findings are not necessary to support the remedies imposed or are not material to the outcome of the case. *Plott Nursing Home*, DAB No. 2426 (2011); *Western Care Mgmt. d/b/a Rehab Specialties Inn*, DAB No. 1921 (2004); *Beechwood Sanitarium*, DAB No. 1824 (2002), *modified on other grounds*, *Beechwood v. Thompson*, 494 F.Supp.2d 181 (D.N.Y. 2007).

III. Applicable Law

The Social Security Act (Act) sets forth requirements for nursing facilities' participation in the Medicare program and authorizes the Secretary of Health and Human Services (Secretary) to promulgate regulations implementing those statutory provisions. Act § 1819 (42 U.S.C. § 1395i-3). The Secretary's regulations are found at 42 C.F.R. Part 483. To participate in the Medicare program, a skilled nursing facility (SNF) must maintain substantial compliance with program requirements. To be in substantial compliance, a facility's deficiencies may pose no greater risk to resident health and safety than "the potential for causing minimal harm." 42 C.F.R. § 488.301.

The Secretary contracts with state agencies to conduct periodic surveys to determine whether skilled nursing facilities are in substantial compliance. Act § 1864(a) (42 U.S.C. § 1395aa(a)); 42 C.F.R. § 488.20. The Act and regulations require that each facility be surveyed once every twelve months, and more often if necessary, to ensure that identified deficiencies are corrected. Act § 1819(g)(2)(A) (42 U.S.C. § 1395i-3(g)(2)(A)); 42 C.F.R. §§ 488.20(a), 488.308.

CMS may impose a CMP for the number of days a facility is not in substantial compliance or for each instance of noncompliance. 42 C.F.R. § 488.430(a). A CMP imposed against a facility on a per day basis will fall into one of two ranges of penalties. 42 C.F.R. §§ 488.408, 488.438. The upper range of a CMP, $3,050 per day to $10,000 per day, is reserved for deficiencies that pose immediate jeopardy to a facility's residents and, in some circumstances, for repeated deficiencies. 42 C.F.R. § 488.438(a)(1)(i), (d)(2). "*Immediate jeopardy* means a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301 (emphasis in original). The lower range of a CMP, $50 per day to $3,000 per day, is reserved for deficiencies that do not constitute immediate jeopardy but either cause actual harm to residents, or cause no actual harm but have the potential for causing more than minimal harm. 42 C.F.R. § 488.438(a)(1)(ii).

A hearing before an ALJ is available to a long-term care facility against which CMS has determined to impose an enforcement remedy. Act §§ 1128A(c)(2), 1866(h) (42 U.S.C. §§ 1320a-7a(c)(2), 1395cc(h)); 42 C.F.R. §§ 488.408(g), 498.3(b)(13). The hearing before an ALJ generally involves a *de novo* standard of review. *See, e.g., Emerald Oaks*, DAB No. 1800, at 11 (2001). A facility has a right to appeal a "certification of noncompliance leading to an enforcement remedy." 42 C.F.R. § 488.408(g)(1); 42 C.F.R. §§ 488.330(e), 498.3. However, the choice of remedies, or the factors CMS considered when choosing remedies, is not subject to review. 42 C.F.R. § 488.408(g)(2). A facility may only challenge the scope and severity level of noncompliance that CMS determined if a successful challenge would affect the range of the CMP amounts that

CMS could collect or a substandard quality of care finding causes the loss of the facility's nurse aide training program. 42 C.F.R. § 498.3(b)(14), (d)(10)(i). The CMS determination as to the level of a facility's noncompliance, including the finding of immediate jeopardy, "must be upheld unless it is clearly erroneous." 42 C.F.R. § 498.60(c)(2); *Woodstock Care Ctr.*, DAB No. 1726, at 9, 38 (2000), *aff'd,* 363 F.3d 583 (6th Cir. 2003).

CMS has the burden of coming forward with evidence to make a *prima facie* showing of a basis for imposition of an enforcement remedy. Petitioner then bears the burden of persuasion to prove by a preponderance of the evidence that it was in substantial compliance with participation requirements or to prove any affirmative defense. *Batavia Nursing and Convalescent Ctr.*, DAB No. 1904 (2004), *aff'd*, 129 F. App'x. 181 (6th Cir. 2005); *Batavia Nursing and Convalescent Inn*, DAB No. 1911 (2004); *Emerald Oaks*, DAB No. 1800; *Cross Creek Health Care Ctr.*, DAB No. 1665 (1998); *see Hillman Rehab. Ctr.*, DAB No. 1611 (1997), *aff'd*, No. 98-3789, 1999 WL 34813783 (D.N.J. May 13, 1999).

The burden of proof that the Departmental Appeals Board (Board) applies is not a rule under the Administrative Procedure Act, 5 U.S.C. § 556(d), but instead is 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. *See, e.g.*, *Batavia Nursing and Convalescent Ctr.*, DAB No. 1904 (2004), *aff'd*, *Batavia Nursing and Convalescent Ctr. v. Thompson*, 129 F. App'x. 181 (6th Cir. 2005). While this rationale was originally set forth in *Hillman Rehab. Ctr.*, DAB No. 1611 (1997), it has not been treated as a binding rule but has been reexamined as appropriate to different types of cases. Moreover, how an ALJ allocates the burden of persuasion is relevant only when the evidence is in equipoise. *Owensboro Place and Rehab. Ctr.*, DAB No. 2397, at 9 (2011) (citing *Azalea Court*, DAB No. 2352, at 16 (2010)); *Fairfax Nursing Home, Inc.*, DAB No. 1794 (2001), *aff'd*, *Fairfax Nursing Home v. Dep't of Health & Human Srvcs.*, 300 F.3d 835 (7th Cir. 2002), cert. denied, 2003 WL 98478 (Jan. 13, 2003).

IV. Findings of Fact and Conclusions of Law

A. Petitioner 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 losses.

42 C.F.R. § 483.25(i) requires:

> (i) *Nutrition.* Based on a resident's comprehensive assessment, the facility must ensure that a resident –

(1) 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

(2) Receives a therapeutic diet when there is a nutritional problem.

According to interpretative guidelines in CMS's State Operations Manual (SOM), the intent of 42 C.F.R. § 483.25(i) is to "assure that the resident maintains acceptable parameters of nutritional status, taking into account the resident's clinical condition or other appropriate intervention, when there is a nutritional problem." SOM App. PP (accessible at http://www.cms.hhs.gov/Manuals/IOM/list.asp). The SOM suggests parameters for evaluating the significance of unplanned and undesired weight loss:

Interval	**Significant Loss**	**Severe Loss**
1 month	5%	Greater than 5%
3 months	7.5%	Greater than 7.5%
6 months	10%	Greater than 10%

The Board has held that unplanned weight loss may raise an inference of inadequate nutrition sufficient to be a CMS *prima facie* showing of a deficiency. *Carehouse Convalescent Hosp.*, DAB No. 1799, at 21-22 (2001). The Board stated that, "[i]f CMS relies on weight loss as evidence of a deficiency, the facility may present rebuttal evidence that the resident did receive adequate nutrition or that the weight loss is due to non-nutritive factors, such as a clinical condition." *Carrington Place of Muscatine*, DAB No. 2321, at 5 (2010), quoting *The Windsor House*, DAB No. 1942, at 18 (2004). The Board's interpretation of 42 C.F.R. § 483.25(i)(1) is that a facility is not strictly liable for a resident's weight loss (*Carehouse*, DAB No. 1799, at 21), but a "facility is responsible for taking all reasonable steps to ensure that the resident receives nutrition adequate to his or her needs" (*Windsor House*, DAB No. 1942 at 18). The Board has stated further that the "clinical condition exception" is narrow and applies only when a facility demonstrates that it cannot provide nutrition adequate for the resident's overall needs so that weight loss is unavoidable. *Windsor House*, DAB No. 1942, at 18. "[T]he mere presence of a significant clinical condition, without additional evidence, does not prove that maintaining acceptable nutritional status is not possible." *Id.*

1. Petitioner did not sufficiently rebut CMS's showing of inadequate nutrition regarding Resident 6's severe unplanned weight loss.

At the time of the January 6, 2011 survey, Resident 6 (R6) was a 94-year-old woman. She was admitted to Petitioner's facility on November 22, 2010, after a hospital stay for a fractured hip and arm. CMS Ex. 16, at 1. R6's diagnoses included depressive disorder, anxiety disorder, hypertension, difficulty in walking, and lack of coordination. CMS Ex.

16, at 1, 85. R6 was alert, with confusion at times, was able to feed herself, and could make her needs known. CMS Ex. 16, at 4, 65, 80.

Petitioner's dietician noted in an assessment document titled "Nutrition Data Collection Tool" that R6 weighed 108 pounds at the time of her November 22, 2010 admission to the facility. Petitioner's dietician indicated that R6's usual body weight was unknown, and her ideal body weight was 105 pounds, plus or minus 10%. CMS Ex. 16, at 4. However, on January 3, 2011, the day before the survey, R6 weighed 89.6 pounds, a loss of approximately 17% of her body weight. CMS Ex. 24, at 2; *see* CMS Ex. 23. According to the SOM guidance, a greater than 5% loss in body weight in one month is considered to be a "severe loss."

In an entry on the Nutrition Data Collection Tool, dated December 2, 2010, Petitioner's dietician stated that R6 was able to feed herself and that she was on a NAS (no added salt) diet with "intake documented as usually good." CMS Ex. 16, at 4. She indicated that R6's albumin was 2.8, which was "mildly depleted but acceptable for advanced age of 94." She stated that she would order "Med Pass 90 cc" as a nutritional supplement three times a day to prevent weight loss and repair R6's visceral protein stores. She indicated that R6 should continue to be monitored for changes. CMS Ex. 16, at 5. Petitioner does not dispute that R6 did not receive the Med Pass supplement daily as ordered.

Petitioner's December 2, 2010 care plan included the following nutritional goals: "Resident will improve nutrition status" and "[r]esident will not have any significant wt changes." CMS Ex. 16, at 6. The care plan listed the following interventions: weigh weekly for one month, then weigh monthly; provide snacks per facility policy, provide dietary supplements, allow adequate time to eat, offer food preferences as available, Med Pass 90 cc three times a day, do labs as ordered, and consult the dietician as needed. CMS Ex. 16, at 6.

During the survey, in an interview on January 4, 2011, Petitioner's dietary manager provided the nurse surveyor the monthly residents' weights obtained the day before. The dietary manager stated that R6 had had the stomach flu for two days in December, but other than that, she was not aware of any changes with R6 in the last 30 days. When asked if she was aware of R6 experiencing an 18-pound weight loss since December 2, 2010, the dietary manager indicated that she would have R6 re-weighed the next day to ensure accuracy of the weight. P. Ex. 1, at 35; CMS Ex. 1, at 35.

In an interview on January 5, 2011, Petitioner's diet technician stated that several of the residents had been re-weighed and provided an updated weight log. R6's re-weight was reported as 90.3 pounds, which verified a 17.7-pound weight loss since her admission less than two months earlier. When asked if she had been made aware of any changes in R6's condition prior to the significant weight loss, the diet technician stated "no." When

asked if R6 was consuming the Med Pass supplement that had been ordered, the diet technician responded that she would have to check with the nurse. P. Ex. 1, at 35.

The registered dietician reevaluated R6 during the survey on January 5, 2011. CMS Ex. 16, at 5. In an entry on the Nutrition Data Collection Tool, the dietician noted that R6 weighed 90.3 pounds, which was an almost 18 pound loss in the last 30 days. The entry stated that R6 had been on a clear liquid diet. R6 had recently been prescribed Lexapro for her depression. The dietician stated that R6's diet was "back to reg[ular] [with] good acceptance/tolerance." She noted that R6 was currently receiving "Med Pass 90 ml" and that R6 accepted and tolerated it well. R6 had a good appetite and had eaten well at dinner that day. The dietician recommended increasing the Med Pass to "120 cc" three times a day to help maximize R6's nutrient intake, promote weight gain, and prevent further weight loss. The dietician also recalculated R6's caloric needs and increased her daily intake to 1500 calories a day. CMS Ex. 16, at 5. R6's physician agreed and ordered that the Med Pass supplement be increased to "120 cc" three times a day. CMS Ex. 16, at 8-10.

Petitioner argues that "[f]luctuations in weight may be caused by a wide variety of factors including changes in fluid volume and metabolic reactions to medical conditions, and of course, variations in scales." P. Pre-hrg. Br. at 8. According to Petitioner, R6 had a plaster cast removed from her arm during December 2010, and the loss of the cast likely contributed to her decreased weight. P. Pre-hrg. Br. at 9. Additionally, Petitioner suggests that R6's appetite may have been suppressed because she had recently started the antidepressant Lexapro. While these factors may have contributed to the weight loss, I find it concerning that staff did not even initially recognize that R6 was experiencing weight fluctuations. Between December 2, 2010 and January 3, 2011, R6 lost 18.4 pounds. Had Petitioner's staff been monitoring R6'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. However, there was an extended period when Petitioner's staff was completely unaware that R6 was losing weight, and at no time did staff modify R6's care plan to recognize and address any weight fluctuations until the state survey alerted Petitioner to the problem. In fact, Petitioner admits that the "first indication" its staff had that R6 was losing weight was when they received the monthly weights on January 3, 2011. P. Pre-hrg. Br. at 11.

Further, there is no documentation that Petitioner ever evaluated the effectiveness of the dietary interventions contained in R6's December 2, 2010 care plan. Although R6's care plan stated that she would receive a Med Pass supplement three times a day, it is questionable how often R6 received it. Although the care plan stated that the dietician would be consulted as needed, it was not until January 5, 2011, after R6 had already lost over 18 pounds, when staff consulted with the dietician regarding R6's weight loss.

I find R6's weight loss was unplanned and undesired. Petitioner's staff did not weigh R6 weekly, as directed by her care plan, and it has admitted that it was unaware until January 2011 that R6 had suffered the severe weight loss. It was incumbent on Petitioner to monitor R6's weight and nutritional status so that any weight loss could be identified and addressed to any extent that the weight loss was avoidable. However, the record does not reflect any such documentation. I conclude that Petitioner did not sufficiently rebut CMS's showing that the facility did not maintain nutrition adequate to R6's needs or show that R6's weight loss was unavoidable.

2. Petitioner did not sufficiently rebut CMS's showing of inadequate nutrition regarding Resident 7's severe unplanned weight loss.

Resident 7 (R7) also suffered a severe weight loss at Petitioner's facility. R7, who was admitted on October 3, 2010, weighed 208 pounds on October 4, 2010. A month later, she weighed 197.8 pounds. On December 2, 2010, R7 weighed 198.6 pounds. Then, on January 3, 2011, she weighed 173.4 pounds. CMS Ex. 23; CMS Ex. 24, at 1; *see* CMS Ex. 17, at 12.

R7's nutrition and hydration plan of care, dated October 5, 2010, indicated that she would not have any significant weight changes through her next review. CMS Ex. 17, at 10. The care plan also listed the following directives: weigh weekly for four weeks, then weigh monthly; liberalized diet as necessary; provide snacks at bedtime per the diabetic diet; provide supplements as ordered; perform labs as ordered; consult the dietician as necessary; monitor for changes; and monitor for signs and symptoms of dehydration. CMS Ex. 17, at 10.

Despite these care plan directives, there is no evidence that Petitioner weighed R7 weekly. From December 2010 to January 2011, R7 lost 25 pounds. She lost 12.69% of her body weight in one month (December 2010 to January 2011) and 16.63% of her body weight in only three months (October 2010 to January 2011). According to the SOM guidance, a greater than 5% loss in body weight in one month, and a greater than 7.5% loss in body weight in three months, are considered to be severe losses.

In an October 26, 2010 entry, Petitioner's dietician recognized that R7's weight was "trending down" but stated that it was "not a significant wt. loss" and that her plan of care should be continued. CMS Ex. 17, at 9. However, the record shows that from October 4, 2010 to November 3, 2010, R7 lost more than ten pounds, which was 4.9% of her body weight. When Petitioner's interdisciplinary care team reviewed R7 on December 28, 2010, the team indicated that R7 was "maintaining" in the area of nutrition, hydration, and weight, and listed no new risk factors or changes in interventions. CMS Ex. 17, at 4. Given that R7 had weighed 208 pounds around the time of her admission in October 3, 2010 and then weighed 198.6 pounds on December 2, 2010, the fact that Petitioner's care team assessed her as "maintaining" her weight is problematic and shows that Petitioner's

staff was not properly monitoring R7's weight and documenting any steps to address a severe weight loss.

Petitioner's staff acknowledges they first became aware of R7's weight decline when she was discovered to weigh 173.4 pounds on January 3, 2011 (P. Pre-hrg. Br. at 9-10, 11; P. Ex. 28 (Robbins Decl. ¶ 56)), which was right before the survey commenced. By this point, R7 had lost almost 35 pounds since her admission in October 2010, a loss in body weight of over 16%. Petitioner's staff had not weighed R7 weekly as care-planned, monitored her nutritional status, or identified her weight loss.

According to Petitioner, R7's weight loss was beneficial to her health because she was "morbidly obese," and R7 was content with losing weight. P. Pre-hrg. Br. at 9. However, if R7's assessment team truly intended for her to lose weight, then I would expect her plan of care to contain this as a goal, which it did not. In fact, her October 5, 2010 nutrition and hydration care plan stated the opposite – that she would *not* have any significant weight changes through the next review. I note further that the dietary manager stated in an interview with a state surveyor that R7's weight loss was not planned. P. Ex. 1, at 37; CMS Ex. 1, at 37.

Petitioner also suggests that R7's hypothyroidism (a condition where the thyroid gland does not produce enough thyroid hormone), her dislike of many foods, and her medications may have accounted for her weight loss. *See* CMS Ex. 17, at 6, 9, 13. Also, Petitioner's Director of Nursing (DON) told surveyors that in December 2010, there was an outbreak of gastrointestinal flu at Petitioner's facility that lasted for 24-48 hours, and R7 was among the residents who caught it. *See* P. Ex. 1, at 37, CMS Ex. 1, at 37; CMS Ex. 6, at 2.

I find that none of these reasons excuses Petitioner's failure to properly monitor R7's nutritional status. Petitioner was aware of R7's hypothyroidism when she was admitted to the facility. While the condition may have caused some weight loss, one would expect that R7's thyroid levels were controlled and monitored. *See* CMS Ex. 36 (Johnson Decl. ¶ 14). If R7's thyroid medication or any other medications were causing side effects such as weight loss, then Petitioner's physician should have been alerted to a significant change in patient condition so that the physician could order any appropriate adjustments such as a medication or diet change.

The fact that R7 did not like a lot of foods is also not an acceptable excuse for Petitioner to not monitor her weight and nutritional status. Petitioner's dietary services should have offered her replacement meals that she liked and offered her snacks and nutritional supplements. Furthermore, while R7's gastrointestinal flu may have accounted for some weight loss, considering its short 24-48 hour duration, I find Surveyor Johnson's testimony credible (CMS Ex. 36, at 3) that it is not reasonable to expect it to have significantly contributed to the severe overall weight loss R7 experienced, especially

considering R7's severe weight loss trend had started before the December onset of her flu.

Petitioner has not shown that R7's unplanned weight loss was attributable to poor overall clinical conditions that were documented during the time of the loss. It was incumbent upon Petitioner to identify and address R7's weight loss, and any related dietary concerns, by implementing appropriate interventions. By the time Petitioner's staff identified her weight loss and took measures to address it during the state survey, the resident had suffered "severe" weight loss under the SOM guidelines. I thus find that Petitioner did not sufficiently rebut CMS's showing that Petitioner did not maintain acceptable parameters of nutrition for R7, as demonstrated by her unplanned and severe weight loss.

3. Petitioner did not sufficiently rebut CMS's showing of severe weight loss in eight other residents.

CMS contends that, in addition to R6 and R7, there were eight other residents who lost more than five percent of their body weight in only one month. CMS Exs. 23-24; CMS Ex. 6, at 2. Petitioner argues that the survey only cited R6 and R7 in the SOD under Tag F325, and CMS did not provide adequate notice for these eight other residents. P. Pre-hrg. Br. at 1; P. Br. at 19.

Notice of additional evidence, however, may be provided through prehearing record development without amending the SOD. *Alden Town Manor Rehab. and Health Care Ctr.*, DAB No. 2054, at 18 (2006); *Livingston Care Ctr.*, DAB No. 1871, at 20 (2003), *aff'd, Livingston Care Ctr. v. U.S. Dep't of Health and Human Srvcs.*, 338 F.3d 168 (6th Cir. 2004). The addition of new issues is permitted provided that timely notice is given to the parties. 42 C.F.R. § 498.56. In this case, the eight residents not cited in the SOD are identified in Petitioner's own weight charts. CMS Ex. 24. Petitioner provided these records to the surveyors, and CMS included them among its proposed exhibits when CMS submitted its prehearing exchange in June 2011. I therefore find that Petitioner received adequate notice that other residents besides R6 and R7 suffered unplanned weight loss. I further find that, inasmuch as Petitioner's unrefuted weight chart does reflect that eight other residents besides R6 and R7 lost more than five percent of their body weight in only one month, this evidence further supports my decision.

Petitioner argues the surveyor admitted at hearing that she and her trainee surveyor did not completely review those residents' medical records. P. Br. at 18; Tr. at 75. Nonetheless, CMS relies on weight loss as prima facie evidence of a deficiency, and Petitioner has not rebutted this evidence with a showing that the weight loss is due to non-nutritive factors. *See Carrington Place of Muscatine*, DAB No. 2321, at 5 (2010). Instead, Petitioner only refers to the testimony of Nurse Consultant Karen Robbins, R.N., to show that no preventable weight loss occurred and that residents' nutritional status was

maintained. P. Ex. 30. Petitioner did not produce any of the relevant plans of care for these residents. Although Ms. Robbins' testimony was not challenged through cross-examination by CMS, without any clinical documentation to support her assertions, I do not find Petitioner has proven by a preponderance of the evidence that it maintained the nutritional status of these residents in response to CMS's prima facie showing of severe weight losses.

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

42 C.F.R. § 483.25 provides:

> (h) *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.

In *Meridian Nursing Ctr.*, DAB No. 2265, at 3 (2009), the Board interpreted the requirements of this subsection, stating:

> Section 483.25(h)(1) requires that a facility address foreseeable risks of harm from accidents "by identifying and removing hazards, where possible, or where the hazard is unavoidable because of other resident needs, managing the hazard by reducing the risk of accident to the extent possible." *Maine Veterans' Home – Scarborough*, DAB No. 1975, at 10 (2005). Section 483.25(h)(2) requires that a facility take "all reasonable steps to ensure that a resident receives supervision and assistance devices that meet his or her assessed needs and mitigate foreseeable risks of harm from accidents." *Briarwood Nursing Center*, DAB No. 2115, at 11 (2007), citing *Woodstock Care Ctr. v. Thompson*, DAB No. 1726 (2000) (facility must take "all reasonable precautions against residents' accidents"), *aff'd*, *Woodstock Care Ctr. v. Thompson*, 363 F.3d 583 (6th Cir. 2003).

The Board has also held that facilities "have the 'flexibility to choose the methods of supervision' to prevent accidents so long as the methods chosen are adequate in light of the resident's needs and ability to protect himself or herself from a risk." *Briarwood Nursing Ctr.*, DAB No. 2115, at 5, citing *Liberty Commons Nursing and Rehab – Alamance*, DAB No. 2070, at 3 (2007).

Petitioner violated 42 C.F.R. § 483.25(h) because staff failed to take all reasonable precautions necessary to prevent foreseeable accidents and injuries for two residents – Resident 3 (R3) and Resident 10 (R10), who suffered falls that resulted in fractures. P. Ex. 1, at 19-20; CMS Ex. 1, at 19-20.

1. Petitioner did not take all reasonable precautions to prevent foreseeable falls and injuries to Resident 3.

R3 was an 88-year-old woman at the time of the survey and was admitted to Petitioner's facility on November 6, 2009. CMS Ex. 15, at 1. R3's diagnoses included hemiplagia, esophagitis, general osteoarthrosis, hypertension, syncope and collapse, difficulty in walking, and dysphagia. CMS Ex. 15, at 1; *see* CMS Ex. 15, at 22. On November 3, 2010, R3 was found on the floor calling for help. P. Ex. 1, at 24; CMS Ex. 1, at 24. According to the SOD, R3's left leg was externally rotated and shorter than her right leg. She had a prominent bulge on her left hip, which was painful when palpated. Five to six staff members lifted R3 and put her back into bed. An x-ray revealed that R3 had fractured her left hip. It is undisputed that it was not until five hours after she was found on the floor that R3 was taken to the emergency room for treatment. P. Ex. 1, at 25, 27; CMS Ex. 1, at 24-25, 26-27.

CMS alleges that Petitioner, despite knowing that R3 was at risk for falls, failed to provide R3 with closer supervision and adequate assistive devices to prevent her accident. CMS further alleges that Petitioner made no changes in its care of R3 even after it became evident that the current measures in place were ineffective. Moreover, CMS contends that, despite the serious nature of R3's injury on November 3, 2010, she waited five hours after falling before being transported to the emergency room, and during this time, Petitioner's DON did not appropriately intervene.

Petitioner argues that it "did everything it could to prevent" R3's fall on November 3, 2010 but that it was "unpreventable." P. Br. at 11. Petitioner asserts that appropriate interventions were in place and that R3 received "appropriate care and treatment once her fall occurred." P. Br. at 14.

I find the record shows that Petitioner did not implement adequate interventions to ensure R3's safety given that she was a known fall risk. Also, when R3 fell in November 2010 and exhibited signs of a possible hip fracture, Petitioner's staff, including the DON, failed to act promptly to provide her with necessary care and treatment. Moreover, Petitioner had previously failed to update R3's care plan to reflect the fact that her treating physician had given an order to administer to R3 a reduced dosage of Ambien because excessive sedation could contribute to a fall.

R3 had a care plan dated September 20, 2010, to address her risk for falls. Under this care plan, staff were required, among other things, to "assist with one," observe her for

medication side effects, and provide appropriate safety and enabler devices. CMS Ex. 15, at 3. Despite the interventions in her care plan, R3 fell on November 3, 2010, and was found on the floor, yelling for help. Staff picked her up, and placed her back into her bed. There is also no dispute that Petitioner's DON, who is a registered nurse, responded to the initial "Code Green" call to R3's room for additional assistance, stood in R3's doorway observing the scene, and left soon after. P. Ex. 1, at 27; CMS Ex. 6, at 6; CMS Ex. 36, at 5 (Johnson Decl. ¶¶ 31-32). The DON purportedly told surveyors that the "nursing staff had things under control" and that the "physician would be contacted to get orders." CMS Ex. 6, at 6. Instead of a registered nurse assessing R3, however, a licensed practical nurse assessed R3's injuries. CMS Br. at 14; Tr. at 84; CMS Ex. 36, at 5 (Johnson Decl. ¶ 32); *see* CMS Ex. 6, at 4. Staff did not call 911 immediately, and it was not until over five hours had passed that R3 was transported to the hospital.

Further, although the DON remained in the facility, no staff consulted him for further advice. According to surveyor notes, Petitioner's Medical Director appeared to question the way Petitioner handled the emergency. CMS Ex. 5, at 7. The DON had an obligation to ensure that R3 received appropriate treatment and services after she fell but did not perform his duty, which potentially placed R3 at further risk of harm.

Before the November 3, 2010 fall, Petitioner had not updated R3's care plan to reflect that her treating physician ordered a reduced dosage, as needed, of the sedative Ambien. R3 took Ambien to help her sleep. *See* Tr. at 47. Following a fall on June 17, 2010, a consultant pharmacist identified a potential adverse event to R3 from a 5 mg dose of Ambien and recommended that the Ambien either be decreased to 2.5 mg at bedtime, as needed, or discontinued entirely. P. Ex. 2, at 10. Specifically, on June 18, 2010, the consultant pharmacist wrote the following note on a Medication Regimen Review Sheet:

> Due to recent fall, the nursing center has requested a review of current medications relating to falls. This patient is receiving Ambien 5 mg at bedtime nightly so this could contribute to a fall due to excessive sedation. Recommend decreasing the dose to 2.5 mg at bedtime and making this order an "AS NEEDED" MEDICATION OR DISCONTINUING THE AMBIEN.

P. Ex. 2, at 12; CMS Ex. 15, at 2.

The record shows further that R3's treating physician agreed with the consultant pharmacist and issued an order on June 25, 2010 for a reduced dosage of Ambien, 2.5 mg at bedtime, as needed. P. Ex. 2, at 12, 14. On June 26, 2010, R3's physician indicated via a handwritten note on the Medication Regimen Review Sheet that R3's Ambien should be "↓ to 2.5 Ambien" at bedtime. P. Ex. 2, at 10, 13.

However, despite the physician's order that the Ambien dosage be reduced to 2.5 mg, Petitioner's staff did not update R3's care plan to reflect this and continued to administer Ambien 5 mg to R3. An entry in R3's Medication Record shows that, on June 26, 2010, 5 mg of Ambien was ordered to be administered at bedtime, 9 p.m. The entry also states the following: "Instructions: continue this order" and "Forever DX: Insomnia." CMS Ex. 15, at 30.

Petitioner's expert witness Dr. Paul Maluso, a Board-certified orthopedic surgeon, noted that on November 2, 2010, the night before she fell, R3 received, a 5 mg dose of Ambien. He opined, however, "to a reasonable degree of medical certainty," that "the medication did not contribute to [R3's] fall. The effects of the Ambien would have worn off long before the resident's fall." P. Ex. 27, at 2 (Maluso Decl. ¶ 6). Petitioner also notes that CMS's witness, Surveyor Johnson, testified on cross-examination that 5 mg of Ambien was the "recommended geriatric dose." Tr. at 47. Petitioner notes further that Surveyor Johnson agreed that if a person took Ambien at bedtime, he or she would not still be drowsy in the morning, because Ambien's "half-life" meant that "within so many hours it would start to be absorbed by the body and then excreted." Tr. at 47.

However, I give Dr. Maluso's and Surveyor Johnson's opinions less weight than the orders of R3's treating physician who had a history of caring for the resident. Both R3's treating physician and the consultant pharmacist were aware that R3 took Ambien at bedtime. Both took this into consideration when the pharmacist recommended, and the physician approved, that the Ambien dosage be reduced. There can be little doubt that the treating physician's reason for decreasing the dosage was due to the fact that he agreed with the consultant pharmacist that a higher dosage could result in excessive sedation and a higher risk for falls. Also, while it may be that 5 mg of Ambien was the "recommended geriatric dose," as testified by Surveyor Johnson, I also give her testimony little weight on this point in light of the orders of R3's treating physician. Once R3's physician gave the order to reduce the dosage of Ambien, Petitioner's staff was required to update R3's care plan and comply with the new order. They did not do so, and I find this increased the likelihood of R3 suffering serious harm from a fall resulting from oversedation.

There were also other reasonable precautions Petitioner's staff could have taken to safeguard R3 from falls. Petitioner had a fall prevention program known as a "Falling Star" program, specifically for residents who were at high risk for falls and who required frequent monitoring. *See* CMS Br. at 9. However, R3 was not included in this program, neither at the outset upon admission assessment nor even later after her falls. P. Br. at 12. Also, as CMS points out, Petitioner could have reasonably implemented additional safety interventions to address R3's risk for falls, such as moving call buttons in close reach of R3 and installing a bed alarm to alert nurses if R3 tried to walk without assistance.

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

R10 was a 66-year-old woman at the time of the survey and was admitted to Petitioner's facility on May 8, 2010. CMS Ex. 18, at 1. R6's diagnoses included deep vein thrombosis, pulmonary embolism, dementia, diabetes, epilepsy, hypothyroidism, hypertension, esophageal reflux, hyperlipidemia, and schizoaffective disorder. CMS Ex. 18, at 1, 20. R10 also had gait unsteadiness, difficulty walking and prior falls. CMS Ex. 18, at 20. R10 was receiving rehabilitation for a previous fracture of her right hip. *See* CMS Ex. 6, at 13. She was taking several different psychoactive medications, including Lamictal, Zyprexa, Risperdal, Xanax, and Phenobarbital. *See* CMS Ex. 18, at 21, 24. R10 was also taking Coumadin. CMS Ex. 18, at 22.

Nursing notes show around 6:45 p.m. on November 12, 2010, R10 was found on the floor. CMS alleges that R10 complained of pain in the "upper area" of her leg. CMS Ex. 18, at 9. The RN supervisor was notified, and she decided not to immediately transfer R10 to the ER. R10 was assisted back into bed. The RN supervisor called the physician and obtained orders for a portable x-ray. Around 7:15 p.m., the x-ray results were called in and showed a left hip fracture. CMS Ex. 18, at 9, 14-15; P. Ex. 5, at 1; P. Br. at 16; *see* CMS Ex. 6, at 13. The RN supervisor did not report the results to the physician immediately because she chose to wait until she received a faxed copy from the provider. The faxed copy did not arrive until 10:00 p.m., at which time staff notified the physician. The physician ordered that R10 be transferred to the ER. R10 left Petitioner's facility via ambulance at 10:30 p.m. on November 12, 2010. CMS Ex. 18, at 9; P. Ex. 1, at 28; CMS Ex. 1, at 28; *see* CMS Ex. 6, at 13.

CMS argues that Petitioner failed to provide the necessary interventions and supervision to prevent R10 from falling and fracturing her hip. CMS also contends R10 waited too long for emergency care and that, after R10 fell, Petitioner failed to monitor R10 for bruising or excessive bleeding even though she was taking the anticoagulant Coumadin.

Petitioner contends that R10 suffered a spontaneous hip fracture that then caused her to fall. Petitioner claims that R10's fracture was due to osteoporosis and osteopenia and was unpreventable and unpredictable. Petitioner contends further that R10 had an appropriate care plan in place and received appropriate care and treatment once her fracture occurred.

The record shows that Petitioner assessed R10 as being at risk for falls upon her admission, completing a "Fall Risk Identification and Plan of Care" dated May 8, 2010. According to this care plan, R10 had a history of falls in the previous three months and required assistance with transferring/ambulating. P. Ex. 5, at 2. Staff were directed to: "[a]ssist w/1;" "[i]nstruct and reinforce proper use of adaptive equipment," observe for medication side effects, such as sedation, confusion, drowsiness, ataxia, weakness or

dizziness; provide appropriate safety and enabler devices (walker); and provide therapy as ordered. P. Ex. 5, at 2. In June 2010, on a "Risk Identification Review" form, Petitioner's nurse stated that there was a continued risk to R10 related to her history of falls. P. Ex. 5, at 3. Further plan of care documentation, dated November 3, 2010, indicated that R10 needed the assistance of one person for transfers and for walking in a room or hallway. The care plan noted that R10 was inconsistent in understanding her limitations. It noted that R10 was taking antipsychotic and anti-anxiety medications, as well as insulin and pain medications. P. Ex. 5, at 16, 21.

Petitioner's records show that, prior to R10's fall on November 12, 2010, she had fallen four days previously. On November 8, 2010, R10's daughter reported that R10 had fallen during the night, apparently when she went to the bathroom. The nurse told R10 that she should ask for help, and R10 stated that she had not wanted to bother staff because they are busy. R10 exhibited no signs or symptoms of injury. Following R10's November 8, 2010 fall, Petitioner's staff documented that R10 was taking medications that affected her balance, dizziness, or caused vertigo; she required a "1/2 SR [side rails] x 2;" and she had been educated related to safety. No additional interventions were implemented. P. Ex. 5, at 24; P. Ex. 28, at 6.

The fact that R10 fell twice in four days (November 8 and 12, 2010) and suffered a fractured hip suggests that Petitioner's interventions to deal with her risk for falls were not adequate to prevent accidental injury. Despite the interventions that were put in place in May 2010 at the time of her admission, R10 fell on November 8, 2010. Although Petitioner claims that its staff updated R10's care plan after she fell, I see no evidence that it modified the interventions that were in place or implemented any additional safety measures to address R10's risk for falls. As CMS points out, following R10's November 8 fall, Petitioner's staff could have designated her to be in the "Falling Star" fall prevention program and thereby ensure that she would receive better identification as a fall risk and more frequent monitoring. Petitioner does not dispute that it did not include her in this program. Further, in a "Post Event Evaluation" form that was completed on November 12, 2010, after R10 fell for the second time and suffered a fractured hip, Petitioner's staff noted that R10 did not have a low bed, a tab alarm, or a sensor pad. P. Ex. 5, at 1. Petitioner could have added these interventions to R10's care plan after R10 fell on November 8, but it did not do so. It was not until November 18, 2010 that Petitioner provided R10 with a sensor pad in bed and a tab alarm out of bed. CMS Ex. 18, at 4.

CMS contends that Petitioner's staff did not call 911, and R10 waited four hours after falling before being transported to the emergency room. The RN supervisor did not report the x-ray results to R10's physician right away when they were called in because she chose to wait until she received a faxed copy from the provider.

Petitioner argues that R10 did not experience any delay in care, noting that "[R10] comfortably waited in her own bed for her x-ray results, which once received, resulted in a transfer to the hospital for an acute level of care." P. Br. at 17. I find Petitioner's characterization of R10 to be inconsistent with other evidence in the record. R10 had fallen, and the x-rays showed that she had fractured her left hip. I find it unlikely that R10 would have been "comfortable" while waiting to be transported to the hospital. More likely than not, R10 would have been experiencing pain while lying in bed with a fractured hip for four hours. CMS Br. at 15.

Petitioner does not satisfactorily explain why it took four hours to have R10 transported to the hospital when her circumstances called for prompt medical attention. Petitioner's own Medical Director stated in an interview that when a nurse suspects a fracture, the nurse should call 911. *See* CMS Ex. 5, at 7. Here, R10 was found on the floor lying on her back around 6:45 p.m., complaining of pain in the upper area of her leg. Around 7:15 p.m., the x-ray results were called in to the RN Supervisor and revealed a fracture of R10's left hip. However, the RN Supervisor chose to wait for a faxed copy of the x-ray results and therefore did not notify R10's physician of the x-ray results until 10:00 p.m. At that time, the physician ordered that R10 be transferred to the ER. R10 left via ambulance at 10:30 p.m. I find that Petitioner's staff failed to respond appropriately to R10's situation by not arranging a prompt transfer to the ER after confirmation of her fracture, and as a result, R10 suffered an inexcusable delay in care for her fractured hip.

CMS also contends that Petitioner's staff failed to monitor R10 for excessive bleeding despite the fact that she was on the anticoagulant Coumadin. Petitioner, however, argues that any abnormal bleeding relating to Coumadin was unlikely. P. Br. at 17. In support of its position, Petitioner offers the testimony of Dr. Maluso, who states that "[R10]'s last PT/INR showed that her clotting levels were within the therapeutic range" and that "[c]onsequently, she was at no greater risk for abnormal bleeding than a patient not on Coumadin." Dr. Maluso also states that R10's taking of Coumadin "would have lowered her risk" for blood clots and that "there was no indication that [R10] had developed a blood clot which would have placed her at increased risk for stroke or embolitic event." According to Dr. Maluso, "[p]atients, even those on Coumadin or other anticoagulants, are unlikely to experience excessive bleeding after a fall." Dr. Maluso states that "[i]t was not likely or even probable that [R10] would suffer an adverse bleeding event or bleed to death while waiting for transfer to the hospital." P. Ex. 27 (Maluso Decl., ¶¶ 17, 18, 20).

When an individual is on Coumadin, blood levels must be monitored very carefully because a possible complication is severe bleeding. CMS Ex. 33; CMS Ex. 36, at 7; Tr. at 67. The Board has repeatedly recognized that Coumadin is extremely "dangerous." *See, e.g., Life Care Ctr. of Elizabethton*, DAB No. 2367, at 12 (2011). After R10 fell, it was necessary for Petitioner's staff to have a heightened concern for her overall condition and monitor her so that if she had any internal bleeding, she could receive immediate

medical treatment. A facility must take every reasonable precaution to prevent injuries, and I find Nurse Johnson's testimony more persuasive regarding the dangers of Coumadin. Petitioner had a duty to monitor R10 for dangerous bleeding considering the monitoring would not be an unreasonable precaution for not such a remote possibility with severe consequences. *See* CMS Ex. 7, at 7.

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

A facility must address its residents' needs by preparing individualized care plans through comprehensive assessments and regular reviews. *See* 42 C.F.R. § 483.20(d). Petitioner did not update the care plan of Resident 11 (R11) in a timely manner after she returned from the hospital in a hard cast that needed frequent monitoring for possible circulatory problems.

R11 was a 94-year-old woman at the time of the survey and was admitted to Petitioner's facility on December 8, 2001. CMS Ex. 19, at 1. R11's diagnoses included hypertension, vertebra fracture, senile depression, dementia, presenile dementia, and muscle weakness. CMS Ex. 19, at 1. A Minimum Data Set assessment (MDS), with a reference date of July 23, 2010, assessed R11 as being, among other things, severely cognitively impaired and requiring total assistance with all activities of daily living. CMS Ex. 19, at 3; *see* P. Ex. 6, at 5. R11 required the assistance of two staff members for transfers. CMS Ex. 19, at 3. The MDS indicated that R11 had no falls or fractures in the previous 180 days. CMS Ex. 19, at 4.

A care plan dated October 12, 2010, identified R11 as being at risk for traumatic skin injury due to "impaired cognition, impaired safety awareness, impaired mobility, [and] fall risk." CMS Ex. 19, at 14. Interventions included: encouraging the resident to wear long sleeves and/or pants; providing geri-sleeves or other protective clothing if unavailable; avoiding stress to skin during transfers and re-positioning; and seating in the common area to provide increased visibility. CMS Ex. 19, at 14.

According to a progress note dated December 20, 2010, at 10:30 a.m., a CNA reported that something was wrong with R11's right leg. A nurse then examined R11's right leg and found that the mid shaft area was bruised with a raised area and felt bones rubbing together. CMS Ex. 19, at 18. The nurse notified an ARNP (advance registered nurse practitioner). The ARNP ordered an x-ray of R11's right lower leg and ankle and pain medication every six hours as needed. P. Ex. 6, at 11. Portable x-rays were taken, and they showed "a proximal fibular fracture and a mid tibia spiral fracture with anterior angulation and slight shortening." CMS Ex. 19, at 17; CMS Ex. 19, at 18. The x-ray report noted also that R11's "bones are osteopenic." CMS Ex. 19, at 17. R11 went to the ER for evaluation and treatment. P. Ex. 6, at 11; CMS Ex. 19, at 9, 18-19.

On December 21, 2010, after she returned from the ER with a temporary soft splint, the facility initiated a care plan for R11 related to her fracture. CMS Ex. 19, at 15. On December 22, 2010, an orthopedic surgeon treated R11, and her leg was placed in a hard plaster type cast. CMS Ex. 19, at 20, 25-26; P. Ex. 1, at 7; CMS Ex. 1, at 7. The SOD alleges that the care plan was not updated to reflect the new cast and need for frequent assessment of R11's foot for complications. According to the SOD, the nursing notes do not contain any entries from December 21, 2010 through January 5, 2011, and there is also no documentation in the medical record that R11 had been monitored and assessed for circulatory problems following the placement of the cast. P. Ex. 1, at 24; CMS Ex. 1, at 24.

CMS argues that R11's medical records do not indicate that she suffered a spontaneous or pathological fracture. CMS asserts that R11's fractures were "most likely the result of [Petitioner's] employee twisting her legs to transfer her from bed to her wheelchair." CMS Br. at 10. CMS contends further that Petitioner's staff failed to closely monitor R11's leg for possible swelling and circulatory problems after she received a hard cast.

Petitioner argues that R11 had spontaneous fractures that occurred without a fall and that the fractures were unforeseeable and unpreventable. Petitioner contends that R11's fractures could have occurred when she received routine care. Petitioner asserts that there was no evidence that the fractures occurred during a transfer. P. Br. at 14-15. Petitioner contends further that R11 was properly monitored for any complications.

Although it is not clear what exactly caused R11's fractures, the record shows that Petitioner's staff failed to properly monitor R11's leg when she returned to the facility with a hard cast. R11 initially had a temporary soft splint when she returned to Petitioner's facility on December 21, 2010, and a care plan was implemented on that date. The approaches on the care plan included the following: pain medication as ordered; monitor for any signs and symptoms of pain or discomfort; monitor circulation in right lower extremity; and bed rest. CMS Ex. 19, at 15.

The next day, on December 22, 2010, R11 had an appointment with the orthopedic surgeon, and her splint was changed to a hard plaster cast. CMS Ex. 19, at 20, 25-26; P. Ex. 1, at 7; CMS Ex. 1, at 7. The nursing notes show that when R11 returned to Petitioner's facility later in the afternoon on December 22, 2010, the nurses monitored her, and documented that her cast was in place, there was no swelling or redness, and she was given her pain medication. CMS Ex. 19, at 20-21. An entry on the care plan dated December 22, 2010, notes that R11 had been to the orthopedic surgeon, the cast was applied, and she was to follow up with the surgeon in two weeks. The entry states that R11's circulation was to be monitored in her right lower extremity. CMS Ex. 19, at 16.

Despite the care planning requirement to monitor R11's circulation, the record contains no further progress notes on R11's condition until January 5, 2011, during the time of the survey. CMS Ex. 19, at 24. Petitioner does not dispute the lack of progress notes, but instead, relies on the direct written testimony of Dr. Maluso, who asserts that monitoring did occur. Petitioner claims that, according to Dr. Maluso, the "methodology for verifying circulation problems has changed in modern orthopedic practice." P. Br. at 15-16. Dr. Maluso states in his declaration that Petitioner's staff "correctly followed the physician's order dated January 21, 2011, to check [R11's] circulation"[3] and opines that "[g]enerally such circulation checks are of very limited value." He goes on to state the following:

> With a hard cast, it is very difficult to gain access to the pulses in the lower limbs. Circulation can only be assessed by checking for capillary refill on the toenail beds, which is of limited value. In addition, in the most feared complication of a fracture, compartmental syndrome which can result in a limb threatening situation, pulses are often still palpable.

P. Ex. 27 (Maluso Decl. ¶ 32).

According to Dr. Maluso, because checking R11's circulation would have had limited value, "the most important sign of complication would have been [R11's] pain level." He notes that R11's pain was frequently and appropriately assessed after her fracture. P. Ex. 27 (Maluso Decl. ¶ 33).

Neither Dr. Maluso nor Petitioner cites to any evidence that lends support to his testimony that circulation checks would have been ineffective for R11 and that the best way to monitor for complications is to evaluate the level of pain. Moreover, I note that Dr. Maluso does not refute CMS's contention that there was no documentation in R11's record that her leg was monitored and assessed for possible circulation problems after she received the hard cast.

From December 23, 2010 to January 4, 2010, there is nothing in the record to indicate that Petitioner's staff monitored R11's leg for circulation problems. After the nursing notes dated December 22, 2010, the next clinical notes concerning R11's leg are dated January 5, 2011 and January 21, 2011. CMS Ex. 19, at 23; P. Ex. 6, at 8.

Further, as previously discussed, Petitioner did not make adequate assessments and develop effective care plans to meet the needs of R6 and R7. These residents

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[3] The January 21, 2011 physician's order to which Dr. Maluso refers states that, on every shift, Petitioner's staff is to monitor R11's cast site at the right lower extremity and monitor for any swelling, redness, and cyanosis to the toes. P. Ex. 6, at 8.

experienced severe weight loss even though they were supposed to be weighed weekly, and their care plans did not plan for their weight losses. Petitioner also did not update R3's care plan when her physician ordered the lowered dosage of Ambien because it could lead to another fall. Petitioner did not also provide R3 and R10 with proper care plans to address their fall risks. In addition, Petitioner did not monitor R10 for excessive bleeding after her fall despite her use of Coumadin which can cause fatal bleeding.

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

Immediate jeopardy exists if a facility's noncompliance has caused, or is likely to cause, "serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301. CMS's determination as to the level of a facility's noncompliance (which includes an immediate jeopardy finding) must be upheld unless it is "clearly erroneous." 42 C.F.R. § 498.60(c); *Woodstock Care Ctr.*, DAB No. 1726, at 9, 38 (2000), *aff'd*, *Woodstock Care Ctr. v. Thompson*, 363 F.3d. 583 (6th Cir. 2003). CMS's determination of immediate jeopardy is presumed to be correct, and Petitioner faces a "heavy burden" to demonstrate that CMS's determination is clearly erroneous. *Owensboro Place and Rehab. Ctr.*, DAB No. 2397, at 9 (2011), citing *Azalea Court*, DAB No. 2352, at 16-17 (2010), and cases cited therein.

Petitioner contends in its posthearing brief that there were no immediate jeopardy level deficiencies. Petitioner argues that it appropriately managed the weight loss suffered by R6 and R7 and that it had appropriate safety measures in place to prevent R3's and R10's injuries, which were not foreseeable or preventable.

I am not persuaded by Petitioner's arguments. When addressing its residents' unplanned weight loss and falls, Petitioner has not shown that serious harm or death was not likely due to its failure to follow resident care plans or to implement appropriate interventions for resident safety. Petitioner failed to appropriately monitor the weights of R6 and R7, and as a result, failed to notice that these residents were losing weight. Both R6 and R7 suffered severe, unplanned weight loss, and by the time Petitioner identified their weight loss and took measures to address it, R6 had lost over 18 pounds since the time of her admission, and R7 had lost almost 35 pounds since the time of her admission. It was fortuitous that the state survey occurred because the likelihood of serious harm would have increased the longer the residents' weight losses went unidentified and unaddressed. Petitioner also did not successfully prove the severe weight losses of eight of its other residents were unavoidable. Inadequate nutrition is a serious problem, especially for elderly individuals who require skilled nursing care – nutrients are critical to the body's metabolism and its healing process. *See* CMS Ex. 36, at 2.

Despite the fact that Petitioner knew that both R3 and R10 were at risk for falls, Petitioner failed to have appropriate interventions in place to prevent them from having accidents. R3 and R10 fell and fractured their hips in separate incidents. R11, who

required total assistance with all activities, suffered a fracture of two bones in her leg. Although the cause of her fractures is not definitive, I find that Petitioner also failed to adequately implement R11's care plan to prevent any further serious circulation complications to a 94-year-old resident. Petitioner has not proven that CMS's determination of immediate jeopardy was clearly erroneous by demonstrating that severe weight loss and injury from falls did not constitute "serious harm" in these circumstances involving frail and elderly residents.

E. The penalty CMS imposed is reasonable.

To determine whether a CMP is reasonable, I apply the factors listed in 42 C.F.R. § 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; and 4) the facility's degree of culpability, which includes neglect, indifference, or disregard for resident care, comfort, or safety. The absence of culpability is not a mitigating factor. The factors in 42 C.F.R. § 488.404 include: 1) the scope and severity of the deficiency; 2) the relationship of the deficiency to other deficiencies resulting in noncompliance; and 3) the facility's prior history of noncompliance in general and specifically with reference to the cited deficiencies. I am neither bound to defer to CMS's factual assertions, nor free to make a wholly independent choice of remedies without regard for CMS's discretion. *Barn Hill Care Ctr.*, DAB No. 1848, at 21 (2002); *Cmty Nursing Home*, DAB No. 1807, at 22 *et seq*. (2002); *Emerald Oaks*, DAB No. 1800, at 9-10 (2001); *CarePlex of Silver Spring*, DAB No. 1683, at 8 (1999).

Petitioner argues that "CMS failed to consider the factors in 42 C.F.R. § 488.438(f) when it imposed a CMP of over $1,000,000.00." P. Br. at 20. First, I note that Petitioner has incorrectly stated the amount of the CMP that CMS imposed. CMS originally imposed a CMP of $5,550 per day from July 20, 2010 through January 19, 2011 (184 days of immediate jeopardy) and then $100 per day from January 20, 2011 through February 14, 2011 (26 days of substantial noncompliance that was not immediate jeopardy), for a total CMP amount of $1,023,800. CMS Exs. 2-4. However, CMS later reduced the penalty, imposing a CMP of $5,550 per day from September 20, 2010 through January 19, 2011 (122 days of immediate jeopardy), and then $100 per day from January 20, 2011 through February 14, 2011 (26 days of substantial noncompliance that was not immediate jeopardy, for a total CMP amount of $679,700. CMS Pre-hrg. Br. at 22.

Unless a facility contends that a particular regulatory factor does not support the CMP amount, the ALJ must sustain it. *Coquina Center*, DAB No. 1860 (2002). Petitioner argues that CMS has not considered the facility's finances when imposing the CMP. P. Request for Hearing. With respect to its financial condition, it is Petitioner's responsibility to show that it cannot pay the CMP. Petitioner was free to call any witnesses to testify to its financial condition or to submit any documentary evidence

regarding its financial condition. However, Petitioner provided no evidence to show that its financial condition hinders it from paying the proposed CMP.

The deficiencies in this case were serious. As stated above, Petitioner's staff failed to adequately monitor the weights of R6 and R7, resulting in severe unplanned weight loss for both. Further, Petitioner did not satisfactorily account for the severe weight losses of eight other residents. Because Petitioner's staff failed to have appropriate interventions in place to prevent accidents, R3 and R10, who were known fall risks, fell and fractured their hips. Petitioner's deficiencies caused R3, R6, R7, and R10 actual harm, for which the facility is highly culpable for the disregard for residents' care, comfort, and safety.

CMS considerably decreased the original CMP duration and determined September 20, 2010 would be an appropriate start date because that was when R3's Fall Risk Identification and Plan of Care was not updated to remove Ambien from her medications, as ordered by her physician. CMS Pre-hrg. Br. at 22. Petitioner argued in its prehearing exchange that this date was nonsensical. P. Pre-hrg. Br. at 16. However, considering that I am finding Petitioner responsible for not following R3's physician's order starting June 25, 2010, CMS's shortening of the CMP duration is actually already quite favorable to Petitioner.

Petitioner contends that CMS failed to consider its history of noncompliance. P. Br. at 20. Petitioner states that it did not have any deficiency above a "D" scope and severity level during surveys conducted in 2007 through 2010, and thus, its history of compliance does not warrant the amount of the CMP. P. Exs. 22-26; CMS Ex. 34. Despite Petitioner's claim that its history of noncompliance is good, I find that the $5,550 per day CMP from September 20, 2010 through January 19, 2011, is much less than the maximum that CMS could have imposed upon Petitioner for immediate jeopardy-level deficiencies. In fact, it is in the lower half of the CMP range for immediate jeopardy level deficiencies ($3,050 per day to $10,000 per day). 42 C.F.R. §488.438(a)(1)(i), (d)(2). I find further that the $100 per day CMP from January 20, 2011 through February 14, 2011, is at the very low end of the CMP range for non-immediate jeopardy level deficiencies ($50 per day to $3,000 per day). 42 C.F.R. § 488.438(a)(1)(ii).

After carefully reviewing the circumstances of this case in light of the relevant factors, I find that the amount of the CMP is reasonable.

V. Conclusion

Petitioner's staff did not realize the severe weight loss of several of Petitioner's residents until the state survey occurred. Petitioner also did not take all reasonable precautions to prevent residents from falling and their related injuries. One resident taking Coumadin was not monitored for excessive bleeding after a serious fall and could have likely experienced implications causing serious harm or death. Petitioner also did not follow a

physician's order to discontinue a resident's sedative, which increased her risk for falling, and then she did in fact fall and fractured her hip. Residents who had just suffered long bone fractures waited for excessive periods of time to be properly treated, and Petitioner's DON was not proactive in addressing emergency situations. Further, Petitioner did not adequately monitor and document its residents' conditions to ensure the sufficiency of their plans of care.

I uphold CMS's determination that Petitioner was not in substantial compliance with program participation requirements, I do not find that CMS's determinations of immediate jeopardy were clearly erroneous, and I find that the CMP that CMS imposed was reasonable.

/s/
Joseph Grow
Administrative Law Judge