Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

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In the Case of:
Bradford County Manor,
Petitioner,
- v
Centers for Medicare & Medicaid Services.

DATE: June 23, 2008 App. Div. Dkt. No. A-08-37 Decision No. 2181

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Bradford County Manor (BCM), a Pennsylvania skilled nursing facility (SNF), and the Centers for Medicare & Medicaid Services (CMS) have appealed the October 20, 2007 decision of Administrative Law Judge (ALJ) Keith W. Sickendick, <u>Bradford</u> <u>County Manor</u>, DAB CR1674 (2007) (ALJ Decision).

At issue before the ALJ was BCM's challenge to CMS's determination that BCM was not in substantial compliance with three Medicare participation requirements: 42 C.F.R. § 483.25(c); 42 C.F.R. § 483.25(i)(1); and 42 C.F.R. § 483.25(j). CMS imposed a per-instance civil money penalty (CMP) of \$2,500 for each of these three instances of noncompliance.

Following an in-person evidentiary hearing, the ALJ rejected CMS's determination that BCM was out of substantial compliance with sections 483.25(c) and 483.25(i)(1). Regarding CMS's determination that BCM was out of substantial compliance with section 483.25(j), which was based on evidence about the nursing care provided to two residents, the ALJ upheld CMS's determination of noncompliance based on the evidence regarding one of those residents.

Accordingly, the ALJ set aside the \$2,500 per-instance CMPs that CMS had imposed for the alleged violations of sections 483.25(c) and 483.25(i)(1), and reduced by half the \$2,500 CMP that had been imposed for the violation of section 483.25(j).

We reverse all but two of the ALJ's conclusions regarding these compliance issues because they are based on errors of law or are not supported by substantial evidence. In view of our resolution of the compliance issues, and for other reasons discussed below, we conclude that CMS was authorized to impose a per-instance CMP of \$2,500 for noncompliance with section 483.25(c), a perinstance CMP of \$1,250 for noncompliance with section 483.25(i)(1), and a per-instance CMP of \$2,500 for noncompliance with section 483.25(j).

Legal Background

The participation requirements for skilled nursing and other long-term care facilities that participate in Medicare and Medicaid are set forth at 42 C.F.R. Part 483, Subpart B. State agencies under contract with CMS perform surveys to verify whether the facilities are complying with those participation requirements. The procedures for survey and certification of long-term care facilities are set out at 42 C.F.R. Part 488, subparts A and E, and in the State Operations Manual (SOM) issued by CMS. A state survey agency reports any "deficiencies," or failures to meet participation requirements, on a standard form called a "Statement of Deficiencies." <u>See</u> 42 C.F.R. §§ 488.301, 488.325(a); SOM Appendix (App.) P, sec. III. The Statement of Deficiencies identifies each deficiency by the applicable regulation and a unique survey "tag" number.

A facility becomes subject to various enforcement remedies, including civil money penalties, when it is found to be not in "substantial compliance" with one or more participation requirements. See 42 C.F.R. §§ 488.400, 488.402(c), 488.406, "Substantial compliance" means a level of compliance 488.408. such that "any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm." Id. § 488.301. CMS's regulations (and we) use the term "noncompliance" to refer to "any deficiency that causes a facility to not be in substantial compliance." Id. § 488.301. CMS may impose a CMP either for the number of days the facility is not in substantial compliance (a per day CMP) or "for each instance that [the] facility is not in substantial compliance" (a per-instance CMP). Id. § 488.430(a). A per-instance CMP must be imposed in the range of \$1,000 to 10,000 per instance. Id. § 488.438(a)(2).

In an ALJ proceeding, a facility may challenge the finding or findings of noncompliance that resulted in the imposition of a CMP or other enforcement remedy. 42 C.F.R. §§ 488.408(g)(1), 498.3(b)(13). Based on factors specified in the regulations, the SNF may also contend that the amount of a CMP imposed by CMS is unreasonable. <u>Capitol Hill Community Rehabilitation and</u> <u>Specialty Care Center</u>, DAB No. 1629 (1997).

In the ALJ proceeding, CMS must make a prima facie showing as to any disputed allegations that the skilled nursing facility (SNF) was not in substantial compliance. If CMS makes a prima facie case, the SNF must prove, by a preponderance of evidence, that it was in substantial compliance. <u>Batavia Nursing and Convalescent</u> <u>Inn</u>, DAB No. 1911 (2004), <u>aff'd</u>, <u>Batavia Nursing & Convalescent</u> <u>Ctr. v. Thompson</u>, 143 Fed. Appx. 664 (6th Cir. 2005); <u>Hillman</u> <u>Rehabilitation Center</u>, DAB No. 1611, at 6 (1997), <u>aff'd</u>, <u>Hillman</u> <u>Rehabilitation Ctr. v. U.S. Dep't of Health and Human Servs.</u>, No. 98-3789 (GEB) (D.N.J. May 13, 1999).

Case Background

A compliance survey of BCM (completed on April 28, 2006) identified the following deficiencies at issue in this appeal:

Tag F314: noncompliance with 42 C.F.R. § 483.25(c)
involving Resident 143;

Tag F325: noncompliance with 42 C.F.R. § 483.25(i)(1)
involving Residents 60 and 9;

Tag F327: noncompliance with 42 C.F.R. § 483.25(j) involving Residents CR3 and 17.

CMS Ex. 2, at 18-20, 22-23. CMS concurred that each of these deficiencies constituted a lack of substantial compliance and imposed a per-instance CMP of \$2,500 for each deficiency. CMS Ex. 4.

BCM then requested and received an ALJ hearing on CMS's deficiency findings. During the in-person evidentiary hearing, the following witnesses testified for CMS: Surveyors Denise Phoenix, Rebecca Lewis, and Tracy Duncan; Shirley Sword, a registered dietician; and Barbara Connors, M.D. Sword and Dr. Connors testified as expert witnesses. Tr. at 413, 557. BCM presented a single witness — Tammy Donovan, R.N., who was BCM's director of nursing at the time of the hearing but not at the time of the survey.

Based on hearing testimony, documentary evidence, and posthearing briefs filed by the parties, the ALJ reached the following conclusions regarding CMS's deficiency findings:

Tag F314: CMS failed to make a prima facie showing that BCM was not in substantial compliance with 42 C.F.R. § 483.25(c) in its care of Resident 143;

Taq F325: CMS made a prima facie showing that BCM was not in substantial compliance with 42 C.F.R. § 483.25(i)(1) in its care of Residents 60 and 9, but BCM rebutted CMS's prima facie case regarding these two residents by a preponderance of evidence;

Tag F327: (a) CMS made a prima facie showing that BCM was not in substantial compliance with 42 C.F.R. § 483.25(j) in its care of Resident CR3, and BCM failed to rebut that prima facie case by a preponderance of evidence; (b) CMS failed to make a prima facie showing that BCM was not in substantial compliance with 42 C.F.R. § 483.25(j) in its care of Resident 17.

ALJ Decision at 3-16. In short, the ALJ rejected all of CMS's deficiency findings, except for the deficiency finding based on the factual allegations concerning Resident CR3.

Both parties subsequently filed timely appeals of the ALJ Decision. CMS appeals the ALJ's determination regarding Resident 143 (tag F314), Resident 60 (tag F325), Resident 9 (tag F325), and Resident 17 (tag F327). BCM appeals the ALJ's determination regarding Resident CR3 (tag F327).

On May 23, 2008, the Board held oral argument on the appeals.

Standard of Review

We review a disputed finding of fact to determine whether the finding is supported by substantial evidence, 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 (at http://www.hhs.gov/dab/guidelines/ prov.html); South Valley Health Care Center, DAB No. 1691, at 2 (1999), aff'd, South Valley Health Care Center v. HCFA, 223 F.3d 1221 (10th Cir. 2000). We do not disturb an ALJ's credibility finding unless it is clearly erroneous. Hotel Reed Nursing Center, DAB No. 2154 (2008).

Discussion

In section 1 (below), we consider the issues raised in BCM's appeal. In sections 2, 3, and 4, we consider the issues raised in CMS's appeal. In section 5, we indicate the extent to which CMS was authorized to impose per-instance CMPs based on our conclusions. Finally, in section 6, we briefly address the ALJ's finding that the state of Pennsylvania was not required to withdraw BCM's authority to conduct a nurse aide training and competency evaluation program (NATCEP) in light of the ALJ's reduction of the total CMP amount to less than \$5,000.

1. Tag F327, Resident CR3

Title 42 C.F.R. § 483.25(j) states that a SNF "must provide each resident with <u>sufficient fluid intake</u> to maintain proper hydration and health" (emphasis added). According to CMS's interpretive guidelines, "sufficient fluid" means "the amount of fluid needed to prevent dehydration (output of fluid far exceeds fluid intake) and maintain health." CMS State Operations Manual (Pub. 100-7), Appendix PP, *Interpretive Guidelines for Long-Term Care Facilities* (SOM App. PP).¹ "The amount [of fluid] needed is specific for each resident, and fluctuates as the resident's condition fluctuates (e.g., increase fluids if resident has fever or diarrhea)." Id.

Resident CR3, who was admitted to BCM on December 22, 2005, received nutrition and fluid through a percutaneous endoscopic gastrostomy (PEG) tube. ALJ Decision at 15. She took no food or fluid by mouth. <u>Id</u>. A Resident Assessment Protocol (RAP) completed on January 2, 2006 identified her as being at risk for dehydration. CMS Ex. 2, at 30-31; CMS Ex. 10, at 2-3.

During the evening of January 16, 2006, Resident CR3 was transferred from BCM to the emergency room (ER) at Troy Community Hospital (TCM) after developing symptoms of respiratory distress. ALJ Decision at 15; CMS Ex. 10, at 19. Upon admission to TCM's ER, Resident CR3 was dehydrated, with the ER physician noting the following clinical signs of dehydration: dry oral mucosa, poor skin turgor, and elevated blood urea nitrogen (BUN). ALJ Decision at 15. Shortly after being seen in the TCM ER, and after receiving intravenous fluids there, Resident CR3 was transferred to Robert Packer Hospital (RPH). <u>Id.</u> at 16, 17 n.7. Resident CR3 was discharged from RPH on January 24, 2007. <u>Id.</u>;

¹ The State Operations Manual is available on CMS's public website at http://www.cms.hhs.gov/Manuals/IOM/list.asp.

P. Ex. 31. The RPH discharge summary indicates that she had been diagnosed and treated for aspiration pneumonia. P. Ex. 31. (Aspiration occurs when food, liquid, or other matter enters the trachea (airway). Tr. at 480.)

During the ALJ proceeding, CMS contended that prior to Resident CR3's January 16, 2006 hospitalization, BCM failed to provide Resident CR3 with the amount of fluid she required. CMS Post-Hearing Br. (May 22, 2007) at 17. In response, BCM contended, among other things, that Resident CR3 could not have tolerated receiving any additional fluid through her PEG tube. BCM Post-Hearing Br. (May 22, 2007) at 11. In support of that contention, BCM pointed to treatment records indicating that a "white frothy discharge" had been observed in Resident CR3's mouth on December 30, 2005; that shortly after this observation, Resident CR3's attending physician, Dr. Good, decreased the rate at which she received liquid nutrition through her PEG tube; and that Resident CR3 was later diagnosed with and treated for aspiration pneumonia. Id. at 11-12. According to BCM, "[t]he presence of the white frothy discharge, the treating physician's decision to reduce the tube feeding rate and the [RPH] Discharge Summary noting that Resident CR3 suffered from aspiration pneumonia all support the contention that additional fluid delivered through the tube would have been inappropriate and/or that Resident CR3 could not tolerate the rate being delivered." Id. at 12.

The ALJ concluded that BCM "has not shown by a preponderance of the evidence that Resident CR3 was not dehydrated" upon her admission to the TCM ER on January 16, 2006. ALJ Decision at 15. The ALJ also rejected BCM's suggestion that it could not have provided adequate fluid through the PEG tube:

[A]lthough Petitioner implied that it could not increase the fluids for this resident (referring to a frothy white discharge and the diagnosis of aspiration pneumonia at Robert Packer Hospital), there is <u>no</u> <u>credible evidence that this resident could not tolerate</u> <u>her tube feedings or that she could not have received</u> <u>additional hydration intravenously</u>. Petitioner had nearly complete control of this resident's intake and output. Further, Petitioner did not elect to provide persuasive expert testimony to support its position that it was impossible to add more fluids for this resident.

<u>Id.</u> at 15-16 (citations and footnote omitted; emphasis added). Based on these findings, the ALJ concluded that CMS had made a prima facie showing of noncompliance with section 483.25(j) and that BCM had failed to rebut CMS's prima facie case. <u>Id.</u> at 6-7.

In its appeal, BCM makes two general contentions. First, BCM contends that, contrary to the ALJ's finding, the record contains "credible evidence" that Resident CR3 could not have received additional fluid through her PEG tube. According to BCM, that evidence includes:

- Testimony by Shirley Sword (the CMS dietician) that liquid nutrition delivered through the PEG tube (called "Jevity") was a "milky colored liquid" (Tr. at 589);
- A December 30, 2005 food and nutrition progress note stating that: (1) Resident CR3 had a "white frothy discharge" from her mouth; (2) "concern" had been raised about Resident CR3's tolerance for tube feeding and whether she was experiencing "reflux"; and (3) Resident CR3's physician, Dr. Good, would be notified of the nursing staff's concern and "may wish to consider reducing feeding rate to 40 cc/hour if GI tolerance is a concern [with] present rate @ 50 cc/hour" (CMS Ex. 10, at 10);
- A nursing note indicating that, on or about January 4, 2006, Dr. Good decreased the tube feeding rate from 50 cc of liquid nutrition per hour to 40 cc per hour (CMS Ex. 10, at 11); and
- The RPH discharge summary indicating a diagnosis of aspiration pneumonia (P. Ex. 31).

<u>See</u> BCM Br. at 3-5. BCM suggests that this evidence proved that providing additional fluid through the PEG tube would have unacceptably increased the risk of aspiration (food or fluid entering the airway). <u>Id.</u> at 6, 8-9. BCM asserts that this evidence should be considered "dispositive" on the issue of Resident CR3's tolerance for additional fluid intake through the PEG tube because Dr. Connors testified (according to BCM) that it was more important to maintain the integrity of Resident CR3's airway than deliver fluid through the PEG tube, and that if delivering additional fluid through the PEG tube would have compromised the airway by causing reflux, then delivering that additional fluid would have been "contraindicated." <u>Id.</u> at 6. BCM further asserts that Resident CR3's hospital diagnosis of aspiration pneumonia is the "most persuasive, if not definitive piece" of evidence that Resident CR3 could not have tolerated additional fluid. <u>Id.</u> at 5 n.16. "It would be impossible," BCM says, "for CR3 to suffer aspiration unless fluid delivered through the PEG was not absorbed but instead collected in the stomach until the pressure generated by the pump was sufficient to breach the pyloric sphincter and push the fluid up the esophagus where it would enter the pharynx and drop into the trachea." <u>Id</u>.

BCM's second contention concerns the ALJ's statement regarding intravenous therapy. In rejecting BCM's argument regarding Resident CR3's ability to tolerate additional fluid through the PEG tube, the ALJ found "no credible evidence . . . that [Resident CR3] could not have received additional hydration intravenously." BCM asserts that this finding was based on testimony by Dr. Connors that BCM could have provided intravenous therapy (in lieu of, or supplementing fluid delivery through the PEG tube) to keep Resident CR3 adequately hydrated. BCM Br. at 9. BCM asserts that the ALJ erred in relying on that testimony because intravenous therapy is not "fluid intake" within the meaning of section 483.25(j). <u>Id.</u> at 10.

Before addressing these contentions, it is important to note that BCM does not challenge the ALJ's conclusion that CMS made a prima facie showing of noncompliance regarding Resident CR3. Τn Woodland Village Nursing Center, DAB No. 2053 (2007), aff'd Woodland Village Nursing Ctr. v. U.S. Dep't of Health & Human Srvcs., No. 07-60005, 2007 WL 2489710 (5th Cir. 2007), the Board held that a "hospital diagnosis of dehydration would itself be sufficient to establish CMS's prima facie case." Here, it is undisputed that Resident CR3 was dehydrated upon her admission to the hospital on January 16, 2006. Thus, in the proceeding below, the burden was on BCM to establish, by a preponderance of evidence, that it took adequate steps, consistent with professional standards of quality, to ensure that Resident CR3 received sufficient fluid intake to maintain proper hydration and Community Skilled Nursing Centre, DAB No. 1987, at 16 health. (2005) (SNF had the burden to show that the resident "became dehydrated despite care that was consistent with professional standards of quality for preventing dehydration in someone of [the resident's] condition"); <u>Sheridan Health Care Center</u>, DAB No. 2178 (2008) (holding that the lead-in language to the quality of care requirements in section 483.25 obligates a facility to take "reasonable steps" and "practicable measures" to achieve the regulatory end).

We also note that BCM does not contend that Resident CR3 received adequate fluid through her PEG tube between December 22, 2005 and

January 16, 2006.² By contending instead that additional fluid could not have been provided through the PEG tube, BCM implicitly contends that it did all that was reasonably required to ensure that Resident CR3 received "sufficient fluid intake" and that her dehydration on January 16, 2006 was unavoidable.

The record as a whole does not support BCM's assertion that Resident CR3 could not have tolerated receiving additional fluid through the PEG tube. The treatment records cited by BCM reveal that on December 30, 2005, BCM's nursing staff expressed concern about "reflux" after observing a white frothy discharge in Resident CR3's mouth. CMS Ex. 10, at 10. However, these same records also show that on December 30 or 31, 2005, a certified registered nurse practitioner (CRNP) examined Resident CR3's oral cavity and concluded that Resident CR3 was "not refluxing TF [tube feeding] formula" and that her secretions were ordinary sputum. Id. at 11. On January 5, 2006, Dr. Good reduced the rate at which Resident CR3 received liquid nutrition through the PEG tube. Id. At the same time, however, Dr. Good ordered additional water flushes - from twice daily ("BID") to every 6 hours - "to ensure est. fluid needs are met." Id. at 11 (Jan. 4, 2006 entry).

Resident CR3's treatment records do not cite Dr. Good's reasons for reducing the tube feeding rate, but to imply (as BCM does) that he reduced the feeding rate in order to prevent reflux seems inconsistent with the CRNP's finding less than a week earlier that Resident CR3 was not refluxing her liquid nutrition. Furthermore, there is no evidence that Dr. Good believed that the rate or amount of tube feeding or water flushes could not be increased, with appropriate precautions, if necessary to ensure that Resident CR3 received sufficient fluid.

BCM contends that "Dr. Connors' cross examination testimony amounts to an admission that the delivery of additional fluid via the PEG tube posed serious risks, particularly when she finally testified that BCM should have used intravenous therapy to provide hydration to CR3." BCM Br. at 7 (citing Tr. at 479-80). However Dr. Connors made no such admission. Under crossexamination, Dr. Connors was asked to <u>assume</u>, for purposes of a hypothetical question, that the amount of fluid Resident CR3 received through her PEG tube was the maximum level she could tolerate but still insufficient to prevent dehydration. Tr. at

² Dr. Connors and Shirley Sword testified that Resident CR3 did not receive sufficient fluids in the facility, Tr. at 470, 580, and BCM does not contend that it rebutted that testimony.

479-80. With this assumption, Dr. Connors testified that BCM would have been obligated to deliver fluids intravenously or to arrange to have intravenous therapy performed at the hospital or another long-term care facility. Tr. at 480. At no point did Dr. Connors express an opinion that during December 2005 and January 2006, Resident CR3 received the maximum amount of fluid she could tolerate through the PEG tube.

In any event, a debate about whether Resident CR3 could have tolerated more liquid through the PEG tube is largely immaterial. If (as BCM now contends) no additional liquid (be it pure water or liquid nutrition) could have been provided through the PEG tube, and if Resident CR3 received inadequate fluid through that tube (a fact that BCM does not dispute), then it was incumbent on BCM to find and implement other measures to ensure sufficient fluid intake. We note in this respect that BCM did not initiate a plan of care to deal with Resident CR3's assessed risk for dehydration because it was relying on her receiving adequate fluid through her PEG tube. CMS Ex. 10, at 3. That exclusive reliance on the PEG tube as the method of fluid delivery clearly left the resident vulnerable to dehydration if fluid delivery through the tube proved inadequate. As noted, Dr. Connors testified that BCM should have provided intravenous therapy if it thought that Resident CR3 was getting insufficient fluid through her PEG tube.³ That testimony is unrebutted, and we see no evidence that BCM considered the feasibility or necessity of providing such therapy in the days leading to Resident CR3's January 16, 2006 hospitalization. Since BCM does not claim here that Resident CR3 received adequate fluid through the PEG tube, its failure to consider other methods of fluid delivery supports the ALJ's finding of noncompliance.

BCM offers no support for its assertion that receiving intravenous fluid is not "fluid intake" within the meaning of section 483.25(j). The regulation's text requires a facility to ensure "sufficient fluid intake" without limiting the scope of the SNF's obligation to particular routes of intake (mouth, tube, or intravenous line). We also note that BCM's own "Hydration" policy recognizes intravenous therapy as a means or method of fluid intake. That policy states that "[i]f fluids by mouth are not tolerated, an IV or tube feeding may be recommended and if

³ Dr. Connors testified that long-term care facilities in Pennsylvania must have staff qualified to administer intravenous fluids. Tr. at 472. If BCM's nursing staff was not qualified to provide intravenous therapy, BCM was obligated to arrange to have a third party provide the service. 42 C.F.R. § 483.75(h)(1).

placed, appropriate fluids will be provided through the IV or tube." CMS Ex. 13, at 2.

BCM faults the ALJ for requiring expert testimony on the issue of whether Resident CR3 could have tolerated additional fluid. BCM Br. at 7. Since BCM's records provide little or no insight into the thinking of Dr. Good (the physician most familiar with Resident CR3's condition) on that issue, it was appropriate for the ALJ to require expert testimony, by Dr. Good or another physician, to help settle the issue. In any event, as we indicated, the issue of Resident CR3's tolerance for liquid through the PEG tube is a red herring. Assuming for the sake of argument that Resident CR3 could not have received more fluid through the PEG tube, the dispositive issue is whether BCM could and should have used other means - such as intravenous therapy to ensure sufficient fluid intake. Based on the testimony of Dr. Connors, which BCM failed to rebut, we find that BCM should have provided (or arranged for) intravenous therapy under these circumstances.

We have considered all of the other points made by BCM in connection with its argument that additional fluid could not have been provided through the PEG tube and find them to be without merit. Accordingly, we uphold the ALJ's conclusion that BCM failed to overcome CMS's prima facie showing of noncompliance regarding Resident CR3.

2. Tag F314, Resident 143

At issue under deficiency tag F143 is whether BCM complied with requirements in 42 C.F.R. § 483.25(c) for the prevention and treatment of pressure sores (also known as pressure ulcers). Section 483.25(c) provides:

(c) Pressure sores. Based on the comprehensive assessment of a resident, the facility must ensure that -

(1) A resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable;

(2) A resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing. Thus, a SNF is under a two-fold obligation. First, under section 483.25(c)(1), the SNF must ensure that a resident who enters the facility without a pressure sore does not develop one, unless such development is clinically unavoidable; second, under section 483.25(c)(2), the SNF must ensure that a resident who has a pressure sore receives "necessary treatment and services to promote healing, prevent infection and prevent new sores from developing."

On March 2, 2006, Resident 143 was re-admitted to BCM following hospitalization for a hip fracture. P. Ex. 3 (BCM0005). According to the Statement of Deficiencies, a March 3, 2006 re-admission assessment performed by the "charge nurse" and verified by the assistant director of nursing noted that Resident 143 had a "Stage I (reddened area without a break in the skin) pressure area on his right heel and outside right foot, " although a "weekly skin assessment" dated March 7, 2006 and signed by the chairperson of BCM's "skin committee" indicated that Resident 143 had no open or reddened areas on the skin.⁴ CMS Ex. 2, at 19. The Statement of Deficiencies further indicates that during an April 26, 2006 interview, BCM's director of nursing confirmed that Resident 143's re-admission skin assessment revealed a stage I pressure sore. Id. at 20. In addition, the Statement of Deficiencies reported that the director of nursing "was unable to provide documented evidence that the facility had provided measures to prevent skin breakdown resulting in a stage IV pressure ulcer on Resident 143's right ankle," and that "[t]here was no documented evidence that the facility [had] implemented a plan of care until March 20, 2006, 18 days after his readmission to the facility." Id.

In its August 19, 2006 request for hearing (RH), BCM asserted, among other things, that Resident 143 had a stage IV pressure sore on March 2, 2006, not a stage I sore, and that the survey agency's failure to recognize this fact led them "to mistakenly conclude" that the pressure sore had worsened in the facility. RH at 15, 18. BCM also asserted that it had established a plan of care to address the stage IV pressure sore by March 2, 2006. Id. at 15.

In its opening argument at the April 2007 hearing, CMS stated:

⁴ The severity of a pressure sore is determined by using "staging" criteria. Stage I pressure sores are the least serious, stage IV pressure sores the most serious. <u>See</u> P. Ex. 18.

Briefly put, Your Honor, the 314 F Tag dealing with pressure sores concerns one resident, the testimony and the evidence will demonstrate that depending upon which staff member at Bradford made an entry, either that resident had a stage 1 pressure sore or stage 4 pressure sore or no pressure sore at all. Apart from that confusion, <u>it was the absolute obligation to</u> <u>minimize whatever wound was on that resident's heel and</u> <u>appropriate clinical interventions were not timely</u> <u>instituted</u>.

Tr. 32-33 (emphasis added). BCM responded:

[CMS counsel] indicated that CMS will show with regard to the wound tag that appropriate clinical interventions were not instituted. This is a surprise because CMS' Exhibit Number 2, the [Statement of Deficiencies] in this matter does not allege that appropriate interventions were not instituted. It alleges that this person developed a stage 4 that was preventable. The facts will show that that is not true. The weight of the evidence clearly indicates that this resident was admitted to the facility with a stage 4 pressure ulcer and that the ulcer never got worse during the resident's stay at the facility.

Tr. at 35.

In its post-hearing brief to the ALJ, CMS argued that as of March 2, 2006, Resident 143 had either no pressure sore or at worst a stage I pressure sore on his right heel, and that BCM failed to implement "timely and appropriate" interventions to prevent the development of a new pressure sore or the worsening of an existing stage I pressure sore. CMS Post-Hearing Br. at 3. CMS pointed to one intervention in particular that, in its view, was not timely implemented - i.e., relieving pressure on Resident 143's right heel by placing a pillow under his right calf. Id. CMS also asserted that "there were no treatment administration records or nurses notes that evidenced pressure relieving devices, with the sole exception of a multi podus boot occasionally used even though it was ordered on 'at all times remove for hygiene.'" Id. at 4. In addition, CMS asserted that "there were no witnesses who testified what they did or observed regarding any preventive measures taken by Bradford or its staff to mitigate the worsening of a pressure sore." Id. Finally, CMS asserted that "[w]hether Resident 143 had a Stage I or Stage IV pressure sore at the time of his readmission on March 2, 2006, the facility had an affirmative obligation to prevent it from

worsening." <u>Id</u>. In its post-hearing brief, BCM continued to assert that Resident 143 had a stage IV pressure ulcer on his right heel on March 2, 2006. BCM Post Trial Br. at 1-3. BCM also asserted that by March 2, 2006, the nursing staff had established a plan of care specifying "appropriate interventions" to prevent skin breakdown. <u>Id.</u> at 1-3.

The ALJ made two key findings of fact: (1) on March 2, 2006, Resident 143 had a stage IV pressure sore on his right heel⁵; and (2) on March 2, 2006, BCM had a written plan of care that had been "specifically developed to address a breakdown on Resident 143's heel as a Stage IV pressure sore." ALJ Decision at 10. Based largely on these two findings, the ALJ concluded:

Because Resident 143 entered with a pressure sore on readmission, CMS cannot satisfy the first alternative basis for a *prima facie* showing, i.e. that the resident entered Petitioner's facility without an ulcer and then developed one. 42 C.F.R. § 483.25(c)(1).

CMS also fails to establish a prima facie showing of a violation of the second prong of 42 C.F.R. § 483.25(c)(2), i.e., that Petitioner failed to deliver necessary care and treatment to promote healing, prevent infection, and prevent new sores. CMS alleges in post-hearing briefs that the pressure sore worsened, but points to no evidence in support of its position. CMS has to present some evidence in support of its prima facie case, it is not enough to simply make an allegation.

Id. at 11.

CMS contends in its appeal that the "preponderance of the evidence does not support a finding that Petitioner care planned appropriate interventions for the pressure sore on March 2, 2006." CMS Br. at 25. CMS also asserts that the "basis of the deficiency is not that a care plan was lacking" but that BCM "failed to timely provide interventions to prevent the worsening of a pressure sore" in violation of the requirement in section 483.25(c)(2) that a SNF deliver "necessary treatment and services

⁵ The ALJ found that there was "no dispute that the breakdown the resident had on his heel (characterized as a black spot/reddened area in a March 3, 2006 nutrition note and in nurse's notes . . .) should be treated as a Stage IV pressure sore." ALJ Decision at 10.

to promote healing, prevent infection and prevent new sores from developing." <u>Id.</u> at 27. CMS asserts that "there is absolutely no evidence that timely interventions were instituted to prevent the worsening of [Resident 143's] pressure sore," noting that "it wasn't until March 9, 2006 that the first order addressing the Stage IV pressure sore was written." <u>Id.</u> at 29.

Asserting that the "gravamen" of the survey agency's deficiency finding was a failure to institute a plan of care for a stage I pressure sore that worsened after March 2, 2006, BCM responds that there is substantial evidence supporting the ALJ's finding that its nursing staff established a plan of care for Resident 143's pressure sore on March 2, 2006. BCM Response Br. at 3. BCM also contends that there is substantial evidence supporting the ALJ's finding that the nursing staff made "timely" interventions to prevent the worsening of Resident 143's pressure sore. <u>Id</u>.

During oral argument, the parties disagreed about the severity of Resident 143's pressure sore on March 2, 2006. BCM maintained that Resident 143 entered the facility on that date with a stage IV pressure sore, while CMS contended that the pressure sore was at most a stage I sore and that it worsened while he was in the facility.⁶ Oral Argument Tr. at 6-7.

Before addressing the parties' arguments, we find that the issue of whether BCM delivered "necessary treatment and services" in compliance with section 483.25(c)(2) was properly before the ALJ. At the beginning of the three-day evidentiary hearing, CMS advised the ALJ and BCM of its intent to show that BCM failed to meet its obligation to implement timely and appropriate "interventions" to "minimize" the wound on Resident 143's right heel, irrespective of its severity. Tr. at 32-33. CMS then proceeded to present testimony purporting to show that BCM failed to implement in a timely manner certain interventions to prevent the pressure sore from worsening or to prevent new sores from The most notable of these interventions were developing. measures to relieve pressure on the right heel. Tr. at 420-23. Although BCM responded in its opening statement at the hearing that it was "surprised" at CMS's description of the issue under tag F314, and although it asserted that the Statement of

⁶ CMS takes the position that it is immaterial whether the resident had a pressure sore on admission because BCM had a duty both to prevent and heal pressure sores. However, CMS "emphatically" disputes that Resident 143 had a stage IV pressure sore on admission. Oral Argument Tr. at 7.

Deficiencies failed to allege a failure to deliver appropriate interventions, BCM did not contend at the hearing that it was unfairly surprised by CMS's characterization of the issue, nor did it ask the ALJ for additional time in order to respond to that issue. In addition, the claim of "surprise" at the opening of the hearing is undercut by BCM's August 19, 2006 request for hearing (RH). The hearing request asserts that BCM took various "skin breakdown precautions" and provided Resident 143 with "specialized wound care services to treat the sore on his heel." RH at 15-16. These assertions show that BCM believed or assumed that the second prong of section 483.25(c) - which requires the provision of "necessary treatment and services to promote healing, prevent infection and prevent new sores from developing" - might be implicated in this case. Furthermore, BCM does not contend in this appeal that it lacked sufficient notice below of CMS's intention to prove a failure to provide "necessary treatment and services." To the contrary, BCM's response to CMS's appeal acknowledges CMS's continuing claim that the facility failed to provide timely and necessary interventions, then responds to that claim on the merits. Response Br. at 3, 7-11.

Turning to the merits, we conclude that the ALJ erred. His conclusion that CMS failed to make a prima facie showing of noncompliance with section 483.25(c)(2) is based on a misapplication of the regulatory standard and is not supported by substantial evidence. The ALJ justified his conclusion by noting that CMS had failed to establish that the pressure sore on Resident 143's right heel had worsened. However, section 483.25(c)(2) does not require CMS to prove that a pressure sore has worsened. Rather, it requires CMS to prove that the facility failed to provide "necessary treatment and services to promote healing, prevent infection, and prevent new sores from developing." Assuming that there was, as the ALJ found, a stage IV pressure sore on Resident 143's right heel on March 2, 2006,⁷

⁷ Contrary to the ALJ's finding, there was - and is - a dispute between the parties about the severity of any pressure sore that existed on March 2, 2006. In our view, the evidence on this issue is conflicting and inconclusive at best. For purposes of our analysis, however, this factual dispute is immaterial because, regardless of the wound's severity or onset date, the record does not support the ALJ's conclusion that CMS failed to make a prima facie showing of noncompliance with section 483.25(c)(2). As indicated in the text above, CMS presented unrebutted evidence of BCM's failure to take timely and necessary (continued...)

BCM was obligated to provide necessary services to promote healing and prevent infection of that wound, and to also provide care and services to prevent new sores from developing on the right heel and in other locations.

Contrary to the ALJ's finding, CMS presented testimony and documentary evidence that BCM failed to provide necessary treatment and services in a timely manner. The nursing records that CMS submitted indicate that it was not until March 9, 2006, more than one week after BCM allegedly established a plan of care to deal with a stage IV pressure sore, that the nursing staff began to provide treatment and services. On that date, the nursing staff sought a physician's order: (1) to apply "skin prep" to Resident 143's heels every eight hours; (2) for a Gaymar mattress (a pressure-relieving mattress); and (3) for a "multi-podus" boot, which suspended and thus relieved pressure on Resident 143's right heel. CMS Ex. 9, at 2; Tr. at 423. (Resident 143 did not start wearing the multi-podus boot until March 10 or 11. CMS Ex. 9, at 2; P. Ex. 13; Tr. at 726.)

Dr. Connors and Surveyor Duncan testified that one elementary intervention that could - and should - have been implemented promptly (a physician's order not being necessary) was to place a pillow under Resident 143's right calf while he was in bed, thus elevating and relieving pressure on the right heel. Tr. at 421-23, 633-34. However, treatment records indicate that a physician order for this measure was not obtained until March 14, 2006, and there is no evidence that it was implemented before the physician ordered it. CMS Ex. 9, at 5. The 12-day delay in implementing this simple preventive measure was significant. CMS's interpretive guidelines state that, for a resident at risk for developing pressure sores, as Resident 143 was, preventive measures must be implemented "promptly" because a pressure sore can develop within two to six hours of the onset of pressure. SOM App. PP. Dr. Connors testified that the delay in placing the pillow under the resident's calf had the potential for causing more than minimal harm. Tr. at 424.

Measures aimed at healing or preventing infection of the right heel's pressure sore were even less timely, according to facility records submitted by CMS. It was not until March 23, 2006 that the nursing staff obtained an order to cleanse and dress the

⁷(...continued) action to promote healing of Resident 143's pressure sore, prevent infection, and prevent new pressure sores from developing. wound. CMS Ex. 9, at 4 (physician order for cleansing and applying a "hydrogel" dressing).

We note that the plan of care that the ALJ identified as having been established on March 2, 2006 to address a stage IV pressure sore on the right heel contained no individualized instructions for treating or preventing infection of that wound.⁸ The plan of care was a form document that contained a generic list of interventions to prevent and treat pressure sores. CMS Ex. 9, at 27. Two of these interventions were:

- "Administer medication and treatments <u>per MD order</u> and monitor for side effects & effectiveness"; and
- "Provide diet, supplements, extra vitamins/protein/minerals <u>as ordered</u> to promote wound healing and skin integrity."

<u>Id.</u> (emphasis added). Thus, the March 2, 2006 plan of care directed the nursing staff to provide "ordered" treatment. Such a directive is ineffective unless there are orders in place for specific treatment. As indicted, facility records submitted by CMS show that physician orders for treatment and prevention were not sought or obtained until March 9, 2006 or later.⁹

⁹ We take note here of CMS's objection to the ALJ's finding that BCM established the plan of care for Resident 143's stage IV pressure sore on March 2, 2006. As the ALJ acknowledged, the date on the plan of care was unclear because it had been written over. ALJ Decision at 10. Apart from that fact, there is reason to doubt that the plan of care was made or established on March 2, 2006 because it specifies interventions – the multi-podus boot and foot cradle, for example – that, according to other facility records, were not ordered by Resident 143's physician until March 9, 2006 or later. However, it is unnecessary for us to delve further into the issue of when BCM established its care plan because BCM's noncompliance rests on its failure to implement necessary preventive and treatment measures until one week (or (continued...)

⁸ The nursing staff did make some handwritten additions to the plan of care's pre-printed list of interventions. CMS Ex. 9, at 27. These additions included instructions to provide a multipodus boot and "foot cradle." <u>Id</u>. Physician orders for these two interventions were not issued until March 9, 2006 (for the multi-podus boot) or March 14, 2006 (for the foot cradle). <u>Id</u>. at 5.

Those records also suggest that BCM did not promptly implement internal procedures for handling residents that experience skin breakdown. BCM had a "skin care committee" that was supposed to meet weekly, "review all residents who experience alterations in skin integrity, " and "provide education to staff regarding individualized treatment plans." CMS Ex. 9, at 10. A "Weekly Skin Assessment Form," signed by the chairperson of the skin care committee on March 7, 2006, indicates that Resident 143 had no "abnormal skin conditions or changes in skin integrity," despite other nursing records showing that, as of March 2, 2006, Resident 143 had a pressure sore on his right heel. CMS Ex. 9, at 24, 27; P. Exs. 2-4. The March 7 signature of the skin committee chairperson on a form indicating that Resident 143 had no abnormal skin changes is evidence that the skin care committee failed to take reasonably prompt action to address a pressure sore that the facility admits was present - and claims was at stage IV - five days earlier.¹⁰

We conclude, on the basis of the evidence just discussed, that CMS made a prima facie showing that BCM was not in substantial compliance with section 483.25(c)(2) in its care of Resident 143. We must therefore consider whether BCM carried its burden of establishing that it was in substantial compliance.

BCM asserts that it provided Resident 143 with a pressure-relieving mattress - called a Silhouette - when he was re-admitted on March 2, 2006. Response Br. at 7. In support of that assertion, BCM cites a manufacturer's description of the mattress. Id. We can find no treatment records confirming that Resident 143 actually received a Silhouette mattress upon readmission, and nursing notes indicate that he did not start using the Gaymar mattress until March 11, 2006. P. Ex. 13 (BCM 0065).

BCM also asserts that "Resident 143 was also provided with specialized wound care services to treat the sore on his heel." Response Br. at 8. However, the documentary evidence that BCM cites for this assertion does not reflect any care given to

⁹(...continued) more) after Resident 143's admission to the facility.

¹⁰ The record contains a second skin assessment form that notes the presence of a pressure sore on Resident 143's right heel. CMS Ex. 9, at 25. However, this form was signed by the skin committee chairperson on March 15, 2006, almost two weeks after Resident 143's admission to the facility. address Resident 143's existing pressure sore. As BCM itself indicates, the evidence merely shows that nurse aides performed "skin assessments" to determine whether any "new skin problems" had developed. P. Ex. 12.

BCM also points to a pre-March 2006 plan of care for pressure sore prevention that called on the nursing staff to turn and reposition Resident 143 every one to two hours (or as needed) if the resident was unable to reposition himself. Response Br. at 6 n.12 (citing P. Ex. 6 (BCM0012)). BCM asserts that documents in BCM Exhibit 10 "documented care provided each day from March 2, 2006, to March 31, 2006, of turning, walking and repositioning Resident 143." Response Br. at 7. However, BCM also states that these activities were done in connection with activities of daily living (ADLs). Id. On its face, this is an admission that the records cited had to do with staff assistance to the resident in performing ADLs and were not specific to pressure sore prevention and treatment. Furthermore, an examination of the records in BCM Exhibit 10 reveals that they do not track whether the turning and repositioning for pressure sore prevention and treatment required by the care plan were provided. Rather, the records track how much assistance staff had to give to Resident 143 in performing ADLs relating to bed mobility, transfers, and walking in his room and on and off the unit. In addition, the time intervals shown on those records do not reflect that the ADL services being tracked were done every one to two hours as the plan of care required for repositioning and turning.

BCM contends that it provided various other services (e.g., physical therapy, nutrition supplements) aimed at mitigating the risk of skin breakdown. BCM Response Br. at 6-11. While some of these services may have been necessary to prevent the development of new pressure sores, BCM did not prove that these services in themselves constituted adequate or sufficient nursing care for healing or preventing infection of what BCM alleged (and the ALJ found) was a stage IV pressure sore. BCM also failed to rebut CMS's evidence that it failed to relieve pressure on the right heel by elevating it with a pillow under the calf. In addition, BCM failed to establish that elevating the right heel was not a "necessary" intervention to promote healing or prevent new sores from developing. Finally, BCM has not endeavored to deny, explain, or excuse the apparent one-week-or-more delay in initiating preventive and treatment measures.⁸

For the reasons discussed, we conclude that BCM failed to overcome CMS's prima facie case of noncompliance with 42 C.F.R. § 483.25(c) concerning Resident 143 by a preponderance of evidence.

3. Tag F325, Residents 9 and 60

Title 42 C.F.R. § 483.25(i)(1) states:

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[.]

According to CMS's interpretive guidelines, the intent of section 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. The interpretive guidelines further state that "unacceptable" parameters of nutritional status include "unplanned weight loss as well as other indices such as such as peripheral edema, cachexia and laboratory tests indicating malnourishment (e.g., serum albumin levels)." Id.

The interpretive guidelines provide the following commentary about "weight" as a parameter of nutritional status:

Since ideal body weight charts have not yet been validated for the institutionalized elderly, weight loss (or gain) is a guide in determining nutritional status. An analysis of weight loss or gain should be examined in light of the individual's former life style as well as the current diagnosis.

Suggested parameters for evaluating significance of unplanned and undesired weight loss are:

Interval	Significant Loss	Severe Loss		
1 month	5.0%	Greater than 5%		
3 months	7.5%	Greater than 7.5%		
6 months	10.0%	Greater than 10%		

SOM App. PP. The interpretive guidelines further state that "[c]linical conditions demonstrating that the maintenance of acceptable nutritional status may not be possible include, but are not limited to, "[r]efusal to eat and refusal of other methods of nourishment"; "[a]dvanced disease (i.e., cancer,

malabsorption syndrome)"; "[i]ncreased nutritional/caloric needs associated with pressure sores and wound healing"; "[r]adiation or chemotherapy"; "[k]idney disease, alcohol/drug abuse, chronic blood loss, hyperthyroidism"; "[g]astrointestinal surgery"; and "[p]rolonged nausea, vomiting, diarrhea not relieved by treatment given according to accepted standards of practice." <u>Id</u>.

The Board addressed the application of section 483.25(i)(1) in <u>The Windsor House</u>, DAB No. 1942 (2004) and <u>Carehouse Convalescent</u> <u>Hospital</u>, DAB No. 1799 (2001). In those decisions, the Board held that unplanned weight loss "may raise an inference of inadequate nutrition and support a prima facie case of a deficiency." <u>Carehouse</u> at 22; <u>see also Windsor House</u> at 17. The Board further held that, if CMS makes a prima facie showing of noncompliance based on unplanned weight loss, the SNF must prove, by a preponderance of evidence, that it provided adequate nutrition and that the weight loss was "attributable to nonnutritive factors" which establish that the weight loss was unavoidable.¹¹ <u>Windsor House</u> at 17; <u>Carehouse</u> at 22. "[T]he facility is responsible for taking all reasonable steps to ensure that the resident receives nutrition adequate to his or her needs." <u>Windsor House</u> at 18.

With these requirements and guidelines in mind, we consider the ALJ's findings of fact and conclusions of law regarding Residents 60 and 9.

a. <u>Resident 60</u>

Resident 60 had a diagnosis of dementia. CMS Ex. 8, at 6. Her "desirable body weight" was 88 to 102 pounds (95 ± 7 pounds). <u>Id.</u> at 23. According to BCM's records, she was found to weigh 76.8 pounds in February 2005; between 81 and 83.6 pounds in April 2005; 88 pounds in May 2005; 93 pounds in June and July 2005; and 92 pounds in August 2005. <u>Id.</u> at 30-32. On or about September 1, 2005, her weight was recorded as 74.8 pounds. <u>Id.</u> at 33. The nursing staff promptly re-weighed her and recorded a weight of 98.6 pounds for September 1, 2005. <u>Id</u>. From that point forward, her weight was reported to be the following:

¹¹ "By its language [section 483.25(i)(1)] requires maintenance of weight only to the extent that weight is a parameter of nutritional status. Where a resident receives adequate nutrition and weight loss is due to non-nutritive factors, then weight may not be a parameter of nutritional status, and weight loss by itself does not provide a basis for a deficiency finding." <u>Carehouse</u> at 21.

September 12, 2005 September 20, 2005 September 26, 2005 October 1, 2005 October 18, 2005 November 7, 2005 December 1, 2005 January 4, 2006 February 15, 2006 February 15, 2006 March 1, 2006	 88.6 pounds 88.4 pounds 87.8 pounds 90.0 pounds 89.2 pounds 87.4 pounds 88.8 pounds 86.8 pounds 81.8 pounds 83.2 pounds 83.2 pounds 81.4 pounds 76 4-77 4 pounds
April 6, 2006 April 27, 2006	76.4-77.4 pounds 79.2 pounds

Id. at 23, 33-38. (The April 27, 2006 weight was taken during the survey.)

Surveyors found a lack of substantial compliance with section 483.25(i)(1) on the ground that BCM allegedly failed to alter Resident 60's diet in response to the "undesirable" weight loss she sustained between September 2005 and April 2006. CMS Ex. 2, at 22-25.

The ALJ found that Resident 60 experienced unplanned weight loss at BCM and that CMS had made a prima facie showing of noncompliance. ALJ Decision at 6. However, the ALJ concluded that BCM "took reasonable steps to ensure that Resident 60 maintained acceptable weight and nutrition." <u>Id.</u> at 12, 14. In support of that conclusion, the ALJ stated:

She was care planned for weight loss due to edema and a variable appetite needing supplements to maintain her weight. Her records show that Petitioner's staff and her physician were aware of her fluctuations in weight and that she was assessed and monitored and that there were interventions. These interventions included providing nutritional supplements, encouraging her to consume her meals, and monitoring her weight. Some of these interventions were successful in stabilizing her weight for a while. The facility could not tube feed this resident, as comfort measures only were to be considered. It is also significant that CMS's witness, Ms. Sword, testified that, in her opinion, Petitioner provided Resident 60 adequate nutrition.

<u>Id.</u> at 14.

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According to CMS, the ALJ's conclusion that BCM took reasonable steps to ensure that Resident 60 maintained an acceptable weight and nutrition is not supported by substantial evidence. CMS Br. at 17-23, 38-44. CMS asserts that all of the relevant evidence points to the opposite conclusion, and that the ALJ failed to consider or evaluate Dr. Connors' unrebutted expert testimony that Resident 60's weight loss was "avoidable." CMS Br. at 17-In addition, CMS asserts that the ALJ ignored evidence 18, 20. that Resident 60 had a poor-to-fair appetite and typically consumed no more than 50% of her meals. Id. at 22. CMS further contends that BCM failed to intervene in a timely manner to stem Resident 60's weight loss. Id. at 39. CMS also contends that the ALJ took Shirley Sword's testimony "out of context," and that Sword clarified on redirect examination that Resident 60 was "offered" sufficient calories but did not consume them. See CMS Br. at 42-43.

BCM responds that there was, in fact, no significant weight loss because Resident 60 weighed almost exactly the same in April 2006 (79.2 pounds) as she did in April 2005 (81-83 pounds). BCM Response Br. at 22. BCM also suggests that the 98.6 pound weight recorded on September 1, 2005 was probably not Resident 60's true weight on that date and thus should not be a basis for finding that she lost significant weight afterward. Id. at 20-22. BCM asserts that a more accurate baseline for judging the magnitude of the weight loss after September 1, 2005 is 88.3 pounds, the average of the weights taken on September 12, September 19, and September 26, 2005. Id. at 21. In addition, BCM relies on testimony by Shirley Sword that the nursing staff offered Resident 60 food and other nutrition that was sufficient to meet <u>Id.</u> at 22. BCM contends that Sword's testimony and her needs. the evidence that Resident 60 weighed the same in April 2006 as she did in April 2005 constitute substantial evidence to support the ALJ's conclusion that the facility was in substantial compliance with section 483.25(i)(1) in its care of Resident 60.

We find the ALJ's one-paragraph analysis of whether BCM carried its burden of proving substantial compliance inadequate for meaningful appellate review. While the ALJ accurately stated that BCM monitored Resident 60's weight loss and implemented some interventions to combat that problem, his decision contains no acknowledgment, discussion or weighing of expert testimony and other evidence calling into question the <u>sufficiency</u> and <u>timeliness</u> of BCM's response to Resident 60's weight loss. This failure to evaluate the evidence is an error of law. <u>See Estes</u> <u>Nursing Facility Civic Center</u>, DAB No. 2000, at 5 (2005) ("While an ALJ does not have to address every fact in the record, he/she must address the evidence that conflicts with the evidence supporting his/her findings of fact"). In view of this error of law, we make our own de novo assessment of whether BCM carried its burden of proof.¹² <u>Evergreene Nursing Care Center</u>, DAB No. 2069 at 10 n. 9 (2007) (When the Board finds that an ALJ's decision is based on factual or legal errors, the Board may issue a new or modified decision or remand the case to the ALJ for that purpose.).

We conclude that BCM did not carry its burden. As a preliminary matter, we find it unnecessary to resolve the parties' dispute about whether 98.6 pounds was Resident 60's true weight on September 1, 2005 because, as we discuss below, the record shows significant weight loss from other, lower benchmarks. Furthermore, regardless of the weight loss that may have occurred during September 2005, we think the record clearly establishes that BCM succeeded in stabilizing Resident 60's weight at the low end of her desirable body weight range of 88 to 102 pounds between mid-September 2005 and early January 2006. In fact, Resident 60's weight remained at or very close to 88 pounds from September 2005 until early January 2006. There is also evidence that, as of September 2005, Resident 60 was receiving "Two Cal," a dietary supplement four times daily ("QID") as well as "super cereal" (a fortified cereal) and milkshakes for lunch and dinner. Tr. at 96-97; CMS Ex. 8, at 4. In addition, progress notes from late 2005 indicate that Resident 60 was followed and monitored by the dietary staff as an "increased nutrition risk," that she received "feeding assistance" from the nursing staff, that her consumption was monitored, and that BCM offered adequate protein and calories to meet her needs. CMS Ex. 8, at 24.

In our view, BCM's noncompliance arose not in 2005, as CMS suggests, but in February and March 2006. In January 2006, Sue White, BCM's registered dietician, noted that Resident 60 had lost 6.2 pounds during the previous six months (from 93 pounds in July 2005 to 86.8 pounds in January 2006) and two pounds within the previous 30 days. CMS Ex. 8, at 23. White characterized the weight loss as "not significant" but "undesirable." Id. She made no changes to Resident 60's dietary regimen, instructing the staff to follow the resident as an "increased nutrition risk per protocol." Id. On February 15, 2005, White reported that Resident 60 had lost 4.2 pounds (or 4.8% of her weight) during

¹² BCM did not appeal the ALJ's finding that Resident 60 sustained unplanned weight loss or his conclusion that CMS had made a prima facie showing of noncompliance regarding that resident. Thus, the burden was on BCM to demonstrate by a preponderance of evidence that it was in substantial compliance.

the previous 30 days and 9.4 pounds (or 10.2% of her weight) during the previous six months (August 2005 to February 2006), noting that Resident 60 was consuming only 50% of her meals. <u>Id</u>. Although the 10.2% weight loss over the previous six months was "significant" according to CMS's interpretive guidelines, White made no changes to any aspect of Resident 60's dietary regimen. <u>Id</u>. By March 1, 2006, Resident 60 weighed 81.4 pounds, 7.4 pounds less than she weighed on December 1, 2005 (88.8 pounds), an 8.3% weight loss over three months earlier. <u>Id</u>. at 23, 36-37. She lost four to five additional pounds (a 5-6% loss) between March 1 and April 6, 2006. <u>Id</u>. at 37.

On March 8, 2006, Resident 60 returned from the hospital following treatment for head injuries she received in a fall. CMS Ex. 8, at 25. On March 13, 2006, White requested a physician's order for additional dietary "supplements" to be provided at 10:00 a.m. (a "healthshake") and 8:00 p.m. (a "magic cup") and for the nursing staff to monitor her intake. <u>Id</u>. White again noted that Resident 60 was consuming no more than 50% of her meals and had poor-to-fair appetite. <u>Id</u>.

What is apparent from this chronology is that <u>by mid-February</u> <u>2006</u>, BCM was aware that, despite the provision of certain dietary supplements and other measures to boost caloric intake (e.g., super cereal, Two Cal), Resident 60 had lost a significant amount of weight and was typically consuming one-half of her meals at best. These facts raise the issue of what BCM should have done at that point to boost her caloric intake. As noted, the dietician ordered additional supplements on March 13, 2006, but this occurred one month after the dietician had reported significant weight loss.

Dietician Shirley Sword testified that Resident 60's main problem was that she was not eating enough of her meals, and the dietician's notes do state that Resident 60's "[i]ntake remains grossly inadequate overall." Tr. at 564; CMS Ex. 8, at 26. Sword also testified that in light of Resident 60's poor intake, it would have been helpful for the nursing staff to count the calories in the food she consumed so that the staff would have a better idea of how to supplement her caloric intake. Tr. at 564. There is no evidence that BCM performed a calorie count of Resident 60's consumption.

Sword also testified that because Resident 60's consumption of between-meal snacks and supplements was high, the nursing staff could have tried to increase her intake by giving her smaller, more frequent meals. Tr. at 564-66. There is no evidence this measure was considered or tried. Asked what else could have been done to stem Resident 60's weight loss, Dr. Connors testified that BCM could have weighed her more frequently, worked with the dietician to determine what foods she was most likely to consume, and assessed her overall medical condition to see if there were any underlying conditions or medications that were causing the weight loss. Tr. at 438-39. BCM does not indicate that any of these steps were taken during February and March 2006.

Dr. Connors also testified that, after Resident 60 was treated for head trauma in early March 2006, the nursing staff should have sought a speech therapy evaluation. At that point, said Dr. Connors, "I would have expected that this resident . . . would have had some kind of speech evaluation, which is very, very important in any type of stroke or a head trauma patient, to determine whether they were going to continue to be able to take in food that they had prior to the incident." Tr. at 429-30. There is no evidence that BCM sought a speech language therapy evaluation of Resident 60 until late April 2006, a delay that Dr. Connors found "inappropriate." CMS Ex. 8, at 22, 25, 26; Tr. at 430.

There is evidence that BCM asked Resident 60's physician if a change in her anti-depression medication would help improve her food intake. <u>See</u> CMS Ex. 8, at 53; Tr. at 611-12. But that request was not made until April 20, 2006, more than two months after the dietician reported significant weight loss. CMS Ex. 8, at 53.

There is also evidence indicating that Resident 60 had medical problems that affected her appetite. The staff dietician noted that a bout with pneumonia in December and January 2006 may have had that effect. CMS Ex. 8, at 23 (entry of Feb. 15, 2006). In addition, Dr. Connors acknowledged that head trauma suffered by Resident 60 may also have reduced her appetite. Tr. at 505. However, Dr. Connors testified that, in her opinion, there was nothing in Resident 60's medical records indicating that the weight loss was unavoidable. Tr. at 439. BCM offered no testimony, expert or otherwise, to rebut that opinion or any other opinion offered by CMS's experts, and there is no evidence that Resident 60 refused to eat or that other measures to encourage consumption would have been unproductive.

BCM's reliance on Shirley Sword's testimony does not help its cause. Sword testified that BCM provided Resident 60 food containing an adequate number of calories. Tr. at 611. As noted, however, and as Sword clarified, Resident 60's problem was her failure to consume all the calories provided. Tr. at 615. There is no indication of a timely and concerted effort by the nursing staff to deal with that problem.

For the reasons above, we affirm the ALJ's conclusion that CMS made a prima facie showing of noncompliance regarding Resident 60 but reverse his conclusion that BCM overcame that prima facie case by a preponderance of evidence.

b. <u>Resident 9</u>

Resident 9 was admitted to BCM on November 25, 2005 following hospital treatment for pneumonia. CMS Ex. 6, at 11; P. Ex. 38 (BCM0213). Her diagnoses upon admission included Alzheimer's dementia. CMS Ex. 6, at 7. According to BCM's records, Resident 9 weighed 189.6 pounds on November 28, 2005. Id. at 14. In March 2006, she weighed 166 pounds, 12.4% less than she did in late November 2005. Id. at 17. By April 27, 2006, she weighed 151.4 pounds, approximately 20% less than she weighed in late November 2005. Id. at 18. The dietary staff determined that her "adjusted ideal body weight" was 137 pounds. Id. at 5.

CMS contended before the ALJ that Resident 9 had experienced significant and unplanned weight loss, and that this weight loss was due partly to the fact that she was consuming only 50% of her meals on average. CMS Post-Hearing Br. at 6-7. CMS also pointed to computer-generated records from BCM's "Care Tracker" system indicating that Resident 9 had missed breakfast 31 times in February and March 2006. <u>Id</u>. In addition, CMS contended that interventions to stabilize her weight were "not timely instituted" and that BCM had failed to show that her weight loss was "clinically unavoidable." <u>Id.</u> at 13.

The ALJ agreed that Resident 9 had experienced "unplanned weight loss" and found that CMS had made a prima facie showing of noncompliance based on that circumstance. ALJ Decision at 12. However, the ALJ also concluded that BCM had taken "all reasonable steps to provide adequate nutrition" to Resident 9 and thus had rebutted CMS's prima facie case. <u>Id.</u> at 12-13. In support of that conclusion, the ALJ stated:

The facility took steps to address Resident 9's weight loss, taking into consideration her initial body weight, her diagnoses, her medication, and her family's preference for feeding her a regular diet. The facility solicited food preferences from the family in an attempt to tailor the resident's diet; monitored her weight to assess the need for supplements; provided supplements; arranged for an oral surgery consult regarding her broken teeth (which might have interfered with her eating); had staff hand-feed her, and changed the consistency of her food in the face of her difficulty consuming meals of a regular consistency (a regular consistency diet having been requested by the resident's family). I find that considering all the factors suggested by the [State Operations Manual], and the requirements of the regulation, Petitioner made reasonable efforts to ensure that Resident 9 maintained an acceptable weight and nutrition status.

<u>Id.</u> at 13-14 (citations and footnote omitted). The ALJ further found that Resident 9 had "complicated medical conditions with many possible factors affecting" her weight; that the nursing staff and Resident 9's attending physician were aware of the difficulty in maintaining Resident 9's weight; that Resident 9 was "assessed and monitored"; and that "various interventions were attempted to ensure [that she] maintained weight." <u>Id.</u> at 13. The ALJ also noted that he had found "no evidence other than weight loss" that Resident 9 was "malnourished."

Regarding CMS's evidence of missed breakfasts, the ALJ stated:

I do not find persuasive the computer printouts [Care Tracker records] obtained by the surveyors and which CMS introduced to show that Resident 9 missed breakfast 31 times in February and March 2006. I find credible and persuasive the testimony of the current DON, Ms. Donovan, that the computer printouts were produced by a new computer system installed shortly before the survey and that staff were not familiar with the system and made entry errors. I also find persuasive the DON's testimony that she investigated the situation and found that the resident did receive most of the breakfast meals, albeit after normal breakfast time, as the facility allowed Resident 9 to sleep-in.

ALJ Decision at 14 (citations omitted).

Citing a March 21, 2006 note by Certified Registered Nurse Practitioner Sally Yoder, CMS asserts that the nursing staff did not know why Resident 9 continued to lose weight during the first three months of 2006. CMS Br. at 5-6 (citing CMS Ex. 6, at 8). CMS asserts that, if BCM did not know the reasons for the weight loss, "it is unclear how the ALJ could have reasoned that steps were taken to address the weight loss." <u>Id.</u> at 6. CMS maintains that there is no or insufficient evidence that BCM took steps to address Resident 9's weight loss. <u>Id</u>. Assuming such steps were taken, they were inadequate, says CMS. <u>Id.</u> at 6-7. In addition, CMS contends that the ALJ's refusal to credit the documentary evidence of 31 missed breakfasts was erroneous because BCM provided no records to corroborate Nurse Donovan's testimony that Resident 9 had received breakfast on days when the Care Tracker printouts showed that she had missed the meal. <u>Id.</u> at 9-10. Finally, CMS complains that the ALJ ignored or erroneously discounted the testimony by CMS witnesses that undercuts his conclusions. <u>Id.</u> at 13.

We agree with the ALJ that Resident 9 presented a complicated clinical picture. The record indicates that she had underlying conditions that may have substantially contributed to her weight loss and made it unavoidable. One of these was her dementia. CMS Ex. 6, at 5; Tr. at 451. A second was diuretic therapy for edema. CMS Ex. 6, at 6, 8. A March 2006 nursing note indicates that her weight dropped to 172 pounds "almost immediately" while she was on big doses of Lasix. Id. at 8. In addition, progress notes indicate that she suffered a respiratory infection in March 2006 that, according to Shirley Sword, may have suppressed her appetite. Id.; Tr. at 608.

As the ALJ found, there is evidence in the record that the nursing staff did respond to Resident 9's weight loss problem. Treatment records indicate that, shortly after her admission in late November 2005, the nursing staff initiated a plan of care to address weight loss. CMS Ex. 6, at 5. Other treatment records confirm that BCM provided between-meal snacks, assisted the resident to eat, encouraged greater food intake, arranged for speech language therapy evaluations to determine the appropriate diet, and adjusted her diet when she encountered difficulty tolerating the consistency of her meals. <u>Id.</u> at 9-13. There is also evidence that the dietary staff, including the facility's "Monthly Weight Loss Committee," monitored the resident's diet and weight throughout the period at issue. P. Ex. 42, at 1 (notes of January 2006 weight loss committee); CMS Ex. 6, at 5, 11-13.

On cross-examination, Surveyor Phoenix clarified that BCM's noncompliance arose in February and March 2006 and that by April 2006, the facility was taking adequate steps to ensure that Resident 9 received adequate nutrition. Tr. at 337, 341-42. According to Surveyor Phoenix, during February and March 2006, the nursing staff failed to "monitor" Resident 9 or implement interventions to stem weight loss. Tr. at 342. However, treatment records indicate that the nursing staff did monitor Resident 9's nutrition and weight during those two months. CMS Ex. 6, at 8-9, 12. Those records acknowledge that Resident 9 had lost significant weight (17-23 pounds since admission), but they attributed most of the weight loss (approximately 17 pounds) to her diuretic therapy and "improvement of edema." <u>Id.</u> at 9, 12. Shirley Sword seems to have acknowledged that some of Resident 9's weight loss could be attributed to her diuretic (Lasix) treatment. Tr. at 573.

Like Resident 60, Resident 9 consumed only a percentage of meals offered to her. When asked what BCM could have done to improve Resident 9's intake, Sword testified that Resident 9 required staff "cueing" during meals. Tr. at 572. Facility records indicate that the nursing staff did feed and cue the resident. CMS Ex. 6, at 8 (March 21 note indicating that Resident 9 was "staff fed"), 12 (April 4 note indicating that resident eats meals "[with] staff encouragement/assist"). Surveyor Phoenix suggested that supplements could have been added (Tr. at 321), but there is also evidence that the resident refused them when they were given (CMS Ex. 6, at 4).

The surveyors failed to identify other specific interventions that could and should have been implemented under these In addition, the dietary staff noted that circumstances. Resident 9 remained above her ideal or desirable body weight in February and March 2006. CMS Ex. 6, at 12. Furthermore, in early March 2006, a dietary technician reported that Resident 9 had had "fairly good" appetite during the previous month. Id. at 9. There is also evidence to support the ALJ's finding that Resident 9's overall nutritional status was good. Id. at 7 (December 28 physician note indicating that nutrition was "excellent"). In view of all this evidence, it is not plain that the nursing staff was deficient in failing to implement additional measures to boost Resident 9's weight during February and March 2006.

As CMS asserts, the nursing staff expressed uncertainty about the reasons for Resident 9's weight loss. CMS Ex. 6, at 8. However, this uncertainty does not necessarily mean that the facility was lax or untimely in responding to the problem.

Regarding the evidence of missed breakfasts, Nurse Donovan testified that she interviewed Resident 9's family and the nursing staff on Resident 9's unit and learned from these interviews that Resident 9 had in fact been offered breakfast on the days when she slept late. Tr. at 852-53. In addition, Nurse Donovan testified that provision of the meals had not been recorded in the Care Tracker system because the nursing staff had erroneously assumed that notation of a late breakfast could not be entered into the system. <u>Id</u>. The ALJ evidently credited this testimony and thus implicitly found that Resident 9 had been offered breakfast on the 31 occasions when she slept through the designated breakfast period. We have carefully reviewed Nurse Donovan's testimony in light of the entire record, and based on that review we cannot say that the ALJ's credibility determination was clearly erroneous.

We are not the trier of fact in the first instance and our appellate role is not to reweigh the evidence. Rather, we review the ALJ's determination for legal errors and lack of "substantial evidence." After a careful review of the record, we conclude, for the reasons above, that the ALJ's findings of fact and conclusions of law regarding Resident 9 are supported by substantial evidence and are free of legal error.

4. Tag F327, Resident 17

Resident 17 was admitted to BCM on February 10, 2006. CMS Ex. 7, at 1. His diagnoses included insulin-dependent diabetes, congestive heart failure, and Alzheimer's dementia. <u>Id.</u> at 1, 15; P. Ex. 22; Tr. at 837. He was able to take food and fluid by mouth. CMS Ex. 7, at 5. A plan of care with a "start date" of February 21, 2006 stated that Resident 17 was at "[r]isk for fluid volume imbalance R/T CHF" (congestive heart failure), and that he had a "[p]otential for dehydration r/t progression of Dementia and variable PO [by mouth] intake of fluids." P. Ex. 22. Shortly after his admission, BCM's dietary staff assessed his fluid and nutritional needs. CMS Ex. 7, at 5. The results of that assessment were reported on an Admission Nutrition and Assessment Form (ANAF) signed by Diet Technician Pam Carlson. The ANAF indicated that, as of February 10-16, 2006, Id. Resident 17 weighed 205.4 pounds (93.4 kilograms) and required 2325-2790 cc of fluid per day. Id.

On February 28, 2006, Resident 17 was sent to the hospital ER after falling and hitting his head. CMS Ex. 7, at 15. The ER physician who examined Resident 17 that day reported that his "hydration status [was] good" and that his tongue was "pink and moist." Id. Lab testing in the ER indicated that he had elevated levels of BUN (urea nitrogen in blood) and creatinine. Id. at 13; Tr. at 455. A February 28, 2006 nurse's progress note indicates that Resident 17's physician, Dr. Good, "would like to see Res. in ER[.]" CMS Ex. 7 at 12. A March 1, 2006 progress note states that Resident 17 would be returning from the emergency room, that Dr. Good "thought he was 'dry,'" and that Resident 17 "was given IV fluids[.]" Id. A March 2, 2006 nursing note reiterated that Resident 17 had received "IV fluids" in the hospital. <u>Id.</u> at 7.

The state survey agency determined that, on a number of days between February 10 and February 27, 2006, Resident 17's daily fluid intake at BCM was less than his estimated daily need, and that there was no indication that BCM had implemented measures to reduce that intake shortfall. CMS Ex. 2, at 28.

The ALJ concluded that CMS had failed to make a prima facie showing that BCM was not in substantial compliance with section 483.25(j), which requires a SNF to provide a resident with "sufficient fluid intake to maintain proper hydration and health." ALJ Decision at 7. In support of that conclusion, the ALJ stated:

CMS has not made a prima facie case of noncompliance with regard to Resident 17, because, even if CMS was able to make a prima facie case that the resident's intake was less than his calculated needs, such argument would fail based on the fact that emergency room records at Troy Community Hospital note that the emergency room physician found his "[h]ydration status is good" and that his tongue was "pink and moist." Although Resident 17's treating physician, Dr. Good, saw him at Troy Community Hospital, thought he was "dry," and ordered intravenous fluids, Dr. Good did not see the resident until hours after his admission to the emergency room. The emergency room physician is very credible, as he actually saw the resident, his job is to assess patients, and he assessed the resident's hydration status as "good" and his tongue as "pink and moist," and he did not order intravenous fluids Even Dr. Connors agreed that lab values administered. which she thought might indicate dehydration [elevated BUN] might be due to trauma and prescriptions.

ALJ Decision at 16 (emphasis added).

In <u>Woodland Village Nursing Center</u>, the Board held that "clinical signs of dehydration or a diagnosis of dehydration are not necessarily required before CMS can find a violation of section 483.25(j)." DAB No. 2053, at 9. The Board further held:

[Section 483.25(j)] focuses on whether the facility is providing services to maintain sufficient hydration and whether any failure to do so has the potential for more than minimal harm. Where a resident has been found to be at risk for dehydration, . . . the compliance analysis must begin with what the facility did to mitigate that risk. To that end, its policies and whether it provided the amount of fluids recommended by the resident's dietician can be critical.

<u>Id.</u> at 9-10.

Thus, by concluding that CMS had not made a prima facie case because the emergency room physician did not find Resident 17 dehydrated regardless of whether BCM ensured that the resident's fluid intake met his calculated needs, the ALJ committed an error of law. Accordingly, we must consider de novo whether CMS made a prima facie showing of noncompliance and, if so, whether BCM carried its burden of showing substantial compliance with section 483.25(j).

CMS submitted Resident 17's ANAF (Admission Nutrition Assessment Form). CMS Ex. 7, at 5. This document indicates that, as of February 10-16, 2006, Resident 17 needed 2325 to 2790 cc of fluid per day. <u>Id</u>. In addition, CMS furnished BCM's "Fluid by Day Chart" for Resident 17. <u>Id.</u> at 17. According to Surveyor Phoenix, this chart shows Resident 17's total daily fluid intake between February 10 and February 27, 2006. Tr. at 263. The chart indicates that Resident 17's daily fluid intake during that 18-day period was as follows:

2/10/06	600	CC	2/11/06	1440 cc
2/12/06	1080	CC	2/13/06	840 cc
2/14/06	3120	CC	2/15/06	1920 cc
2/16/06	2640	CC	2/17/06	3360 cc
2/18/06	1080	CC	2/19/06	1320 cc
2/20/06	1920	CC	2/21/06	1861 cc
2/22/06	720	CC	2/23/06	961 cc
2/24/06	1200	CC	2/25/06	720 cc
2/26/06	1560	CC	2/27/06	960 cc

On its face, the Fluid by Day chart indicates that on 14 days between February 10 and February 27, 2006 (excluding February 10), Resident 17 received less than his estimated daily fluid requirement. On those 14 days, Resident 17 received only 31 to 83% of his minimum daily fluid requirement.¹³

Surveyor Phoenix and Dr. Connors testified that the disparity between Resident 17's estimated daily fluid requirement (as shown

¹³ This range is derived from the highest (1920 cc) and lowest (720 cc) recorded intake on the days when intake did not equal or exceed 2325 cc, excluding February 10, the date of Resident 17's admission.

on the ANAF) and the amount of daily fluid he actually received (as reported on the Fluid by Day chart) created a potential for dehydration. Tr. at 256, 454. In addition, Surveyor Phoenix testified that during the survey she discussed the Fluid by Day chart with BCM's registered dietician (Sue White) and dietary technician (Pam Carlson). Tr. at 264-65, 269-70. Surveyor Phoenix testified that when she asked these employees what interventions the facility had put in place to increase fluids for Resident 17, she "got no response." Tr. at 264.

In addition to evidence about daily fluid intake in February 2006, CMS submitted Food and Nutrition Progress Notes for March 2006. CMS Ex. 7, at 7-8. The entry for March 2, 2006 states in relevant part:

Res was sent out to TCH on 2/28 for ERO d/t \triangle [change] in mental status. Res received IV fluids @ hosp as res appeared dry. Res placed on I/O monitoring starting this AM to closely monitor fluid intake.

<u>Id.</u> at 8. The entry for March 10, 2006, signed by registered dietician Susan White, states in part:

He is averaging ~ 1630 cc fluid intake/day per I/O (needs 2325-2800).

Id. at 7. The entry for March 16, 2006 states in relevant part:

Fluid intake remains below est. fluid needs. Fluid needs recalculated based on current wt. 187.6# (obtained 3-13-06) = 2125-2550 cc/day. Res started on hourly hydration to promote ↑ [increased] fluid intake. Res showing no s/s [signs or symptoms] of dehydration at this time. MD made aware of inadequate fluid intake. Variable PO intake continues @ meals.

Id. (emphasis added).

In short, CMS presented: (1) documentation that Resident 17 received less (sometimes substantially less) than his minimum estimated daily requirement of fluid, as determined by BCM's dietary staff, between February 10 and March 16, 2006; and (2) testimony that BCM failed to provide surveyors with evidence of any interventions aimed at increasing Resident 17's fluid intake during that period. This evidence established that BCM failed to ensure that Resident 17 had "sufficient fluid intake to maintain proper hydration and health." Testimony by Dr. Connors and Surveyor Phoenix that inadequate fluid intake by Resident 17 during February and March 2006 created a risk of dehydration is sufficient proof that BCM's regulatory violation created the potential for more than minimal harm to Resident 17. Based on this evidence, we conclude that CMS made a prima facie showing that BCM was not in substantial compliance with section 483.25(j) in its care of Resident 17. Thus, we next consider whether BCM overcame CMS's prima facie case.

BCM asks us to focus on two pieces of evidence: an Input-Output (I/O) record purporting to show fluid intake by Resident 17 during his first seven days in the facility (CMS Ex. 7, at 9), and the testimony of Tammy Donovan (Tr. at 834-38). Nurse Donovan testified that in accordance with BCM's hydration policy, the nursing staff measured Resident 17's fluid input and output during the first seven days of his stay.¹⁴ Tr. at 834, 837. The I/O record appears to show that from February 10 through February 17, 2006, Resident 17's daily fluid input totals were as follows:

February	10	720	CC
February	11	1800	CC
February	12	2160	CC
February	13	780	CC
February	14	3000	CC
February	15	2640	CC
February	16	2760	CC
February	17	2480	CC

CMS Ex. 7, at 9.

Considering the daily totals for February 11 through February 17, Nurse Donovan testified that Resident 17 received average daily fluid intake of 2238 cc per day of pure (non-food-based) fluid.¹⁵ Tr. at 835. In addition, Nurse Donovan testified that the Resident received an additional 300 cc of fluid per day from the

¹⁴ BCM's hydration policy called on the nursing staff to complete an "I/O record" in order to "determine if the resident is at risk for dehydration and whether or not the resident needs to be placed on I/O monitoring." CMS Ex. 13, at 2.

¹⁵ It is not clear from the record which of the seven days Nurse Donovan considered, but presumably they were February 11 through 17, 2006 since BCM's counsel stated during oral argument that the total for February 10 included only part of that day because that was the day Resident 17 was admitted. Oral Argument Tr. at 46.

food he consumed. Tr. at 835-36. Thus, she testified that Resident 17 received approximately 2538 cc (2238 cc of pure fluid plus 300 cc of food-based fluid) per day, which, she said, was adequate to meet his fluid needs. Tr. at 837.

The ALJ Decision does not address this testimony, presumably because the ALJ concluded that CMS had not made its prima facie Since that conclusion was error, we must address Nurse case. Donovan's testimony. We do so and find that it is not persuasive. The assumption underlying Nurse Donovan's testimony is that the totals listed on the I/O record do not include the 300 ccs of fluid that she states Resident 17 would have received through meals he consumed each day. However, her testimony did not provide a basis for that assumption and BCM cites no other evidence supporting it. We note that the I/O form itself is structured to record fluid intake during each shift on each day and then to record the total of those figures. There is no indication that in recording the intake for each shift, staff were not to include fluids consumed through meals. We also note that some food items that could be consumed as part of a meal or snacks (e.g., ice cream and jello) are listed on the bottom of the form together with their liquid content. Furthermore, BCM's Hydration Nursing and Nutrition Services policy provides procedures for I/O monitoring and specifies among other things that -

I/O record will be completed by nursing staff. Fluids consumed at meals, nourishments, between meals, with meds and any other fluids that the resident may consume will be recorded and totaled on the I/O record by nursing.

CMS Ex. 13. at 2. This policy supports our finding that the totals recorded on the I/O form include all fluid consumed by the resident each day.

But even assuming the I/O record totals do not include fluids consumed through meals and that Nurse Donovan is correct that Resident 17 received approximately 2500 cc of fluid per day between February 10 and February 17, BCM has failed to overcome CMS's prima facie case. The I/O record covers only the first seven days after Resident 17's admission. By contrast, the Fluid by Day chart that CMS relies upon includes the entire 18-day period from Resident 17's admission to BCM on February 10, 2006 through the date preceding his admission to the emergency room on February 27, 2006. As discussed, the totals on the Fluid by Day chart indicate that the resident received less than his minimum daily fluid needs for all but three of those days, the exceptions being February 14, February 16, and February 17, 2006. (The Fluid by Day chart, incidentally, shows a lower amount of fluid intake on all but three of the days that overlap the days reported on the I/O record.) BCM has not rebutted the accuracy of the totals on the Fluid by Day chart or shown that they do not include all fluids received by the resident each day. Neither has BCM attempted to reconcile the differences in many of the totals between the two charts.

The record also shows that the failure to meet Resident 17's fluid intake needs persisted even after he returned from the hospital on March 1, 2006. In mid-March 2006, the registered dietician reported that Resident 17 was then receiving an average of only 1600 cc of fluid per day, which was approximately 30% less than his estimated daily need as of February 10, 2006 (2325-2790 cc) and 25% less than his estimated daily as of March 16, 2006 (2125-2550 cc). In addition, BCM presented no evidence that, between February 18 and March 16, 2006, it implemented measures to increase fluid intake. While the record shows a March 2, 2006 order to start Resident 17 on "I/O monitoring," there is no record of such monitoring during March 2006. In addition, BCM made no attempt to prove that deficient fluid intake between February 18 and mid-March 2006 created no risk of more than minimal harm to Resident 17.

During oral argument, BCM argued for the first time that, in evaluating whether Resident 17's fluid intake requirements had been met, the Board should rely on certain instructions for completing the Minimum Data Set (MDS) rather than its dietician's assessment of Resident 17's daily fluid needs. Oral Argument Tr. The MDS is a data-collection tool used to assess a at 46-49. long-term care facility resident's clinical and functional status and to identify factors that could affect that status. 42 C.F.R. § 483.315(e). The instructions cited by BCM state that the "Dehydrated; Output Exceeds Intake" box located at J1 on the MDS should be checked if two or more listed indicators are present. See BCM Exs. 18, 19. One of the listed indicators states that "Resident usually takes in less than the recommended 1500 ml of fluids daily" and specifies "(water or liquids in beverages, and water in high fluid content foods such as gelatin and soups)." The instructions then note that "[t]he recommended intake level has been changed from 2500 ml to 1500 ml to reflect current practice standards." BCM Ex. 18. BCM argues that we should find that Resident 17's fluid intake needs were met based on the 1500 ml figure in this instruction even though its dietician, consistent with BCMs written policies, calculated substantially greater fluid needs based on factors unique to this resident, including body weight. CMS Ex. 7 at 5; CMS Ex. 13 at 2. (CMS's

interpretive guidelines also use body weight and provide for calculating a fluid amount that is "specific for each resident" and that "fluctuates as the resident's condition fluctuates." SOM App. PP.)

The record in this case contains some evidence related to this issue: the MDS instructions (BCM Ex. 18); testimony by CMS's dietician that she was not familiar with the instructions (Tr. at 584-85); and unrebutted testimony by Dr. Connors that a resident's unique clinical condition might require the provision of more than 1500 ml per day (Tr. at 533-34). However, no witness testified that 1500 ml should have been accepted as representing Resident 17's daily fluid needs rather than the amount calculated by BCM's dietary staff (using a 25-30 cc-per-kilogram formula). CMS Ex. 7 at 5.

The Board generally does not address issues that could have been presented to the ALJ but were not. <u>Estes Nursing Facility Civic</u> <u>Center</u> (citing Board Guidelines). BCM did not contend before the ALJ that Resident 17's fluid intake needs were met based on the 1500 ml "standard" in the MDS instructions, nor did BCM raise that issue in its notice of appeal and accompanying brief. For that reason, and consistent with Board procedures and application of those procedures in prior cases, we do not decide that issue.

In summary, we conclude that the ALJ's finding that CMS did not make a prima facie case of noncompliance with 42 C.F.R. §483.25(j) in connection with Resident 17 was based on an error of law, and that CMS did make a prima facie case of noncompliance that BCM failed to rebut by a preponderance of evidence.

5. The CMPs

For each of the three deficiency tags at issue - F314, F325, and F327 - CMS imposed a \$2,500 per-instance CMP. The ALJ rejected CMS's deficiency findings under tags F314 and F325 and accordingly vacated the two CMPs (totaling \$5,000) associated with those findings. The ALJ also reduced by half the CMP for tag F327 (the hydration tag) in order to account for his conclusion that BCM had provided sufficient fluid intake to Resident 17, one of the two residents (the other being Resident CR3) whose care was cited by CMS as noncompliant with section 483.25(j).

We have concluded that BCM was not in substantial compliance with section 483.25(c) in its care of Resident 143, and that BCM was not in substantial compliance with section 483.25(j) in its care

of Resident 17. We have also affirmed the ALJ's conclusion that BCM was not in substantial compliance with section 483.25(j) in its care of Resident CR3. BCM does not contend in its appeal that the amount of any per-instance CMP imposed by CMS was unreasonable in amount. Accordingly, we find that CMS was authorized to impose a \$2,500 per-instance CMP for noncompliance with section 483.25(c), and a \$2,500 per-instance CMP for noncompliance with section 483.25(j).¹⁶

Regarding the noncompliance with section 483.25(i)(1) cited under taq F325, which involved two residents (60 and 9), we have concluded that BCM was not in substantial compliance regarding Resident 60. Thus, a basis existed for CMS to impose a CMP for noncompliance with section 483.25(i)(1). The issue is whether we should affirm, as reasonable in amount, the full \$2,500 CMP imposed by CMS for tag F325 given the fact that we have also affirmed the ALJ's conclusion that BCM was in substantial compliance with section 483.25(i)(1) in its care of Resident 9. It appears that, in this circumstance, the ALJ would have imposed only half of the CMP amount for tag F325 - or \$1,250 - as he did when he found noncompliance involving one of the two residents implicated by tag F327. Because neither party has raised an issue about the manner in which the ALJ handled this issue, we duplicate the ALJ's approach with respect to tag F325. We thus conclude that CMS is authorized to impose a CMP of \$1,250 for BCM's noncompliance with 42 C.F.R. § 483.25(i)(1). In sum, we uphold per-instance CMPs totaling \$6,250.

6. Withdrawal of approval of NATCEP

In view of his conclusion that only a 1,250 CMP was reasonable, the ALJ further concluded that the state of Pennsylvania was not required to withdraw BCM's authority to offer or conduct a nurse aide training and competency evaluation program (NATCEP) and that "[a]pproval of Petitioner to conduct a NATCEP program should not be withdrawn." ALJ Decision at 17. That conclusion concerns the requirement in section 1819(f)(2)(B)(iii)(I)(c) of the Social Security Act, which prohibits a state from approving a long-term care facility's NATCEP if, within the previous two years, the facility had "been assessed a civil money penalty . . . of not

¹⁶ We have held that when an ALJ upholds the noncompliance determination identified by CMS as the basis for a CMP, as we have done regarding tags F314 and F327, the amount of the CMP should be regarded as presumptively reasonable unless the SNF contends that the relevant regulatory factors do not support it. <u>Residence at Kensington Place</u>, DAB No. 1963 (2005).

less than \$5,000." Accord 42 C.F.R. § 483.151(b)(2)(iii). Since we find that per-instance CMP amounts totaling \$6,250 are reasonable, the predicate for the ALJ's conclusion regarding BCM's NATCEP clearly is no longer correct, and we therefore strike that conclusion.

<u>Conclusion</u>

Based on our analysis of the law and discussion of the evidence of record set out above, the ALJ Decision is affirmed in part and reversed in part. We strike the following numbered findings of fact and conclusions of law (FFCLs) from the ALJ Decision: Findings of Fact A.8.c., A.8.d, A.10.b, and A.10.d; and Conclusions of Law B.3, B.6 (as it pertains to Resident 60), B.10, B.11, B.12, and B.13. We also modify Finding of Fact A.12.b to read as follows:

The emergency room physician found Resident 17's hydration status to be "good" and his tongue to be "pink and moist." CMS Ex. 7, at 15-16. However, laboratory tests showed elevated BUN and creatinine levels, and the resident's personal physician (who saw the resident in the hospital) thought the resident was "dry" and ordered intravenous fluids. Id. at 7, 12; Tr. at 436.

In addition, we make the following new FFCLs:

Board FFCL 1: Bradford County Manor failed to timely implement necessary treatment and services to promote healing and prevent infection of a pressure sore on Resident 143's right heel and to prevent Resident 143 from developing additional pressure sores.

Board FFCL 2: Bradford County Manor was not in substantial compliance with 42 C.F.R. § 483.25(c).

Board FFCL 3: Bradford County Manor failed to take adequate measures during February and March 2006 to determine the reasons for Resident 60's weight loss and to implement appropriate interventions to stem that loss.

Board FFCL 4: Bradford County Manor was not in substantial compliance with 42 C.F.R. § 483.25(i)(1).

Board FFCL 5: Bradford County Manor failed to ensure that Resident 17 had sufficient fluid intake during December 2005 and January 2006.

Board FFCL 6: Bradford County Manor was not in substantial compliance with 42 C.F.R. § 483.25(j).

Board FFCL 7: A per instance civil money penalty of \$2,500 is reasonable for Bradford County Manor's noncompliance with 42 C.F.R. § 483.25(c).

Board FFCL 8: A per instance civil money penalty of \$1,250 is reasonable for Bradford County Manor's noncompliance with 42 C.F.R. § 483.25(i)(1).

Board FFCL 9: A per instance civil money penalty of \$2,500 is reasonable for Bradford County Manor's noncompliance with 42 C.F.R. § 483.25(j).

_____/s/ Leslie A. Sussan

/s/ Constance B. Tobias

/s/

Sheila Ann Hegy Presiding Board Member