Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

In the Case of:	
Stone County Nursing & Rehabilitation Center,) DATE: October 1, 2009))
Petitioner,	<pre>) Civil Remedies CR1918) App. Div. Docket No. A-09-90)</pre>
- v) Decision No. 2276)
Centers for Medicare & Medicaid Services.))

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Stone County Nursing & Rehabilitation Center (the facility), an Arkansas skilled nursing facility (SNF), appeals the March 9, 2009 decision of Administrative Law Judge (ALJ) José A. Anglada, <u>Stone County Nursing & Rehabilitation Center</u>, DAB CR1918 (2009) (ALJ Decision). The ALJ sustained a determination by the Centers for Medicare & Medicare Services (CMS) that the facility was not in substantial compliance with certain Medicare participation requirements from April 6 through June 14, 2007. The ALJ also upheld CMS's finding that the facility's noncompliance had created a situation of "immediate jeopardy" on April 6 and 7, 2007. Finally, the ALJ sustained CMS's decision to impose enforcement remedies for the facility's noncompliance. Those remedies included a \$3,050 per-day civil money penalty (CMP) for April 6 and 7, 2007.

In this appeal, the facility challenges the ALJ's factual findings and legal conclusions that support the imposition of the

\$3,050 per-day CMP. Because those findings and conclusions, which concern a single resident (Resident 13), are supported by substantial evidence and free of legal error, we affirm the ALJ Decision.

Legal Background

The requirements for SNFs and other long-term care facilities for participation in Medicare and Medicaid are set forth in 42 C.F.R. Part 483, subpart B. State agencies under contract with CMS perform surveys to verify that SNFs comply with these requirements. A state survey agency reports any "deficiencies" (failures to comply with participation requirements) on a standard form called a "Statement of Deficiencies" (SOD). The SOD identifies each deficiency with a unique survey "tag" number that corresponds to the section of Part 483 allegedly violated.

CMS may impose enforcement remedies, including CMPs, when it finds that a SNF is not in "substantial compliance" with one or more participation requirements. <u>See</u> 42 C.F.R. §§ 488.400 <u>et</u> <u>seq</u>. "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." <u>Id.</u> § 488.301. CMS's regulations (and we) use the term "noncompliance" to refer to "any deficiency that causes a facility to not be in substantial compliance." Id.

The amount of a CMP depends in part on the "seriousness" - that is, the scope and severity - of a SNF's noncompliance. See 42 C.F.R. § 488.404. The most serious deficiency is one that creates "immediate jeopardy." Id. § 488.404(b). If CMS finds that the noncompliance is at the immediate jeopardy level, any CMP that CMS elects to impose for that noncompliance must be in the range of \$3,050 to \$10,000 per day. Id. § 488.438(a)(1).

In an ALJ proceeding concerning a SNF's alleged noncompliance with Part 483 requirements, "CMS has the burden of coming 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 of noncompliance with a regulatory requirement." <u>Evergreen Nursing Care Center</u>, DAB No. 2069, at 7. "If CMS makes this prima facie showing, then the SNF must carry its ultimate burden of persuasion by showing, by a preponderance of the evidence, on the record as a whole, that it was in substantial compliance during the relevant period." <u>Id.;</u> <u>see also Batavia Nursing and Convalescent Inn</u>, DAB No. 1911 (2004), <u>aff'd</u>, <u>Batavia Nursing and Convalesent Center v.</u> Thompson, No. 04-3687 (6th Cir. 2005).

Case Background

A survey completed on April 10, 2007 (April survey) by the Arkansas Department of Health and Human Services (state survey agency) found the facility noncompliant with various participation requirements. P. Ex. 1. The state survey agency also found that with respect to one resident - Resident 13 - the facility's noncompliance was at the level of immediate jeopardy on April 6 and 7, 2007. <u>Id.</u> at 12, 34, 70. (Unless otherwise indicated, the dates of documents or occurrences discussed in this decision are from 2007.)

Based on deficiency findings from the April survey and a subsequent revisit survey, CMS imposed a \$3,050 per day CMP for April 6 and 7; a \$350 per day CMP that ran from April 8 through May 31; a \$50 per day CMP that ran from June 1 through June 14; and a denial of payment for new admissions (DPNA) that ran from May 19 through June 14. CMS Ex. 66. The facility appealed CMS's enforcement action by requesting a hearing before the ALJ.

With the consent of the parties, the ALJ made a decision on the written record. As we explain more fully below, the ALJ concluded that the facility was not in substantial compliance with three participation requirements during the April survey. ALJ Decision at 7-19. The ALJ also concluded that CMS's immediate jeopardy finding was not clearly erroneous. <u>Id.</u> at 21-22. Based on these and other conclusions, the ALJ sustained the remedies imposed by CMS.¹ Id. at 26.

The facility filed a timely request for review of the ALJ Decision. The facility attached additional evidence to its request for review.

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 --Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's Participation in the Medicare and Medicaid Programs*, http://www.hhs.gov/dab/guidelines/prov.html (Board Guidelines).

¹ The ALJ made other conclusions (found in sections IV.A.3, IV.C, IV.D, and IV.E of the ALJ Decision) that neither party challenges in this appeal.

Discussion

The facility has limited its appeal to the ALJ's findings and conclusions that support the immediate-jeopardy-level CMP.² As noted, those findings and conclusions concern a single resident -Resident 13. Finding that the facility failed to consult with Resident 13's physician and otherwise ensure that Resident 13 received necessary treatment and services for pressure sores on her right foot and ankle, the ALJ concluded that the facility was not in substantial compliance with the physician consultation requirement in section 483.10(b)(11) (tag F157) and the pressure sore treatment and prevention requirement in section 483.25(c) (tag F314) during the April survey. ALJ Decision at 12-17. The ALJ also concluded that his findings regarding Resident 13 established that the facility was noncompliant with the administration requirement in section 483.75 (F490). Id. at 18. In addition, the ALJ concluded that CMS's finding that the noncompliance involving Resident 13 had created a situation of immediate jeopardy on April 6 and 7 was not clearly erroneous. Before discussing the facility's objections to those conclusions, we address the facility's request to admit new evidence.

1. The Board declines to admit the facility's new evidence into the record of this case.

The facility submitted new evidence with its request for review: a report prepared by Karl E. Steinberg, M.D., who states that he is a "Board-Certified Family Physician in the full-time clinical practice of geriatrics and long-term care in San Diego County, California." The report expresses opinions concerning the quality of the medical care furnished by the facility to Resident 13 and the merits of CMS's determination of noncompliance and immediate jeopardy finding.

The Board "may admit evidence into the record in addition to the evidence introduced at the ALJ hearing (or the documents considered by the ALJ if the hearing was waived), if the Board considers that the additional evidence is relevant and material

² The facility does not challenge the ALJ's conclusion that CMS had sufficient grounds to impose the \$350 and \$50 per day CMPs. ALJ Decision at 23-25. The facility also does not question the lawfulness of the DPNA or the ALJ's conclusion that its nurse aide training and competency evaluation program (NATCEP) was subject to a two-year suspension. <u>Id.</u> at 22. Thus, we affirm without further discussion the ALJ's decision upholding these remedies and the loss of the facility's NATCEP.

to an issue before it." 42 C.F.R. § 498.86. "In deciding whether to admit additional evidence, the Board considers whether the proponent of the new evidence has shown good cause for not producing it during the ALJ proceeding." <u>Ocean Springs Nursing</u> <u>Center</u>, DAB No. 2212, at 4 (2008) (citing ¶ 3(f) of the Board Guidelines).

In explaining why it failed to submit Dr. Steinberg's report during the ALJ proceeding, the facility asserts that it "decided not [to] engage an expert prior to submission of its brief to the Administrative Law Judge" because it "felt that its arguments to the Administrative Law Judge were persuasive without the assistance of an expert." RR at 4. The facility further asserts that it elected not to hire an expert after weighing "cost against benefit." Id. The facility suggests that it had difficulty finding an expert but offers no details about the timing, intensity, and results of its search.

It appears from these statements that the facility is seeking to introduce Dr. Steinberg's report not because it believes it has good cause for failing to introduce expert testimony during the ALJ proceeding, but because it made the wrong cost-benefit calculation and is dissatisfied with that proceeding's outcome. Dissatisfaction with the ALJ Decision is clearly not good cause for the failure to produce an expert report below. For this reason, we decline to make that report part of the record of this case.

2. The ALJ's conclusion that the facility was noncompliant with 42 C.F.R. § 483.10(b)(11) in its care of Resident 13 is supported by substantial evidence and free of legal error.

In relevant part, section 483.10(b)(11)(i) requires a SNF to "immediately . . . consult with the resident's physician . . . when there is . . . [a] <u>significant change in the resident's</u> physical, mental or psychosocial <u>status</u> (i.e., a deterioration in health, mental, or psychosocial status <u>in either life-threatening</u> conditions or clinical complications)" (emphasis added). By this regulation's terms, a "significant change" means "a deterioration in health, mental, or psychosocial status in either lifethreatening conditions or <u>clinical complications</u>" (emphasis added). Interpretive guidelines published by CMS in Appendix PP of the State Operations Manual (SOM) state that "clinical complications" include "such things as development of a stage II pressure sore . . . " SOM (CMS Pub. 100-7), Appendix PP, Interpretive Guidelines for Long-Term Care Facilities (tag F157).³ Thus, section 483.10(b)(11)(i)(B) "directs the facility to consult with the physician immediately not only where a resident's 'significant change' is in a 'life-threatening' condition, but also when the change involves non-emergency clinical complications such as the development of a stage II pressure sore . . ." <u>The Laurels at Forest Glenn</u>, DAB No. 2182, at 12 (2008).

CMS's determination that the facility was noncompliant with section 483.10(b)(11) was based on survey findings regarding four residents, including Resident 13, who had, or were at risk of developing, pressure sores. P. Ex. 1, at 2. Although there is (as the ALJ acknowledged) inconsistency in the facility's records regarding some aspects of Resident 13's "pressure sore history," the facts material to the ALJ Decision are not in dispute.

Resident 13 was admitted to the facility on January 30, hospitalized on February 1, and readmitted to the facility on February 11. P. Ex. 3, at 17, 20-22. The next day, February 12, a nurse noted on the facility's standard pressure sore form that Resident 13 had a stage II pressure sore on the right heel that measured 1 cm x 1 cm.⁴ <u>Id</u>. at 11. According to the facility's records, that pressure sore grew significantly larger over the next month. On March 12, the right heel pressure sore measured 4 cm x 3 cm; on March 18, it measured 5 cm x 4 cm. <u>Id</u>. at 88, 98. Equally significant, the facility's records indicate that the right heel pressure sore was a stage IV wound during March. <u>Id</u>. Also that month, Resident 13 developed two additional pressure sores (first reported on March 26): a stage II wound on the right outer ankle, and a stage IV wound above the right heel. Id. at 90-93, 137.

⁴ The severity of a pressure sore is determined by using "staging" criteria. Stage I pressure sores are the least serious; stage IV pressure sores are the most serious. SOM, Appendix PP (tag F157); <u>see also</u> CMS Ex. 40, at 17, 19-20; P. Ex. 3, at 12.

³ "The Board has repeatedly explained that the SOM does not itself have the force of law, but may be 'useful guidance as to CMS's interpretations of applicable law." <u>Columbus Nursing &</u> <u>Rehabilitation Center</u>, DAB No. 2247, at 23 (2009) (quoting <u>Cal</u> <u>Turner Extended Care Pavilion</u>, DAB No. 2030, at 13 (2006)). The SOM is available on CMS's public website at http://www.cms.hhs. gov/Manuals/IOM/list.asp.

On April 6, during the survey, Resident 13's physician, Frederick Dibrell, M.D., was notified about the wounds on Resident 13's right foot and ankle. P. Ex. 3, at 205. In response, he prescribed an antibiotic and instructed the nursing staff to clean and dress the affected areas. Id. at 205, 207-09; see also P. Ex. 1, at 5.

Based on these undisputed facts, the ALJ found that the right heel pressure sore had deteriorated between mid-February and mid-March and that this "change" necessitated physician consultation. ALJ Decision at 15. The ALJ also found that "at no time during the deteriorating progression of the sore was the treating physician notified of the change." Id. In addition, the ALJ found no evidence that the facility notified Dr. Dibrell about the new pressure sores prior to the April survey. Id. In short, the ALJ concluded that the facility was not in substantial compliance with section 483.10(b)(11)(i) as of April 6 because it had failed to consult immediately (i.e., during March) with Dr. Dibrell about "significant changes" in Resident 13's condition those changes being the deterioration of her right heel pressure sore and the appearance of new pressure sores during March.

The facility contends that substantial evidence does not support the ALJ's finding that the right heel pressure sore deteriorated after her February readmission. RR at 10-12, 18. We disagree. The facility's records, including its standard pressure sore form, clearly show that the dimensions of that wound increased four-fold (or more) between mid-February and mid-March. Those records also indicate that the wound was at stage II on February 12 and at stage IV on March 12. According to the pressure sore form, stage II "denotes [p]artial thickness loss of skin layers either dermis or epidermis," while stage IV denotes that "[a] <u>full</u> thickness of skin and subcutaneous tissue is lost, exposing muscle and/or bone." P. Ex. 3, at 11 (emphasis added). The ALJ reasonably inferred from these facts that the right heel pressure sore had, in fact, deteriorated after readmission.

The facility asserts that the right heel pressure sore was found to be at stage IV in mid-March 2007 not because the wound had worsened after February 12 (when the wound was reported to be at stage II), but because "eschar" covering the wound precluded an assessment of its actual severity. RR at 5, 10. The facility maintains that it staged the right heel pressure sore in accordance with a Resident Assessment Instrument protocol which directs the assessor to classify a pressure sore as a stage IV wound if the "presence of eschar precludes accurate staging of the ulcer." Id.; see also SOM, Appendix PP (tag F314). The ALJ considered but rejected this contention for the following reason, to which the facility takes no exception:

Petitioner provides no support in the record for the reasoning employed in designating the resident's sore on March 12, 2007, as stage IV. <u>Specifically, there is</u> an absence of facility rationale in the documentation that reflects a basis for labeling the sore as stage IV for a reason other than the definition found in the <u>Pressure Sore Form</u>. Thus, Petitioner's position regarding this issue is presented as mere argument in the aftermath without any reference in the record of a failed attempt to "stage" the sore in question.

ALJ Decision at 14-15 (emphasis added). The absence of contemporaneous supporting documentation was a sound reason to reject the facility's argument. In fact, none of Resident 13's treatment records indicate that eschar was present on the right heel during March 2007 or, if was present, that it precluded an assessment of the wound's severity in accordance with the staging criteria shown on the facility's standard pressure sore form.⁵

The facility also points to statements by Dr. Dibrell during the April survey and in a subsequent affidavit that the right heel pressure sore was "stable" throughout the relevant period. RR at 6, 16-18; see also P. Ex. 3, at 65; P. Ex. 7, at 2. However, Dr. Dibrell did not explain how or why his claim of wound stability was consistent with evidence that the wound had more than tripled in size after February 12 and that the wound had a small amount of "bloody drainage" on April 6. P. Ex. 3, at 2; P. Ex. 7. Dr. Dibrell also failed to specify the clinical basis for his assertion that the right heel pressure sore was stable. A HHS Clinical Practice Guideline, entitled Treatment of Pressure Ulcers, states that a pressure ulcer is "stable" if it is "clean, dry, nontender, nonfluctuant, nonerythematous, and nonsuppurative." P. Ex. 4, at 3. It is unclear whether Resident 13's right heel pressure sore met this definition throughout the

⁵ The facility asserts that eschar was continuously present on Resident 13's right heel from at least January 10, 2007 (when Resident 13 was in the hospital) through the date of the survey. RR at 10. However, facility records do not confirm that. Although a January 12 hospital nursing assessment indicates that eschar was forming on resident's right heel, P. Ex. 3, at 34, the February 12 entry on the facility's standard pressure sore form indicates no eschar and notes that the right heel pressure sore was "pink," id. at 11.

relevant period because the facility's periodic written assessments of that wound do not include findings regarding all of the definition's clinical criteria. Moreover, Dr. Dibrell did not indicate in his affidavit that the pressure sore met the HHS guideline's definition of a stable pressure ulcer or point to any contemporaneous medical records to back up his opinion. Even if we found that the right heel pressure sore was stable throughout the relevant period, we would not disturb the ALJ's conclusion that the facility was noncompliant with section 483.10(b)(11) because the facility does not dispute the ALJ's finding that the appearance of <u>new</u> pressure sores in March constituted a significant change in Resident 13's status.

The facility maintains that there was no need to notify or consult with Dr. Dibrell in March about the significant changes in Resident 13's status because Dr. Dibrell knew about them when they occurred. RR at 6. The facility points to an April 6 nursing note which states that Dr. Dibrell knew about the "areas [of concern on the right foot and ankle] prior to [the facility's April 6] phone call" to him. P. Ex. 3, at 205. However, the note does not indicate precisely when Dr. Dibrell first learned about those concerns or what he knew about Resident 13's right foot and ankle. Id.

The facility also relies on the affidavit of Lisa Rhoades, its Director of Nursing (DON), who declared:

Dr. Dibrell, Resident #13's attending physician, made rounds several times on Resident #13 between the time of admission and the time of the Survey. Dr. Dibrell was aware of the Resident's condition, and there was not lack of physician notification.

P. Ex. 9, \P 3. This statement has minimal probative value because it lacks specificity and foundation. In particular, the statement does not indicate when or how Dr. Dibrell first learned about the deterioration of Resident 13's right heel pressure sore or about the appearance of new pressure sores during March. The statement also does not specify the foundation for DON Rhoades's assertion that Dr. Dibrell was aware of the resident's condition, and it appears to be merely an inference that if he made rounds during March, he must have been aware then that the right heel pressure sore had deteriorated and that new pressure sores had appeared on Resident 13's right foot and ankle. In addition, daily nursing notes and other contemporaneous treatment records do not corroborate Nurse Rhoades's assertion that the facility notified Dr. Dibrell about those problems prior to the April In short, while the record shows that Dr. Dibrell knew, survey.

prior to the April survey, that Resident 13 had a right heel pressure sore, the facility failed to establish that he became aware <u>during March</u> that the wound had deteriorated or that Resident 13 had developed new pressure sores on her right foot and ankle.

In any event, a physician's "awareness" of a significant change does not discharge the facility's express obligation under section 483.10(b)(11)(i) to "consult" with the physician. The requirement to consult means that the facility must engage in a dialogue with the physician about an appropriate response to the significant change or changes. <u>Magnolia Estates Skilled Care</u>, DAB No. 2228, at 9 (2004). Treatment records do not show that the facility either informed or consulted with Dr. Dibrell during March about the growth of Resident 13's right heel pressure sore or the appearance of new pressure sores.

The facility contends that it did not violate section 483.10(b)(11)(i) because "there is no evidence that additional or more frequent physician notification prior to the survey "would have changed the course of treatment for [Resident 13] in any meaningful or beneficial way." RR at 6. In other words, the facility contends that Resident 13's physician would not have ordered new treatment or changed existing treatment had he been notified about Resident 13's new or deteriorating pressure sores prior to the April survey. This argument is undercut by the fact that when Dr. Dibrell was informed about the deterioration of Resident 13's condition, he ordered additional medical treatment. P. Ex. 3, at 205, 207-09. Furthermore, compliance with the physician consultation requirement "is not contingent on how the physician might respond, but on the existence of facts [e.g., a significant change] requiring notification." NHC Healthcare Athens, DAB No. 2258, at 6-7 (2009). Thus, we need not speculate about whether pre-survey consultation with Dr. Dibrell would have changed the course of Resident 13's treatment.

For the reasons discussed, we affirm the ALJ's conclusion that the facility was not in substantial compliance with section 483.10(b)(11) during the April survey.

3. The ALJ's conclusion that the facility was noncompliant with 42 C.F.R. § 483.25(c) in its care of Resident 13 is supported by substantial evidence and free of legal error.

Section 483.25(c) provides:

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; and

(2) A resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing.

In <u>Woodland Village Nursing Center</u>, the Board explained that this regulation requires the SNF to "ensure" pressure sore "healing and prevention" as the outcome of resident care "unless the facility can prove with clinical evidence that a negative outcome was unavoidable despite the facility having furnished all necessary care." DAB No. 2172, at 13 (2008). Thus, deterioration of the right heel pressure sore and the development of new pressure sores on Resident 13's right foot and ankle during March were sufficient to find noncompliance with section 483.25(c) unless the facility proved that it had timely taken all necessary measures, consistent with professional standards of care, to promote the healing of these sores, prevent infection, and prevent even more pressure sores from developing. Petitioner did not make this showing.

The ALJ found that a "delay in physician involvement in the treatment of R13's pressure sores prevented the resident from receiving the necessary treatment and services to promote healing." ALJ Decision at 17 (emphasis added). He also found that CMS had "established a prima facie case that [the facility] failed to ensure . . that [Resident 13's] skin condition was monitored" and "that increased caloric and protein needs were assessed upon development of pressure sores with interventions developed to promote healing." Id. These findings imply a conclusion by the ALJ that the facility was not in substantial compliance with section 483.25(c)(2) because it did not ensure that a resident with pressure sores receives necessary treatment and services to promote healing, prevent infection, and prevent new sores from developing.

Substantial evidence supports the ALJ's conclusion that the facility failed to ensure the timely provision of treatment and services necessary to promote healing and prevent development of new pressure sores. Despite the persistence and deterioration of Resident 13's right heel pressure sore and the appearance of new pressure sores during March, it was not until the April survey that the facility consulted with Dr. Dibrell about those problems. When that consultation finally occurred, Dr. Dibrell ordered additional treatment (an antibiotic, wound cleansing and dressings). P. Ex. 3, at 205, 207-09. A dietician also determined that Resident 13 required additional protein intake to promote pressure sore healing. P. Ex. 1, at 20. There is no evidence to suggest that these measures were unnecessary prior to the April survey - i.e., in March - when the growth of the right heel pressure sore and the appearance of new pressure sores on Resident 13's right foot and ankle were first documented. In addition, the facility does not challenge the ALJ's finding that it failed to provide a timely assessment of Resident 13's caloric and protein needs.

We also note that CMS determined, and the facility does not dispute, that the facility failed to assess Resident 13 adequately for pain. Daniel J. McElroy, R.N., a CMS Nurse Consultant and qualified nursing home surveyor, stated in a declaration that stage II ulcers "are much like minor burns and may be painful," that the "edges of Stage III and Stage IV ulcers are likely to have intact nerves and be painful," that "residents may be unable to communicate their pain," and that the "minimum assessment recommended by the National Pressure Ulcer Advisory Panel" includes an inquiry into whether the resident is experiencing pain as a result of the pressure sore. CMS Ex. 71, Noting that Resident 13 had impaired cognition, Nurse at 7. McElroy accurately asserted that there was "no evidence that Stone County assessed Resident #13 for pain" related to her pressure sores. Id.

The facility maintains that Resident 13's pressure sores were "appropriately treated in accordance" with clinical practice guidelines. RR at 20-21. The facility asserts that, in response to physician orders issued in mid-February, it applied Lantiseptic to Resident 13's pressure sores, used heel boots and an "alternating air mattress," and "consistently repositioned and turned the Resident to relieve her pressure sores and to promote their healing." Id.

For the following reasons, these contentions, and the evidence upon which they are based, do not persuade us that the ALJ erred in concluding that the facility was not in substantial compliance with section 483.25(c). First, the record does not establish that the nursing staff <u>consistently</u> implemented the treatment and interventions - Lantiseptic and repositioning, for example ordered by Dr. Dibrell in February. The facility produced a chart, entitled "Treatment Procedures," that lists the treatment and other interventions provided to Resident 13 during each nursing shift in April. P. Ex. 3, at 208. This chart indicates that the nursing staff repositioned Resident 13 and applied Lantiseptic to her heels during each shift that month. <u>Id</u>. However, the facility failed to produce a similar chart for the key months of February and March. In addition, the facility's daily nursing notes for February and March only occasionally mention the interventions undertaken to heal Resident 13's pressure sores and prevent new ones from developing. <u>See</u> P. Ex. 3.

Second, Dr. Dibrell failed to respond adequately to the fact that the right heel pressure sore grew substantially larger after February 12. Although Dr. Dibrell asserted that the right heel pressure sore was "stable," he specified no clinical basis for that assertion and never stated that this wound met the HHS clinical practice guideline's definition of a stable pressure sore throughout the relevant period.

Third, even if the condition of Resident 13's right heel pressure sore remained static after February 12, that fact would not necessarily show that the facility had met its obligation to promote healing. A facility must "do more than just maintain the status quo for a resident who suffers from pressure sores" and is "obligated to promote healing[.]" Beechwood Sanitarium, DAB CR821, at 14 (2001), aff'd, DAB No. 1906 (2004). A pressure sore that persists without improvement for a long period, like the pressure sore on Resident 13's right heel, is not healing. Woodland Village Nursing Center at 13. "In order to avoid a deficiency finding in that circumstance, the facility [must] show that the failure to achieve healing was clinically unavoidable, despite implementing measures to address the persistent sore" Id. at 13-14. Here, the facility has not alleged, much less proved, that the lack of healing on Resident 13's right heel was clinically unavoidable.

Fourth, the facility's arguments overlook the fact that the record reflects no response by the nursing staff to the new pressure sores that Resident 13 developed during March. Dr. Dibrell expressed no opinion about that apparent lapse, nor did he claim that the new pressure sores were unavoidable. In addition, Dr. Dibrell did not assert that the treatment he ordered in April was unnecessary prior to the survey.

Even if that additional treatment was unnecessary, the facility failed to comply with section 483.25(c)(2)'s mandate to provide "necessary services." Necessary services include timely assessment and evaluation of the efficacy of existing treatment and prevention measures, especially when the resident develops new pressure sores in the course of treatment. See SOM App. PP (tag F157). It is apparent that by mid-to-late March, despite various interventions (such as the application of Lantiseptic), Resident 13's right heel pressure sore had grown larger and her right foot and ankle had developed additional pressure sores. At that point, the facility was obligated to do more than merely continue with currently prescribed interventions and hope the The facility needed to determine the reasons situation improved. for the apparent lack of healing and the appearance of new pressure sores and consult with Dr. Dibrell to determine whether additional treatment and prevention measures were needed. Affidavit of Dennis Adams, R.N., CMS Ex. 68, at 2-3 (asserting that the facility "failed to ensure that the treatment was changed as needed as the [right heel] pressure sore declined and new pressure sores developed"). However, there is no evidence of such an inquiry by the facility's nursing staff during March, even though it was required by facility policy. The facility's Skin Integrity and Wound Management policy (dated October 2002) instructed the nursing staff to complete a "weekly skin report" and to submit that report to the Director of Nursing (DON). CMS The report had to specify whether a resident's Ex. 40, at 96. skin problem was improving or not improving. Id. The DON would then, according to the policy, "assess for need of change of treatment" in the event of non-improvement. Id. We see no evidence, and the facility does not allege, that the nursing staff complied with this policy during the relevant period.

The facility raises other objections to the ALJ's analysis of the compliance issue (see RR at 5-9), but those objections lack merit or do not undermine the ALJ's ultimate conclusion that the facility failed to provide, or ensure the timely delivery of, necessary services to Resident 13. The facility contends, for example, that substantial evidence does not support the ALJ's finding that the facility failed to "monitor" Resident 13's skin RR at 8. What the ALJ meant by this particular condition. If he meant that the nursing staff failed to finding is unclear. observe and track Resident 13's skin condition, we would disagree because the record indicates that the nursing staff did those However, as we have discussed, the facility was required things. to do more than simply "monitor" Resident 13's skin condition. Section 483.25(c)(2) required the facility to assess the observed deterioration of Resident 13's right foot and ankle and determine, through consultation with the physician, whether additional treatment or other measures were necessary to promote healing and prevent new pressure sores. The facility was also obligated to implement the treatment procedures for repositioning.

The facility also contends that the ALJ erroneously found that its practice was to not notify a physician of a pressure sore unless it was open or ruptured. RR at 7. This contention stems from comments made to surveyors by Nurse Humphrey, the facility's Assistant Director of Nursing. According to surveyor notes, Nurse Humphrey commented in two separate interviews - one of which concerned Resident 12, and the other Resident 13 - that there was no need to call a physician about a pressure sore unless it was an open or ruptured wound. CMS Ex. 19, at 4; CMS In her affidavit, Nurse Humphrey stated that her Ex. 20, at 4. comment about the need to notify a physician was not made "with regard to" Resident 13 "but with regard to a different resident in connection with a different issue." P. Ex. 10, \P 3. Regardless of which resident or issue was involved, the ALJ reasonably regarded the statement as describing a facility practice because the statement was made by a facility employee with apparent supervisory authority and responsibility. CMS Ex. 19, at 4; CMS Ex. 20, at 4. The facility asserts that the comment was merely evidence that Nurse Humphrey "did not understand the appropriate practice" and is not evidence that the facility engaged in inappropriate practices. RR at 7. However, the facility had the burden of proving that it engaged in appropriate practices, and it does not point us to any evidence that Nurse Humphrey's statements misrepresented the facility's actual pre-survey practices.

For the foregoing reasons, we affirm the ALJ's conclusion that the facility was not in substantial compliance with section 483.25(c) during the April survey.

4. The facility has failed to allege any grounds to disturb the ALJ's conclusion that the facility was noncompliant with 42 C.F.R. § 483.75.

Under tag F490, the state survey agency cited the facility for noncompliance with section 483.75, which states in its prefatory paragraph that a facility "must be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident." The Board has held that a determination that a SNF failed to comply substantially with section 483.75 may be derived from findings that the SNF was not in substantial compliance with other participation requirements. Life Care Center at Bardstown, DAB No. 2233, at 28 (2009); Britthaven, Inc. d/b/a Britthaven of Smithfield, DAB No. 2018, at 22 (2006).

After noting that the facility had failed to present any argument about the merits of the deficiency finding under tag F490, the ALJ found that the noncompliance cited under tags F157 and F314 the survey findings alleging noncompliance with sections 483.10(b)(11) and 483.25(c) - established that the facility had not been administered effectively to help Resident 13 attain her highest practicable well-being. ALJ Decision at 19. Although the facility had policies or "systems" to help ensure that residents received adequate treatment, the ALJ found that those systems "were not effective to prevent" the regulatory violations cited under tags F157 and F314. Id. For those reasons, the ALJ concluded that the facility was not in substantial compliance with section 483.75 during the April survey and that this noncompliance was at the immediate jeopardy level on April 6 and 7. Id.

In this appeal, the facility "asserts that, to the extent the Board agrees . . . that Tags F157 and F314 should not have been cited at the immediate jeopardy level, then to cite Tag F490 at the immediate jeopardy level would not be appropriate, and [the ALJ's] decision upholding such an immediate jeopardy citation with respect to Tag F490 would be an erroneous conclusion of law." RR at 8 (emphasis added). This statement does not dispute the ALJ's conclusion that the facility was noncompliant with section 483.75 during the April survey. The statement merely objects to CMS's finding that the noncompliance was serious enough to place one or more residents in immediate jeopardy. We thus affirm the ALJ's conclusion that the facility was not in substantial compliance with section 483.75 during the April survey. We add that the ALJ's conclusion, even if it were disputed, appears to be wholly justified by the circumstances. The record reveals that the facility's nursing staff neglected for almost three weeks (between mid-March and early April) to consult with a physician about deteriorating or newly appearing pressure sores, some of which were classified as severe (stage In addition, the Assistant Director of Nursing IV) wounds. advised surveyors that the facility's practice was to consult with a physician only about "open" pressure sores - a practice that the facility has neither explained nor defended. The ALJ could reasonably infer from these and the other relevant circumstances that the facility's "systems" or procedures for consulting with the physician and ensuring the well-being of residents were ineffective.

5. The ALJ properly concluded that CMS's immediate jeopardy finding was not clearly erroneous.

Immediate jeopardy is defined as a situation in which a SNF's noncompliance with one or more requirements of participation "has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident" (emphasis added). CMS's determination about the level of noncompliance must be upheld unless it is clearly erroneous. 42 C.F.R. § 498.60(c). Under the clearly erroneous standard, CMS's immediate jeopardy finding is presumed to be correct, and the SNF has a heavy burden to overturn it. Edgemont Healthcare, DAB No. 2202, at 20 (2008) (citing cases); Daughters of Miriam Center, DAB No. 2067, at 7 (2007). We agree with the ALJ that the facility failed to carry its heavy burden of showing clear error in CMS's immediate jeopardy finding.

The facility objects to the immediate jeopardy finding on several grounds (RR at 9-22), some of which we have already rejected on the merits as unsubstantiated or unpersuasive. The facility contends, for example, that the immediate jeopardy finding was based on the "flawed assumption" that the right heel pressure sore "deteriorated" after February 12. RR at 9-12. The facility contends that the right heel pressure sore was, in fact, "stable" between February 12 and the April survey and that Resident 13's physician was aware of the condition of her right foot and ankle throughout that period. The facility also contends that Resident 13's pressure sores were "appropriately treated." RR at 20-21. In addition, the facility reiterates its argument that the SOD improperly attributed to Nurse Humphrey a comment that the facility would notify a physician only when a pressure sore was an "open" wound. RR at 16, 19. We have already determined that substantial evidence supports the ALJ's findings rejecting these contentions.

We briefly address the facility's other contentions on this issue, none of which are persuasive. First, the facility contends that the immediate jeopardy finding was based on the erroneous factual assumption that Resident 13 had no pressure sores upon her readmission to the facility on February 11 but developed one on her right heel shortly after readmission. RR at 9, 12-15. In support of this contention, the facility points to an "immediate jeopardy worksheet" prepared by one of the surveyors. RR at 14 (citing P. Ex. 5). However, the worksheet does not even imply, much less state, that the appearance of a facility-acquired pressure sore on February 12 was the basis for the immediate jeopardy finding. In chronological fashion, the worksheet cites periodic measurements and other observations of the right heel pressure sore between February 12 and the April survey as well as the measurements and observations of the additional pressure sores that appeared during March. P. Ex. 5, at 4. That chronological presentation suggests that the surveyors based their immediate jeopardy finding on the facility's deficient response to the evolving circumstances after February 11, and not on a finding that the facility failed to prevent the right heel pressure sore.⁶

The facility asserts that the SOD inaccurately states that the right heel pressure sore had *continually* declined after Resident 13's readmission on February 11. RR at 15-16 (citing P. Ex. 1, at 3, 18, 54, 77-78). In support of this contention, the facility points to treatment records showing that this wound contracted slightly from 5 cm x 4 cm on March 13, to 5 cm x 3 cm on March 26. Id. The facility also contends that the SOD incorrectly reported that the right heel pressure sore was 8 cm x7 cm on April 6. RR at 16. The facility accurately notes that other measurements taken on that date indicate that this pressure sore was smaller than 8 cm \times 7 cm. See, e.g., P. Ex. 1, at 19-20 (indicating that the right heel pressure sore measured 4 cm x 4 The facility does not explain how or why these facts or cm). discrepancies necessarily undermine CMS's judgment that the noncompliance had caused, or was likely to cause, serious harm, impairment, or death. The measurement discrepancies do not obviate the fact that the right heel pressure sore deteriorated from stage II to stage IV during the period at issue. Furthermore, the facility does not acknowledge that Resident 13 developed additional pressure sores during the relevant period, one of which was classified as a stage IV wound.

The facility asserts that the SOD inaccurately attributed a statement to its medical director, James E. Zini, D.O. RR at 17. According to the SOD, Dr. Zini stated in an April 9 interview that it appeared to him that the facility's "system" for treating and preventing pressure sores "fell apart." P. Ex. 1, at 76. The facility now suggests that CMS should have given this statement no weight or significance in light of Dr. Zini's affidavit. However, Dr. Zini merely indicates in that affidavit

⁶ The SOD seems to indicate that Resident 13 was readmitted on February 11 without a pressure sore on her right heel. P. Ex. 1, at 17 (¶ b). However, hospital and facility records indicate that Resident 13 had a stage II pressure sore on her right heel upon readmission. P. Ex. 3, at 22, 60. As we have indicated, any dispute about the existence of a pressure sore on February 11 is immaterial because the noncompliance in this case relates to post-February 11 lapses in the facility's care of Resident 13.

that he did "not recall" stating that the "system had fallen apart." P. Ex. 12. He did not contradict or deny making the statement. Id.

The facility cites other alleged inaccuracies in the SOD and immediate jeopardy worksheet. RR at 14-17. We have carefully considered the facility's assertions about those alleged inaccuracies but find that they are meritless or immaterial and need no discussion. The facility fails to explain how the other alleged inaccuracies render CMS's immediate jeopardy finding clearly erroneous.

Finally, the facility asserts that there was no causal connection between its noncompliance and Resident 13's condition. RR at 21-22. "[I]n order for an immediate jeopardy citation to be appropriate," says the facility, "[Resident 13's] condition would have to rise to the level of harm dictated by the immediate jeopardy criteria and the Nursing Center's non-compliance with applicable federal regulations would have to be the cause therefore." Id. (italics in original). The facility asserts that this is not the case because Resident 13 had a pressure sore upon her February 11 readmission to the facility and because she was also "suffering from several other serious conditions" during the two months leading up to the April survey. RR at 22 (citing P. Ex. 3, at 20).

The facility's causation argument suggests that Resident 13 suffered no actual harm from the noncompliance. This suggestion overlooks the deterioration of the right heel pressure sore and the appearance of new pressure sores in March. CMS could reasonably have concluded, based on the survey findings, that Resident 13 suffered serious actual harm when the right heel pressure sore deteriorated from stage II to stage IV or when she developed new pressure sores, one of which was a stage IV wound, on the right foot and ankle. The facility's causation argument also overlooks the fact that CMS may find immediate jeopardy even if the noncompliance has not caused actual harm; CMS may find immediate jeopardy if the noncompliance is "likely to cause" serious injury, harm, impairment, or death. The facility has simply failed to demonstrate that its noncompliance - namely, its inattention or inadequate response to certain pressure sores on Resident 13's right foot and ankle after February 12 - was not likely to cause serious harm, impairment, or death. As the facility indicates, Resident 13's condition was fragile during the relevant period. It is reasonable to think that a resident in that condition might be acutely vulnerable to the complications - such as infection or even death - which can result from untreated or inadequately treated pressure sores.

SOM Appendix PP (tag F157) (discussing the potential complications from a pressure sore).

For all of the reasons discussed above, we affirm the ALJ's conclusion that CMS's immediate jeopardy finding was not clearly erroneous.

Conclusion

The ALJ Decision is supported by substantial evidence and free of legal error.

/s/ Judith A. Ballard

/s/ Sheila Ann Hegy

/s/

Stephen M. Godek Presiding Board Member