Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

In the Case of:	DATE: January 10, 2007
Tri-County Extended Care Center,	
Petitioner,	Civil Remedies CR1388 App. Div. Docket No. A-06-52
- v. -	Decision No. 2060
Centers for Medicare & Medicaid Services.	

FINAL DECISION ON REVIEW OF
ADMINISTRATIVE LAW JUDGE DECISION

Tri-County Extended Care Center (Tri-County) appealed the January 13, 2006 decision of Administrative Law Judge (ALJ) Jose A. Anglada. Tri-County Extended Care Center, DAB CR1388 (2006). The ALJ sustained a determination by the Centers for Medicare & Medicaid Services (CMS) that Tri-County failed to comply substantially with federal requirements governing the participation of long-term care facilities in Medicare and Medicaid. He upheld CMS's imposition of a civil money penalty (CMP) of $400 per day from December 14, 2001 through January 30, 2002.

As explained below, we uphold the ALJ Decision.

Applicable legal provisions

Long-term care facilities participating in the Medicare and Medicaid programs are subject to survey and enforcement procedures set out in 42 C.F.R. Part 488, subpart E, to determine if they are in substantial compliance with applicable program

requirements which appear at 42 C.F.R. Part 483, subpart B. "Substantial compliance" means a level of compliance such that "any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm." 42 C.F.R. § 488.301. "Noncompliance," in turn, is defined as "any deficiency that causes a facility to not be in substantial compliance." 42 C.F.R. § 488.301.

A long-term care facility found not to be in substantial compliance is subject to various enforcement remedies, including CMPs. 42 C.F.R. §§ 488.402(c), 488.408. A per-day CMP may start to accrue as of the date that the facility was first out of compliance, as determined by CMS or the state, and continues until the date the facility achieves substantial compliance. 42 C.F.R. § 488.440(a),(b).

Standard of Review

Our standard of review on a disputed conclusion of law is whether the ALJ decision is erroneous. Our standard of review on a disputed finding of fact is whether the ALJ decision is supported by substantial evidence on the record as a whole. Guidelines for Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's Participation in the Medicare and Medicaid Programs; see also Batavia Nursing and Convalescent Center, DAB No. 1911, at 7 (2004), aff'd, Batavia Nursing & Convalescent Ctr. v. Thompson, No. 04-3687 (6th Cir. Aug. 3, 2005); Hillman Rehabilitation Center, DAB No. 1611, at 6 (1997); aff'd, Hillman Rehabilitation Ctr. v. U.S. Dep't of Health and Human Servs., No. 98-3789(GEB) at 21-38 (D.N.J. May 13, 1999).

Proceedings Below

The ALJ conducted a two-day hearing, and the transcript of that hearing is part of this record. The ALJ admitted CMS Exhibits 1 through 40, Petitioner Exhibits 1 through 8 and 10 through 13, and ALJ Exhibits 1 through 3. The ALJ made 11 numbered and lettered findings of fact and conclusions of law (FFCLs), and, on appeal, Tri-County excepts to all of them.

Analysis

1. Tri-County's general arguments are without merit.

Tri-County makes several general arguments regarding the ALJ Decision. Request for Review (RR) at 4-18.

Tri-County argues that the ALJ misallocated the burden of proof. RR at 4. We disagree. The ALJ advised the parties prior to the hearing that he intended to apply the decision of the Board in Hillman Rehabilitation Center, DAB No. 1611, regarding the allocation of the burden of proof. Order dated Sept. 9, 2002. In Hillman, the Board held that, before the ALJ, a rehabilitation agency must prove substantial compliance by the preponderance of the evidence, once CMS has established a prima facie case that the agency was not in substantial compliance with relevant statutory or regulatory provisions. In Cross Creek Health Care Center, DAB No. 1655 (1998), the Board found that this standard applies in cases involving nursing facilities and in Batavia explained the statutory and regulatory basis for the conclusion. The ALJ Decision notes, however, that under Fairfax Nursing Home v. U.S. Dep't of Health and Human Servs., 300 F.3d 835 (7th Cir. 2002), cert. denied, 537 U.S. 1111 (2003) (affirming Fairfax Nursing Home, DAB No. 1794 (2001)), the "allocation of the burden of proof is material only where the evidence is in equipoise, and the evidence in this case is not in equipoise." ALJ Decision at 20.

Tri-County argues that contrary to what the ALJ held, the burden of proof is on CMS. According to Tri-County, the standard in Hillman conflicts with the Administrative Procedure Act (APA) and is also invalid because it is a substantive rule that was not promulgated pursuant to the notice and comment procedures in the APA. RR at 4-8.

For the reasons discussed later in this analysis when we address each disputed deficiency, we conclude that the evidence in this case is not in equipoise for any of the deficiencies. Thus, as the ALJ indicated, for purposes of this case, it is immaterial where the burden of persuasion lies. In any event, we reject Tri-County's contention that placing the ultimate burden of persuasion on the facility to show substantial compliance violates the APA. As the Board has previously stated, the burden of proof that the Board applies is not a rule under the APA but instead is in the nature of an order setting forth a rationale, based on the statute and regulations, that establishes precedent for ALJ hearings in these cases. See, e.g., Batavia Nursing and Convalescent Center, DAB No. 1904. Furthermore, while Hillman was the first Board decision addressing burden of proof in cases to which the procedures at 42 C.F.R. Part 498 apply, the rationale in Hillman has not been treated as a binding rule but has been reexamined as appropriate to different types of cases.

In a section of its brief entitled "Tri-County prevails when the evidence is in equipoise," Tri-County appears to be arguing that

the burden of proof shifts back to CMS if a facility rebuts an element of CMS's prima facie case. RR at 10-18. This reflects a fundamental misunderstanding of the process used in deciding these cases. As explained in Hillman, once CMS establishes a prima facie case, the provider bears the burden from that point forward. In determining whether CMS has established a prima facie case, the ALJ does not weigh CMS's evidence against the provider's evidence. Rather, as Hillman says, if CMS has come forward with evidence related to disputed findings that is sufficient (together with any undisputed findings and relevant legal authority) to establish a prima facie case that CMS had a legally sufficient basis for its action, then the provider bears the burden of showing that it was in substantial compliance during the time at issue. The provider may do this in a number of ways, including disproving facts on which CMS has relied as a basis for its prima facie case. However, a provider's attack on CMS's evidence does not reshift the burden of proof to CMS, even if the ALJ ultimately determines the provider's evidence is more persuasive.

Tri-County argues that the ALJ applied the wrong standard in determining whether it was in substantial compliance with program requirements. According to Tri-County, the ALJ "has taken the position that a provider's staff must at all times deliver the highest possible standard of medical care and services" and endorsed "a strict liability standard of deficiency." RR at 9. Tri-County maintains that the correct standard is whether the facility takes "reasonable," or "practicable," measures to comply with the participation requirements. Id. Tri-County relies on Crestview Parke Care Center v. Thompson, 373 F.3d 743 (6th Cir. 2004) (Crestview). The court in Crestview found that the general quality of care regulation, 42 C.F.R. § 483.25, which requires a facility to provide "necessary care and services" to enable a resident to attain and maintain his "highest practicable physical, mental, and psychosocial well-being," is not a "strict liability" regulation. 373 F.3d 743 (emphasis added). The court explained that the word "practicable" suggests that a "'reasonableness' standard inheres in the regulation" and that it would be possible for a facility to show "a justifiable reason" for violating section 483.25. Id. Relying on Crestview's discussion of that regulation, Tri-County asserts that a facility may not be cited for a deficiency if it has taken "reasonable measures" to be in compliance. RR at 9.

We find no merit in these assertions in part because they are based on a misreading of Crestview. The court did not find, as Tri-County would have us believe, that a facility must do for the resident only what is "practicable" for it to do under the

circumstances. The court merely found that section 483.25 does not foreclose the possibility that a violation of section 483.25 could be excused for some "justifiable" reason. Furthermore, as we noted in Ridge Terrace, DAB No. 1834 (2002), the word "practicable" in section 483.25 refers to the resident's condition, not to the care and services that the facility must provide:

> [T]he requirement in section 483.25 that a facility provide to each resident "the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being" means that a facility must provide care and services so that a resident attains the highest level of well-being the resident is capable of attaining, not that a facility is excused from providing such care and services if it is not "practicable" to monitor its staff to ensure compliance.

DAB No. 1834, at 8.

As we have said, the quality of care regulations under section 483.25 "hold facilities to meeting their commitments to provide care and services in accordance with the high standards to which they agreed but do not impose strict liability, i.e., they do not punish facilities for unavoidable negative outcomes or untoward events that could not reasonably have been foreseen and forestalled." Tri-County Extended Care Center, DAB No. 1936, at 7 (2004).

In any event, Tri-County points to no examples in the ALJ Decision of the alleged legal error, and we find no instance in which the ALJ applied a "strict liability" standard of compliance or found the facility noncompliant because of a failure to take "impracticable" or "unreasonable" actions. Rather, the ALJ held the facility to the standards enunciated in the relevant participation requirement and its own policies and care plans and found noncompliance by applying the "substantial compliance" standard mandated by the regulations.

Finally, Tri-County argues that a facility has discretion in determining how to meet program requirements (RR at 13) and that a facility must balance program requirements, e.g., standards for care of pressure sores with a resident's right to refuse treatment (RR at 17). Such considerations are not present here; the ALJ determined Tri-County was not in substantial compliance

because it failed to follow its own policies, its own care plans, or doctors' orders.[1] In other words, Tri-County is being held accountable for failing to follow its own standards for meeting program requirements.

Therefore, we find all of Tri-County's general arguments to be without merit.

2. Substantial evidence supports the ALJ's conclusion that Tri-County was not in substantial compliance with 42 C.F.R. § 483.25 because it failed to provide necessary care for a resident with a suprapubic catheter.

Section 483.25 provides that "each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental and psychosocial well-being in accordance with the comprehensive assessment and plan of care."

The resident at issue in this deficiency, R174, had a suprapubic catheter.[2] Based on the surveyor's testimony and the documentary evidence, the ALJ found that the surveyor observed brown purulent drainage around the catheter site that had a foul odor, that Tri-County had not followed its own policy or the resident's care plan by cleaning the site once a shift, and that the condition of the site and the absence of care posed a potential for infection for R174. ALJ Decision at 6-10. The ALJ concluded that Tri-County failed to provide necessary care as required by section 483.25.

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[1] While Tri-County asserted in effect that one resident was refusing treatment, the ALJ found that Tri-County did not document any refusal of treatment. ALJ Decision at 12. While section 483.10(b)(4) provides that a resident has the right to refuse treatment, section 483.20(k)(1)(ii) requires that, when a facility does not provide care because a resident refuses care, the facility must document its decision in its care planning process.

[2] As to this resident, Tri-County's witness explained that, "there was a surgically created opening between his lower abdomen and his bladder in which a Foley catheter, which is a silicone/latex type of tube, is placed into the bladder for urine drainage." Tr. at 388.

On appeal, Tri-County argues that the ALJ "completely ignores the evidence and testimony offered at the hearing and blindly adopted the testimony of CMS' witness which did nothing more than parrot the survey results." RR at 19. We disagree. As discussed below, the ALJ explained the bases for his numbered and unnumbered findings and his evaluation of the persuasiveness of the witnesses' testimony.

First, the ALJ explained that he found the surveyor's testimony more persuasive than that of Tri-County's witness because that witness did not personally observe the condition of the drainage and catheter. ALJ Decision at 9. He noted that the employee who had observed what the surveyor observed was not called to testify. Id.

Second, the ALJ explained that he found the surveyor's testimony more persuasive because Tri-County's witness's testimony was not fully responsive to the surveyor's description of the drainage as foul smelling and was not consistent with the facility's own written catheter care policies. ALJ Decision at 8-9.

Third, as the ALJ explained, Tri-County's witness' testimony was based on a misunderstanding of what constitutes compliance. The witness testified that the facility was in compliance because there was no actual infection present at the superpubic site and therefore "the resident did not have any mental, physical, or psychosocial harm based on anything that the surveyor alleged in the Statement of Deficiencies." RR at 19, citing Tr. at 388. The ALJ wrote, in addressing similar arguments below, that "[i]n order for Petitioner to be found non compliant with respect to [this citation], it is not necessary that CMS establish that R174 showed evidence of an infectious process at the suprapubic site." ALJ Decision at 7. This is correct. The issue is whether the condition of R174's superpubic site and the care provided "pose[d] no greater risk to resident health or safety than the potential for causing minimal harm." 42 C.F.R. § 488.301; Woodland Village Nursing Center, DAB No. 2053, at 6 (2006); see Western Care Management Corp., DAB No. 1921 (2004). Tri-County's witness did not address this standard. In contrast, the surveyor testified that the residents with superpubic catheters are at heightened risk for urinary tract and site infections (Tr. at 28) and that the conditions and lack of care she observed posed a potential for urinary tract and skin infections for R174 (Id. at 47-49).

Fourth, the ALJ explained why he found that Tri-County's documentary evidence did not support its witness's testimony that the superpubic site was cleaned each shift, but, rather, showed

that R174 was given only sporadic catheter care. ALJ Decision at 8. On appeal, Tri-County offers no arguments as to why the ALJ's findings about the documentary evidence are not supported by substantial evidence.

Finally, Tri-County appears to argue that, under Federal Rule of Evidence (FRE) 407, the ALJ erred in considering the fact that R174's doctor, after being informed of the drainage observed by the surveyor, ordered the site cleaned three times a day and monitored. RR at 14. FRE 407 makes inadmissable certain evidence related to actions taken after an injury or harm. Tri-County's argument is without merit for a number of reasons. First, Tri-County does not cite any objection it made to the admission of this evidence (see Tr. at 47-48 when the surveyor discussed the doctor's order), and, as CMS points out, the doctor's order was included in Tri-County's exhibits (CMS Response at 22, citing P. Ex. 5, at 74). Second, evidence may be received in Part 498 hearings even if inadmissable under the Federal Rules of Evidence. 42 C.F.R. § 498.61. Third, as explained previously by the Board, FRE 407 arises in the context of tort cases and promotes a public policy of not discouraging parties from voluntarily adopting subsequent safety precautions. Part 498 cases differ materially because they arise "in the context of statutory and regulatory obligations of skilled nursing facilities to maintain substantial compliance with Medicare participation requirements." Omni Manor Nursing Home, DAB No. 1920, at 44 (2004), aff'd, Omni Manor Nursing Home v. Thompson, No. 04-3835 (6th Cir. Oct. 11, 2005) Thus, admitting evidence of corrective actions would not have the unintended consequence of discouraging facilities from taking such actions. Fairfax Nursing Home, DAB No. 1794, at 9; see also 2 Weinstein's Federal Evidence 407.05[3], p. 407-27 (2nd Ed. 2001) (recognizing an exception to FRE 407 where remedial action is mandated by superior governmental authority.) Fourth, even if the evidence about the doctor's subsequent order is disregarded, we find that there is still substantial evidence to support the ALJ's finding. See ALJ Decision at 7-9.

> *4. Substantial evidence supports the ALJ's conclusion that Tri-County was not in substantial compliance with 42 C.F.R. § 483.25(c) because it failed to provide necessary treatment and services for pressure sores.*

Section 485.25(c)(2) provides:

> Based on the comprehensive assessment of a resident, the facility must ensure that . . .[a] resident having pressure sores receives necessary treatment and services

to promote healing, prevent infection and prevent new sores from developing.

(a) Resident 101

The ALJ found that R101 had multiple medical problems and required extensive assistance for bed mobility; that several pressure sore assessments evaluated R101 as a high risk for the development of pressure sores; that, at the time of the survey, R101 had a sore on the bony protuberance of his right outer ankle; and that, over the course of three days, the surveyor repeatedly observed R101 to be without the pressure relieving therapies for the ankle that were either ordered by the doctor or included in his care plan, such as heel protectors, gel pads, and proper positioning. The ALJ concluded that Tri-County was not in compliance with 42 C.F.R. § 483.25(c). ALJ Decision at 15-17.

On appeal, Tri-County cites the testimony of one of its witnesses who stated that "we did provide care and we did provide treatment." RR at 26, citing Tr. at 312. This testimony is too general and unspecific to address the surveyor's specific observations. Tri-County's remaining arguments are completely nonresponsive to the ALJ findings. They involve the chronic nature of the sore on R101's right ankle, his debilitated condition, and the alleged facts that the sore reappeared in the beginning of November after R101 had been out with his daughter, that his daughter was very involved in his care, that he had no other skin breakdowns, and that the sore eventually healed. RR at 23-26. Tri-County fails to explain how any of these points address the basis of the ALJ's deficiency finding, i.e., that, over the course of three days, the surveyors repeatedly observed R101 without heel protectors or the gel pad or proper positioning.

(b) Resident 107

The ALJ found that R107 had multiple medical problems; that assessments determined he was at high risk for pressure sores; that he was bedfast and required extensive assistance from staff in all aspects of care, including mobility; that he was to be repositioned every two hours or whenever necessary; that he returned from hospitalization on December 8, 2001 with a pressure sore on his left buttock for which a doctor ordered a hydrocolloid wafer to be applied every three to five days; that on two days the surveyor observed R107 on his back for over a two-hour period; that on two days the surveyor observed the sore to be without the hydrocolloid wafer (Tegasorb), the second time after she has pointed out it was missing the day before.

On appeal, Tri-County argues that this wound healed in January; that this resident had medical conditions which interfered with skin healing; that he was combative and resistant to care; that if he was not receiving appropriate care he would have had problems in addition to skin breakdown or more skin breakdown; that the resident could have been repositioned without the surveyor knowing it; that a facility witness testified the records showed the resident was repositioned every two hours; that the resident was in isolation so observation by the surveyor would have been difficult; that the resident received dialysis treatment three times a week and was required to lie on his back with no pressure relieving devices; and that the dietary department implemented nutritional interventions. RR at 29-33.

As the ALJ pointed out, many of the factual assertions on which Tri-County relies are not material to the bases for the deficiency finding, i.e., the failure to reposition R107 and the failure to maintain the hydrocolloid wafer. Moreover, Tri-County's arguments do not establish that the ALJ findings were not based on substantial evidence in the record as a whole. The ALJ discussed why he found the surveyor's observations about the failure to reposition credible and pointed out that Tri-County's witness, who had no personal knowledge of these incidents, failed to cite any specific portion of the treatment record documenting repositioning (as counsel also fails to do on appeal). ALJ Decision at 12. Additionally, Tri-County fails to address the ALJ's point that, even if R107 was somehow repositioning himself on his back between the times of surveyor observation, the repeated absences of the hydrocolloid wafer provided a sufficient basis for the deficiency finding as to this resident.

Finally, we note that Tri-County's discussion of inferences displays a misunderstanding of the review process. Tri-County complains that CMS's prima facie case depends on "inference stacking." RR at 14-15. As an example, Tri-County cites the facts related to R107. Tri-County does not dispute that a doctor ordered a Tegasorb hydrocolloid wafer dressing and a surveyor observed the wound, on two different days, without any dressing. However, Tri-County argues, "to make a singular observation that a Tegasorb dressing was not on a resident at a particular moment in time, to be a violation, requires one to infer either that . . . ." and Tri-County lists a number of inferences one could make to account for the absence of the dressing. However, no inferences are needed here. Rather, when a doctor orders a dressing and the surveyor observes that there is no dressing, CMS has established a prima facie case. CMS does not have to prove, through inference or otherwise, why the dressing was missing. See Alden Town Manor Rehabilitation and HHC, DAB No. 2054 (2006).

(c) Resident 121

The ALJ found that R121 had multiple medical problems; that an assessment determined that she was at high risk for pressure sores; that she had intact heels on admission in October but that on November 1 she had a stage I sore on her right heel, which, by December 10, had progressed to a stage III sore; that the care plan called for bilateral heel protectors while in bed and elevation of R121's heels off the bed as much as possible; that on December 10 the doctor ordered the right heel covered with a dry dressing; that on December 11 at 8:02 a.m. a surveyor observed R121 with her right heel protector turned sideways and her right heel resting on the mattress and at 10:50 a.m. the surveyor observed R121 sitting in a wheelchair in the lounge with no sock or slipper on her right foot and her right heel, with the dressing, resting on the carpet; that on December 12 at 8:23 a.m. the surveyor observed R121 lying in bed with no heel protectors and both heels resting on the mattress and at 10:16 the surveyor observed R121 without the dressing on her right foot and the heel resting directly on the floor and that two treatment nurses were unaware how long it had been off. ALJ Decision at 13-15.

On appeal, Tri-County argues that its witness had extensive nursing experience; that R121 was noncompliant with care; that R121 was able to “pick up her legs and move them off the bed” (RR at 26, citing Tr. at 314); that her ability to move about the bed could affect things like heel devices or bolsters; that, when residents can move themselves, it is not unusual to observe such appliances out of place and, when the condition is observed, it is immediately corrected; that one witness had first-hand knowledge of R121's removing dressings from her heel; that R121 was on a Select low air loss mattress, which is a “totally pressure relieving device” (RR at 26, citing Tr. at 315) and made other pressure relieving strategies such as heel protectors unnecessary (RR at 26, citing Tr at 315); that Tri-County retained Alpha Wound Care to provided specialized services for residents with skin care issues, including R121; that R121's sore had necrotic tissue that required removal on December 10; that if R121 had not been receiving appropriate skin care she would have developed other pressure sores but did not; and that the sore at issue took over four months to heal because of persistent non-compliance by R121.

As the ALJ pointed out in his decision, many of the factual assertions on which Tri-County relies are not material to the basis for the deficiency finding, i.e., the failure to maintain heel protectors, elevation, and a dressing. In fact, Tri-County offers no evidence to dispute the surveyor’s observation that

R121 was without heel protectors, heel elevation and dressing on December 12. Tri-County relies instead on general allegations that R121 was "non-compliant" with her care. RR at 26, citing Tr. at 313. However, the ALJ could reasonably refuse to infer that R121, who could not get out of bed without assistance, somehow managed to dispose of all of these devices before the surveyor walked into the room.[3] Further, even if there was more specific evidence about R121's alleged resistance to these interventions, when a facility cites such resistance as a basis for not following a care plan or doctor's orders, it should be able to document its efforts to address the resident's interference with its implementation of the care plan. Finally, the alleged fact that R121 was on a pressure-relieving mattress did not, by itself, excuse Tri-County from providing these interventions.[4] Rather, it is reasonable to infer that, if the heel protectors and elevation were not therapeutic, the care plan would have been amended to eliminate them. See Crestview Parke Care Center v. Thompson, 373 F.3d 743, at 753 (6th Cir. 2004) (rejecting the argument that a pressure relieving mattress authorized a facility to disregard a doctor's order for heel protectors and stating that "the proper course of action is to rework the patient's comprehensive care plan in a venue other than HHS's administrative appeals process.")

5. Substantial evidence supports the ALJ's conclusion that Tri-County was not in substantial compliance with 42 C.F.R. § 483.35(d)(1) and (2) because it failed to provide food that was palatable and at the proper temperature.

Section 483.35(d)(1) and (2) provide:

> (d) Food. Each resident receives and the facility provides–
> (1)Food prepared by methods that conserve nutritive value, flavor and appearance;

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[3] Tri-County states that "the witness has personal first hand knowledge, through observation, that R#121 has removed dressing from her heel." RR at 29, citing Tr. at 343-344. This is a misrepresentation of the testimony. The witness said she had not seen R121 take a dressing off. Tr. at 344, line 10.

[4] The Tri-County nurse testified that the ordered dressing should have been present even if the resident was on a low air loss mattress. Tr. at 326.

> (2) Food that is palatable, attractive and at the proper temperature.

The ALJ adopted the survey findings that on December 10, 2001 the breakfast food was not served according to the facility policy because it was held on a steam table at 120 degrees Fahrenheit, while the facility policy called for the food to be delivered at 140 degrees or greater. ALJ Decision at 17-18; see also Tr. at 234; CMS Ex. 29. The ALJ also adopted the survey findings that, on December 12, 2001, the surveyors found that food being delivered to rooms was being transported in an unheated cart and was served at temperatures that did not meet Tri-County's standards. Id. The surveyor and administrative dietary staff determined that, for the test tray, the pureed oatmeal was 115 degrees, the scrambled eggs were 100 to 102 degrees, the sausage biscuit/gravy was 110 degrees, the sausage patty was 86 degrees, and the cooked cereal tasted warm but not hot. Id. In addition, the milk was served at 50 degrees when facility policy called for cold foods to be served less than or equal to 41 degrees. Id.[5]

On appeal, Tri-County does not contest the ALJ's findings as to the temperature of the steam table or the palatability or temperature of the food as measured by the surveyor and dietary staff. RR at 33-35. Instead, Tri-County argues that it served over 1,000 meals per day; that the surveyor observed one tray each day; that if food was too cold when served, the facility microwaved it to raise the temperature, that most residents interviewed had no concerns and many told the surveyors the food was palatable; that special measures are taken to address food preferences; that a representative of the dietary department attended the resident council's monthly meetings; that food served in rooms is held in a heated hot cart; that most of the residents interviewed by the surveyors did not complain about

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[5] While ALJ made no specific finding as whether the unpalatability of the food posed a potential for more than minimal harm, such a finding is implicit in his determination that Tri-County was not in substantial compliance with section 483.35(d)(1) and(2). In any event, Tri-County did not challenge the ALJ Decision on this basis, and even stated that "[o]bviously, the concern of the regulation is that residents consume an appropriate amount of food to maintain their physical well-being." RR at 33-34. Additionally, the record contains testimony from a surveyor about the potential for more than minimal harm posed by unpalatable food. Tr. at 243.

temperature or palatability; and that the local county inspects Tri-County for the palatability of its food. RR at 34-35.

Most of these allegations are not responsive to the bases of the deficiency finding, i.e., that served food did not meet temperatures called for by Tri-County's policy and was unpalatable. The allegations that are responsive were addressed by the ALJ. For example, the ALJ noted that failure to serve hot food is not resolved by heating meals in a microwave when residents complain because meals should be served at correct temperatures to all residents and, as the surveyor testified, remedial microwaving reduces palatability. ALJ Decision at 18; see also Tr. at 247. Further, while Tri-County complains that only two trays were observed on two different days, it does not identify any basis for the ALJ to have concluded that the tested food was unrepresentative of the condition of the remainder of the food. Finally, Tri-County does not contest the surveyor's testimony that temperature standards are related to palatability (Tr. at 242) or offer evidence to rebut the surveyor's testimony that the test tray food tasted unpalatable (Id. at 243), even though Tri-County's food services manager also tasted the food and could have testified as to its palatability (Id. at 242).

6. Substantial evidence supports the ALJ's conclusion the amount of the CMP is reasonable.

The ALJ upheld CMS's imposition of a $400 per day CMP from December 14, 2001 through January 31, 2002. Tri-County challenges the per day amount of the CMP but raises no arguments as to the duration of the CMP.

The regulations specify that a per-day CMP that is imposed against a facility will fall into one of two broad ranges of penalties. 42 C.F.R. §§ 488.408, 488.438. The lower range, from $50 per day to $3,000 per day, applies to deficiencies that do not constitute immediate jeopardy, but either cause actual harm to residents or cause no actual harm, but have the potential for causing more than minimal harm. 42 C.F.R. § 488.438(a)(2). Since the ALJ upheld CMS's finding of isolated deficiencies, some of which constituted actual harm that was not immediate jeopardy, the lower range applies here. ALJ Decision at 1.

The regulation provides factors for CMS to take into account in determining the amount of CMP to impose. Those factors are:

> (1) The facility's history of noncompliance, including repeated deficiencies.

> (2) The facility's financial condition.
>
> (3) The factors specified in § 488.404.
>
> (4) *The facility's degree of culpability*. Culpability for purposes of this paragraph includes, but is not limited to, neglect, indifference, or disregard for resident care, comfort or safety. The absence of culpability is not a mitigating circumstance in reducing the amount of the penalty.

42 C.F.R. § 488.438(f) (emphasis in original). The provision incorporated by reference, 42 C.F.R. § 488.404, sets out general factors to be considered in selecting a remedy. This regulation explains that the initial question in selecting any remedy is the seriousness of the deficiencies, as determined by considering at least how severe the harm involved and how widespread each deficiency was. 42 C.F.R. § 488.404(a) and (b). CMS may then consider other factors in setting the specific remedy, which –

> may include but are not limited to the following:
>
> > (1) The relationship of one deficiency to other deficiencies resulting in noncompliance.
> >
> > (2) The facility's prior history of noncompliance in general and specifically with reference to the cited deficiencies.

42 C.F.R. § 488.404(c).

In order to put Tri-County's specific assertions in the proper context, we first note that CMS is not required, as part of its case in chief, to present evidence on any or all of these factors or to explain its reasoning process in determining the amount to impose. Clermont Nursing & Convalescent Ctr., DAB No. 1923 (2004), aff'd sub nom. Clermont Nursing & Convalescent Ctr. v. Leavitt, 142 Fed. App. 900 (6th Cir. 2005). If the facility offers evidence on any of the factors to suggest that the amount is unreasonable, the ALJ (and, on appeal, the Board) weighs that evidence along with any other evidence present in the record relevant to those factors in determining whether the CMP is reasonable. Emerald Oaks, DAB No. 1800 (2001).

Tri-County argues that the ALJ "employed a process that abrogates his responsibilities with respect to the CMS calculation." RR at 35. Tri-County makes three specific points in support of this argument. First, as to the factor of a facility's prior history

of noncompliance, Tri-County argues that "there can be no negative inference with regard to this factor" because "there is simply no evidence of any past noncompliance." RR at 36. In response, CMS points to CMS Exhibit 12, which shows that Tri-County was cited for multiple deficiencies on September 22, 2000 (approximately a year prior to the survey at issue) including two areas that were cited in the survey at issue here. CMS Br. at 37. Therefore, Tri-County is incorrect that the record contains no evidence of past noncompliance.

Second, as to the factor of a facility's financial condition, Tri-County argues the ALJ "did not receive any information about what the facility's financial condition even was . . . ." RR at 36. Again, this is incorrect. CMS points to CMS Exhibit 11, Tri-County's balance sheet, which showed a net income in 2001 of $839,805 and a general fund balance of $1,130,168. Therefore, the record does contain evidence of financial condition.

Third, as to the factors of seriousness and culpability, Tri-County argues that "the ALJ utterly failed to discuss the seriousness of the alleged deficiencies and fails to discuss the facility's culpability at all." RR at 37, citing ALJ Decision at 20. We disagree. The ALJ's discussion of the deficiencies and his discussion under FFCL B at page 19 (finding that "A basis exists to impose remedies against Tri-County for deficiencies that are less than immediate jeopardy level of noncompliance") both address the seriousness of the deficiencies and Tri-County's responsibility for those deficiencies.

Therefore, we conclude Tri-County has failed to show the ALJ erred in upholding CMS's imposition of a $400 per day CMP, which is at the low end of the $50 to $3,000 per day CMP range for non-immediate jeopardy deficiencies.

7. The ALJ did not deprive Tri-County of due process.

Tri-County argues that "the ALJ's conduct and bias deprived Tri-County of due process." RR at 38. Tri-County asserts that "during the hearing a number of rulings were made which prejudiced the presentation of a case by Tri-County." RR at 38. Tri-County then cites a number of rulings in the transcript that allegedly show bias. Additionally, Tri-County alleges that, in 27 decisions, this ALJ never "has found against CMS." Id.

The Board has discussed, in several prior cases, the law governing challenges to ALJ decisions based on claims of bias and prejudice as follows:

> In Edward J. Petrus, Jr., M.D., and The Eye Center of Austin, DAB No. 1264 at 23-26 (1991)[aff'd sub nom., Petrus v. I.G., 966 F.2d 675 (5th Cir. 1992), cert. denied, 506 U.S. 1048 (1993)], the Board described the standard for disqualifying a judge on a charge of bias. The Supreme Court, the Board noted, has held that "[t]he alleged bias and prejudice, to be disqualifying, must stem from an extrajudicial source and result in an opinion on the merits on some other basis than what the judge learned from his participation in the case . . . ." United States v. Grinnell Corp., 384 U.S. 563, 583 (1966); see also Tynan v. United States, 376 F.2d 761 (D.C. Cir. 1967), cert. denied, 389 U.S. 845 (1967); Duffield v. Charleston Area Medical Center, 503 F.2d 512, 517 (4th Cir. 1974).

St. Anthony Hospital, DAB No. 1728, at 84 (2000), aff'd, 309 F.3d 680 (10th Cir. 2002); see also Madison Health Care, Inc., DAB No. 2049 (2006); Britthaven of Goldsboro, DAB No. 1960 (2005); Tri-County Extended Care Center, DAB No. 1936. Nor is it evidence of bias that the ALJ's view of the record was not in accordance with Tri-County's views. See Meadow Wood, DAB No. 1841, at 10 (2002), aff'd, Meadow Wood Nursing Home v. HHS, 364 F. 3d 786 (6th Cir. 2004)("[W]eighing of testimony and evidence in the record is the essential task of an ALJ and can hardly be viewed as a demonstration of bias toward the party that does not prevail on the merits, however disappointed.").

We have reviewed the rulings cited by Tri-County and concluded that they are legally sound and they do not constitute evidence of bias or deprivation of due process.

- Tri-County complains that the ALJ refused to permit testimony to the effect that R101's daughter routinely transferred him and injured the skin on his ankle in October. RR at 38, citing Tr. at 286-287. However, CMS did not cite Tri-County for injuring R101's ankle in October. As discussed above, CMS cited Tri-County for failing to provide heel protectors or the gel pad or proper positioning for the ankle in mid-December. Thus, the daughter's actions in October are not relevant or material, and it was not error to exclude such testimony.

- Tri-County complains the ALJ erroneously sustained objections when counsel sought to establish the qualifications of its witness. RR at 38, citing Tr. at

317-318. This mischaracterizes these rulings, which were based on lack of foundation at the point the objections were made. Subsequently, the witness was allowed to give her opinion on standards of care for pressure sores. Tr. at 318-322.

- Tri-County complains that the ALJ sustained an objection "with the identical question immediately asked again without objection or ruling." RR at 39, citing Tr. at 341. However, the transcript shows that the questions were not identical.

- Tri-County complains the ALJ interfered with its counsel's examination and sustained an objection to a question that was not asked. RR at 39, citing Tr. at 351-355 and Tr. at 354, line 19. While pages 353 to 355 may evidence some brief confusion as to the nature of the objection and the scope of the ruling, such confusion is not unusual in the context of multiple people talking and was not harmful here. The ALJ instructed Tri-County's counsel to resume questioning his witness and overruled CMS counsel's subsequent objection. Tr. at 355, lines 4-14.

- Tri-County complains because the ALJ sustained CMS counsel's objection that a question called for speculation. RR at 39, citing Tr. at 364. However, Tri-County rephrased this question in the following lines and there was no objection. Tr. at 364, beginning at line 23.

- Tri-County complains that the ALJ "took over" the cross-examination of one of its witnesses. RR at 39, citing Tr. at 381-884. This mischaracterizes the actions of the ALJ. CMS counsel had completed his questioning of this witness. The ALJ then asked some questions related to the witness' personal knowledge of the facts about which she testified, i.e., turning the resident. This was perfectly appropriate.

Therefore, none of these rulings show that the ALJ denied Tri-County of due process.

Finally, the fact that this ALJ has previously ruled against facilities does not establish that Tri-County was deprived of due process in this case or that the other facilities were deprived of due process. As explained above, the ALJ has committed no error, and his findings are supported by substantial evidence in

the record as a whole; therefore, Tri-County has received the process that is due under Part 498. Further, as shown by the cases cited by Tri-County, the ALJ has not always ruled against facilities. See e.g., Homestead of Denison, DAB CR830 (2001).

Conclusion

For the reasons discussed above, we affirm and adopt the ALJ Decision in its entirety, including the findings of fact and conclusions of law.

/s/
Judith A. Ballard

/s/
Leslie A. Sussan

/s/
Donald F. Garrett
Presiding Board Member