Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

In the Case of:	DATE: April 3; 2009
Gooding Rehabilitation & Living Center,	
Petitioner,	Civil Remedies CR1834 App. Div. Docket No. A-09-04
- v. -	Decision No. 2239
Centers for Medicare & Medicaid Services.	

FINAL DECISION AND PARTIAL REMAND ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Gooding Rehabilitation & Living Center (Gooding, Petitioner), appeals the August 26, 2008, decision of Administrative Law Judge (ALJ) Richard J. Smith. Gooding Rehabilitation & Living Center, CR1834 (2008) (ALJ Decision). Following an evidentiary hearing and post-hearing briefing, the ALJ sustained the determination by the Centers for Medicare & Medicaid Services (CMS) that from September 14 through November 6, 2006, Gooding was not in substantial compliance with 42 C.F.R. § 483.25(c), one of the federal requirements governing the participation of long-term care facilities in the Medicare and Medicaid programs. That regulation requires, in relevant part, that a facility ensure that a resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing.[1] The ALJ Decision concerns a

[1] The regulation also requires that when a resident enters the facility without pressure sores, the facility ensure that the

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resident of Gooding's facility who had a pressure sore upon readmission. Over an 11-day period, the pressure sore worsened to the point that the resident needed surgery to treat it, and the resident died during surgery. The ALJ determined that Gooding's noncompliance posed immediate jeopardy for the period September 14, 2006 through November 6, 2006 and sustained the remedies that CMS imposed: a $3,050 per-day civil money penalty (CMP) totaling $164,700; a Denial of Payment for New Admissions (DPNA) from October 19, 2006 through November 6, 2006. The ALJ also upheld the State's suspension of Gooding's Nurse Aide Training and Competency Evaluation Program (NATCEP) for two years, effective September 14, 2006, as a consequence of these remedies.

On appeal Gooding argues, as it did before the ALJ, that the sore was not a pressure sore, its worsening was unavoidable, and that Gooding provided all necessary care and treatment to the resident. For the reasons set out below, we sustain the ALJ's determination that Gooding was not in substantial compliance with section 483.25(c) and that CMS had a basis to impose a CMP and DPNA. However, we conclude that the immediate jeopardy was abated on September 14, 2006, and thus reverse the ALJ's determination that the noncompliance posed immediate jeopardy for the period September 15 through November 6, 2006, and remand for the ALJ to determine a reasonable amount for the CMP during that period. We sustain the other remedies.

Applicable Legal Provisions

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

(continued)
resident does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable. However, that requirement is not at issue here.

A long-term care facility found not to be in substantial compliance is subject to various enforcement remedies, including a per-day CMP. 42 C.F.R. §§ 488.402(c), 488.408. For noncompliance determined to pose immediate jeopardy, CMS may impose per-day CMPs that range from $3,050 - $10,000 per day. 42 C.F.R. § 488.408(e)(2)(i),(ii). For noncompliance at less than the immediate jeopardy level, CMS may impose a per-day CMP of $50-3,000 per day. 42 C.F.R. § 488.408(d)(1)(iii). 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. "Immediate jeopardy" is defined as "a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301. CMS may also impose a DPNA when a facility is not in substantial compliance. 42 C.F.R. §§ 488.406 and 488.408, 488.417(a). When CMS imposes a CMP of $5,000 or more or a DPNA or finds noncompliance constituting substandard quality of care, the facility cannot be approved to offer NATCEP. 42 C.F.R. § 483.151(b)(2).

The applicable program requirement at issue here, codified at 42 C.F.R. § 483.25(c), addresses the prevention and treatment of pressure sores (also known as pressure ulcers).[2] This case involves subparagraph (2) of section 483.25(c), which provides in relevant part:

> (c) Pressure sores. Based on the comprehensive assessment of a resident, the facility must ensure that-
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> * * * *
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> (2) A resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing.

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[2] The State Operations Manual (SOM), CMS's interpretive guidelines for surveyors, states that "[a]lthough the regulatory language refers to pressure sores, the nomenclature widely accepted presently refers to pressure ulcers, and the guidance provided in this document will refer to pressure ulcers." SOM, App. PP, at F314. In this decision, the two terms are interchangeable.

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; Batavia Nursing and Convalescent Inn, DAB No. 1911, at 7 (2004), aff'd, Batavia Nursing & Convalescent Ctr. v. Thompson, 143 F. App'x 664 (6th Cir. 2005).

Case Background[3]

Resident 1, who was 81 years old at the time of the events leading to the survey, was originally admitted to Petitioner's facility on October 29, 2002 with diagnoses including coronary artery disease, organic brain syndrome with dementia, emphysema, aortic abdominal aneurysm, atrial fibrillation, benign prostatic hypertrophy, peripheral vascular disease, and peptic ulcer disease. ALJ Decision at 7, citing CMS Exhibits (Exs.) 15, at 40; 29, at 4-5. On July 29, 2006, Resident 1 underwent an above-the-knee amputation of his right leg, related to his peripheral vascular disease, at St. Luke's Magic Valley Regional Medical Center; he was readmitted to Gooding on August 1, 2006. On August 29, 2006, Resident 1 was readmitted to St Luke's and underwent a revision of the right above-knee amputation stump, which had developed sepsis and multiple areas of deep necrotic tissue.

Following that procedure, Resident 1 was readmitted to Gooding on September 1, 2006, with "open areas" to his coccyx and right inner thigh. ALJ Decision at 11. Gooding's records for that date describe the open area on the resident's coccyx as a Stage II pressure ulcer that was 0.5 by 3.5 cm and .1 cm deep, pink in color, with no drainage or odor, no tunneling, and with no signs or symptoms of an infection. Id. citing CMS Ex. 15, at 120 ("Skin Impairment" sheet), 186 ("Skin at Risk Actual" sheet, which the parties stipulated was part of the resident's care plan

[3] The information in this section is drawn from the ALJ Decision and the record and is presented to provide a context for the discussion of the issues raised on appeal. Nothing in this section is intended to replace or modify the ALJ's findings of fact or conclusions of law.

(CMS Exs. 30, 31)). At that time, the facility assessed the resident as at a high level of risk for skin problems and a physician ordered "careful skin care." Id. at 10, citing CMS Ex. 15, at 136, 181. Interventions listed for the coccyx wound on September 1 included a daily skin check, a two-hour turning schedule, positioning the resident off of his back, the use of an "air loss mattress," and catheter care every shift and as needed. Id. at 181, 183. On September 5, 2006, a physician gave telephone orders for a "low air loss mattress replacement system." CMS Ex. 15, at 137.

A "Skin Impairment" sheet of September 4, 2006 describes the coccyx ulcer as having a necrotic area measuring 4 x 2 cm out of a 5 x 2 cm area. Id. at 120. A nurse's note on September 6, 2006 describes the coccyx wound as "necrotic and larger than prior to hospitalization." ALJ Decision at 9, 11, citing CMS Exs. 9, at 3; 15, at 71.

On September 11, 2006, at around 10:00 p.m., Gooding sent Resident 1 to the emergency room of nearby Gooding County Memorial Hospital because he had tachycardia and hypotension. A certified physician assistant at the hospital noticed a purulent odor emanating from the resident. After the dressing over the wound was removed, the physician assistant described the wound as large, around 6" in diameter, appearing necrotic with blackened tissue, with a very foul odor, and at stage 3 to 4. Transcript of Hearing (Tr.) at 117-23; ALJ Decision at 12, citing CMS Ex. 15, at 40-42. On September 12, 2006, Resident 1 was transferred to St. Luke's Magic Valley Regional Medical Center for treatment of the large infected coccyx ulcer, a right thigh ulcer, and his infected non-healing right above-knee amputation. There, a physician described the coccyx ulcer as "a large, very foul smelling, obvious stage 4 sacral decubitus ulcer measuring 10 x 15 centimeters with overlying skin gangrene," and advised that the resident needed "aggressive wound debridement of his sacral and thigh decubitus ulcers." ALJ Decision at 12, citing CMS Ex. 15, at 99. However, on September 14, 2006, the resident developed severe hypotension in the operating room and died; the cause of death was listed as perioperative myocardial infarction due to surgery for sacral decubitus ulcer. ALJ Decision at 12-13, citing P. Ex. 6, at 1 (death certificate).

The Idaho Department of Health and Welfare (IDHW, State survey agency) conducted a complaint survey of Gooding on September 14, 2006 and found that that Gooding violated the pressure sore regulation at 42 C.F.R. § 483.25(c) because it failed to adequately assess, and appropriately intervene, to prevent further deterioration of the pressure ulcers on Resident 1's

coccyx and right thigh. IDHW further determined that Gooding's noncompliance posed immediate jeopardy to resident health and safety.[4]

IDHW informed Gooding in a letter dated September 28, 2006 that-

> [o]n September 14, 2006 [date of the survey], the facility submitted a credible allegation that the immediate jeopardy was corrected. After review of your Plan of Correction, it was determined that the immediate jeopardy to the residents had been removed. However, the deficiencies as identified on the revised CMS Form 2567L remain.

CMS Ex. 12, at 1. IDHW further stated that based on the deficiencies and on Gooding's history of noncompliance, IDHW was recommending that CMS impose the remedies of termination of Gooding's Medicare provider agreement, a DPNA, and a CMP of $3,050 per day effective September 14, 2006.

CMS agreed with IDHW's deficiency findings in a letter to Gooding dated October 4, 2006. CMS Ex. 14. CMS's letter also stated that-

> [t]he survey team found and notified you that the most serious deficiency constituted immediate jeopardy (Severity/Scope = J) to resident health and safety and substandard quality of care. By the conclusion of the survey, the state survey team determined that the deficiency was sufficiently improved to abate the immediate jeopardy.

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[4] IDHW also determined that Gooding, in its treatment of Resident 1, failed to comply substantially with regulations addressing neglect of residents and the treatment of residents with urinary incontinence, at levels of scope and severity that did not pose immediate jeopardy. 42 C.F.R. §§ 483.13(c), 483.25(d). The ALJ did not address those two deficiency findings, because he found that the remedies that CMS imposed were justified by the presence of the immediate jeopardy level deficiency under section 483.25(c). ALJ Decision at 2, n.2. On remand, the ALJ should consider these findings to the extent necessary for him to determine a reasonable CMP amount for the period of noncompliance following abatement of the immediate jeopardy.

Id. at 1. The letter instructed Gooding to submit a Plan of Correction within 10 days and to correct all the deficiencies no later than November 28, 2006. The letter also stated that, among the remedies imposed, CMS intended to seek a $3,050 per day CMP starting September 14 for the immediate-jeopardy level pressure sore deficiency. Id. at 2. Gooding apparently submitted a plan of correction on October 12, 2006. See CMS Ex. 1 (survey report and POC). Based on IDHW's site visit on December 14, 2006, CMS determined that Gooding was in substantial compliance as of November 7, 2006. CMS Ex. 17.

The ALJ Decision and Gooding's appeal

The ALJ found that the ulcers on Resident 1's coccyx and thigh grew worse while the resident was at Gooding during the period September 1 through 11, 2006, "culminating in his hospitalization and the final surgery to debride the wounds" during which the resident died. Focusing on the ulcer on the resident's coccyx, which he found was a pressure ulcer (rejecting Gooding's argument that it was not), the ALJ found that from September 1 through 11, 2006 the coccyx skin "deteriorated into a very large and deep wound with extensive central necrosis." ALJ Decision at 18-19. The ALJ cited the testimony of the certified physician assistant who examined the resident at the emergency room that the coccyx wound was the worst he had ever seen, with necrotic, blackened, dead tissue and the sacrum visible through the wound. Id. at 18, citing Tr. at 123.

The ALJ then found that despite the coccyx ulcer being observed to have become necrotic as early as September 4 (and again on September 6), there was little documentation of the ulcer after September 9, 2006, when the Director of Nursing (DON) checked the wound, but did not document any assessment of it. Id. at 19, citing Tr. at 214. Despite Resident 1 having an order for "careful skin care" there was no evidence, the ALJ found, that staff actually saw the coccyx sore between September 9 and 11, 2006. Id. On September 11 at about 8:30 p.m., when Gooding staff noted that the coccyx ulcer was very foul smelling, they neither investigated the odor nor told the emergency room about it or about the resident's sores, transferring him instead for other reasons.[5] Id. at 15, 19.

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[5] The odor was reported in an entry to the nurse's notes at 10:50 p.m., after the resident had been taken to the emergency room. ALJ Decision at 15, citing CMS Ex. 9, at 1.

The ALJ also determined that Gooding should have contacted the resident's physician when the coccyx ulcer was seen to be necrotic on September 4, citing the testimony of the surveyor that necrotic tissue warranted a phone call to the physician for further instructions and perhaps a change in his plan of care, and the testimony of Gooding's expert physician witness that it was important to watch such necrosis. Id. at 19, citing Tr. at 211-12, 640-41. Finally, he determined that Gooding should have, but had not, apprised emergency room staff of the coccyx ulcer when Gooding transferred the resident on the evening of September 11, 2006, for tachycardia and hypotension. The ALJ noted that shortly after the resident arrived at the emergency room, his coccyx ulcer was described as "purulent," "rotting," and "very foul." Id. at 15, citing Tr. at 118, 121.

The ALJ thus determined that "Petitioner's failure to more carefully assess the development of the [coccyx] wound and contact Resident 1's physician when necrotic tissue developed, or to give an accurate assessment of Resident 1's condition to the emergency room given the state of Resident 1's skin issues, persuades me that Petitioner failed to furnish what was necessary to treat Resident 1's existing sores." Id. at 19. The ALJ held that Gooding had failed to "go beyond merely what seems reasonable to, instead, always furnish what is necessary to prevent new sores unless clinically unavoidable, and to treat existing ones as needed," as the Board has held is required to comply with section 483.25(c). ALJ Decision at 6-7, 18, citing Koester Pavilion, DAB No. 1750, at 30, 32 (2000). The ALJ Decision identifies two findings of fact and conclusions of law (FFCLs), which Gooding appeals:

> A. Petitioner was out of substantial compliance with the participation requirement at 42 C.F.R. § 483.25(c), Tag F314, and its noncompliance with the requirement constituted immediate jeopardy.
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> B. The remedies imposed are reasonable.

ALJ Decision at 6, 20.

Gooding's primary argument on appeal, as before the ALJ, is that the ulcer on Resident 1's coccyx was not a pressure ulcer but a "stasis ulcer," the onset and worsening of which were unavoidable results of the severe peripheral vascular disease that led to the amputation of Resident 1's right leg. Gooding also argues, as it did below, that the resident received all necessary care and treatment at Gooding. Gooding further argues that it was subject to a burden of proof that violated federal law. We address these arguments below.

Analysis

1. Requiring Gooding to prove that it was in substantial compliance with the regulation was not contrary to the Administrative Procedure Act

The Board has long held that in an ALJ proceeding, CMS must make a prima facie showing as to any disputed allegations that the nursing facility was not in substantial compliance, and that if CMS makes a prima facie case, the facility must prove by a preponderance of evidence that it was in substantial compliance.[6] Batavia Nursing and Convalescent Inn; Hillman Rehabilitation Center, DAB No. 1611, at 6 (1997), aff'd, Hillman Rehabilitation Ctr. v. U.S. Dep't of Health & Human Servs., No.98-3789 (GEB) (D.N.J. May 13, 1999). Gooding argues that requiring it to prove that it was in substantial compliance violates the requirement in the Administrative Procedure Act (APA) that "[e]xcept as otherwise provided by statute, the proponent of a rule or order [at a hearing] has the burden of proof." 5 U.S.C. § 556(d). The Board however has considered and rejected that identical argument on several occasions. Essentially, the Board has observed that the facility appealing a CMS finding of noncompliance with program requirements is the "proponent of an order" from the government certifying that it is in substantial compliance with SNF requirements, so that it may continue to participate in the Medicare program with no restrictions on payment. Batavia at 15-20; see also Sanctuary at Whispering Meadows, DAB No. 1925, at 14-17 (2004), aff'd, Sanctuary at Whispering Meadows v. Thompson, 151 F. App'x 386 (6th Cir. 2005); Hillman at 17. Gooding provides no reason to

[6] Although the ALJ did not separately address the issue, CMS's unrebutted evidence that the pressure sore on Resident 1's coccyx worsened significantly at Gooding, which we discuss below, established a prima facie case of a violation of section 483.25(c)(2) and shifted to Gooding the burden to establish that it was in substantial compliance. See, e.g., Woodland Village Nursing Center at 15, and n.9 (upholding ALJ finding of a deficiency where the prima facie case was established by undisputed evidence that pressure sore worsened); Clermont Nursing and Convalescent Center DAB No. 1923, at 8-10 (2004), aff'd, Clermont Nursing & Convalescent Ctr. v. Leavitt, 142 F. App'x 900 (6th Cir. 2005) (sustaining a deficiency where the ALJ observed that a prima facie case may be established by showing that a resident had a pressure sore that worsened or became infected).

reconsider in this case the Board's analyses in those decisions. Accordingly, we adopt those analyses without repeating them here and conclude that the ALJ properly allocated to Gooding the burden of proving compliance after CMS made its prima facie case.

2. Substantial evidence supports the ALJ's determination that the coccyx wound was a pressure ulcer[7]

Gooding argues extensively that the coccyx ulcer was a stasis ulcer caused by the resident's peripheral vascular disease and that the ulcer's infection and rapid worsening were unavoidable consequences of that disease and the necrosis and gangrene that developed at the site of the resident's leg amputation. Gooding alternately argues that coccyx ulcer was a "Kennedy terminal ulcer" symptomatic of the "melt down" that the resident experienced as he neared death, including his vascular condition. See, e.g., P. RR at 11. Gooding cites among other things the opinion of its expert physician witness that the "exploded" appearance of the coccyx wound in photographs taken at the hospital and the "copious foul smelling discharge" indicated that the infection of the wound likely developed not from pressure but from "deep hematogenous spread of infection" from the amputation stump, for which the coccyx ulcer provided an exit. P. Ex. 5, at 3. Gooding also cites the testimony of the CMS expert acknowledging that a sacral ulcer could be unavoidable in a very sick person with poor perfusion of vital organs, as Gooding says was the case with Resident 1. Tr. at 319. Gooding notes that the resident had ulcers that were not over weight-bearing areas, such as an ulcer in his groin. Gooding argues that exacerbation of the coccyx ulcer seen at the hospital occurred over the course of only one or two days, which is evidence that it was not a pressure ulcer but was part of the larger peripheral disease process. Gooding argues that the ulcer's worsening could not have been prevented through interventions designed to treat pressure ulcers and that Gooding is not subject to sanction based on the requirements for the prevention and treatment of pressure sores at section 483.25(c).

The ALJ considered Gooding's arguments about the cause of the coccyx ulcer but found that it was a pressure ulcer. Substantial evidence supports his finding. Gooding's own contemporaneous records refer to the coccyx wound as a pressure ulcer, and the

[7] We confine our discussion to the ulcer on Resident 1's coccyx, as that was the focus of the ALJ's analysis and Gooding's appeal of the ALJ Decision.

certified physician assistant at Gooding County Memorial Hospital who examined the resident's coccyx wound testified that it was a pressure ulcer, and noted that it is common for pressure ulcers to develop over the sacrum. E.g. Tr. at 123, 135; CMS Ex. 15, at 186 (September 1, 2006 "Skin at Risk Actual" sheet from the resident's care plan, with box checked identifying the "actual skin problem" as "pressure ulcer" located at the coccyx). Furthermore, as found by the ALJ, Gooding records show that the facility had assessed Resident 1 as at moderate or high risk for friction and shear but that staff had trouble keeping Resident 1 off his back. CMS Ex. 15, at 36-37; ALJ Decision at 18. These statements by Gooding staff indicate that pressure played a role in the development of the coccyx ulcer.

The statement by CMS's expert physician witness that Gooding cites to the effect that a sacral ulcer could be unavoidable is irrelevant to the issue of whether the coccyx wound was a pressure sore. On that issue, CMS's expert physician witness specifically testified that he considered the coccyx wound to be a pressure ulcer, and that it would be very difficult for him to ascribe it to anything else. Tr. at 291. He also found it "extremely unlikely" that the necrosis seen in the coccyx area was caused by bacteria at the amputation site, as Gooding argues. He stated instead that a "pressure insult" could have caused the deep tissue necrosis seen at the coccyx site. Tr. at 303-04. A Vice President of Clinical Review of Gooding's parent corporation testified that the coccyx ulcer was at a pressure site, and Gooding's nurse's notes reflect that staff had trouble keeping the resident positioned off his back, as had been ordered as an intervention for the coccyx sore. CMS Exs. 9, at 1; 15, at 36-37; Tr. at 724. This indicates that the facility recognized that pressure was a factor in the ulcer's development and treatment. None of the testimony Gooding cites denies that the coccyx is a location prone to pressure sores or that pressure could have exacerbated this ulcer, regardless of the role that peripheral vascular disease may have played in its development. Thus, the record contains substantial evidence supporting the ALJ's finding that the resident had a pressure sore on his coccyx, and the ALJ properly applied the requirements of section 483.25(c)(2).

3. The ALJ's conclusion that Gooding failed to comply substantially with 42 C.F.R. § 483.25(c) is supported by substantial evidence and free of legal error

Gooding argues that its staff "did everything in their power to help and care for Resident 1," who "received all necessary care and treatment" while at Gooding. P. Request for Board Review of

the ALJ Decision (RR) at 12, 17. Gooding asserts that it changed the resident's dressing every three to five days, treating the wound with Duoderm, and that it checked the dressing for signs of infection daily. Gooding also asserts that it employed the special "air loss mattress" that had been prescribed for the resident and that it endeavored to reposition the resident every two hours, but that he would not stay positioned off his back.[8] Id. at 20-21.

That Gooding took some measures to address the ulcer on Resident 1's coccyx is uncontested but demonstrates no error in the ALJ's findings about the inadequacies of Gooding's assessments or its failures to inform the physician and hospital staff about the resident's condition. Gooding does not dispute the ALJ's finding that Gooding should have notified the resident's physician when the ulcer became necrotic on September 4, 2006 but did not. Moreover, the ALJ's finding is supported by substantial evidence. In addition to the surveyor's testimony that necrotic tissue warranted a phone call to the physician, which the ALJ cited, CMS's expert physician witness also testified that the physician should have been notified, and an LPN for Gooding who had treated Resident 1 testified that the development of necrotic tissue on September 4 was the type of change that should have been reported to his physician, and that she did not know why the physician had not been informed. Tr. at 292-93, 526. Nor does Gooding dispute that it did not apprise the emergency room staff about the resident's coccyx ulcer, much less its severity.

Gooding also does not dispute the ALJ's account of the record of Gooding's monitoring and assessments of the coccyx ulcer. As the ALJ discussed, these records show that after the ulcer was seen

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[8] The record contains conflicting evidence about whether the facility employed the "air loss mattress" prescribed for the resident. While Gooding's LPN witness had no doubt that an "air mattress" had been used before and after the resident's hospitalization that ended September 1, 2006, a surveyor reported seeing in what had been the resident's room only a mattress of the type typically used at nursing homes, and that she was unable to determine from talking with staff if or when the prescribed mattress had been used for the resident. Tr. at 210-11, 461. The ALJ Decision cites CMS's assertion regarding the surveyors' inability to verify use of the prescribed mattress, but makes no finding that the facility failed to do so. See ALJ Decision at 13. Resolving this factual issue is not necessary to our decision.

to be necrotic on September 4 and 6, there was no further documented observation of its condition save an entry in the nurse's notes, made after the resident's transfer, that the coccyx was very foul smelling on September 11 at about 8:30 p.m. Additionally, Gooding's records contain no measurements of the ulcer after September 4, 2006, despite the facility's instruction on September 1 on the resident's care plan to measure the ulcer weekly, requiring that the wound be measured on September 11, 2006. CMS Ex. 15, at 186. Moreover, the care plan required "[d]aily evaluation of dressing status and the surrounding area," and daily skin checks. Id. at 183, 186. While Gooding asserts that its nursing staff "was looking at the coccyx wound daily [except] the day of discharge," the record shows that these were observations of *the wound dressing* and not the wound itself or the skin area around the dressing. P. RR at 20; Tr. at 460-61, 493. While an LPN testified that Gooding staff "looked at the skin around" the dressing (Tr. at 460-61), the record does not document such observations. CMS Ex. 9 (nurse's notes). We agree with the ALJ that while nursing notes contain statements that the dressing was "intact to the coccyx," those statements "do not describe the wound's condition in any meaningful way." ALJ Decision at 19; CMS Ex. 9, at 1. Gooding staff were not required to remove the dressing over the wound daily. Thus, staff might not have been able to observe the whole wound area daily. However, Gooding does not dispute that it was required to check the area around the dressing daily. Merely documenting that the dressing was intact failed to describe the condition of the skin visible around the dressing. This failure violates not only the facility's own requirements in the care plan for daily skin checks and evaluation of the area around the dressing but the physician order for "careful skin care."

The gaps in the facility's documented assessments of the coccyx ulcer and the incomplete nature of the assessments that are documented are disturbing in light of the ulcer's significant worsening from September 1 through September 11, 2006. As recounted above, the stage II ulcer that on September 1 was 0.5 by 3.5 cm and pink with no odor or infection grew to 5 x 2 cm and was necrotic by September 4, and deteriorated further into the large, foul-smelling, necrotic, 6" (15.24 cm) Stage III-to-IV ulcer observed shortly after the resident's transfer to the emergency room on September 11. Gooding's failure to monitor and assess the coccyx ulcer regularly and with sufficient detail regarding its condition amounted to a failure to provide "necessary treatment and services to promote healing, prevent infection" as required by the regulation because it prevented Gooding from taking timely interventions to address the ulcer's deterioration, as did Gooding's failure to notify the physician

when necrosis was observed on September 4. Gooding's failure to monitor and assess the ulcer more carefully also caused Gooding to remain unaware of the extent to which the ulcer had grown in size and severity; Gooding staff were thus surprised to learn of the descriptions of the ulcer recorded after the resident was transferred to the emergency room on September 11, 2006. Tr. at 468, 594-95. And Gooding's failure to inform emergency room staff of the coccyx wound was also a failure to provide necessary treatment and services. Hospital staff were required to discover the serious wound for themselves and handle an unanticipated medical issue. In addition, treatment was delayed because the hospital needed to transfer the resident to a hospital equipped to address such a severe pressure ulcer.

4. Gooding's argument that the ulcer's worsening was unavoidable provides no basis to reverse the ALJ's determination that Gooding failed to comply substantially with section 483.25(c)

Gooding also argues, as it did before the ALJ, that the severe deterioration of the coccyx ulcer was unavoidable as it occurred too rapidly, during the 24-48 hours prior to the resident's transfer to the emergency room, for Gooding to have provided effective treatment. Gooding cites the testimony of CMS's expert physician witness that deep wounds such as the resident had on his coccyx can develop within 24 to 48 hours. Tr. at 335. Gooding also asserts that staff saw the coccyx ulcer two or three days prior to Resident 1's transfer to the emergency room and that the ulcer's condition had not changed since September 1. P. Response to CMS Reply to P. Request for Appeal at 30, citing Tr. at 66.[9]

Gooding's argument that the deterioration was unavoidable has no merit. Section 483.25(c) requires that a facility "ensure" that a resident with pressure sores "receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing." ALJ Decision at 6-7. To that end, as the Board has recognized, the preamble to the Notice of Final Rulemaking for section 483.25 provides that facilities "should

[9] Gooding cites "Petitioner's Exhibit 14 at 66." P. Response to CMS Reply to P. Request for Appeal at 30. Petitioner's Exhibit 14 is four pages of nurse's notes for the period September 1 - 11, 2006. It is apparent from Gooding's submissions to the Board that citations to pages of "Petitioner's Exhibit 14" refer to pages of the hearing transcript instead.

always furnish the necessary treatment and services to prevent the development of pressure sores or, at the least, to promote the healing of sores that have developed." Clermont Nursing and Convalescent Center at 9; Koester Pavilion, DAB No. 1750, at 30-31 (2000), citing 56 Fed. Reg. 48,826, at 48,851 (Sept. 26, 1991); see also Woodland Village Nursing Center, DAB No. 2172, at 13 (2008) ("[the] regulatory language on pressure sore treatment and prevention applies a particularly demanding standard, i.e., that the facility must 'ensure' healing and prevention as the outcomes of that treatment and those services unless the facility can prove with clinical evidence that a negative outcome was unavoidable despite the facility having furnished all necessary care."). Thus, as the ALJ recognized, the Board has concluded that a facility cannot claim unavoidability unless it first shows that it furnished all necessary treatment and services, which we have already concluded Gooding did not. Gooding thus cannot avoid responsibility for the deterioration of the pressure ulcer on the resident's coccyx where, among other failures, it took no action to address the increased size of the ulcer and the development of necrosis which staff observed as early as September 4 and again on September 6. The possibility that a pressure sore can worsen within one or two days in a resident with vascular problems, as CMS's expert physician witness testified, only emphasizes how important it was for Gooding to have taken action at that time and the gravity of Gooding's failure to have done so.

Gooding relies on a nurse's statement that she saw the coccyx ulcer "two or three days prior to his admission to Gooding Hospital . . . but was not concerned about it as its condition had not changed from his admission date on September 1, 2006." P. Response to CMS Reply to P. Request for Appeal at 30.[10] Gooding does not dispute the ALJ's finding that the September 9 observations of staff were not recorded in Gooding's records. Moreover, the unrecorded characterizations of the ulcer on September 9 are markedly at odds with the observations that are recorded in Gooding's and the hospitals' records. The claim that

[10] Gooding attributes that observation to the DON, but it appears that Gooding actually refers to an LPN who testified that she saw the coccyx ulcer on September 9 when she changed the resident's dressing and that there was no necrosis and it was approximately the same size as on September 1. Tr. at 667, 669. The DON, who did not testify, told the surveyors that she had observed the wound on September 9 and that it looked about the same as on September 4. Tr. at 66, 214.

the ulcer was the same size on September 9 as on September 1 or 4 and was not necrotic is inconsistent with facility records documenting that the ulcer became necrotic and grew substantially from September 1 to September 4 and was necrotic on September 6. CMS Ex. 15, at 71, 120. It is also inconsistent with the dramatic descriptions of the wound recorded after the resident's arrival in the emergency room on September 11, 2006, where it was noted to be 6" in diameter, foul-smelling, and with blackened necrotic tissue. Gooding does not address the discrepancies between the undocumented observations on September 9 and the condition of the wound as documented by other staff and by hospital records. Even if the condition of the wound was as unremarkable on September 9 as Gooding claims, that would not excuse Gooding's failure to have recorded any measurements or visual descriptions of the wound on September 11, when it was noted to have a pronounced foul odor.

In conclusion, we find that substantial evidence in the record supports the ALJ's conclusion that Gooding did not provide the care and treatment required by the regulation and thus cannot, as a matter of law, claim that the worsening condition of the pressure sore was unavoidable.

5. We sustain the ALJ's determination that CMS's finding of immediate jeopardy was not clearly erroneous, but reverse the ALJ's determination that the immediate jeopardy continued after September 14, 2006, and remand for the ALJ to determine the amount of the CMP for the non-immediate jeopardy period. We sustain the other remedies.

"Immediate jeopardy" is defined as "a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301. CMS's determination that a deficiency constitutes immediate jeopardy "must be upheld unless it is clearly erroneous." 42 C.F.R. § 498.60(c)(2); Woodstock Care Center, DAB No. 1726, at 9 (2000), aff'd, Woodstock Care Ctr. v. Thompson, 363 F.3d 583 (6th Cir. 2003). The provider bears the burden of proving that CMS's immediate jeopardy determination is clearly erroneous. E.g., Liberty Commons Nursing & Rehab Center – Johnston, DAB No. 2031 at 18-19 (2006), aff'd, Liberty Commons Nursing & Rehab Ctr. – Johnston v. Leavitt, 241 F. App'x 76 (4th Cir. 2007).

The ALJ determined that CMS's finding of immediate jeopardy was not clearly erroneous in light of Gooding's noncompliance and the fact that "the resident's wounds worsened under Petitioner's care, becoming necrotic and necessitating transfer to a hospital

and then to another hospital where he died during an operation to debride the wounds." ALJ Decision at 19-20. While Gooding says the ALJ erred in his conclusion that CMS's finding of immediate jeopardy was not clearly erroneous, Gooding makes no argument specific to the immediate jeopardy definition but merely relies on the same arguments it made as to why it should not have been cited as noncompliant, i.e., that the coccyx ulcer was not a pressure ulcer and its worsening was unavoidable. Inasmuch as we have already rejected those arguments, we can uphold the ALJ's determination on this issue without further discussion. However, we note that there can be no real dispute that the noncompliance here put Resident 1 in immediate jeopardy since Gooding's failure to adequately assess and care for Resident 1's pressure sore resulted in actual harm - his hospitalization and death during surgery.

We do not, however, uphold the ALJ's determination as to the duration of the immediate jeopardy.[11] The ALJ concluded that Gooding "was out of substantial compliance with the participation requirement at 42 C.F.R. § 483.25(c), at a level of immediate jeopardy, from September 14, 2006 through November 6, 2006," the entire period of Gooding's noncompliance, and sustained CMS's imposition of a $3,050 per day CMP for that period. ALJ Decision at 20. Gooding disputes the ALJ's conclusion, asserting, as it did before the ALJ, that the State surveyors "received a plan of correction and concluded that if there was an immediate jeopardy it had been corrected." P. Response to CMS Reply to RR at 35; P. Response to CMS Post-Hearing Br. at 51. We conclude that the record as a whole does not support the ALJ's determination that the immediate jeopardy continued during the period September 15, 2006 through November 6, 2006.

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[11] As Gooding acknowledges, NATCEP cancellation is required as a matter of law where, as here, a finding of substandard quality of care is upheld or a DPNA is imposed. P. Response to CMS Reply to RR at 38; see sections 1819(f)(2)(B) and 1919(f)(2)(B) of the Social Security Act (42 U.S.C. §§ 1395i-3(f)(2)(B), 1396r(f)(2)(B)); 42 C.F.R. §§ 483.151(b)(2)(iv), 483.151(b)(3)(ii) and (iii); see also 42 C.F.R. § 488.301. Accordingly, we uphold the ALJ's conclusion affirming the loss of NATCEP without further discussion. Based on our decision sustaining the noncompliance finding, we also sustain the DPNA. See 42 C.F.R. § 488.417 (CMS may impose a DPNA when a facility is not in substantial compliance).

As recounted above, CMS informed Gooding in a letter of October 4, 2006 that "[b]y the conclusion of the survey [September 14, 2006], the state survey team determined that the deficiency was sufficiently improved to abate the immediate jeopardy." CMS Ex. 14, at 1. The AEM Nursing Home Enforcement History (a computer printout) submitted by CMS also states unambiguously that the immediate jeopardy began and ended on September 14, 2006. CMS Ex. 19 at 1. The survey team coordinator testified on direct examination that "[t]he jeopardy was corrected" before the surveyors left the facility because "there was an examination with our surveyors . . . of residents that had existing pressure ulcers in the building to ensure that we didn't see any seriousness to the extent of the other resident before we left the building." Tr. at 54-55. The surveyor's reference to an examination of the other residents relates to one of the interventions listed in Gooding's written plan for abatement of the immediate jeopardy, which the surveyors received and accepted on September 14, 2006. CMS Ex. 1 at 7, 33. The same surveyor testified again on cross-examination that there was no longer immediate jeopardy "[w]hen they gave us an acceptable plan of correction and after we looked to make sure other residents were safe before leaving the building," although Gooding was not at that time in substantial compliance with the pressure ulcer regulation. Tr. at 98.

The ALJ did not address this compelling evidence that the immediate jeopardy was abated during the survey on September 14, 2006, and CMS does not discuss (much less dispute) any of this evidence on appeal, except to refer to the statement in the October 4 letter that CMS intended to impose a CMP of $3,050 per day starting on September 14, 2006 for the immediate jeopardy level noncompliance.[12] Neither does CMS discuss its subsequent letter, dated December 28, 2006, which states, "As we also advised you in our October 4, 2006 letter, we are assessing a $3,050 'per day' civil money penalty . . . for a total of 54 days of substantial noncompliance . . . (September 14, 2006 through

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[12] CMS argues that the CMP amount is reasonable because Gooding did not meet its burden to show that it achieved substantial compliance before November 6, 2006. CMS Br. at 22. However, the issue with respect to the duration of immediate jeopardy is not when the facility achieved substantial compliance with all requirements, but, rather, when it was found to have abated the immediate jeopardy level of its noncompliance.

and including November 6, 2006)."[13] CMS Ex. 17, at 1. We have considered the letter and find that it does not change our conclusion that the ALJ erred in upholding a CMP of $3,050 per day for the period of noncompliance after September 14, 2006.

We note at the outset that the quoted portion of the December 28, 2006 letter misstates what the October 4 letter "advised" the facility. The October 4 letter stated only that the $3,050 per day CMP "start[ed] September 14, 2006", not that it continued beyond that date. Furthermore, as indicated above, the October 4 letter clearly stated that the surveyors had found the immediate jeopardy abated by the end of the survey. Arguably CMS could have disagreed with that finding and made a finding that the immediate jeopardy continued beyond that date. However, there is no evidence that CMS rejected this state survey finding. We conclude that the weight of the evidence in the record as a whole clearly supports a conclusion that the immediate jeopardy did not continue through November 6, 2006 but, rather, was abated on September 14, 2006. Accordingly, we further conclude that the ALJ committed an error of law in finding that a CMP in the amount of $3,050 per day (an amount that exceeds the regulatory range for noncompliance at less than the jeopardy level) was reasonable for the period of noncompliance from September 15 through November 6, 2006. We reverse that finding and remand to the ALJ to determine a reasonable CMP for the period of noncompliance from September 15 through November 6, 2006 in light of our conclusion that the immediate jeopardy was abated on September 14, 2006. In making this determination, the ALJ may receive additional evidence or conduct further proceedings as necessary.

On appeal Gooding does not dispute the ALJ's decision to sustain CMS's determination that Gooding did not attain substantial compliance until November 7, 2006. That was the date CMS found the facility to be in substantial compliance based on IDHW's site visit to Gooding on December 14, 2006 and was also the date that Gooding asserted (on its Plan of Correction) it would return to substantial compliance. ALJ Decision at 20; CMS Exs. 1, 17. Accordingly, we affirm the ALJ's determination as to the duration of the period of noncompliance.

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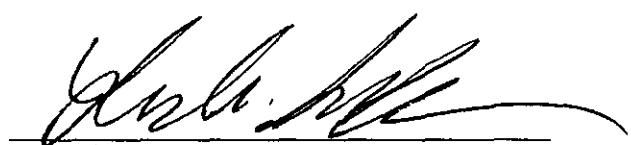
[13] The ALJ noted that CMS had sent this letter but did not address the conflict between this letter and the evidence that the immediate jeopardy was abated on September 14, 2006, including CMS's earlier letter and the surveyor testimony.

Conclusion

Based on the above analysis, we sustain the portion of the ALJ's FFCL 'A' stating that Gooding was out of substantial compliance with the participation requirement at 42 C.F.R. § 483.25(c), and modify the remainder of the FFCL to state that Gooding's noncompliance with the requirement constituted immediate jeopardy on September 14, 2006, and continued at less than immediate jeopardy through November 6, 2006. We modify his FFCL B to state that the $3,050 per-day CMP imposed for the immediate jeopardy on September 14, 2006 is reasonable, and that CMS also had the authority to impose the DPNA in light of Gooding's noncompliance. We remand the appeal to the ALJ to determine the amount of the CMP for the period during which Gooding's noncompliance did not constitute immediate jeopardy. Since we have affirmed the DPNA, the loss of NATCEP is unaffected by the remand.

Stephen M. Godek



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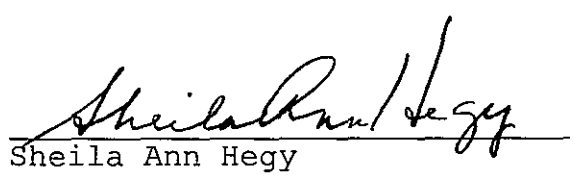

Sheila Ann Hegy
Presiding Board Member