Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

In the Case of:	DATE: September 30, 2008
Edgemont Healthcare,	
Petitioner,	Civil Remedies CR1741 App. Div. Docket No. A-08-90
	Decision No. 2202
- v. -	
Centers for Medicare & Medicaid Services.	

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Edgemont Healthcare (Edgemont, Petitioner) requested review of the decision of Administrative Law Judge (ALJ) Steven T. Kessel in Edgemont Healthcare, DAB CR1741 (2008) (ALJ Decision). The ALJ Decision upheld the determination by the Centers for Medicare & Medicaid Services (CMS) to impose on Edgemont a civil money penalty (CMP) of $4,050 per day for the period November 14, 2006 through January 15, 2007 and a CMP of $250 per day for the period January 16, 2007 through February 1, 2007. CMS imposed the CMPs based on the findings of the State survey agency that Edgemont was not in substantial compliance with several Medicare and Medicaid participation requirements, that Edgemont's noncompliance posed immediate jeopardy until January 16, 2007 and that Edgemont's noncompliance continued at a level of less than immediate jeopardy until February 1, 2007. The ALJ addressed only the findings that Edgemont failed to comply with the pressure sore prevention requirements of 42 C.F.R. § 483.25 and with the requirement at 42 C.F.R. § 483.20(k)(3)(i) that the services provided by the facility meet "professional standards of quality." The ALJ concluded that: 1) Edgemont failed to substantially comply with these requirements; 2) CMS's determination that this noncompliance posed immediate jeopardy

was not clearly erroneous; 3) the amounts of the CMPs for the periods of immediate jeopardy and less than immediate jeopardy were reasonable in light of this noncompliance; and 4) Edgemont neither abated the immediate jeopardy nor achieved full compliance earlier than the dates found by CMS. Edgemont takes exception to all of the ALJ's findings of fact and conclusions of law (FFCLs) except the FFCL that the $250 per day CMP for the period of less than immediate jeopardy was reasonable.

For the reasons explained below, we affirm the ALJ's conclusions that Edgemont failed to substantially comply with the pressure sore requirements of section 483.25 and that CMS's determination that this noncompliance was at the immediate jeopardy level was not clearly erroneous. Those conclusions are supported by substantial evidence in the record and provide adequate authority for imposing the CMPs. The ALJ's conclusions on the issues of the amounts and duration of the CMPs are also legally correct and supported by substantial evidence in the record. We do not need to reach the issue of whether the ALJ's findings are legally sufficient to support the ALJ's conclusion that Edgemont failed to meet professional standards of quality since neither the reasonableness of the amounts of the CMPs nor their duration depends on a conclusion that Edgemont also failed to meet professional standards of quality.

Legal Background

Long-term care facilities participating in the Medicare and Medicaid programs are subject to the 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" is defined as "a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health and safety than the potential for causing minimal harm." 42 C.F.R. § 488.301. "Noncompliance" means "any deficiency that causes a facility to not be in substantial compliance." Id. CMS may impose a CMP for the days on which the facility is not in substantial compliance. 42 C.F.R. §§ 488.404, 488.406 and 488.408. Where the noncompliance poses immediate jeopardy, CMS may impose a penalty in the range of $3,050 to $10,000 per day. 42 C.F.R. § 488.438(a)(1)(i). "Immediate jeopardy" is defined as a situation in which a provider's noncompliance "has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301. The regulations set out a number of factors that CMS considers in determining the amount of a CMP. 42 C.F.R. §§ 488.438(f), 488.404. These factors include

the facility's history of noncompliance, its financial condition, and the seriousness of the noncompliance. Id. A CMP accrues until either the facility achieves substantial compliance or its provider agreement is terminated. 42 C.F.R. §§ 488.454(a).

The first participation requirement at issue here, 42 C.F.R. § 483.25(c)(1), is one of several "quality of care" requirements in section 483.25. The lead-in language to section 483.25 states that "[e]ach 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." Section 483.25(c)(1) 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 . . . .

The second participation requirement addressed by the ALJ, 42 C.F.R. § 483.20(k)(3)(i), provides:

> (3) The services provided or arranged by the facility must–
> (i) Meet professional standards of quality . . . .

Factual Background[1]

Edgemont was found noncompliant with both section 483.25(c)(1) and section 483.20(k)(3)(i) based on its care of two residents, Resident 14 and Resident 5. Resident 14, a long-time resident of Edgemont, was assessed in July and October 2006 as at high risk for the development of pressure sores. P. Ex. 1, at 225. In October 2006, she suffered a fall, resulting in severe fractures in her leg. She was treated at a hospital[2] and discharged to Edgemont on November 3, 2006 with an immobilizer positioned on her right leg just above her knee and down to her ankle. ALJ Decision at 5; CMS Ex. 9, at 10. An immobilizer is a device that holds a fractured extremity in position while healing takes place

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[1] This background information is drawn from the ALJ Decision and the record and is undisputed.

[2] The fractures occurred while the resident was in the psychiatric unit of a hospital to which she had been transferred from Edgemont on October 26, 2006. See, e.g., P. Ex. 40, at 3.

and is held in place by a set of velcro straps that can be loosened or opened. ALJ Decision at 5. The transfer document from the hospital included as an attachment an undated order signed on or about November 3 by Dr. Moran, an orthopedic physician, stating "Knee immobilizer to . . . [right] knee at all times." ALJ Decision at 5-6, citing P. Ex. 32, at 5, and CMS Ex. 28, at 110.[3] The care plan put in place by Edgemont on November 3 identified "Skin Breakdown" as a problem and stated "Check under edges of immobilizer brace [every] shift for Breakdown."[4] CMS Ex. 28, at 36; P. Ex. 40, at 4-6. On November 4, Resident 14's treating physician at Edgemont, Dr. McKemie, ordered a "weekly skin assessment." CMS Ex. 28, at 61. From November 3 until November 14, 2006 (except on one occasion), facility staff limited its skin checks of the resident's leg to looking at the skin that remained exposed and checking around the edges of the immobilizer. ALJ Decision at 6. The one exception occurred on November 8 when the immobilizer was removed for purposes of performing an x-ray of the resident's leg. At that time, one of Edgemont's nurses checked the skin that had been covered by the immobilizer and observed no skin breakdown. Id.; P. Ex. 41, at 2-3 (Declaration of Pam Brown). Subsequently, on November 14, a second orthopedic physician, Dr. Cheng, removed the immobilizer and discovered a Stage IV pressure sore on Resident 14's Achilles tendon and above her right ankle. ALJ Decision at 6.

Resident 5 had multiple pressure sores at the time of his admission to Edgemont in September 2006 and was assessed by Edgemont's staff to be at high risk for pressure sores secondary to diabetes. ALJ Decision at 10, citing P. Ex. 36, at 1 and CMS Ex. 21, at 10; CMS Ex. 9, at 14; CMS Ex. 21, at 31. His care plan included the following interventions to address this risk:

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[3] We identify this order later as Dr. Moran's November 3, 2006 order.

[4] The ALJ Decision states that Edgemont's staff was instructed "to monitor the resident's skin condition during every nursing shift." ALJ Decision at 5, citing CMS Ex. 28, at 36. The citation is to a page in Resident 14's care plan containing the entry quoted in the text above. Thus, the ALJ did not adopt the finding in the Statement of Deficiencies, which Edgemont disputed below, that "the resident's current plan of care, initiated on 11/3/06" required the facility "to check under the immobilizer brace each shift for skin breakdown." CMS Ex. 9, at 9 (emphasis added). According to Edgemont's nurse Marilyn Bertram, this instruction was added to Resident 14's plan of care on December 13, 2006. P. Ex. 40, at 4-5.

observing the resident's skin for redness, skin assessment per facility protocol, reporting open areas to the physician promptly, and providing treatment per physician order. CMS Ex. 21, 15 31. Resident 5 had a diagnosis of sleep apnea, for which the prescribed treatment included wearing a Continuous Positive Airway Pressure (C-PAP) mask while sleeping. ALJ Decision at 10. The supplier's educational material stated that users could develop redness or sore spots on their face, nose or forehead from the C-PAP mask or straps. Id., citing CMS Ex. 9, at 16. The mask is affixed to the user's head and face by adjustable straps. ALJ Decision at 10. On January 8, 2007, a surveyor observed an area of redness and a scab on the bridge of Resident 5's nose. Id., citing CMS Ex. 9, at 14. A registered nurse on Edgemont's staff told the surveyor on January 11 that she had observed a sore on the bridge of the resident's nose while performing a skin assessment on January 9 and that the sore had been there for several days before she performed the assessment, but that she did not document the sore or report it to the resident's treating physician or to Edgemont's wound nurse. ALJ Decision at 10, citing CMS Ex. 9, at 15; CMS Ex. 29, at 11. During a skin assessment on January 11, Edgemont's skin nurse documented a pressure sore in the same location. CMS Ex. 9, at 15-16; CMS Ex. 21, at 55.

The ALJ Decision

The ALJ made the following FFCLs, of which only FFCL 4 is undisputed.

1. Petitioner failed to comply with Medicare participation requirements.
   a. Petitioner failed to comply substantially with the requirement in 42 C.F.R. § 483.25(c) that it protect its residents against the development of pressure sores.
      i. Petitioner failed to protect Resident # 14 against the development of pressure sores.
      ii. Petitioner failed to protect Resident # 5 against the development of pressure sores.
   b. Petitioner failed to comply substantially with the requirement of 42 C.F.R. § 483.25(k)(3)(i) that it provide care to its residents that met professional standards of quality.
2. Petitioner did not prove to be clearly erroneous CMS's determination that Petitioner's failure to comply with the requirements of 42 C.F.R. §§ 483.25(c) and 483.20(k)(3)(i) was so egregious as to comprise immediate jeopardy.
3. Civil money penalties of $4,050 per day for each day of the period of immediate jeopardy are reasonable.

4. Civil money penalties of $250 for each day of the period beginning January 16 and ending February 1, 2007 are reasonable.

ALJ Decision at 3, 5, 10, 12, 14, 15, and 16. As explained later, we do not reach FFCL 1.b. and reach FFCL 2 only to the extent that it relates to 42 C.F.R. § 483.25(c).

Discussion[5]

The ALJ applied the proper standard in determining whether Edgemont substantially complied with section 483.25(c)(1).

Edgemont argues that the ALJ "made significant errors of law concerning the standard to be applied to the Petitioner in this appeal." Request for Review (RR) at 15. In particular, Edgemont takes exception to the ALJ's statement (at page 4 of the ALJ Decision) that "a facility must do its utmost to assure that none of its residents develops a sore." RR at 15-16. Quoting a dictionary definition of "utmost," Edgemont argues that "[t]his is a much greater duty than that imposed upon participating facilities by [the] regulations," which "require the facility to take all reasonable and necessary measures in order to ensure that pressure ulcers do not develop." RR at 16, citing, inter alia, Koester Pavilion, DAB No. 1750 (2000).

We conclude that the ALJ did not mischaracterize the applicable standard in the statement Edgemont quotes. In Koester Pavilion, the Board concluded that, in meeting the requirement in section 483.25(c)(1), "a facility must ensure no resident develops pressure sores unless clinically unavoidable in order for the facility to meet the overall quality of care requirement to provide what is necessary for each resident to 'attain or maintain the highest practicable . . . well-being.'" Koester Pavilion at 31-32 (emphasis in original), citing section 483.25. Under this regulatory standard, "a facility should go beyond merely what seems reasonable to, instead, always furnish what is necessary to prevent new sores unless clinically

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[5] We have fully considered all of Edgemont's arguments on appeal, regardless of whether we have specifically addressed particular assertions or documents. We do not address Edgemont's arguments to the extent that they concern findings made by the surveyors on which the ALJ did not rely. Similarly, we do not address Edgemont's arguments that certain statements elicited by the surveyors from Edgemont staff are not reliable where the ALJ did not rely on those statements.

unavoidable . . ." Id. at 32. Stating that a facility must do its "utmost" is consistent with stating that it must "go beyond what merely seems reasonable" and instead "always" do "what is necessary." Edgemont, on the other hand, conflates the regulatory standard as described in Koester with a less onerous standard. Doing what is "reasonable and necessary" arguably implies that all that is necessary is what is reasonable, while Koester requires that a facility "go beyond" what is reasonable.[6] Contrary to what Edgemont suggests, this does not make the regulation "a strict liability regulation" which requires facilities "to acquire superhuman or clairvoyant powers in dealing with" pressure sores, nor is Edgemont being held to such a standard. RR at 16. As the Board has 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" articulated in the regulations but "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), aff'd, Tri-County Extended Care Ctr. v. Leavitt, No. 04-4199 (6th Cir. Dec. 14, 2005).

Edgemont also challenges the following statement in the ALJ Decision:

> Inevitability may be a defense in the circumstance where a facility takes all reasonable measures to protect a resident and the resident develops a sore in spite of those measures. But, it is *never* a defense where a facility has failed to discharge its regulatory obligations.

ALJ Decision at 4 (italics in original). Edgemont asserts that "according to the regulation, a facility unequivocally has a defense if a pressure ulcer was clinically unavoidable. There is no question of whether it may have such a defense." RR at 17 (emphasis in original).

We find no error in the ALJ's reading of the regulation.

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[6] We note that, like Edgemont, the ALJ elsewhere articulates a less onerous standard than that set by section 483.25(c)(1). See, e.g., ALJ Decision at 4 (referring to the duty to take "all reasonable measures" or "all steps that were reasonable and necessary" to protect its residents from developing pressure sores). We nevertheless conclude that the ALJ applied the appropriate standard.

Section 483.25(c)(1) requires a facility "to ensure" that 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[.]" (Emphasis added.) The Board has held that "the term 'clinically unavoidable' means not just unsurprising given the clinical condition of the resident, but incapable of prevention despite appropriate measures taken in light of the clinical risks." Harmony Court, DAB No. 1968, at 11 (2005), aff'd, Harmony Court v. Leavitt, No. 05-3544, 2006 WL 2188705 (6th Cir. Aug. 1, 2006); see also Livingston Care Center, DAB No. 1871, at 11, n.4 (2003) ("a pressure sore can be considered unavoidable only if routine preventive care is provided," citing State Operations Manual, App. PP), aff'd, Livingston Care Ctr. v. U.S. Dep't of Health & Human Servs., 388 F.3d 168 (6th Cir. 2004).

Here, Edgemont knew that both Resident 14 and Resident 5 were at high risk for developing pressure sores and that the devices that were ordered for treatment of their medical conditions increased the risk of causing pressure sores for these residents. Yet, as discussed later in this decision, Edgemont did not show it took any steps to clarify the orthopedic physician's order to keep Resident 14's immobilizer on at all times or that it planned for how to address the increased risk of pressure sores posed by Resident 5's C-PAP mask. In other words, Edgemont did not show it was incapable of taking steps to minimize risks to the resident in order to ensure the highest practicable physical well-being of the resident. Therefore, the ALJ correctly concluded that Edgemont did not show that the pressure sore was clinically unavoidable in the case of either Resident 14 or Resident 5.

The ALJ did not err in concluding that Edgemont failed to substantially comply with section 483.25(c)(1) with respect to Resident 14.

In his discussion of FFCL 1.a.i, the ALJ found that Edgemont failed to protect Resident 14 against the development of pressure sores under her immobilizer. The ALJ rejected Edgemont's argument that Dr. Moran's November 3, 2006 order did not permit it to remove the immobilizer for skin checks. Moreover, according to the ALJ, Edgemont "would not have been excused from its failure to do more for Resident # 14 even if the physician who applied the immobilizer had in fact ordered that the device not be removed under any circumstances." ALJ Decision at 8. In particular, the ALJ found that Edgemont's staff "knew or should have known that, while the resident wore the immobilizer, she was at a greatly increased risk for development of pressure sores on

the skin that was under the device[.]" Id. at 8. The ALJ opined that–

> [t]he heightened risks to Resident # 14 made it incumbent on Petitioner's staff to assess the resident's risk for pressure sores on the area beneath the immobilizer and to discuss with the resident's physicians the best way to address those risks. At the least, Petitioner's staff should have identified the increased risk to the resident and discussed it with the resident's treating physicians. It should have asked for advice as to what measures it could have taken in order to minimize the resident's risk of developing a sore.

Id. at 8. The ALJ made this point again later in his decision, stating that "[t]he staff's duty in this case was to raise questions as to whether they were providing adequate care to the resident by not checking under the immobilizer. . . . At the least, the staff could have queried the [resident's] physicians about the care that had been prescribed." Id. at 14.

Below, we discuss the arguments Edgemont made in support of its exception to this FFCL.

1. Substantial evidence in the record supports the ALJ's finding that Dr. Moran's order permitted Edgemont staff to remove Resident 14's immobilizer for skin checks.

Edgemont argues that the ALJ's conclusion that Edgemont failed to substantially comply with the requirement that it protect its residents against the development of pressure sores "is based on an erroneous reading of the record . . . as to whether or not an order to remove the immobilizer was in place." RR at 3. In finding that Dr. Moran's November 3, 2006 order for "Knee immobilizer to . . . [right] knee at all times" permitted Edgemont's staff to remove Resident 14's immobilizer for skin checks, the ALJ relied on a January 16, 2007 letter from Dr. Moran to the Kentucky Office of Inspector General which stated: "Clearly, the immobilizer could be removed for bathing and skin care." ALJ Decision at 6 (citing CMS Ex. 28, at 23) and 8. Edgemont, however, relies on an August 17, 2007 declaration by Dr. Moran which states that in limiting skin checks to the edges of the immobilizer, Edgemont's staff followed his order. RR at 8; ALJ Decision at 8; P. Ex. 32, at 1. The declaration disavows Dr. Moran's January 16 letter as "general comments" that "do not represent" his order and explains that Dr. Moran was unaware when he signed the letter that Resident 14 had developed a pressure

sore and "was not fully informed of the circumstances of the case." P. Ex. 32, at 1.

We conclude that the ALJ's finding that Dr. Moran's order permitted the removal of Resident 14's immobilizer for skin checks is supported by substantial evidence in the record. The ALJ found "not credible" Dr. Moran's August 17, 2007 declaration disavowing his January 16, 2007 letter. ALJ Decision at 8. The Board generally defers to an ALJ's determination of the weight to be attributed to the evidence before him. Pacific Regency Arvin, DAB No. 1823, at 22 (2002). We find no reason not to do so here. Since Dr. Moran's August 17, 2007 declaration was prepared for use in this litigation, it is reasonable to give it less weight than his earlier statement, which it directly contradicts. Moreover, the declaration does not provide a cogent explanation of Dr. Moran's position that the description of the order in his January 16, 2007 letter is incorrect. Indeed, if the same reasons given in his declaration were applied to his order, the order would have to be read as permitting Edgemont's staff to remove the immobilizer for skin checks. If Dr. Moran did not know about the circumstances of Resident 14's case when he wrote the letter on January 16, 2007 stating that the immobilizer could be removed for skin care, he certainly did not know about those circumstances on November 3, 2006 when he gave the order for the immobilizer.

Edgemont argues in effect that the ALJ's finding that Dr. Moran's order permitted removal of the immobilizer for skin checks is not dispositive because its staff acted reasonably in interpreting the order as prohibiting removal of the immobilizer under any circumstances. Reply Br. at 2. We need not address whether that was the case, however, since the ALJ considered whether Edgemont substantially complied with section 483.25(c)(1) "even if the physician who applied the immobilizer had in fact ordered that the device not be removed under any circumstances." ALJ Decision at 8. As discussed below, we agree with the ALJ's conclusion that even based on this assumption, Edgemont failed to substantially comply with section 483.25(c)(1).

2. The ALJ did not err in concluding that merely performing the weekly skin check required Dr. McKemie's order was not sufficient to substantially comply with section 483.25(c)(1).

Edgemont takes the position that it substantially complied with section 483.25(c)(1) regardless of whether Dr. Moran's order permitted removal of the immobilizer for skin checks, as the ALJ found. Edgemont argues specifically that it complied with Dr. McKemie's November 4, 2006 order for weekly skin checks by

checking the skin underneath the immobilizer when the immobilizer was removed for an x-ray. RR at 19. In response to this argument below, the ALJ stated:

> I am not persuaded that Petitioner fulfilled its duty to the resident by checking her skin on the 6th of November but not thereafter. The resident's risk of development of a severe pressure sore was such that even weekly checks of her skin may have been inadequate to fully protect her. P. Ex. 35, at 3. Petitioner's staff should have known that and should have factored that possibility into its investigation of how best to protect the resident. But, clearly, it failed to do so.

ALJ Decision at 9-10. Edgemont asserts correctly that the immobilizer was removed for the x-ray on November 8, not November 6 as stated in the ALJ Decision. RR at 19, n.12, citing P. Ex. 1, at 53; P. Ex. 41, at 2; and P. Ex. 3, at 20. If a skin check had been conducted on November 6, more than one week would have elapsed before next time the immobilizer was removed, on November 13. However, the ALJ Decision does not rely on the November 6 date to find that Edgemont did not perform weekly skin checks.

Edgemont takes exception to the ALJ's conclusion, asserting that "[t]his is a blatant substitution of the ALJ's judgment for the competent medical judgment of the attending physician, for which [the ALJ] had no authority." RR at 19. We do not agree.

To support his conclusion, the ALJ cited the declaration of orthopedic physician Mark O. Gladstein, M.D., which was submitted by Edgemont. The declaration states in pertinent part:

> This patient [Resident 14] was discovered to have developed a skin ulcer on the posterior aspect of her calf. If that ulcer is considered a pressure ulcer, I do not find it surprising that one would occur in that area, since the risk of such pressure from the use of an immobilizer is common, and <u>I have seen such ulcers arise even where immobilizers are removed regularly for skin assessments</u>. Such ulcers are commonplace despite adequate nursing care and diligence.

P. Ex. 35, at 3 (emphasis added). Although Dr. Gladstein did not specify what he meant by regular removal of an immobilizer, the ALJ could reasonably infer from Dr. Gladstein's declaration that a pressure sore could develop underneath an immobilizer in less than a week. Moreover, in relying on Dr. Gladstein's expert opinion, the ALJ did not ignore Dr. McKemie's medical judgment. Dr. McKemie's order for weekly skin checks did not reflect any

opinion as to the frequency with which the immobilizer would have to be removed for skin checks in order to prevent pressure sores from developing underneath the immobilizer since, according to Dr. McKemie, his order did not anticipate that the immobilizer would be removed at all. P. Ex. 33, at 2.

In addition, Edgemont cannot reasonably argue that the one weekly skin check met the regulatory standard when its own judgment appeared to be that more frequent skin checks were necessary. See, e.g., Woodland Village Nursing Center, DAB No. 2053 (2006), aff'd, Woodland Village Nursing Ctr. v. U.S. Dep't of Health & Human Servs., 239 F. App'x 80 (5th Cir. 2007) (a facility's "failure to follow its policy . . . could support a prima facie showing of a violation of [section 483.25] since one could reasonably infer that the policy . . . reflect[ed] the [facility]'s determinations of what care and services were necessary to permit the resident to attain or maintain the highest practicable physical, mental, and psychosocial well-being. . . ."). Edgemont's Skin Care Protocol stated that all residents "will be assessed weekly and PRN [as needed] for any indication of skin problems." CMS Ex. 32, at 1 (emphasis added). Following that protocol, Edgemont included in Resident 14's November 3, 2006 care plan an instruction to check under the edges of the immobilizer for skin breakdown each shift. P. Ex. 1, at 225; CMS Ex. 28, at 36. It therefore appears that, were it not for Edgemont's alleged understanding of Dr. Moran's order as not permitting the removal of Resident 14's immobilizer for skin checks, Edgemont would likely have required skin checks underneath the immobilizer more frequently than on a weekly basis. It was entirely appropriate for Edgemont to require more frequent skin checks than ordered by Dr. McKemie, moreover, since Dr. McKemie's order was a general order which was not based on Edgemont's assessment of Resident 14 as being at high risk for pressure sores or the higher risk presented by the immobilizer. See P. Ex. 33, at 2 (Dr. McKemie's declaration stating that order for weekly skin checks "is facility protocol for all residents"); see also RR at 6 (describing Dr. McKemie's order for weekly skin checks as "a general order" for "every resident . . . regardless of his or her risk for skin breakdown").

Edgemont also asserts that "evidence was submitted which demonstrated that staff provided excellent preventative care including documenting assessments of lower extremities (including circulatory conditions, presence/absence of edema), placement of immobilizer and placement of leg, application of preventative ointment to areas around immobilizer, obtaining OT/PT suggestions, providing dietary supplements, physician visitation, discussion at weekly clinical meetings, and much more." RR at

18, citing P. Ex. 1, at 56-70, 159-164, 199, and CMS Ex. 28, at 285. However, Edgemont did not provide any evidence that these interventions addressed the increased risk of pressure sores under Resident 14's immobilizer. In any event, these interventions were not sufficient to meet the regulatory standard since Edgemont's nursing staff could not monitor their effectiveness without removing the immobilizer for skin checks more frequently than weekly.

We note finally that, even if a weekly skin check were sufficient to ensure that Resident 14 did not develop a pressure sore that was clinically avoidable underneath the immobilizer, it is questionable whether the skin check on November 8 was done to comply with Dr. McKemie's order. This skin check occurred when the x-ray technician informed Edgemont's nurse, after an x-ray had been taken with the immobilizer in place, that it was necessary to remove the immobilizer in order to get a good x-ray. While the immobilizer was removed for the x-ray, the nurse who was present assessed the exposed skin. P. Ex. 41 (Declaration of Pam Brown), at 2-3, citing P. Ex. 3, at 19-20, CMS Ex. 29, at 106, and CMS Ex. 28, at 113. Since it was only by happenstance that Edgemont checked the skin underneath the immobilizer on November 8, there was no assurance that Edgemont would have provided the requisite care if Resident 14 had worn the immobilizer for another week or if a similar situation had arisen with respect to another resident. Moreover, Edgemont's declarants identified a "skin assessment" performed on November 9 without removing the immobilizer, not the nurse's assessment on November 8, as the skin check required by Dr. McKemie's order. P. Ex. 37 (Declaration of Joann Hill), at 6, citing CMS Ex. 28, at 154; P. Ex. 40 (Declaration of Marilyn Bertram), at 4-5.

3. The ALJ did not err in concluding that Edgemont failed to substantially comply with section 483.25(c)(1) because its staff did not question Resident 14's physicians about Dr. Moran's order.

As indicated above, the ALJ concluded that, assuming Dr. Moran's order did not permit removal of the immobilizer under any circumstances, Edgemont had a duty at that time to question Resident 14's physicians about whether they could provide adequate care to Resident 14 without removing the immobilizer. Edgemont takes issue with this conclusion on the ground that the ALJ ignored physicians' declarations which Edgemont asserts establish that the immobilizer "could not have been removed because of the fragility of the fracture." RR at 18; see also RR at 22-24 (citing the declarations of Drs. Moran, McKemie and Cheng, Jackson and Gladstein at P. Exs. 29 and 32-35).

Contrary to what Edgemont argues, the ALJ specifically acknowledged Edgemont's reliance on "physicians who now contend that checking around the edges of the immobilizer rather than removing the immobilizer to perform skin checks was adequate protection of the resident given the need to maintain stability in her fractured leg." ALJ Decision at 13. The ALJ stated, moreover, that "I do not take issue with these physicians' assessments of what was appropriate." Id. The ALJ nevertheless concluded that Edgemont had a duty to question Resident 14's physicians about Dr. Moran's order even if "[i]t is possible that such . . . . consultation might have led to a conclusion that removing the immobilizer to check the resident's skin posed greater risks to the resident than leaving the immobilizer on at all times." Id. at 9; see also id. at 13.

We agree that the fact that Resident 14's physicians, as well as outside experts, concurred after reviewing Resident 14's medical record that the risks of removing the immobilizer outweighed the benefits is simply irrelevant here. A facility must comply with the applicable participation requirements regardless of whether its compliance would have changed the outcome in the case of a particular resident; otherwise, the facility's inadequate care and services poses a risk of actual harm to other residents who may be similarly situated. Accordingly, in determining whether Edgemont furnished the care and services necessary to ensure that Resident 14 did not develop pressure sores that were clinically avoidable under the immobilizer, we must consider what Edgemont's staff knew at the time it was caring for Resident 14. Cf. Emerald Oaks, DAB No. 1800 (2001) (finding that the risk of harm from a facility's failure to implement its anti-neglect policy must be judged by what the facility knew for should have known at the time of the incident, not subsequent history or hindsight medical opinion).

The ALJ reasonably concluded that, given the state of Edgemont's knowledge, Edgemont did not satisfy the requirements of section 483.25(c)(1) by simply following Dr. Moran's order (as Edgemont's staff allegedly understood it). Even before Resident 14 returned to the facility with an immobilizer on her leg, Edgemont knew that Resident 14 was at high risk for pressure sores. In addition, Edgemont does not dispute the ALJ's finding that Edgemont knew or should have known that the immobilizer greatly increased Resident 14's risk of developing pressure sores. Moreover, Edgemont does not allege that it had any reason to believe that Dr. Moran was aware of its assessment of Resident 14's risk of pressure sores when he gave his order. Indeed, it is reasonable to infer that he was not aware of Edgemont's assessment at that time since he stated in his declaration that

he "was not fully informed of the circumstances of the case" when he signed the January 16, 2007 letter explaining his order.[7] P. Ex. 32, at 1. Had Dr. Moran been aware of the resident's high risk for pressure sores, it is possible that he might have clarified that his order permitted removing the immobilizer for skin checks, or might have changed his order to permit this assuming that it did not already do so. Although this possibility should have been apparent to Edgemont, Edgemont did not explore the possibility by informing Dr. Moran of the resident's high risk for pressure sores and questioning him about whether the immobilizer should be removed for skin checks in light of that risk.[8] Thus, Edgemont did not provide the care and services necessary to ensure that Resident 14 did not develop pressure sores that were clinically avoidable, as required by section 483.25(c)(1).

Edgemont also argues, however, that it need not have pursued the matter with Resident 14's physicians since Resident 14's pressure sore was unavoidable. We discuss this argument below.

4. <u>The ALJ did not err in rejecting Edgemont's argument that the pressure sore Resident 14 developed under the immobilizer was unavoidable.</u>

The ALJ rejected Edgemont's argument that the pressure sore that Resident 14 developed was "clinically unavoidable" within the meaning of the regulation, as well as the same argument regarding Resident 5, stating that "the possibility that sores were unavoidable gave Petitioner no excuse for failing to discharge its responsibilities." ALJ Decision at 14.

On appeal, Edgemont again argues that Resident 14's pressure sore was unavoidable, stating that "CMS did not establish that the facility failed to meet any of [the] requirements" in CMS's State

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[7] We also note that since Resident 14's injury occurred at a facility other than Edgemont, it was less likely that Edgemont's assessment would have been communicated to Dr. Moran than if Resident 14 had been at Edgemont when she was injured.

[8] The ALJ Decision states that Edgemont should have consulted with Resident 14's "physicians," which presumably refers to Dr. McKemie as well as Dr. Moran. Even if only Dr. Moran (or another orthopedic physician) could have clarified the order for the immobilizer, Edgemont staff could have communicated their concerns to Dr. McKemie, who could have in turn raised them with Dr. Moran.

Operations Manual (SOM) for determining whether a pressure sore is unavoidable. RR at 17. Contrary to what Edgemont indicates, however, the facility, not CMS, bears the burden of showing that a pressure sore was unavoidable. See, e.g., Harmony Court at 11 (referring to a facility's "burden of proof on the issue of whether a pressure sore is unavoidable"). In any event, Edgemont's position that it met the requirements in the SOM (which was issued by CMS as guidance to surveyors) is not consistent with the facts as we have found them. The provisions in the SOM to which Edgemont cites state that a facility must have: 1) evaluated the resident's condition and pressure ulcer risk factors; 2) defined and implemented interventions that are consistent with a resident's needs, goals and recognized standards of practice; 3) monitored and evaluated the impact of the interventions; and 4) revised the approaches as appropriate. RR at 17.[9] Although Edgemont had previously assessed Resident 14 as at high risk for pressure sores, Edgemont does not point to any evidence that it formally reassessed the risk after concluding that Dr. Moran's order did not permit it to remove the immobilizer for skin checks. Moreover, as indicated above, Edgemont did not provide any evidence that its interventions addressed Resident 14's increased risk of pressure sores under the immobilizer. Furthermore, the evidence discussed above supports a finding that Edgemont would not be able to monitor the effectiveness of any preventive care it provided without removing the immobilizer more frequently than weekly. Finally, without such monitoring, Edgemont would have no basis for revising the approaches it initially took. Thus, Edgemont failed to take steps to minimize Resident 14's risk of developing pressure sores as required under section 483.25(c)(1).[10]

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[9] These provisions appear in Revision 36 of the SOM, dated 8/1/08, under Appendix (App.) PP, F314.

[10] Edgemont also asserts that Resident 14 "had every possible situation, condition, co-morbidity, and complication" consistent with the development of either a "stasis ulcer" or an unavoidable pressure sore. RR at 17, n.11. The SOM distinguishes between a stasis ulcer (which it states is now known as a "venous insufficiency ulcer") and a pressure sore. SOM, App. PP, F314 ("Definitions: § 483.25"). Edgemont argues that if the surveyors had considered whether or not Resident 14's ulcer was a stasis ulcer, "the deficiency may not have been cited[.]" Id. at 11, n.6. This argument is not persuasive. The ALJ found that the resident's pressure sore was diagnosed as a Stage IV pressure sore when the immobilizer was removed on

(continued...)

Edgemont also cites Life Care Center of Paradise Valley, DAB CR1673 (2007) in support of its position that the pressure sore that developed underneath Resident 14's immobilizer was unavoidable. RR at 21. The Board is not bound to follow ALJ decisions. Florence Park Care Center, DAB No. 1931, at 30, n.13 (2004). In any event, contrary to what Edgemont argues, the holding in Life Care that the facility failed to properly treat a pressure sore that had developed under a resident's immobilizer does not "implicitly recognize[]" that the pressure sore was unavoidable due to the physician orders requiring the immobilizer to remain in place. Id. Moreover, on the facts of this case, we cannot conclude that Edgemont reasonably relied on Dr. Moran's order (as Edgemont staff understood that order). In view of Edgemont's assessment of Resident 14 as being at high risk for pressure sores and the absence of any indication that Dr. Moran was aware of this risk, Edgemont should have sought clarification of the order since it may have been able to minimize the increased risk of Resident 14 developing a pressure sore under the immobilizer (and provide earlier treatment of any sore that developed) if it were able to remove the immobilizer.

The ALJ did not err in concluding that Edgemont failed to substantially comply with section 483.25(c)(1) with respect to Resident 5.

In his discussion of FFCL 1.a.ii, the ALJ found that "Petitioner and its staff failed to anticipate and to plan for, as well as react to, the problems that Resident # 5 faced as a consequence of wearing a C-PAP mask." ALJ Decision at 11. In particular, the ALJ found that "the resident was not specifically assessed for the possibility that his use of a C-PAP mask might cause skin problems. Nor were specific interventions designed to protect him against skin breakdown caused by his use of the mask. When problems became evident the staff failed to record them, assess them, and plan care specifically to address them." Id.

Edgemont does not dispute the ALJ's finding that it failed to assess Resident 5 "specifically" for the risk of pressure sores caused by his use of a C-PAP mask. Instead, Edgemont asserts, as it did below, that its staff "was familiar with the risks associated with the use of C-PAP masks, and further trained to

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[10] (...continued)
November 14, 2006. ALJ Decision at 6. Edgemont does not dispute this finding or point to any evidence in the record that this diagnosis was incorrect.

monitor all potential sources for pressure in providing care for residents at high risk for skin breakdown." RR at 14. However, we agree with the ALJ that such general training was inadequate since "[t]he mask's distributor had issued a specific warning that the mask posed a hazard of skin abrasions to those who wore it" which "put Petitioner and its staff on notice of a problem that transcended the general issue of the resident's vulnerability to skin problems." ALJ Decision at 12. Moreover, while Edgemont's staff might have been familiar with the risk of pressure sores posed by the use of the C-PAP mask, Edgemont does not point to any evidence in the record showing that it planned specific interventions designed to protect Resident 5 from developing pressure sores as a result of using the mask. Instead, Edgemont states only that "once the abrasion . . . developed, the facility did what was necessary to ensure that it properly healed [.]" RR at 21. As the ALJ Decision indicates, however, it is unnecessary to consider whether Edgemont appropriately treated the pressure sore once it was identified. ALJ Decision at 12. Section 483.25(c) imposes two separate requirements: to ensure that a resident who enters the facility without pressure sores does not develop pressure sores that are clinically avoidable, and to ensure that a resident who has pressure sores receives necessary treatment to promote healing, prevent infection and prevent new sores from developing. A facility can satisfy the latter obligation, as Edgemont asserts it did here, without satisfying the former obligation. Similarly, it is irrelevant whether, as Edgemont asserts, its staff successfully treated the pressure sores that Resident 5 had when he was admitted to the facility. See RR at 21. Accordingly, Edgemont failed to provide the necessary care and services to prevent Resident 5 from developing a pressure sore as a result of using the C-PAP mask.

Edgemont also argues that the development of Resident 5's pressure sore was unavoidable.[11] RR at 21. Edgemont argues in particular that CMS did not establish that Edgemont failed to meet the requirements in the SOM for determining that a pressure sore is unavoidable. RR at 17. As noted in the discussion of the same argument with respect to Resident 14, the burden rests on Edgemont, not CMS. In any event, as with Resident 14, Edgemont's position that it met the requirements in the SOM with respect to Resident 5 is not consistent with the facts as we have

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[11] While Edgemont at one point suggests that the "abrasion" that developed on the bridge of Resident 5's nose was not a pressure sore, elsewhere it describes it as a "low-grade pressure ulcer." Compare RR at 21, 25.

found them. Indeed, Edgemont does not dispute the ALJ's finding that it failed to take even the basic step of assessing Resident 5 for possible problems related to using the C-PAP mask. ALJ Decision at 11.

Edgemont nevertheless argues that Resident 5's pressure sore was unavoidable due to "the probability of occurrence as outlined in . . . published information" about the C-PAP mask. RR at 22. The record includes information from the distributor of Resident 5's C-PAP mask which identifies as a potential problem "develop[ing] redness or sore spots on your face, nose or forehead from the mask or straps." CMS Ex. 33, at 3. The record also includes selected pages from the website of the Sleep Apnea Health Center, which identifies "[i]rritation of . . . the skin on the face" as a problem that may occur with the C-PAP mask. CMS Ex. 34, at 1. Even if it were very likely that Resident 5 would develop a pressure sore as a result of using the C-PAP mask, that does not mean that a pressure sore was unavoidable. On the contrary, this likelihood would require Edgemont to take steps to minimize the increased risk that Resident 5 would develop a pressure sore. Thus, Edgemont's reliance on this published information undercuts its argument that Resident 5's pressure sore was unavoidable.

We need not reach the question whether the ALJ erred in concluding that Edgemont failed to substantially comply with section 483.20(k)(3)(i).

In concluding that Edgemont failed to substantially comply with section 483.20(k)(3)(i) (FFCL 1.b), the ALJ stated that Edgemont's failure to consider whether more could be done to protect Resident 14 from the risk caused by the use of the immobilizer "was a violation of professional standards of quality incorporated into the regulations." ALJ Decision at 13. Edgemont argues that "there was never any particular professional standard of quality cited by CMS that the facility failed to follow other than an alleged failure to comply with Resident #14's attending physician's order to conduct weekly skin checks." RR at 23. Edgemont also argues that the ALJ improperly "piggybacks" the requirement in section 483.25(c) to create "an additional standard to which the facility must be obligated," noting that section 483.25(c) was not cited in the survey report as a basis for finding a deficiency under section 483.20(k)(3)(i). Id. at 25.

We have determined that we need not reach the question of whether the ALJ erred in concluding that Edgemont failed to substantially

comply with section 483.20(k)(3)(i) (and therefore whether the ALJ erred in concluding that CMS's determination that such noncompliance posed immediate jeopardy was not clearly erroneous). A facility's noncompliance with even one participation requirement is a sufficient basis for the imposition of a CMP. See 42 C.F.R. § 488.430(a) (CMS may impose a CMP for "the number of days a facility is not in substantial compliance with one or more participation requirements."). Moreover, the factual basis for the deficiency citation under section 483.20(k)(3)(i) was the same as for the deficiency citation under section 483.25(c)(1). Finding that Edgemont violated two participation requirements rather than one based on the same set of facts would not make Edgemont's noncompliance any more serious. The seriousness of Edgemont's noncompliance was the only factor the ALJ considered in concluding that the CMP amount was reasonable. Since, as discussed below, we agree with that conclusion, the result in this case would be the same regardless of whether Edgemont failed to substantially comply with section 483.20(k)(3)(i) in addition to section 483.25(c)(1).

The ALJ did not err in concluding that CMS's determination that Edgemont's noncompliance with section 483.25(c)(1) posed immediate jeopardy was not clearly erroneous.

CMS's determination as to the level of noncompliance must be upheld unless it is clearly erroneous. 42 C.F.R. § 498.60(c); see also Beverly Health Care Lumberton, DAB No. 2156, at 4 (2008), citing Woodstock Care Center, DAB No. 1726, at 39 (2000), aff'd, Woodstock Care Ctr. v. Thompson, 363 F.3d 583 (6th Cir. 2003). The Board has held that section 498.60(c) "places the burden on the SNF [skilled nursing facility] — a heavy burden, in fact — to upset CMS's finding regarding the level of noncompliance." Liberty Commons Nursing & Rehab Center v. Johnston, DAB No. 2031, at 18 (2006), aff'd, Liberty Commons Nursing and Rehab Center - Johnston v. Leavitt, 241 F. App'x 76 (4th Cir. 2007), quoting (with emphasis in original) Barbourville Nursing Home, DAB No. 1962 (2005), aff'd, Barbourville Nursing Home v. U.S. Dep't of Health & Human Servs., No. 05-3241 (6th Cir. April 6, 2006).

In upholding CMS's determination of immediate jeopardy (FFCL 2), the ALJ found that "there was a very high risk that Resident # 14 would develop a pressure sore as a consequence of wearing an immobilizer," that the "entity that distributed the C-PAP mask worn by Resident 5 warned that the mask could cause skin problems," and that Edgemont's staff "was aware of these risks."

ALJ Decision at 14. The ALJ stated that "[g]iven that, their failure to act aggressively to take every reasonable measure to protect the residents put these residents at a very heightened probability of serious injury, harm, or death." Id. In addition, the ALJ noted that Edgemont "offered no persuasive evidence to show that CMS's determination of immediate jeopardy was clearly erroneous." Id.

Edgemont does not dispute that, if it failed to comply substantially with section 483.25(c)(1) or section 483.20(k)(3)(i) with respect to Resident 14, that noncompliance would be at the immediate jeopardy level. Edgemont nevertheless argues that immediate jeopardy did not exist because Edgemont was not out of compliance with respect to Resident 14 and Resident 5's pressure sore did not pose immediate jeopardy. RR at 25-26; Reply Br. at 3-4. As discussed above, however, we uphold the ALJ's findings with respect to Resident 14. Thus, regardless of whether Edgemont's noncompliance with respect to Resident 5 also constituted immediate jeopardy, the ALJ could properly determine that CMS's immediate jeopardy determination was not clearly erroneous. See Barn Hill Care Center, DAB No. 1848, at 19, n.20 (2002) ("[I]mmediate jeopardy can exist regardless of the scope of the deficiency . . . because there are some deficiencies that, even though not widespread or even a pattern, are so egregious that they meet the definition of immediate jeopardy at 42 C.F.R. § 488.301.").

Edgemont argues further that the immediate jeopardy as to Resident 14 was removed on November 14, 2006, when the pressure sore under the immobilizer was discovered, after which time Edgemont "demonstrated compliance[.]" RR at 26. In response to the same argument below, the ALJ stated as follows:

> Petitioner . . . reasons that the facility implemented appropriate care for this resident on that date thereby removing any risk that the resident would suffer additional harm. However, the immediate jeopardy in this case – while it certainly is evidenced by the deficiencies in care that Petitioner provided to Residents #s 5 and 14 – is not confined to the very limited circumstances in which Petitioner provided care to the two residents. The evidence shows that Petitioner's staff failed to recognize its obligations and to discharge them properly. That is a *general problem* of staff training, education and performance, evidenced to be sure by deficient conduct in caring for two residents, but not limited only to the care that these residents received. Petitioner eliminated the immediate jeopardy only when it implemented numerous

> corrective actions. These were not completed until January 16, 2007. CMS Exhibit 10.

ALJ Decision at 15 (italics in original). On appeal, Edgemont argues that the immediate jeopardy was removed on November 14, when Resident 14's immobilizer was removed, since "[t]he facility had no other residents with this condition[.]" RR at 26. We agree, however, that Edgemont's noncompliance arose from a "general problem of staff training," and was not limited to Edgemont's failure to provide the requisite care to residents whose situation was precisely the same as that of Resident 14 (or Resident 5). This is evident from the actions Edgemont took to correct its noncompliance, including in-service training "regarding P/P revisions, Performing skin assessments/Skin care per Care plans and MD orders, information re: specialty device usage, reporting skin breakdown or other acute conditions to MD, obtaining clarification orders . . . ." CMS Ex. 10, at 19-20. Edgemont suggests in the alternative that the immediate jeopardy was removed no later than December 2006, asserting that "staff was in serviced [sic] on these issues in December[.]" RR at 26. However, Edgemont does not challenge the ALJ's finding that the corrective actions it undertook to ensure that staff were properly trained to provide the care required by the regulations were not completed until January 16.

Accordingly, we conclude that there was no error in the ALJ's conclusion that CMS's determination of immediate jeopardy was not clearly erroneous or in the ALJ's finding regarding the duration of the immediate jeopardy.

The ALJ did not err in concluding that a $4,050 per day CMP for each day of immediate jeopardy was reasonable.

Noting that the CMP amount is "relatively modest in that it is at the low end of the immediate jeopardy range," the ALJ concluded that the $4,050 per day immediate jeopardy-level CMP was "justified by the seriousness of Petitioner's noncompliance." ALJ Decision at 15-16.

Edgemont takes exception to this conclusion (under FFCL 3) based on its position that no immediate jeopardy existed, a position which we have rejected. Edgemont also argues that it is "a single-owned facility, not part of a corporate chain and does not have the financial capability of paying" a CMP in this amount for the extended period of immediate jeopardy (November 14 through January 15) found by the ALJ. RR at 27. Edgemont asserts that its inability to pay the CMP is demonstrated by the fact that the

Kentucky Department for Medicaid Services (State agency) found that Edgemont qualified for continued Medicaid reimbursements during the first month of the state fiscal year 2008 (June 2007), when such reimbursements would normally be suspended. Id. The ALJ rejected a similar argument about Edgemont's financial condition, finding that Edgemont "has not offered any detailed evidence of its actual financial condition," such as evidence to support its contentions that it is not part of a chain of nursing facilities, that it operated at a loss the previous year, and that payment of the CMP would constitute an undue hardship. ALJ Decision at 16. The ALJ also stated that Edgemont had not provided evidence that explained how the "asserted waiver" by the State agency "came to be granted." Id. at 17.

Edgemont takes issue with the ALJ's finding that Edgemont had not provided adequate evidence of its financial condition, citing the declarations of its owner, Ms. Haefer, and its administrator, Ms. Duffy. RR at 4, citing P. Ex. 31 (Declaration of Bonnie Haefer), at 7-8, ¶¶ 19-22; P. Ex. 30 (Declaration of Shanna Duffy), at 6, ¶ 19. In her declaration, Ms. Haefer refers to Edgemont's May 21, 2007 letter to the State agency requesting continuation of Medicaid payments during the month of June 2007 based on "the hardship criteria." P. Ex. 27, at 1, cited at P. Ex. 31, at 7. However, neither that letter nor the State agency's letter approving the request (P. Ex. 27, at 3) specifically identify the applicable criteria. Ms. Haefer's declaration also refers to an August 16, 2007 letter sent to her by Edgemont's certified public accountant (CPA). P. Ex. 31, at 7-8, ¶ 20. That letter states that, although the financial statements and corporate income tax returns for Edgemont had not yet been completed, "it appears that the Company will report a fairly significant operating loss for the year ended December 31, 2006." P. Ex. 27, at 4. However, the letter contains no information about the data on which the CPA based his prediction. Ms. Haefer's declaration otherwise consists of undocumented assertions about Edgemont's financial condition, as does the declaration of Ms. Duffy. Thus, as the ALJ found, the record contains no evidence of Edgemont's actual financial condition. Moreover, although the ALJ Decision put Edgemont on notice that the absence of specific information prevented him from considering whether Edgemont's financial condition warranted a reduction in the amount of the CMP, Edgemont made no attempt to submit such information on appeal to the Board or to explain why such information had not been proffered. Accordingly, we conclude that the ALJ did not err in not relying on Edgemont's asserted financial condition as a factor in determining whether the CMP amount was reasonable.

Edgemont also argues that the CMP amount is excessive since "the facility's compliance history was exemplary." RR at 27. The ALJ Decision states merely that CMS offered no evidence concerning Edgemont's compliance history. ALJ Decision at 15. In its response to Edgemont's request for review, however, CMS notes that it had offered evidence (an "OSCAR report") of Edgemont's compliance history dating back to 2003. CMS Response at 14, n. 8, citing CMS Ex. 4 (showing that in 2005 Edgemont was cited for one Life Safety Code violation and in 2006 Edgemont was cited for two Life Safety Code violations as well as seven other non-immediate jeopardy-level deficiencies). Although the ALJ incorrectly stated that there was no evidence of Edgemont's compliance history, we conclude that he did not err in not considering Edgemont's allegedly "exemplary" compliance history in determining whether the CMP amount was reasonable. The Board has held that although a "history of non-compliance" is one of the factors to be considered in assessing the reasonableness of a CMP, the absence of a history of noncompliance is not a mitigating factor. Western Care Management Corp., d/b/a Rehab Specialties Inn, DAB No. 1921, at 93 (2004), citing Franklin Care Center, DAB No. 1900 (2003) and 42 C.F.R. § 488.438(f).

Conclusion

For the reasons explained above, we affirm and adopt the numbered FFCLs in the ALJ Decision with the following changes. We delete FFCL 1.b. and we modify FFCL 2 to read as follows:

> Petitioner did not prove to be clearly erroneous CMS's determination that Petitioner's failure to comply with the requirements of 42 C.F.R. § 483.25(c) was so egregious as to comprise immediate jeopardy.

/s/
Judith A. Ballard

/s/
Sheila Ann Hegy

/s/
Stephen M. Godek
Presiding Board Member