**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Easley Living Center
(CCN: 42-5018),

Petitioner

v.

Centers for Medicare and Medicaid Services.

Docket No. C-09-87

Decision No. CR2301

Date: December 29, 2010

# DECISION

Petitioner, Easley Living Center, was not in substantial compliance with program participation requirements due to a violation of 42 C.F.R. § 483.25(c)[1] from August 30, 2008 through September 15, 2008. There is a basis for the imposition of an enforcement remedy. The following enforcement remedies are reasonable: a civil money penalty (CMP) of $3,550 per day effective August 30, 2008 through September 10, 2008; a CMP of $100 per day effective September 11, 2008 through September 15, 2008; a denial of payment for new admissions (DPNA) from September 14, 2008 through September 15, 2008; and withdrawal of the authority to conduct a nurse aide training and competency evaluation program (NATCEP).

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[1] References are to the 2007 version of the Code of Federal Regulations (C.F.R.) in effect at the time of the survey, unless otherwise indicated.

## I. Background

Petitioner, located in Easley, South Carolina, is authorized to participate in the Medicare program as a skilled nursing facility (SNF) and in the Medicaid program as a nursing facility (NF). Petitioner was subject to a complaint investigation and extended survey by the South Carolina Department of Health and Environmental Control (the state agency) on September 3, 2008. The state agency concluded, based on the findings of the investigation and survey, that Petitioner was not in substantial compliance with program participation requirements and that there was immediate jeopardy and substandard quality of care. A September 22, 2008 revisit survey concluded that immediate jeopardy was abated but that Petitioner continued not to be in substantial compliance. The Centers for Medicare and Medicaid Services (CMS) notified Petitioner by letter dated October 30, 2008, that CMS was imposing: a CMP of $3,550 per day beginning on August 30, 2008; a DPNA beginning on September 14, 2008; and discretionary termination of Petitioner's provider agreement on September 26, 2008, if the immediate jeopardy was not removed by that date. In addition, CMS indicated in the letter that any previously granted authority to conduct a NATCEP would be withdrawn. CMS advised Petitioner by letter dated November 5, 2008, that the September 22, 2008 revisit survey found the immediate jeopardy was abated, but Petitioner remained out of substantial compliance with participation requirements. CMS advised Petitioner that: it was reducing the CMP to $100 per day effective September 11, 2008; the DPNA remained in effect; and discretionary termination on September 26, 2008 was changed to mandatory termination on March 3, 2009, if Petitioner did not achieve substantial compliance prior to that date. The state agency notified Petitioner by letter dated December 2, 2008, that a revisit survey on October 20, 2008 concluded that Petitioner returned to substantial compliance with participation requirements effective September 16, 2008. Joint Stipulations dated March 4, 2009; CMS Exhibits (CMS Exs.) 1, 2, 9; Petitioner's Exhibits (P. Exs.) 1, 2.

Petitioner requested a hearing by letter dated November 6, 2008. The case was assigned to me for hearing and decision on November 19, 2008. On February 2, 2009, I set this case for hearing on June 23 through 26, 2009, in Greenville, South Carolina. On June 8, 2009, the parties filed a joint, written waiver of an oral hearing and requested that I establish a briefing schedule to develop the case for a decision on the documentary evidence and the parties' briefs. On June 11, 2009, I issued an order accepting the waiver of oral hearing subject to 42 C.F.R. § 498.66(b)(1) and set a schedule for the parties to brief the issues. CMS submitted a brief (CMS Br.) and CMS Exs. 1 through 13. Petitioner submitted a brief (P. Br.) and P. Exs. 1 through 15. Petitioner filed its reply brief (P. Reply) on August 28, 2009, and CMS waived its right to file a reply brief. No

objection has been made to my consideration of the proffered evidence and CMS Exs. 1 through 13 and P. Exs. 1 through 15 are admitted as evidence.[2]

## II. Discussion

### A. Issues

The issues in this case are:

> Whether there is a basis for the imposition of an enforcement remedy; and,
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> Whether the remedies proposed are reasonable.

### B. Applicable Law

The statutory and regulatory requirements for participation by a long-term care facility are found at sections 1819 (SNF) and 1919 (NF) of the Act and at 42 C.F.R. Part 483. Section 1819(h)(2) of the Act vests the Secretary of Health and Human Services (Secretary) with authority to impose enforcement remedies against a SNF for failure to comply substantially with the federal participation requirements that sections 1819(b), (c), and (d) of the Act established.[3] Pursuant to section 1819(h)(2)(C), the Secretary may continue Medicare payments to a SNF not longer than six months after the date the facility is first found not in compliance with participation requirements. Pursuant to section 1819(h)(2)(D), if a SNF does not return to compliance with participation requirements within three months, the Secretary must deny payments for all individuals

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[2] Petitioner argues that CMS inappropriately relies upon uncorroborated and self-serving hearsay statements of a physician and nurse at the hospital. P. Reply at 5-6. Petitioner does not advise me which document that CMS offered contains the objectionable hearsay statements. Accordingly, Petitioner has waived its objection. Notice of Case Assignment and Prehearing Case Development Order, ¶ A.5.a (Nov. 19, 2009). Further, hearsay may be admitted in this proceeding if it is relevant and authentic. I recognize the hearsay nature of most all of the documentary evidence offered and admitted in this case. I am presumed to have the ability to determine the credibility of each piece of evidence and its probative value, and I have carefully done so in this case.

[3] Section 1919(h)(2) of the Act gives similar enforcement authority to the states to ensure that NFs comply with the participation requirements that sections 1919(b), (c), and (d) of the Act established.

admitted to the facility after that date – commonly referred to as the mandatory or statutory DPNA. In addition to the authority to terminate a noncompliant SNF's participation in Medicare, the Act grants the Secretary authority to impose other enforcement remedies, including a discretionary DPNA, CMPs, appointment of temporary management, and other remedies such as a directed plan of correction. Act § 1819(h)(2)(B).

The Secretary has delegated to CMS and the states the authority to impose remedies against a long-term care facility that is not complying substantially with federal participation requirements. "*Substantial compliance* means a level of compliance with the requirements of participation 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 (emphasis in original). A deficiency is a violation of a participation requirement established by sections 1819(b), (c), and (d) of the Act or the Secretary's regulations at 42 C.F.R. Part 483, subpart B. State survey agencies survey facilities that participate in Medicare on behalf of CMS to determine whether the facilities are complying with federal participation requirements. 42 C.F.R. §§ 488.10-.28, 488.300-.335. The regulations specify the enforcement remedies that CMS may impose, if a facility is not in substantial compliance with Medicare requirements. 42 C.F.R. § 488.406.

The regulations specify that a CMP that is imposed against a facility on a per day basis will fall into one of two ranges of penalties. 42 C.F.R. §§ 488.408, 488.438. The upper range of a CMP, $3,050 per day to $10,000 per day, is reserved for deficiencies that pose immediate jeopardy to a facility's residents and, in some circumstances, for repeated deficiencies. 42 C.F.R. § 488.438(a)(1)(i), (d)(2). "*Immediate jeopardy* means 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 (emphasis in original). The lower range of a CMP, $50 per day to $3,000 per day, is reserved for deficiencies that do not constitute immediate jeopardy but either cause actual harm to residents, or cause no actual harm but have the potential for causing more than minimal harm. 42 C.F.R. § 488.438(a)(1)(ii).

Petitioner was notified that the state agency could not approve Petitioner to conduct a NATCEP and would be required to withdraw any prior approval to conduct a NATCEP based upon the extended survey and remedies. CMS Ex. 2, at 7-8. Pursuant to sections 1819(b)(5) and 1919(b)(5) of the Act, SNFs and NFs may only use nurse aides who have completed a training and competency evaluation program. Sections 1819(e) and 1919(e) of the Act impose upon the states the requirement to specify what NATCEPs they will approve that meet the requirements that the Secretary established and a process for

reviewing and re-approving those programs using criteria that the Secretary set. Pursuant to sections 1819(f)(2) and 1919(f)(2), the Secretary was tasked to develop requirements for approval of NATCEPs and the process for review of those programs. The Secretary promulgated regulations at 42 C.F.R. Part 483, subpart D.

Pursuant to 42 C.F.R. § 483.151(b)(2) and (e)(1), a state may not approve and must withdraw any prior approval of a NATCEP offered by a SNF or NF that has been: (1) subject to an extended or partial extended survey under sections 1819(g)(2)(B)(i) or 1919(g)(2)(B)(i) of the Act; (2) assessed a CMP of not less than $5,000; or (3) subject to termination of its participation agreement, a DPNA, or the appointment of temporary management. Extended and partial extended surveys are triggered by a finding of substandard quality of care during a standard or abbreviated standard survey and involve evaluating additional participation requirements. "Substandard quality of care" is identified by the situation where surveyors identify one or more deficiencies related to participation requirements established by 42 C.F.R. § 483.13 (Resident Behavior and Facility Practices), § 483.15 (Quality of Life), or § 483.25 (Quality of Care) that are found to constitute either immediate jeopardy, a pattern of or widespread actual harm that does not amount to immediate jeopardy, or a widespread potential for more than minimal harm that does not amount to immediate jeopardy without actual harm. 42 C.F.R. § 488.301.

The Act and regulations make a hearing before an administrative law judge (ALJ) available to a long-term care facility against which CMS has determined to impose an enforcement remedy. Act §§ 1128A(c)(2), 1866(h); 42 C.F.R. §§ 488.408(g), 498.3(b)(13). The hearing before an ALJ is a *de novo* proceeding. *Residence at Salem Woods*, DAB No. 2052 (2006); *Cal Turner Extended Care Pavilion*, DAB No. 2030 (2006); *Beechwood Sanitarium*, DAB No. 1906 (2004); *Emerald Oaks*, DAB No. 1800, at 11 (2001); *Anesthesiologists Affiliated*, DAB CR65 (1990), *aff'd*, 941 F.2d 678 (8th Cir. 1991). A facility has a right to appeal a "certification of noncompliance leading to an enforcement remedy." 42 C.F.R. § 488.408(g)(1); 42 C.F.R. §§ 488.330(e), 498.3. However, the choice of remedies, or the factors CMS considered when choosing remedies, are not subject to review. 42 C.F.R. § 488.408(g)(2). A facility may only challenge the scope and severity level of noncompliance that CMS determined if a successful challenge would affect the range of the CMP that may be imposed or impact the facility's authority to conduct a NATCEP. 42 C.F.R. §§ 498.3(b)(14), (d)(10)(i). The CMS determination as to the level of noncompliance, including the finding of immediate jeopardy, "must be upheld unless it is clearly erroneous." 42 C.F.R. § 498.60(c)(2). *Woodstock Care Ctr.*, DAB No. 1726, at 9, 38 (2000), *aff'd*, 363 F.3d 583 (6th Cir. 2003). The Departmental Appeals Board (Board) has long held that the net effect of the regulations is that a provider has no right to challenge the scope and severity level

assigned to a noncompliance finding, except in the situation where that finding was the basis for an immediate jeopardy determination. *See, e.g., Ridge Terrace*, DAB No. 1834 (2002); *Koester Pavilion*, DAB No. 1750 (2000). ALJ Review of a CMP is subject to 42 C.F.R. § 488.438(e).

The standard of proof, or quantum of evidence required, is a preponderance of the evidence. CMS has the burden of coming forward with the evidence and making a *prima facie* showing of a basis for imposition of an enforcement remedy. Petitioner bears the burden of persuasion to show by a preponderance of the evidence that it was in substantial compliance with participation requirements or any affirmative defense. *Batavia Nursing & Convalescent Inn*, DAB No. 1911 (2004); *Batavia Nursing & Convalescent Ctr.*, DAB No. 1904 (2004), *aff'd, Batavia Nursing & Convalescent Ctr. v. Thompson*, 129 F. App'x 181 (6th Cir. 2005); *Emerald Oaks*, DAB No. 1800; *Cross Creek Health Care Ctr.*, DAB No. 1665 (1998); *see Hillman Rehab. Ctr.*, DAB No. 1611 (1997), *aff'd*, No. 98-3789, 1999 WL 34813783 (D.N.J. May 13, 1999).

### C. Analysis

My conclusions of law are set forth in bold followed by a statement of the pertinent facts and my analysis. The surveyors allege in the statement of deficiencies (SOD) for the survey that ended on September 3, 2009, that Petitioner violated 42 C.F.R. §§ 483.25(c) (Tag F314, scope and severity (s/s) J, indicating isolated immediate jeopardy) and 483.75 (Tag F490, s/s J).[4] CMS Ex. 1, at 5-13. The SOD for the revisit survey completed on September 22, 2008, alleges the same deficiencies but at the scope and severity of D, which means isolated instances of more than minimal harm, with no actual harm or immediate jeopardy. The alleged violation of 42 C.F.R. § 483.75 (Tag F490) derives from the alleged violation of 42 C.F.R. § 483.25(c) (Tag F314), and the same facts are alleged as the basis for both deficiencies. I conclude that it is not necessary to address the alleged violation of 42 C.F.R. § 483.75, as the deficiency cited under 42 C.F.R. § 483.25(c) provides a sufficient basis for the enforcement remedies imposed in this case.

I have carefully considered all the evidence and the arguments of both parties, though not all may be specifically discussed in this decision. I discuss the credible evidence given the greatest weight in my decision-making.[5] The fact that evidence is not specifically

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[4] An alleged violation of 42 C.F.R. § 483.10(b)(11) (Tag F157, s/s J) was deleted after informal dispute resolution. CMS Ex. 1, at 2.

[5] "Credible evidence" is evidence that is worthy of belief. *Blacks Law Dictionary* 596 (18th ed. 2004). The "weight of evidence" is the persuasiveness of some evidence compared to other evidence. *Id.* at 1625.

discussed should not be considered sufficient to rebut the presumption that I considered all the evidence and assigned such weight or probative value to the credible evidence that I determined appropriate within my discretion as an ALJ. There is no requirement for me to discuss the weight given every piece of evidence considered in this case, nor would it be consistent with notions of judicial economy to do so.

**1. Petitioner violated 42 C.F.R. § 483.25(c) (Tag F314).**

**2. There is a basis to impose an enforcement remedy.**

**3. Petitioner has not shown that the determination of immediate jeopardy was clearly erroneous.**

The quality of care regulation includes the requirement that a facility ensure that a resident who enters the facility without a pressure sore does not develop one, unless clinically unavoidable, and that a resident entering with a pressure sore receives treatment and services necessary for healing, to prevent infection, and to prevent other sores from developing. 42 C.F.R. § 483.25(c). CMS has adopted definitions for terms related to the regulation that surveyors are to apply in conducting surveys. A "pressure sore," often referred to as a "pressure ulcer," is any lesion of the skin caused by unrelieved pressure that damages the underlying tissue. State Operations Manual, Interpretive Guidelines for Long-Term Care Facilities, No. 100-07, appendix PP (SOM, app. PP), Tag F314.

The application of the regulation is well-established by decisions of various appellate panels of the Board. *Koester Pavilion*, DAB No. 1750 and *Cross Creek Health Care Ctr.*, DAB No. 1665 are leading decisions in this area. The Board has noted that the pressure sore regulation contains two prongs: (1) a facility must ensure a resident who enters the facility without sores does not develop sores, unless the resident's clinical condition demonstrates that pressure sores are unavoidable; and (2) a resident with pressure sores must receive necessary treatment and services to promote healing, prevent infection and prevent new sores. With respect to prevention and treatment of pressure sores, the Board has concluded that a facility bears a duty 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." *Koester Pavilion*, DAB No. 1750, at 32; *Meadow Wood Nursing Home*, DAB No. 1841 (2002) (holding loose dressing contaminated with fecal matter constitutes violation); *Ridge Terrace*, DAB No. 1834, at 15-16 (finding a single observation by a surveyor of a nurse aide cleaning an open sore area with a stool-stained washcloth was sufficient to sustain a deficiency finding under this Tag). Once CMS establishes a *prima facie* case, the facility bears the burden of showing that the development, or deterioration, of a pressure sore was clinically unavoidable.

In *Clermont Nursing and Convalescent Ctr.*, DAB No. 1923, at 9-10 (2004), *aff'd*, *Clermont Nursing and Convalescent Ctr. v. Leavitt,* 142 Fed. App'x 900 (6th Cir. 2005), the Board provided the following analysis:

> The standard of necessity is expressly articulated in the regulation. The primary regulatory requirement is that residents must receive, and facilities must provide, "the necessary care and services" for attainment or maintenance of the highest practicable resident well-being. 42 C.F.R. § 483.25 (emphasis supplied). The regulation then goes on to provide that a resident with pressure sores must receive "necessary treatment and services" for healing, prevention of infection, and prevention of yet more pressure sores. 42 C.F.R. § 483.25(c)(2) (emphasis supplied). We therefore reject Clermont's contention that the standard is "nowhere in the regulation." That argument is belied by the plain language of the regulation.
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> Moreover, as we explained in *Koester Pavilion*, in the preamble to the final regulation, CMS expressly declined to use "less demanding" language with respect to a facility's obligation to "ensure" outcome of treatment for pressure sores. *Koester Pavilion* at 30, quoting 56 Fed. Reg. 48,826, at 48,850 (Sept. 26, 1991). CMS recognized that factors beyond required treatment and services, such as disease process and resident compliance, affect care outcome. *Id.* However, CMS also recognized that the regulation allows a facility to put forward "available clinical evidence" to show that "a negative resident care outcome was unavoidable." *Id.* The preamble further provides that facilities "should always furnish the necessary treatment and services" for pressure sore prevention or healing. *Id.* at 30-31 (emphasis supplied). Thus, a facility may provide necessary treatment and services to ensure the prevention or healing of pressure sores, yet still be confronted with a negative outcome. In that instance, the facility may put forward clinical evidence to show that the outcome was unavoidable.

*See also Woodland Vill. Nursing Ctr.*, DAB No. 2172, at 12-14 (2008).

The surveyors allege in the SOD for the September 3, 2008 survey that Petitioner violated 42 C.F.R. § 483.25(c) based upon examples of Residents 1 and 4. The surveyors specifically allege, based upon review of Petitioner's records and staff interviews, that

Petitioner failed to ensure that the residents received necessary treatment and services to promote the healing of their pressure ulcers and to prevent infections in their ulcers. CMS Ex. 1, at 5-6. I find that the surveyor's allegations are well-founded and I conclude that CMS has made a *prima facie* showing of a violation of 42 C.F.R. § 483.25(c) that Petitioner has failed to rebut.

a. Facts

Resident 1 was reported to be 78 years old when he was admitted to the Greenville Hospital System on June 16, 2008. CMS Ex. 6, at 111; P. Ex. 9, at 4. His most recent admission to Petitioner's facility occurred on November 21, 2005. CMS Ex. 6, at 11. His diagnoses included, *inter alia*: a history of cerebral vascular accident (CVA) with residual left-sided facial weakness; congestive heart failure; diabetes mellitus; hypertension; vascular dementia; peripheral vascular disease; diabetic heel ulcer; history of partial right foot amputation; cellulitis; coronary artery disease; end stage renal disease for which he was receiving hemodialysis; chronic anemia secondary to renal dialysis; and glaucoma. CMS Ex. 6, at 11, 111, 134, 144-45; P. Ex. 6, at 1, 8.

Petitioner's clinical records[6] for Resident 1 show that he developed a pressure ulcer on his left lateral foot on August 20, 2007. The wound is described as a blister and rated as a Stage II pressure sore[7] that measured approximately four by two and one-half centimeters with no depth, no odor, and no drainage. P. Ex. 6, at 38, 42; CMS Ex. 6, at 62, 106. As of October 11, 2007, the ulcer had worsened and was rated as a Stage III, three by two centimeters and one centimeter deep, with some drainage but no odor. The entry on December 27, 2007, shows that the ulcer had improved to a Stage II ulcer that was one-half by one-half centimeter with no measurable depth, no odor, and no drainage. The ulcer continued to be assessed as a Stage II, with increases and decreases in its dimensions, but no odor or drainage, between December 27, 2007 and April 9, 2008.

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[6] There are discrepancies between the residents' wound care summary reports and their pressure sore progress reports that are in evidence. I do not discuss the discrepancies as Petitioner was not cited for a documentation deficiency and the existence of the discrepancies does not affect my decision.

[7] The SOM defines the four stages of pressure sores. A Stage II pressure sore is a "[p]artial thickness skin loss involving epidermis, dermis, or both [that is] . . . . superficial and presents clinically as an abrasion, blister, or shallow crater." SOM, app. PP, Tag F314, (citing the National Pressure Ulcer Advisory Panel (NPUAP)); CMS Ex. 6, at 185-88 (Petitioner's policy contains definitions of ulcer stages similar to those in the SOM).

On April 16, 2008, the wound had worsened. Although it continued to be staged as a Stage II, one by one and one-half centimeters with no depth, it was reported to include brown tissue, and there was a small amount of drainage with an odor. On May 7, 2008, the wound had worsened and was assessed as a Stage III ulcer, two by two centimeters, one and one-half centimeters deep, brown tissue, moderate drainage with an odor. A physician's note dated May 23, 2008, indicates concern about the resident's low grade temperature and the foul odor of the foot ulcer. CMS Ex. 6, at 134. A note dated May 30, 2008, states that Resident 1's left heel ulcer did not look good, as: it was deeply necrotic; dead skin, subcutaneous tissue and tendon were excised; bone was exposed; and it could not be confirmed that he had the heel protectors previously ordered on May 16, 2008. CMS Ex. 6, at 116, 119; P. Ex. 6, at 11, 17. A bone scan of the left foot on June 9, 2008, indicated possible osteomyelitis, an infection of the bone. P. Ex. 6, at 3. On June 11, 2008, the wound was assessed as more severe at a Stage IV,[8] more than six by four centimeters and three centimeters deep. The tissue was grey, and there was moderate discharge and an odor. P. Ex. 6, at 38-41, 42-84; CMS Ex. 6, at 62-105, 106-09.

A nurse's note dated June 13, 2008, states that it was a late entry for June 13, 2008 at 6:00 a.m. The note states that the dressing was changed on Resident 1's wound, which was covered with grey slough, and that there was a moderate amount of foul smelling drainage on the old dressing. The note states the wound was cleaned and redressed. P. Ex. 6, at 114; CMS Ex. 6, at 43. A nurse's notes entry, dated June 13, 2008 at 2:00 p.m., indicates that the family reported that Resident 1 was drifting in and out, and he seemed to have passed out. The nurse checked and found that the resident was not responsive. The physician was contacted, and he ordered that Resident 1 be sent to the emergency room. Resident 1 was transported by ambulance at 2:20 p.m. P. Ex. 6, at 114; CMS Ex. 6, at 43. Petitioner admits that the 2:00 p.m. note was incorrectly dated June 13, 2008 and that it should have been dated June 15, 2008, the date Resident 1 was sent to the hospital. Petitioner also concedes that no dressing change occurred during the morning of June 15, 2008. P. Br. at 3-4; P. Reply at 2-4. Petitioner does not deny the erroneous entry on its Treatment Record or Flow Sheet (P. Ex. 6, at 105; P. Ex. 1, at 9-10; CMS Ex. 1, at 9-10) that indicates a dressing change was done the morning of June 15, 2008.

A history and physical completed on June 15, 2008, at 6:52 p.m. indicates that Resident 1 had an infected left diabetic foot ulcer with possible sepsis and an altered mental state due to that problem. Resident 1's left lower extremity was reported to be swollen with a

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[8] Stage IV is defined as "[f]ull thickness skin loss with extensive destruction, tissue necrosis, or damage to muscle, bone, or supporting structures (e.g., tendon, joint capsule). Undermining and sinus tracts also may be associated with Stage IV pressure ulcers. SOM, app. PP, Tag F314.

malodorous discharge from his wound and no sensation below the knee. P. Ex. 9, at 1-2, 7-8; CMS Ex. 6, at 140-41. A consultation on June 15, 2008, concluded that the resident would most likely need an amputation, as there was no way to salvage the left lower leg due to osteomyelitis and the necrotic ulceration. P. Ex. 9, at 11, 13; CMS Ex. 6, at 138. On June 18, 2008, Resident 1 underwent a left above the knee amputation due to the osteomyelitis of the left heel and the large ulcer on his foot that would not heal. CMS Ex. 6, at 114.

Resident 4, who was 69 at the time of the survey, was originally admitted to Petitioner's facility on April 28, 2008. CMS Ex. 7, at 69, 72. Resident 4's diagnoses included, *inter alia*, peripheral vascular disease with a history of a left below the knee amputation, diabetes with diabetic neuropathy, coronary artery disease with a history of a coronary artery bypass, hypertension, chronic obstructive pulmonary disease, and congestive heart failure that was considered stable. CMS Ex. 7, at 56, 58, 60; CMS Ex. 12, at 5. Resident 4 was admitted with a Stage II ulcer on her right heel that measured four by three and one-half centimeters with no depth measured, and it was red with a small amount of drainage and no odor. Between April 28, 2008 and August 8, 2008, Petitioner's clinical records show that the resident continued to have a Stage II ulcer that varied in size and varied in the amount of drainage from small to large amounts, but never with an odor. On August 15, 2008, the size of the wound had increased to seven by more than five centimeters by two tenths of a centimeter deep, with large serous drainage and an odor. The wound was assessed as being unchanged on August 22 and 29, 2008. CMS Ex. 7, at 5-21, 89-90; P. Ex. 7, at 26-42. The heel ulcer was evaluated at the hospital, on August 30, 2008 at 3:46 p.m., as being very malodorous and down to the bone, with pus emanating from it. CMS Ex. 12, at 6; P. Ex. 10, at 3. Resident 4 also had a smaller vascular ulcer on her right lateral leg throughout the same period. CMS Ex. 7, at 23-32, 91-92; P. Ex. 7, at 15-16, 18-25. The ulcer on the right leg was also assessed at the hospital on August 30, 2008, as being malodorous with visible pus. CMS Ex. 12, at 6-7; P. Ex. 10, at 3.

On August 30, 2008, Resident 4 was confused with low blood oxygen saturation. She was sent to the emergency room at 9:15 a.m. on August 30, and she was admitted to the hospital at 2:00 p.m. CMS Ex. 7, at 55; P. Ex. 7, at 2-4. A final Surgical Routine report, dated September 2, 2008, contains the examination of Resident 4's leg and foot and reflects gangrene with both necrotic tissue and bone visualized. P. Ex. 7, at 131-32. A discharge summary, dated September 3, 2008, shows that Resident 4's discharge diagnoses were a urinary tract infection, a necrotic and possibly infected right foot, diabetes mellitus, and that she underwent a right above the knee amputation on August 31, 2008. CMS Ex. 12, at 3-4; P. Ex. 7, at 134-35; P. Ex. 10.

b. Analysis

I have no difficulty concluding that CMS has made a *prima facie* showing of a violation of 42 C.F.R. § 483.25(c), with more than minimal harm to both Residents 1 and 4, based upon the undisputed evidence from Petitioner's clinical records. Resident 1 developed a pressure sore while at Petitioner's facility, and the sore worsened. Resident 4 was admitted with a pressure ulcer and the ulcer worsened. Above the knee amputations were performed in each case. The evidence shows that Resident 1 was admitted to Petitioner on November 21, 2005. On August 20, 2007, he developed a Stage II pressure sore on his left lateral foot. By October 11, 2007, the ulcer had worsened to a Stage III ulcer with drainage and odor. The ulcer had improved to a Stage II ulcer by December 27, 2007, evidence that the ulcer could heal. The ulcer was worse on April 16, 2008. It was evaluated as a Stage III ulcer on May 7, 2008, with drainage and odor. The ulcer was characterized as deeply necrotic with exposed bone on May 30, 2008. On June 11, 2008, the ulcer was assessed as Stage IV. On June 18, 2008, Resident 1's left leg was amputated above the knee. The evidence shows that Resident 4 was admitted to Petitioner's facility on April 28, 2008, with a Stage II ulcer on her right heel. The evidence shows that the ulcer was stable until August 15, 2008, when the size of the wound was increased, and there was drainage and an odor. On August 31, 2008, Resident 4's right leg was amputated above the knee because of gangrene and necrotic bone associated with the ulcer. These facts are not disputed.

CMS has made a *prima facie* showing of a deficiency under 42 C.F.R. § 483.25(c) (Tag F314) and that the deficiency constituted more than minimal harm to Petitioner's residents. Accordingly, the burden of persuasion is upon Petitioner to show by a preponderance of the evidence that it was in substantial compliance or that it had an affirmative defense, such as unavoidability. As already discussed, the Board has recognized that a facility may provide necessary treatment and services to ensure the prevention or healing of pressure sores, yet still be confronted with a negative outcome, in which case the facility may put forward clinical evidence to show that the outcome was unavoidable. *Clermont Nursing and Convalescent Ctr.*, DAB No. 1923, at 9-10. Petitioner fails to satisfy its burden in this case.

Petitioner argues that the CMS *prima facie* case relies upon the fact that maggots were found in the wounds of both Resident 1 and Resident 4 "several hours" after they were admitted to the hospital. P. Br. at 6. Petitioner argues that because CMS fails to identify any specific acts or omissions on the part of Petitioner the CMS case must fail. Petitioner's theory is that the presence of maggots is not conclusive evidence of wrongdoing by Petitioner because there are possible sources for the maggots other than Petitioner's facility. Petitioner asserts that CMS is attempting to impose strict liability upon Petitioner, and the Board has previously found strict liability should not be applied in these cases. P. Br. at 7. Petitioner's arguments are wrong in several respects. The CMS case is not based only upon the presence of maggots in the ulcers of the residents.

The worsening of the ulcers in each resident that Petitioner's clinical records reflect, the admitted documentation errors by Petitioner's staff, the fact that Resident 1's dressing was not changed on June 15, 2008 before he went to the hospital, and the maggots in the wound are each pieces of evidence that support the government's *prima facie* showing. The evidence cited in the SOD[9] and admitted as evidence by CMS is sufficient for a *prima facie* showing of the deficiency, even without consideration of the maggots discovered at the hospital. Further, CMS does not argue that Petitioner is strictly liable, and I do not apply a strict liability standard. Rather, Petitioner is granted the opportunity to present its defenses.

Petitioner argues regarding Resident 1 that: the pressure sore on his left foot was unavoidable; Petitioner took all appropriate steps to heal the ulcer and prevent infection; and wound changes reflected in the clinical record are consistent with appropriate treatment. Petitioner relies upon the affidavit of Toni Silver, who has a Master of Science in Nursing, is a board certified Advanced Practice Registered Nurse, and is a Certified Wound Care Specialist. P. Br. at 2-3 (citing P. Ex. 14). Nurse Silver is not a physician, and her affidavit does not reflect the special expertise or experience necessary for her to opine credibly upon whether or not the development and worsening of pressure ulcers is unavoidable. Her affidavit also fails to show how much experience she actually has in wound care. I do accept her degree and certifications as evidence that she has knowledge of wound care and is qualified to render opinions regarding appropriate wound care and the prevention of infection. However, both her affidavit and the clinical record show that Nurse Silver provided wound care for Residents 1 and 4, and it is not surprising that Nurse Silver would opine that her treatment of the residents was appropriate. Nurse Silver opines that, due to Resident 1's significant circulatory impairment, the ulcer on the left lateral foot was unavoidable. I do not find that Nurse Silver has the credentials to render a credible or weighty opinion in this regard. Even if I found Nurse Silver had sufficient experience to render an opinion regarding the unavoidability of the development or worsening of a pressure sore, her opinion here is unsupported by any citation to, or evaluation of, the clinical evidence to show how severely the resident's circulation was actually impaired, or the interventions that were implemented to address the impaired circulation to avoid the development of an ulcer or its worsening. Her opinion is also inconsistent with the evidence that Resident 1's ulcer actually improved for a time, reflecting that his circulation was not so impaired as to prevent improvement.

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[9] Additional factual findings in the SOD support the surveyor's conclusion that a deficiency existed. However, I find that discussion of those additional facts is not necessary to conclude that there was a *prima facie* showing by CMS. CMS Ex. 1, at 5-11.

Petitioner argues that the surveyor identified no failure or omission by Petitioner related to Resident 1, other than the documentation error and the failure to change the dressing on June 15, 2008. P. Br. at 4. Petitioner's argument shows that Petitioner misunderstands its burden. CMS has made a *prima facie* showing of a deficiency under 42 C.F.R. § 483.25(c), based on the worsening of Resident 1's ulcer and the related infection. Petitioner thus has the burden to show it did all that was necessary to prevent and heal the resident's ulcer. Petitioner does not meet its burden. Petitioner elected to waive an oral hearing and present its defense based upon its clinical records and a few affidavits. However, Petitioner admits before me that its clinical records are in error, and that casts doubt upon the credibility of the remainder of Petitioner's clinical records. Petitioner argues that its records show that it performed all tasks related to the care and treatment of Resident 1's pressure sore appropriately. P. Br. at 4-5; P. Reply at 3-4. I cannot agree with that conclusion, based upon the affidavit of Nurse Silver or the admittedly erroneous clinical records. Even if I agreed with Petitioner that its records show that Petitioner executed all tasks appropriately in the case of Resident 1, that does not satisfy Petitioner's burden to show that it did all that was necessary.

Regarding Resident 4, Petitioner asserts that staff appropriately treated the pressure ulcer on her right heel to promote healing and prevent infection. Petitioner asserts that changes in size and appearance were consistent with appropriate treatment. Petitioner cites the affidavit of Nurse Silver in support of its assertions. Nurse Silver states that Resident 4 had compromised circulation of the lower extremities. Although not specifically stated, as I read her affidavit, Nurse Silver's opinion is that the development and worsening of Resident 4's heel ulcer was unavoidable. I do not find that opinion credible or weighty, for the same reasons discussed above regarding her opinions related to Resident 1. Nurse Silver states that the changes in the resident's wound reflected in the clinical record may be consistent with appropriate treatment. I accept, based upon her training, that Nurse Silver may be correct that changes in the resident's ulcer reflected in the clinical record at any given time, including increased size of the ulcer or the presence of odor or drainage, may be consistent with, or at least not inconsistent with, appropriate treatment. However, Nurse Silver does not testify or even suggest that the state of the resident's ulcer when it was first seen in the emergency room on August 30, 2008, is consistent with an appropriately treated pressure ulcer.

Petitioner asserts that the only wrongdoing identified in the SOD regarding its treatment of Resident 4 was a documentation error that involved staff documenting treatment for Resident 4 the day after she went to the hospital and was not present in the facility. P. Br. at 6 (citing P. Ex. 1, at 11). Petitioner argues that the surveyors cited no other wrongdoing related to Resident 4. Petitioner also argues that it performed all tasks related to Resident 4's care and treatment appropriately. P. Br. at 6. Neither argument is persuasive for the same reasons they were not persuasive in the case of Resident 1.

Nurse Silver also opines that the signs and symptoms displayed by each of the residents when they were sent to the emergency room were completely unrelated to their pressure ulcers. I find that opinion is not credible or weighty. Nurse Silver does not have the qualifications to credibly opine as to whether symptoms, such as those displayed by the residents, may have been caused by gangrenous (dead or necrotic) tissue or bone or infection associated with the ulcer or the bone. I conclude that Nurse Silver's opinions expressed in her affidavit are insufficiently credible or weighty to meet Petitioner's burden of persuasion.

Petitioner also relies upon the affidavit of Christopher J. Patterson, M.D., a Certified Medical Director, who has been Petitioner's Medical Director since 1999. P. Br. at 8, 12; P. Ex. 15. Dr. Patterson attests that he reviewed the medical records for Resident 1 and Resident 4. Based upon his review of the records, Dr. Patterson opined that both residents suffered from vascular impairments that made development of pressure ulcers clinically unavoidable. He further opined that Petitioner did not do, or fail to do, anything that caused either resident to develop pressure ulcers or that caused their ulcers to deteriorate. He opined that the wound care provided the residents was appropriate and that nothing in the records indicates that the care provided by the facility caused, or was likely to cause, serious injury, harm, impairment, or death. He opined that the facility was not the source of the maggots in the residents' wounds.

As a medical doctor, Dr. Patterson is certainly qualified to render medical opinions. He does not attest that he was the treating physician for either resident or that he examined either resident. I do not give significant weight to his conclusory opinion that the residents' vascular impairments were so significant as to make the development of ulcers unavoidable. Dr. Patterson cites to no specific evidence upon which his opinion is based, related to studies of the residents' circulatory systems or the opinions of qualified physicians who actually examined the residents and assessed their circulation. Dr. Patterson's opinion is also inconsistent with the fact that Resident 1's ulcer improved for a time and that Resident 4's ulcer remained stable for roughly four months prior to its significant worsening. I also do not consider weighty Dr. Patterson's opinion that Petitioner did not do, or fail to do, anything that caused either resident to develop pressure ulcers or that caused the worsening of their ulcers. Dr. Patterson does not attest that he evaluated alternative interventions that were not implemented, or not fully implemented, that may have helped prevent ulcers or their exacerbation. Thus, Dr. Patterson did not assess whether or not Petitioner did all that was necessary to prevent or heal ulcers. I also do not find weighty Dr. Patterson's opinion that no care provided caused, or was likely to cause, serious injury, harm, impairment, or death, *i.e.*, immediate jeopardy. There is no dispute that the deterioration of the ulcers for both residents

necessitated above the knee amputations for both residents. Regarding his opinion that Petitioner was not the source of the maggots, whether or not Petitioner was the source of maggots in the residents' wounds does not impact my conclusion that CMS made a *prima facie* showing or my conclusion that Petitioner has failed to rebut the *prima facie* case. It also does not establish an affirmative defense.

I conclude that Petitioner also failed to show that the CMS determination that there was immediate jeopardy was clearly erroneous. The CMS determination about the level of noncompliance must be upheld unless it is clearly erroneous. 42 C.F.R. § 498.60(c). The CMS determination that there was immediate jeopardy is presumed correct, and the facility has a heavy burden to overturn it. *Stone County Nursing & Rehab. Ctr.*, DAB No. 2276, at 17 (2009); *Edgemont Healthcare*, DAB No. 2202, at 20 (2008); *Daughters of Miriam Ctr.*, DAB No. 2067, at 7 (2007). Petitioner was not in substantial compliance, because it did not show that it provided necessary care and services for Residents 1 and 4 to prevent worsening of their ulcers, to prevent infections, and to promote healing. The evidence shows that the residents' pressure sores deteriorated to such a degree that they both needed above the knee amputations. The worsening of the residents' ulcers and the amputations they suffered are clearly serious harm, and the gangrene and infections they suffered posed a serious threat such that the residents could have died. Based upon the evidence in this case, CMS's determination is not clearly erroneous.

**4. The remedies proposed are reasonable.**

I have concluded that Petitioner violated 42 C.F.R. § 483.25(c) and that the violation posed immediate jeopardy to one or more facility residents. If a facility is not in substantial compliance with program requirements, CMS has the authority to impose one or more of the enforcement remedies listed in 42 C.F.R. § 488.406, including a CMP. The regulations specify that a CMP that is imposed against a facility on a per day basis will fall into one of two ranges of penalties. 42 C.F.R. §§ 488.408, 488.438. The upper range of a CMP, $3,050 per day to $10,000 per day, is reserved for deficiencies that pose immediate jeopardy to a facility's residents and, in some circumstances, for repeated deficiencies. 42 C.F.R. §§ 488.438(a)(1)(i), (d)(2). "*Immediate jeopardy* means 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 (emphasis in original). The lower range of a CMP, $50 per day to $3,000 per day, is reserved for deficiencies that do not constitute immediate jeopardy but either cause actual harm to residents, or cause no actual harm but have the potential for causing more than minimal harm. 42 C.F.R. § 488.438(a)(1)(ii).

If I conclude, as I have in this case, that there is a basis for the imposition of an enforcement remedy and the remedy proposed is a CMP, my authority to review the reasonableness of the CMP is limited by 42 C.F.R. § 488.438(e). The limitations are: (1) I may not set the CMP at zero or reduce it to zero; (2) I may not review the exercise of

discretion by CMS in selecting to impose a CMP; and (3) I may only consider the factors specified by 42 C.F.R. § 488.438(f) when determining the reasonableness of the CMP amount. In determining whether the amount of a CMP is reasonable, the following factors specified at 42 C.F.R. § 488.438(f) must be considered: (1) the facility's history of non-compliance, including repeated deficiencies; (2) the facility's financial condition; (3) the seriousness of the deficiencies as set forth at 42 C.F.R. § 488.404(b), the same factors CMS and/or the state were to consider when setting the CMP amount; and (4) the facility's degree of culpability, including, but not limited to, the facility's neglect, indifference, or disregard for resident care, comfort, and safety. The absence of culpability is not a mitigating factor.

The factors that CMS and the state were required to consider when setting the CMP amount and that I am required to consider when assessing the reasonableness of the amount are set forth in 42 C.F.R. § 488.404(b): (1) whether the deficiencies caused no actual harm but had the potential for minimal harm, no actual harm with the potential for more than minimal harm, but not immediate jeopardy, actual harm that is not immediate jeopardy, or immediate jeopardy to resident health and safety; and (2) whether the deficiencies are isolated, constitute a pattern, or are widespread. My review of the reasonableness of the CMP is *de novo* and based upon the evidence in the record before me. I am not bound to defer to the CMS determination of the reasonable amount of the CMP to impose, but my authority is limited by regulation as already explained. I am to determine whether the amount of any CMP proposed is within reasonable bounds, considering the purpose of the Act and regulations. *Emerald Oaks*, DAB No. 1800, at 10 (2001); *CarePlex of Silver Spring*, DAB No. 1683, at 14–17 (1999); *Capitol Hill Cmty. Rehab. and Specialty Care Ctr.*, DAB No. 1629 (1997).

CMS proposed the following remedies: a CMP of $3,550 per day effective August 30, 2008 through September 10, 2008, the period of immediate jeopardy; a CMP of $100 per day effective September 11, 2008 through September 15, 2008; a DPNA from September 14, 2008 through September 15, 2008; and withdrawal of the authority to conduct a NATCEP. Petitioner asserts that the imposition of a CMP is erroneous or unreasonable. P. Br. at 14; P. Reply at 7. Petitioner does not specifically state why the CMP is unreasonable or dispute the date CMS determined that Petitioner returned to substantial compliance, except to the extent that Petitioner's position is that it remained in substantial compliance.

I have concluded that Petitioner was not in substantial compliance from August 30, 2008 through September 10, 2008, and that the noncompliance posed immediate jeopardy. Thus, a CMP in the upper range of $3,050 to $10,000 per day is authorized for each day of immediate jeopardy. 42 C.F.R. § 488.438(a)(1)(i). I have received no evidence regarding Petitioner's financial condition or a history of noncompliance. I conclude based on the evidence of record that Petitioner's noncompliance was extremely serious and resulted in serious harm to both residents. I further conclude that Petitioner was

culpable in its failure to deliver necessary care and services to prevent the significant deterioration of the residents' ulcers. The $3,550 per day CMP that CMS proposed is at the low end of the upper range, and it is not unreasonable. I also conclude that the $100 per day CMP effective September 11, 2008 through September 15, 2008, is not unreasonable given the seriousness of the deficiency after immediate jeopardy was abated, the culpability of the facility, and the fact that the per day CMP is at the low end of the lower range of authorized CMPs. 42 C.F.R. § 488.438(a)(1)(ii).

CMS had authority to impose the discretionary DPNA because Petitioner was not in substantial compliance, and I have no authority to review the choice of that remedy. 42 C.F.R. § 498.3(b)(14); 42 C.F.R. §§ 488.406, 488.408(g)(2). Petitioner's loss of authority to conduct a NATCEP and its ineligibility to be approved to conduct a NATCEP for two years following the survey are required by law due to the facts that an extended survey was conducted, a DPNA was imposed, and the CMP was $5,000 or more. Act § 1819(f)(2)(B).

## III. Conclusion

For the forgoing reasons, I conclude that Petitioner was not in substantial compliance with program participation requirements from August 30, 2008 through September 15, 2008. I further conclude that the following enforcement remedies are reasonable: a CMP of $3,550 per day effective August 30, 2008 through September 10, 2008, the period of immediate jeopardy; a CMP of $100 per day effective September 11, 2008 through September 15, 2008; a DPNA from September 14, 2008 through September 15, 2008; and withdrawal of the authority to conduct a NATCEP.

/s/
Keith W. Sickendick
Administrative Law Judge