**Department of Health and Human Services**

**DEPARTMENTAL APPEALS BOARD**

**Civil Remedies Division**

Amberwood Gardens
(CCN: 05-5750),

Petitioner

v.

Centers for Medicare and Medicaid Services.

Docket No. C-09-494

Decision No. CR2369

Date: May 6, 2011

# DECISION

Petitioner, Amberwood Gardens, violated 42 C.F.R. § 483.25(c)[1] as alleged by the survey of Petitioner's facility completed on March 30, 2009, and the violation caused actual harm. There is a basis for the imposition of an enforcement remedy. A per instance civil money penalty (PICMP) of $4,050 is a reasonable enforcement remedy.

## I. Background

Petitioner is located in San Jose, California, and participates in Medicare as a skilled nursing facility (SNF). On March 30, 2009, the California Department of Public Health (state agency) completed a survey of Petitioner's facility and found that Petitioner was not in substantial compliance with program participation requirements due to an alleged violation of 42 C.F.R. § 483.25(c). The Centers for Medicare and Medicaid Services (CMS) notified Petitioner by letter dated April 8, 2009, that it was imposing the

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[1] References are to the 2008 revision of the Code of Federal Regulations (C.F.R.) in effect at the time of the survey, unless otherwise indicated.

following enforcement remedies: a PICMP of $4,050; a denial of payments for new admissions (DPNA) effective April 23, 2009, if Petitioner did not return to substantial compliance before that date; and termination of Petitioner's provider agreement effective September 30, 2009, if Petitioner did not return to substantial compliance before that date. CMS also advised Petitioner that it could not conduct a Nurse Aide Training and Competency Evaluation (NATCEP) program for two years. CMS notified Petitioner by letter dated April 17, 2009, that a revisit survey concluded that Petitioner returned to substantial compliance effective April 13, 2009, and that the DPNA and termination remedies were rescinded.

Petitioner timely requested a hearing before an administrative law judge (ALJ) on June 3, 2009. The case was assigned to me for hearing and decision on June 8, 2009, and an Acknowledgement and Prehearing Order (Prehearing Order) was issued at my direction. On March 2, 3, and 4, 2010, a hearing was convened in San Jose, California, and a transcript (Tr.) of the proceedings was prepared. CMS offered CMS exhibits (CMS Exs.) 1 through 19 that were admitted as evidence. Tr. at 34. Petitioner offered Petitioner exhibits (P. Exs.) 1 through 13 that were admitted as evidence. Tr. at 43, 77, 598. However, for reasons discussed hereafter, P. Ex. 5 is stricken and not considered for any purpose. CMS called the following witnesses: Dan R. Berlowitz, M.D. and Surveyor Grant Maher, R.N. Petitioner called two witnesses: Nayanatara Rao, M.D.; and Mildred Canlas, R.N., Petitioner's Director of Nursing (DON). The parties filed post-hearing briefs (CMS Br. and P. Br., respectively) and post-hearing reply briefs (CMS Reply and P. Reply, respectively).

## II. Discussion

### A. Issues

The issues in this case are:

> Whether there is a basis for the imposition of an enforcement remedy; and
>
> Whether the remedy imposed is 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 (nursing facility (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 established by sections 1819(b), (c), and (d) of the Act.[2] Pursuant to 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 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 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, civil money penalties (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). "*Noncompliance* means any deficiency that causes a facility to not be in substantial compliance" with program participation requirements. 42 C.F.R. § 488.301 (emphasis in original). A deficiency refers to a facility's failure to meet or 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. 42 C.F.R. § 488.301. 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.

Petitioner was notified in this case that it would be ineligible to conduct a NATCEP for two years. 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 established by the Secretary and a process for reviewing and re-approving those programs

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

using criteria set by the Secretary. 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: (1) has been 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) has been assessed a CMP of not less than $5,000; or (3) has been 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 and there is no actual harm. 42 C.F.R. § 488.301.

The Act and regulations make a hearing before an 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. *The Residence at Salem Woods*, DAB No. 2052 (2006); *Cal Turner Extended Care*, 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(b)(13). However, the choice of remedies or the factors considered by CMS 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 determined by CMS 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 (the 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), No. 98-3789, 1999 WL 34813783 (D.N.J. May 13, 1999).

### C. Findings of Fact, Conclusions of Law, and Analysis

My conclusions of law are set forth in bold text followed by my findings of fact and analysis. The survey that ended on March 30, 2009, was a complaint survey that found Petitioner in violation of 42 C.F.R. § 483.25(c) (Tag F314) at a scope and severity level of G, indicating that the violation caused actual harm to Resident 1, the only resident involved. CMS Ex. 2.

The March 12, 2009, complaint that triggered the survey was received by the state agency from staff at the Kaiser Permanente®, Santa Clara Medical Center, where Resident 1 was admitted with unstageable wounds on his right buttock, left heel, and a Stage 4 wound to the bone on his right foot. Surveyor Grant Maher, R.N., was assigned to investigate the complaint and he conducted the survey. CMS Exs. 1, 17, at 3-4. The state agency concluded that the complaint was substantiated based on Surveyor Maher's investigation. CMS Exs. 1, 2. The SOD prepared by Surveyor Maher alleges, that Petitioner violated 42 C.F.R. § 483.25(c) and that the violation caused actual harm to Resident 1, because: (1) Petitioner failed to assess why Resident 1 put his right foot underneath his left leg causing pressure on the right foot, which caused the pressure ulcers; (2) Petitioner failed to alter treatment when the ulcers did not heal after two weeks and worsened; and (3) Petitioner failed to detect an infection in the ulcer after documenting an odor. CMS Ex. 2, at 1-2. I conclude that Petitioner did violate 42 C.F.R. § 483.25(c) and that deficiency resulted in actual harm to Resident 1.

I have carefully considered all the evidence, including the documents and the testimony at hearing, 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. [3] The fact that evidence is not specifically 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. Petitioner's violation of 42 C.F.R. § 483.25(c) resulted in actual harm to Resident 1.**

**3. There is a basis for the imposition of an enforcement remedy.**

**a. Facts**

Resident 1 was 77 years old when he was admitted to Petitioner's facility on February 9, 2008. His diagnoses included coronary artery disease and a history of cerebrovascular accident (stroke) with residual paralysis on his right side. He was incontinent of bowel and bladder and he was fed by a nasogastric tube. He was dependent on staff for all his activities of daily living (ADLs), and he was severely cognitively impaired. Resident 1 began positioning his right leg under his left leg in a way that caused pressure on the lateral aspect of his right foot. Two pressure ulcers developed on the lateral aspect of his right foot.[4] The ulcers were first observed as blisters on November 4, 2008. Ulcer 1, or Site 1 as it is referred to in Petitioner's records, was documented as two by one and one-half centimeters and one-tenth centimeter deep without odor or drainage. Ulcer 2, or Site 2, was documented as one and one-half by one and one-half centimeters without odor or drainage and intact. A physician's progress note dated December 9, 2008, described the ulcers as two quarter-sized areas of eschar. [5] Skin Integrity Sheets from November 4,

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[3] "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.

[4] Pressure ulcers are also referred to as "pressure sores" or "decubitus ulcers." State Operations Manual (SOM), app. PP, Tag 314. In this decision, I refer to the wound on Resident 1's right lateral foot variously as "pressure ulcer," "pressure sore," and "wound."

[5] Eschar is thick, leathery, black or brown in color, dead or devitalized tissue that has lost its usual physical properties and biological activity. It may be loose or firmly adhered to the wound. SOM, app. PP, Tag 314.

2008 to March 4, 2009, document a worsening of the pressure sores. By February 24, 2009, the sores had enlarged to the point that they joined, forming a single, large sore measuring ten centimeters by two centimeters, with an undetermined depth due to a covering of black eschar that was reported on that date to have a moist border and odor. Joint Stipulation of Undisputed Facts, ¶¶ 7-14.

Resident 1's Minimum Data Set (MDS) with an assessment reference date of February 6, 2009, indicates that he rarely made himself understood; he sometimes understood; he was totally dependent on staff for ADLs; he was incontinent of bowel and bladder; and he had two Stage 4 pressure ulcers. CMS Ex. 5, at 17-20. These aspects of his assessment are consistent with his Resident Assessment Protocol notes dated February 22, 2008. P. Ex. 10. When Resident 1 was admitted to Petitioner on February 9, 2008, he was assessed as having no skin problems. CMS Ex. 5, at 14. In February 2008, he was assessed as being at mild risk for developing pressure sores, but in August 2008, November 2008, and February 2009, he was assessed as being at moderate risk for pressure ulcers. CMS Ex. 5, at 16.

The evidence includes six care plans that address problems related to skin breakdown. The earliest care plan has an onset date or beginning date of February 20, 2008, shortly after Resident 1's admission. CMS Ex. 5, at 31. The second care plan begins on November 4, 2008. CMS Ex. 5, at 25. The third care plan is dated December 3, 2008. CMS Ex. 5, at 24. Both the November and December care plans address the two ulcers on Resident 1's lateral right foot. The fourth care plan dated February 5, 2009, addresses impaired skin integrity and a wound on the resident's forehead. CMS Ex. 5, at 33. The fifth care plan dated February 20, 2009, addresses a blister on the resident's left heel. CMS Ex. 5, at 32. The sixth care plan in evidence is dated March 9, 2009, the day Resident 1 left Petitioner's facility, and addresses the new ulcer on the resident's right buttock or sacrum. CMS Ex. 5, at 2.

The February 20, 2008 care plan shows that Resident 1 was assessed as at risk for skin breakdown due to immobility, incontinence, and the fact he was in bed most of the time. CMS Ex. 5, at 31. On November 4, 2008, the poor positioning of his right leg under his left leg and his annoyance with repositioning were added as problems or concerns. The care plan reflects that it was reviewed in May, August, and November 2008, and in February and May[6] 2009. The following interventions were listed: turn and reposition every two hours and as necessary; keep him clean and dry; provide pressure-relieving devices; provide adequate nutrition and hydration; refer to the physician as needed; treat and medicate as ordered; monitor and document food intake daily; laboratory testing as

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[6] Resident 1 died in March 2009, and I recognize that the May 2009 review date was a planned or scheduled review that likely did not occur.

necessary; evaluate skin daily; risk assessment with the Braden scale quarterly; clean dry linens; reduce excessive moisture; and, on November 4, 2008, the intervention of monitoring the position of the right leg was added. CMS Ex. 5, at 31.

The care plan dated November 4, 2008, reflects updates on November 12 and 18, 2008 and January 16 and 21, 2009, the latter related to an abrasion on the resident's forehead.[7] The care plan states that a problem or concern is the resident's positioning of his right leg under his left leg and the resident's annoyance with repositioning. Interventions related to the right lateral foot ulcers were: apply betadine and cover with a dry dressing every day; monitor position of leg; keep the wound sites off the bed; use heel protector at all times; and notify physician of any untoward complications. CMS Ex. 5, at 25.

The care plan dated December 3, 2008, with updates on December 4, 9, and 20, 2008 and January 6, 2009,[8] addressed the pressure ulcers on Resident 1's right lateral foot. The care plan reflects that it was reviewed on December 17, 18, 23, 2008 and January 6 and 13, 2009. The care plan notes visits by the physician and ordered interventions, including continuing to keep the site clean and dry, to continue betadine dressing, to monitor proper positioning of the right leg, and to notify the physician of complications. On December 4, 2008, there was a modification that required that the sites continue to be painted with betadine and have foam applied for protection. On December 20, 2008, the order was to continue betadine, apply Xeroform (petrolatum gauze), and cover with a dry dressing. The order to use betadine and Xeroform was continued on January 6, 2009, with no mention of using a dry dressing. CMS Ex. 5, at 24.

The care plan dated February 5, 2009, lists as a problem the resident's impaired skin integrity and lists as interventions that staff should carry-out treatment orders; monitor for signs and symptoms of infection; and notify the physician as necessary. The care plan form also includes problems or concerns dated March 1, 2009, related to an abrasion or wound on the left side of the resident's forehead; and March 9, 2009, related to the resident's altered mental state. CMS Ex. 5, at 33.

A MDS Resident Care Conference Review form dated February 10, 2009, states that Vitamin C was added to Resident 1's medications to address his wound and he was to

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[7] The dates are written "1/16/08" and "1/21/08" but, considering the context, the writing of "08" was clearly a scrivener's error. Furthermore, the entries relate to an abrasion on the resident's forehead and orders reflect that the abrasion occurred in February 2009. CMS Ex. 5, at 22.

[8] The date is written as "1/6/08" but, considering the context, the writing of "08" was clearly a scrivener's error.

have range of motion exercise three times per week. CMS Ex. 5, at 21. The physician actually ordered the Vitamin C on January 30, 2009. CMS Ex. 5, at 29.

The care plan that addressed the left heel blister is dated February 20, 2009, with an update on March 6, 2009. On February 20, the pressure sore was described as redness with a blister. On March 6, the ulcer was described as covered with a dark brown scab. The interventions listed were to apply betadine and cover with a dry dressing daily; keep load or weight off the site; keep the site clean and dry; and notify the physician of any untoward complications. CMS Ex. 5, at 32.

The care plan for the right buttock pressure sore dated March 9, 2009, described the sore as redness with purplish skin discoloration. Interventions listed were to: apply Calmoseptine®, a multipurpose moisture barrier, every shift; turn and reposition every two hours; keep the site clean and dry; and notify physician of any untoward complications. CMS Ex. 5, at 2.

The clinical record presented for my consideration includes the following physician's orders on the date or dates indicated, while Resident 1 was in Petitioner's facility:

| **Date** | **Order** |
|---|---|
| 5/1- 2/2008 | Range of motion exercises and contracture prevention by restorative nursing assistant (RNA) for upper and lower extremities.[9] CMS Ex. 5, at 28. |
| 11/4/2008 | May use heel protector at all times when in bed. Monitor placement of heel protector every shift. CMS Ex. 5, at 28. |
| 11/4/2008 | Clean blisters, site 1 and 2, on left[10] lateral foot with normal saline, pat dry, apply betadine, cover with dry dressing daily for two weeks and then reassess. May use heel protector at all times when in bed. Monitor placement of heel protector every shift. CMS Ex. 5, at 96. |
| 11/18/2008 | Clean right lateral foot with normal saline, pat dry, apply betadine, cover with dry dressing daily for two weeks and reassess. CMS Ex. 5, at 95. |
| 12/3/2008 | Clean right lateral foot with normal saline, pat dry, apply betadine, cover |

[9] An order dated August 29, 2008, required that Resident 1 wear a "right resting splint," but that splint was apparently for the right arm as the "brace" for the right leg was not ordered until December 2008. Dr. Rao, Resident 1's treating physician, was uncertain whether the splint was for the right arm or not. Tr. 171-72.

[10] This is obviously a scrivener's error as the evidence shows blisters on the right lateral foot not the left.

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| | with dry dressing daily for two weeks and then reassess. CMS Ex. 5, at 42. |
| 12/4/2008 | Clean right lateral foot with normal saline, pat dry, apply betadine, cover with dry dressing, apply foam daily for two weeks and then reassess. CMS Ex. 5, at 41. |
| 12/9/2008 | Clean right lateral foot with normal saline, pat dry, apply betadine, cover with Xeroform, cover with dry dressing daily, apply foam for protection, for two weeks and then reassess. Occupational therapy (OT) was also ordered to address the right lower leg contracture. CMS Ex. 5, at 40. |
| 12/23/2008 | Clean right lateral foot with normal saline, pat dry, apply betadine, cover with Xeroform, cover with dry dressing daily, apply foam for protection, for two weeks and then reassess. CMS Ex. 5, at 38. |
| 1/6/2009 | Clean right lateral foot with normal saline, pat dry, apply betadine, cover with Xeroform, cover with dry dressing daily, apply foam for protection, for two weeks and then reassess. CMS Ex. 5, at 37. |
| 1/19/2009 | Resident will wear right knee brace three times per day, 10 a.m. to Noon, 2 p.m. to 4 p.m., and 6 p.m. to 8 p.m. CMS Ex. 5, at 28. |
| 1/20/2009 | Clean right lateral foot with normal saline, pat dry, apply betadine, cover with Xeroform, cover with dry dressing daily, apply foam for protection, for two weeks and then reassess. CMS Ex. 5, at 36. |
| 1/30/2009 | Vitamin C, 500 milligrams, one tablet, two times each day for wound healing. CMS Ex. 5, at 29. |
| 2/4/09 | Clean right lateral foot with normal saline, pat dry, apply betadine, cover with Xeroform, cover with dry dressing daily, apply foam for protection, for fourteen days, then reassess. CMS Ex. 5, at 35. |
| 2/5/09 | Right knee flexion contractures worsening with right lateral foot necrotic eschars – inevitable/unavoidable wounds. Ok to leave foot open to air during daytime and bootie at night time. CMS Ex. 5, at 28, 35. |
| 2/5/09 | Paint right lateral foot with betadine daily, leave open to air for two weeks and then reassess. Apply booty at night time. CMS Ex. 5, at 34. |
| 2/18/2009 | Continue to paint right lateral foot with betadine daily. Leave open to air for two weeks and then reassess. CMS Ex. 5, at 22. |
| 2/20/2009 | Paint left heel blister with betadine and cover with a dry dressing every day for fourteen days and then reassess. Resident may use heel protector on left heel. CMS Ex. 5, at 22. |
| 2/26/2009 | Apply betadine to right lateral foot and cover with a dry dressing for fourteen days then reassess. Apply heel protector each shift. CMS Ex. 5, at 23. |
| 3/6/2009 | Continue to paint left heel with betadine and cover with dry dressing every day for fourteen days and then reassess. Apply Calmoseptine® to buttocks every shift. CMS Ex. 5, at 23. |
| 3/9/2009 | Apply Calmoseptine® to right buttock, Stage I sore, every shift for two |

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| | weeks then reassess. CMS Ex. 5, at 26. |

Skin Integrity Sheets refer to the ulcers on the right lateral foot as Site 1 and Site 2. First noted on November 4, 2008, Site 1 is described as a Stage II, two by one and one-half centimeters and one-tenth centimeter deep, that appeared as a dry blister, reddened, with no bleeding, and superficial skin thickness loss. The treatment was betadine dressing. On November 11, 2008, the ulcer was noted to be an undetermined stage, one and three-tenths centimeter by one and four-tenths centimeter, of undetermined depth, and it appeared as a dry blister covered with a black scab and the surrounding area was reddened. The treatment continued to be a betadine dressing. On November 18, 2008, Site 1 had increased to two by one and eight-tenths centimeters of undetermined depth and stage, covered with a dry black scab, and betadine dressing remained the treatment. No odor, necrosis, tunneling, or drainage was noted on any of these dates. CMS Ex. 5, at 78. On November 25, December 2, and December 9, 2008, Site 1 was assessed as two and one-half by two centimeters, depth and stage undetermined, covered with an intact dry, black scab, and betadine continued as the treatment. On December 9, 2008, a Xeroform dressing and dry dressing are also listed as part of the treatment. On December 16, 2008, Site 1 was larger at three by two centimeters, covered by a dry and intact black scab, and treatment was listed as betadine, Xeroform, and dry dressing. On December 24, 2008, the wound was larger at three and one-half by two centimeters, stage and depth undetermined, covered by a dry and intact black scab, and with no change in treatment. No necrosis, drainage, tunneling, or odor was noted on any of these dates. CMS Ex. 5, at 79. From December 30, 2008 through January 13, 2009, Site 1 is described as three by two and one-half centimeters of undetermined depth and stage, covered by an intact, dry, black scab, and betadine, Xeroform, and/or dry dressings are listed as the treatment. No necrosis, drainage, tunneling, or odor was noted on any of these dates. CMS Ex. 5, at 80. On January 20, 2009, Site 1 had increased in size to four by two centimeters but was otherwise unchanged. Treatment listed was betadine, Xeroform, and dry dressing. On January 27 and February 3, 2009, the wound measured five by two centimeters but the description was otherwise the same. Betadine and Xeroform were listed as treatments on January 27 but only betadine was listed on February 3, 2009. On February 10, 2009, Site 1 was measured as four and two-tenths by two centimeters and the black scab was described as having the appearance of eschar. On February 17, 2009, Site 1 was measured at five by three and one-half centimeters, still covered by a dry black scab or eschar, no bleeding, undetermined stage and depth, and betadine was listed as the treatment. No necrosis, drainage, tunneling, or odor was noted on any of these dates. CMS Ex. 5, at 81.

On November 4, 2008, Site 2 was described as a blister on the right lateral foot, Stage I, with dry skin intact, measuring one and one-half by one and one-half centimeters. The entry for November 11, 2008, describes the site as one and four-tenths by one and three-tenths centimeters, undetermined depth and stage, with a dark brown scab and reddened area around the scab. On November 18, 2008, the size of the site had changed to one and

one-half by one and two-tenths centimeters and the reddened area was described as betadine stained. No odor, drainage, necrosis, or undermining or tunneling was noted on the three days and betadine dressing was listed as the treatment. CMS Ex. 5, at 82. On November 25, the size of Site 2 was two by two centimeters. On December 2, the size was two by one and seven-tenths centimeters. On December 9, the size was reported to be two by one and eight-tenths centimeters. On December 16 and 24, 2008, the size was reported as increased to two and one-half by two centimeters. Site 2 was described as a dry, intact, black scab covering the blistered area; of undetermined depth and stage; with no odor, drainage, necrosis, undermining, or tunneling. The treatment for November 25 and December 2 was listed as betadine, with Xeroform and dry dressing added on December 9, 16, and 24. CMS Ex. 5, at 83. Site 2 measurements for December 30 were two and one-half by two centimeters. On January 6, 2009, the site measured two by two and one-half centimeters. On January 13, measurements were three by two centimeters. On January 20, the site measured three by two centimeters. On January 27, the site measured two and one-half by two centimeters. On February 3, the site measured three by two and one-half centimeters. On February 10 and 17, 2009, the site measured three and one-half by two centimeters. From December 30, 2008 through February 17, 2009, the site was described as covered by an intact, dry black scab or eschar; the wound was of undetermined depth and stage; and there was no odor, drainage, necrosis, tunneling, or undermining. The February 17, 2009 note also states that there was no bleeding. Treatments listed on various dates and in various combinations were betadine, Xeroform, and dry dressing. CMS Ex. 5, at 75-76.

Assessments dated February 24 and March 4, 2009, show that Sites 1 and 2 had merged into a single wound covered with a black scab. On February 24, the wound measured ten by three centimeters, of undetermined depth and stage, the black scab was noted to have moist margins, and there was an odor. Treatment continued to be betadine. On March 4, 2009, the wound measured nine by three centimeters, of undetermined depth and stage, with a black scab that had moist margins, slight bleeding, and odor, and the treatment was still betadine. CMS Ex. 5, at 77.

Skin Integrity Sheets also document the discovery of a Stage II ulcer on Resident 1's left heel on February 20, 2009, that was three by two centimeters. The ulcer had increased in size to six by seven centimeters on March 4, 2009. The ulcer appeared as a blister and subsequently developed a dry scab. Betadine was the only treatment listed. CMS Ex. 5, at 84. The presence of the left heel ulcer was documented at the hospital on March 10, 2009. CMS Ex. 5, at 124. The record before me does not include Skin Integrity Sheets for a right buttock pressure sore, but a care plan was prepared that reflects an onset date of March 9, 2009. CMS Ex. 5, at 2. The right sacral/buttock pressure ulcer was documented at the hospital on March 10, 2009, as three by two and one-half centimeters, covered with black eschar, and unstageable. CMS Ex. 5, at 121. The hospital also documented a two by three centimeters ulcer on the top of the left foot on March 10, 2009. CMS Ex. 5, at 122.

Interdisciplinary Progress Notes dated between August 29, 2008 and March 9, 2009, and Weekly Nursing Summaries from October 27, 2008 through March 1, 2009, are in evidence. The progress notes generally reflect that Resident 1 was being tube fed, he was being turned and repositioned, and he was receiving OT services, though the frequency of these cares and services is not consistently documented. CMS Ex. 5, at 44-74, 85-94, 101-02.

A Weekly Nursing Summary for October 27 to November 2, 2008, shows that Resident 1 could be up in his wheelchair for short periods; his position in bed needed to be changed every two hours; his skin was intact but dry and fragile; there was redness in the groin, and there was no mention of any pressure ulcer. CMS Ex. 5, at 87. A progress note at 9:00 a.m. on November 4, 2008, indicates that the CNA found a blister on the resident's right lateral foot and the nurse found two blisters on the lateral right foot when she examined Resident 1. The note states that Resident 1's physician, Dr. Rao, was contacted and she ordered application of betadine, covering with a dry dressing, and the use of a heel protector at all times. CMS Ex. 5, at 93. A note dated November 18, 2008, at 2:40 p.m. indicates that the resident's right lateral foot was reassessed. Site 1 was dry and covered with an intact black scab. Site 2 was dry and with a dark brown scab over part of the site. The surrounding area is noted to be betadine stained. The physician ordered continuation of use of betadine dressing for two weeks and then the sites were to be reassessed. CMS Ex. 5, at 85. A Weekly Nursing Summary for November 16 to 23, 2008, indicates that Resident 1 could be up in his wheelchair most of the day, he needed to change his position every two hours, his skin was intact but dry and fragile, and he had two blisters on his right lateral foot that were to be washed with normal saline, patted dry, coated with betadine, covered with a dry dressing for two weeks, then reassessed. CMS Ex. 5, at 101.

A progress note dated December 3, 2008 at 11:55 a.m., indicates that the right lateral foot was reassessed; there were two sites; both were betadine-stained; and Dr. Rao ordered to continue the betadine paint for fourteen days and then reassess. CMS Ex. 5, at 57. A note dated December 4, 2008 at 11:00 a.m., indicates that Dr. Rao saw the resident and ordered a change of treatment for the right lateral foot, but the change is not reflected in the note. CMS Ex. 5, at 57. On December 9, 2008, an 11:40 a.m. note indicates Dr. Rao saw the resident again and ordered that treatment be changed for the right lateral foot, but again the note does not reflect how treatment was changed. CMS Ex. 5, at 57. A note dated December 23, 2008 at 2:30 p.m. indicates the resident's blisters on his right lateral foot were reassessed and they were observed to be dry blisters that were betadine stained. Dr. Rao is noted to have seen the resident and she ordered that the betadine dressing be continued for another fourteen days and then reassessed. CMS Ex. 5, at 58. On December 30, 2008, a note indicates that the physician was contacted for an order for four scoops of protein powder that were added to the resident's liquid tube feeding. CMS Ex. 5, at 58.

A January 6, 2009 note at 1 p.m. indicates the resident's right lateral foot was reassessed, the two blisters were still covered with a blackish scab that was dry and intact, and the physician ordered new treatment to continue, though the note does not indicate what treatment. CMS Ex. 5, at 58. A note at 1 p.m. on January 19, 2009, reflects an order for a right knee brace. CMS Ex. 5, at 48. A note at 10 a.m. on January 20, 2009, indicates that the right lateral foot was reassessed, and the two sites were still covered by intact, dry, black scabs. Dr. Rao ordered new treatment, which was to keep the sites clean and dry and to continue betadine and Xeroform treatment for two weeks. CMS Ex. 5, at 45.

A note dated February 4, 2009 at noon, indicates that Resident 1's right lateral foot was reassessed and the two sites were still covered by intact, dry, dark brown scabs. The physician's order was to continue to treat with betadine and Xeroform and cover with a dry dressing daily for fourteen days and then reassess. The physician also ordered that the resident be kept clean and dry. CMS Ex. 5, at 46. However, a note dated February 5, 2009 at 11 p.m., states that Dr. Rao saw Resident 1 and ordered that treatment be changed to just painting the sites with betadine and leaving them open to the air, except at night when a booty was to be applied. CMS Ex. 5, at 46. A note dated February 18, 2009 at 1 p.m., shows that the right lateral foot was reassessed as still having two sites of dry black scab or eschar. The sites were dry and intact, and Dr. Rao gave a new treatment order to continue painting with betadine. CMS Ex 5, at 46. A note dated February 20, 2009 at 10:30 a.m., documents the discovery of a small, fluid-filled, intact, blister on Resident 1's left heel and the physician's order to apply betadine and cover with a dry dressing. CMS Ex. 5, at 46. A note dated February 26, 2009, indicates that Resident 1 was seen by Dr. Rao, that the two sites had merged into one covered by a black scab; that Dr. Rao had ordered a change in treatment, but how is not specified; and Dr. Rao ordered that a heel protector be applied every shift. CMS Ex. 5, at 44.

Weekly Nursing Summaries for December 28, 2008 to February 15, 2009, show that the resident was bedbound, he was to be repositioned every two hours, his skin was intact, and no new treatment was listed for the wounds on his right foot. CMS Ex. 5, at 61-74. A Weekly Nursing Summary for the period February 22, 2009 to March 1, 2009, indicates that the resident was bedbound, his position was to be changed every two hours; his skin was intact; and a new treatment listed was to apply betadine to the right lateral foot for fourteen days. CMS Ex. 5, at 7, 59.

A March 6, 2009 note indicates that the left heel was reassessed and the blister still had a dry, intact, brown scab, with a small amount of drainage. Dr. Rao gave a new treatment order to paint the left heel with betadine and to apply Calmoseptine® to the left and right buttocks as a preventive measure. CMS Ex. 5, at 44. On March 9, 2009 at about 11 a.m., a red area with purplish/bluish skin color in the middle of the site was discovered on the resident's right buttock. The note states the physician was contacted, and she gave a treatment order for the redness, but what order was received is not specified, except that the site was to be kept clean and dry. CMS Ex. 5, at 44. A note dated March 9, 2009 at 4

p.m., indicates that Resident 1 was sent to the emergency department with a rapid respiratory rate and altered mental status. CMS Ex. 5, at 44.

A physician's progress note by Dr. Rao, dated December 9, 2008, states that facility nursing staff was concerned that Resident 1was always keeping his right leg under the left; the right leg was contracted at the knee; he had non-healing eschar on the lateral aspect of the right foot despite dressings and booties; and he was not cooperative lately with activities of daily living. Dr. Rao described Resident 1's right lateral foot as having two areas of quarter-size, black eschar, not moist, no drainage, soft to touch, and touching the bed constantly with pressure of the left leg on the right foot. She ordered that the right foot be cleaned with normal saline, to apply betadine to "thicken skin to prevent breakdown;" to keep the right foot from being positioned under the left leg; to place pillows between the legs; and prevent worsening of the contracture at the knee. CMS Ex. 5, at 5-6. An OT plan of treatment dated December 15, 2008, states that Resident 1 was going to have a knee brace applied to his right knee three times per day for two hours each to prevent further contracture and that OT would be working to maintain or improve his ROM. CMS Ex. 5, at 12. OT notes dated January 13 and 14, 2009, show that Resident 1 received his knee brace and it was being used. CMS Ex. 5, at 10. An OT note dated January 19, 2009, indicates that CNA's were trained to apply the resident's knee brace and the splinting schedule was posted in the room by the nurse. CMS Ex. 5, at 9. A nurse practitioner's progress note dated February 20, 2009, states that the contracture of the right knee is increasing. CMS Ex. 5, at 30.

Resident 1 was sent to the emergency room on March 9, 2009, where he was evaluated as being nonresponsive. CMS Ex. 5, at 103. He was admitted to the hospital with a diagnosis of septic shock. He was noted to have pressure ulcers on his lateral right foot and left heel and a pressure ulcer on his coccyx. CMS Ex. 5, at 104-09. On March 11, 2009, a podiatry consult evaluated the right foot pressure ulcer as having no odor or drainage, dry eschar on most of the lateral right foot, with edema, and the examiner could probe the wound to the bone. The left heel ulcer was noted to have superficial necrosis. Osteomyelitis was diagnosed related to the right foot ulcers. It was recommended that the family consult with orthopedics regarding a below the knee amputation. The order was to continue wet to dry dressing and betadine for the wound. CMS Ex. 5, at 111. A hospital patient progress record dated March 13, 2009, indicates that Resident 1 suffered from right foot osteomyelitis and Methicillin-resistant Staphylococcus aureus (MRSA). The note indicates that the family declined a below the knee amputation of Resident 1's right leg and the family was considering changing the level of care to comfort care. CMS Ex. 5, at 133. Resident 1 died on March 15, 2009, due to sepsis secondary to osteomyelitis and bacteremia. CMS Ex. 5, at 110, 129.

### b. Analysis

#### (i) The Participation Requirement

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 care and services necessary for healing, to prevent infection and prevent other sores from developing. 42 C.F.R. § 483.25(c). CMS has adopted definitions for terms related to 42 C.F.R. § 483.25(c) 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. SOM, app. PP, Tag F314.

The Board has applied the regulation in various decisions, including *Koester Pavilion*, DAB No. 1750 and *Cross Creek Health Care Ctr.*, DAB No. 1665, which 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; *see also Meadow Wood Nursing Home*, DAB No. 1841 (2002) (noting loose dressing contaminated with fecal matter constitutes violation); *Ridge Terrace*, DAB No. 1834, at 15-16 (2002) (holding 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.

The Board 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), 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.
>
> 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 <u>always</u> furnish the <u>necessary</u> 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).

**(ii) The *Prima Facie* Showing of a Violation**

Petitioner and CMS debate in detail the treatment ordered by Dr. Rao for Resident 1. However, the parties' focus upon Dr. Rao and her selected treatment is in error. Dr. Rao was the treating physician for Resident 1 and her relationship was with Resident 1 and her responsibility was to her patient. Dr. Rao was not Petitioner's Medical Director, and there was no evidence that she was employed by or under contract to Petitioner as staff. While some evidence suggests that Dr. Rao's chosen treatment modality may not be favored by all in her profession, there is no lack of disagreement in the medical profession regarding proper treatment for complicated problems such as pressure ulcers and diabetes. But I need not resolve whether or not Dr. Rao's treatment modality was the best for Resident 1. I also need not resolve whether Petitioner's Medical Director should have intervened and challenged Dr. Rao's decision-making. Rather than question Dr. Rao's choice of treatment, the correct focus in this proceeding is upon Petitioner, the regulated entity. 42 C.F.R. § 488.26. Indeed, my jurisdiction is limited to the issues of whether or not Petitioner was in substantial compliance with program participation

requirements and whether or not reasonable enforcement remedies are proposed by CMS. 42 C.F.R. §§ 488.408(g); 498.1; 493.3(b)(13). Petitioner attempts to focus upon Dr. Rao and her chosen treatment to support its positions that the development and worsening of the ulcers was unavoidable and that Petitioner had no alternative but to follow Dr. Rao's orders. However, Petitioner cannot hide behind the physician arguing that it did all that the physician ordered. Petitioner cannot meet its burden to establish the defense of unavoidability, as I conclude that Petitioner has failed to show by a preponderance of the evidence that it provided the necessary care and treatment identified by the care planning team and specified by Resident 1's care plan.

The SOD alleges that Petitioner violated 42 C.F.R. § 483.25(c) and that the violation caused actual harm to Resident 1, because: (1) Petitioner failed to assess why Resident 1 put his right foot underneath his left leg causing pressure on the right foot, which caused the pressure ulcers; (2) Petitioner failed to alter treatment when the ulcers did not heal after two weeks and worsened; and (3) Petitioner failed to detect an infection in the ulcer after documenting an odor. CMS Ex. 2, at 1-2. The SOD clearly alleges that Petitioner violated both prongs of 42 C.F.R. § 483.25(c), i.e. Petitioner failed to provide necessary treatment and services to prevent pressure ulcers and Petitioner failed to provide necessary care and services to promote healing, prevent infections, and prevent the development of new ulcers.

Surveyor Maher testified at hearing that he cited Petitioner for a deficiency under Tag F314 because:

> [Petitioner] did not do all necessary things, to prevent the sore and then they did not do what was necessary to prevent further sores, to treat the sores he had, or to prevent infection. So, I think they failed to meet the regulation on both prevention and on treatment.

Tr. at 504. Surveyor Maher's testimony was consistent with his Declaration, in which he opined that Petitioner failed to prevent the development of Resident 1's pressure ulcers and failed to heal the pressure ulcers and prevent infection. CMS Ex. 17, at 5-7, 9-11, 12. On cross-examination, however, Surveyor Maher testified that there was a decision made in his office to have the SOD focus upon treatment of the pressure ulcers rather than their prevention. Tr. at 533-34, 547-49. Petitioner argues based on Surveyor Maher's testimony, that it was not cited for violation of both prongs of 42 C.F.R. § 483.25(c). P. Br. at 4. Counsel for CMS advised me at hearing that, regardless of the testimony of Surveyor Maher, CMS proceeds upon both prongs of the regulation and that the CMS position is that the SOD gave Petitioner adequate notice to defend against both prongs. Tr. at 551-54. Surveyor Maher's testimony was, at best, confusing. Surveyor Maher made clear that he thought Petitioner violated both prongs of the regulation and that he disagreed with others at the state agency on how to proceed. Of course, it was CMS that

imposed the PICMP in this case and it is CMS that is before me, not the state agency. Furthermore, the issue before me is whether or not there is a basis to impose the PICMP. My construction of the allegations of the SOD is that it provided Petitioner adequate notice that it needed to defend against both prongs of 42 C.F.R. § 483.25(c) and that is, in fact, what Petitioner has done. P. Br. at 4-16. Contrary to Petitioner's assertion, the disagreement was not between the surveyor and CMS, but rather between the surveyor and some unspecified persons at the state agency. Contrary to Petitioner's assertion, I do not conclude that the fact that officials at the state agency viewed the facts differently than the surveyor or CMS undermines the credibility of the charged violation of 42 C.F.R. § 483.25(c). Evidence, its weight and credibility, is often viewed differently by different individuals or parties, which partly explains why ALJs are necessary.

I have no difficulty concluding in this case that there has been a *prima facie* showing of a violation of 42 C.F.R. § 483.25(c)(1) and (2). The evidence shows that Resident 1 did not have pressure sores upon admission to Petitioner; Resident 1 subsequently developed pressure sores on his right lateral foot; Resident 1's pressure ulcers did not heal, but became infected; Resident 1 developed additional pressure sores; and the evidence shows that Petitioner failed to follow care planned interventions, which were necessary care and services to prevent and promote the healing of pressure ulcers. There is no dispute that the pressure ulcers in this case amounted to actual harm. Thus, the burden is upon Petitioner to rebut the *prima facie* showing or to establish an affirmative defense.

**(iii) Petitioner's Defense**

Petitioner does not argue that CMS failed to make a *prima facie* showing of a violation of both prongs of 42 C.F.R. § 483.25(c). Rather, Petitioner argues that the evidence shows that the development and deterioration of Resident 1's pressure ulcers were unavoidable. Tr. 66-70. Petitioner argues that the definitions of avoidable and unavoidable adopted by CMS in the SOM should be treated as establishing the elements of the affirmative defense of unavoidability. P. Br. at 5-7. The SOM sets forth CMS guidance and policy to guide and direct state survey agencies in the survey process. Guidance to surveyors for each condition for participation is set forth in the SOM, app. PP by "Tag." Although the SOM does not have the force and effect of law, the provisions of the Act and regulations interpreted clearly do have such force and effect. *Northwest Tissue Ctr. v. Shalala*, 1 F.3d 522 (7th Cir. 1993); *State of Indiana by the Indiana Dep't of Public Welfare v. Sullivan*, 934 F.2d 853 (7th Cir. 1991). Thus, while the Secretary may not seek to enforce the provisions of the SOM, she may seek to enforce the provisions of the Act or regulations as interpreted by the SOM. The SOM, app. PP, Tag F314 provides the following definitions of avoidable and unavoidable pressure ulcers:

> "Avoidable/Unavoidable" Pressure Ulcers
>
> "Avoidable" means that the resident developed a pressure ulcer and that the facility did not do one or more of the following: evaluate the resident's clinical condition and pressure ulcer risk factors; define and implement interventions that are consistent with resident needs, resident goals, and recognized standards of practice; monitor and evaluate the impact of the interventions; or revise the interventions as appropriate.
>
> "Unavoidable" means that the resident developed a pressure ulcer even though the facility had evaluated the resident's clinical condition and pressure ulcer risk factors; defined and implemented interventions that are consistent with resident needs, goals, and recognized standards of practice; monitored and evaluated the impact of the interventions; and revised the approaches as appropriate.

The definitions adopted by CMS for the SOM, are consistent with prior discussions of the terms by the Board in the context of pressure ulcer cases. I conclude that SOM definitions accurately summarize the elements of the affirmative defense of unavoidability. However, applying these definitions to the facts of this case compels the conclusion that Petitioner has failed to establish that Resident 1's ulcers were unavoidable because Petitioner has not produced evidence to show that it implemented care planned interventions; that it monitored the impact of interventions implemented; and that it took appropriate action to revise interventions as necessary.

On February 9, 2008, when Resident 1 was admitted to Petitioner's facility, he was assessed as being at risk for the development of pressure ulcers, albeit a mild risk. CMS Ex. 5, at 1, 14, 16. Resident 1's February 20, 2008 care plan shows that his care planning team[11] adopted the following interventions: turn and reposition every two hours and as necessary; keep Resident 1 clean and dry; provide pressure-relieving devices; provide adequate nutrition and hydration; refer to the physician as needed; treat and medicate as ordered; monitor and document food intake daily; laboratory testing as necessary; evaluate skin daily; risk assessment with the Braden scale quarterly; clean dry linens; and reduce excessive moisture. CMS Ex. 5, at 31. The fact that the care planning team adopted these interventions supports my conclusion that the team determined that the

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[11] Also referred to as the interdisciplinary team. 42 C.F.R. § 483.20(k)(2)(ii).

interventions were necessary care and services for the prevention of pressure ulcers. Applying the definitions of "avoidable" and "unavoidable" that Petitioner advocates from the SOM, the evidence shows that in February 2008, the resident's clinical condition and pressure ulcer risk factors were evaluated; the interventions were defined consistent with the resident's identified needs and goals. It is undisputed in this proceeding that the interventions from February 2008 were consistent with the standards of practice. The problem for Petitioner is that the evidence does not show that the interventions planned by the care planning team in February 2008 were actually implemented, monitored and evaluated, and then modified as necessary. Specifically, the evidence does not show which, if any, pressure-relieving devices were attempted or implemented; there is no nutritional assessment in the clinical records or evidence reflecting monitoring of the resident's nutritional intake and level of hydration; and there is no evidence of laboratory testing[12] that might indicate malnutrition or dehydration or other factors that might contribute to the formation of pressure ulcers or their delayed healing. There is some evidence that the resident had a special mattress, but the type of mattress is not specifically indicated and there is no evidence of the assessment of its effectiveness. Tr. 200-03. The evidence shows that Resident 1 was dependent upon tube feeding for his nutrition and likely his hydration. There is no nutritional assessment that indicates the necessary caloric intake or level of hydration and no documentary evidence that daily intake was being monitored as required by the care plan. Other than the addition of four scoops of protein powder to the residents feeding on December 30, 2008 (CMS Ex. 5, at 58) and the addition of Vitamin C on January 30, 2009 (CMS Ex. 5, at 21, 29), there is no evidence that Resident 1's nutritional or hydration status was evaluated or monitored after the pressure ulcers on his right lateral foot developed in November 2008.

Petitioner acknowledges in its Post-Hearing Brief the interventions that were planned when Resident 1 was admitted to the facility in 2008. Petitioner argues that Dr. Rao's testimony supports its position that nursing staff consistently implemented the planned interventions. P. Br. at 8. However, Dr. Rao's testimony is not as unequivocal as Petitioner suggests. Dr. Rao's testimony was that she believed that staff carried out her orders – she did not testify that she knew staff carried out her orders or the care planned interventions. Her self-limited response does not support a conclusion that the interventions were consistently implemented. Tr. at 118-27, 200-03. Dr. Rao readily admitted that she did not know the type of mattress used for Resident 1, a clear indication that she was not supervising or monitoring the interventions being implemented, other than perhaps, her orders regarding treatment of the specific pressure ulcers. The evidence shows that Dr. Rao was frequently at the facility (Tr. at 583) and initially she saw

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[12] The SOM, app. PP, Tag 314, recognizes that laboratory tests are of limited utility. Nevertheless, Resident 1's care planning team planned the intervention, which should have been attempted, monitored, and modified as necessary.

Resident 1 every week (Tr. at 159-60, 194-95) but she could not recall whether she or her nurse practitioner saw Resident 1 more often than every thirty days (Tr. at 122-24, 160) after his pressure ulcers developed. Certainly, Dr. Rao was not at the facility all the time (Tr. at 197) and she was not supervising facility staff or their implementation of care planned interventions. Thus, I conclude that Dr. Rao's testimony is not credible on the issue of whether staff was implementing care planned interventions, particularly absent corroborating documentary evidence. Even if I accept Dr. Rao's testimony as establishing that staff consistently carried out all the care planned interventions, that does not establish that the staff or the care planning team actually evaluated the effectiveness of those interventions and modified them to meet the resident's needs as required.

The evidence also shows that Petitioner failed to perform care planned pressure ulcer risk assessments. The February 2008 care plan required that Resident 1's risk for developing pressure ulcers be assessed every quarter. CMS Ex. 5, at 31. There is no dispute that no assessment was done for six months between February 2008 and August 2008. CMS Ex. 5, at 16; P. Br. app. A, at 1; P. Reply at 3.

The care plan dated November 4, 2008, shows that the care planning team assessed the cause of the pressure ulcers on the right lateral foot to be the positioning of the right leg under the left leg resulting in pressure on the right lateral foot. The planned interventions to address the positioning of the right leg were to monitor the position of the leg and to wear a heel protector. It was noted that the resident became annoyed when attempts were made to reposition the leg, but no interventions were listed to address the resident's resistance to repositioning and I have received no separate care plan that addressed his resistance. CMS Ex. 5, at 25. On November 4, 2008, the intervention to monitor the position of the right leg was added to the February 20, 2008 care plan. CMS Ex. 5, at 31. The care plan dated December 3, 2008, also required monitoring of the position of the right leg. CMS Ex. 5, at 24. It was not until December 9, 2008, that Dr. Rao addressed the positioning of the right leg in her progress note recording her visit with the resident on December 9, 2008. She notes that nursing staff expressed concern because of the positioning of the right leg and she also notes that the resident was resisting care. Her plan was for the RNA to administer range of motion exercises; to keep the right foot from being positioned under the left leg; to use pillows between the legs; and to prevent worsening of the contracture of the knee. CMS Ex. 5, at 5-6. The December 3 care plan was updated on December 9, 2008, with a note that the resident was seen by Dr. Rao. No intervention to use pillows between the legs was added to the care plan dated December 3, 2008 (CMS Ex. 5, at 24), the care plan dated November 4, 2008 (CMS Ex. 5, at 25), or the care plan dated February 20, 2008 (CMS Ex. 5, at 31).

Although not mentioned in her progress note, the record shows that Dr. Rao issued an order on December 9, 2008, for OT to address the right leg contracture. CMS Ex. 5, at 40. OT began seeing Resident 1 related to the right knee contracture on December 11, 2008 and on December 15, 2008, Dr. Rao approved an OT plan for the resident to receive

a right knee brace. CMS Ex. 5, at 12. However, it was not until January 13, 2009, that the brace was received and applied by OT staff, the treatment nurse was not trained until January 16, 2009, and the CNA's were not trained to apply the brace until January 19, 2009. CMS Ex. 5, at 9-12. It was not until January 19, 2009, that Dr. Rao ordered the use of the right knee brace three times per day for two hour periods. CMS Ex. 5, at 28; Tr. 179. The use of the right knee brace was not added as an intervention on the care plans. Dr. Rao testified that if the brace was not used as ordered, the contracture could have worsened. Tr. at 180. An order dated February 5, 2009, indicates that the right knee flexion contracture was worsening. CMS Ex. 5, at 35. Nurse Practitioner Schuler saw Resident 1 on February 20, 2009, and she specifically noted that the right knee contracture was increasing. CMS Ex. 5, at 30. However, there is no evidence that the effectiveness of the knee brace was evaluated by the care planning team or whether there was any consideration of whether to modify or change that intervention.

Dr. Rao testified that she was not aware of any signs of infection, including redness around the eschar, swelling of the foot or area surrounding the eschar, a fever, or elevated white blood cell count. Tr. 142-44. She testified that had she been notified that the wound on the right foot had changed to having a moist area around the eschar, she would have examined the wound or had her nurse practitioner do so as that was a sign of possible infection. She testified that odor or drainage could also indicate that the wound was infected. The possibility of infection would cause her to change her treatment orders and to order laboratory testing. Tr. 226-28. Petitioner's clinical records show that on February 24, 2009, the wound measured ten by three centimeters, the black scab was noted to have moist margins and there was an odor. Treatment continued to be betadine. On March 4, 2009, the wound measured nine by three centimeters, of undetermined depth and stage, with a black scab that had moist margins, slight bleeding, and an odor. CMS Ex. 5, at 77. Petitioner has presented no evidence that Dr. Rao was actually notified of the changes in the wound. I infer based on Dr. Rao's testimony and the fact that there was no change in treatment of the wounds on and after February 24, 2009, that Petitioner failed to comply with the requirements of its care plans to notify the physician of any "untoward complications." CMS Ex. 5, at 24-25; Tr. 268-70. The evidence does show that Dr. Rao saw Resident 1 on February 26, 2009, and ordered a change of treatment, but the progress note does not record how treatment was changed. CMS Ex. 5, at 44, Tr. 305-06. An order dated February 26, 2009 indicates that betadine was to be applied to the right lateral foot and then covered with a dry dressing for 14 days, then reassessed. The order also states that a heel protector was to be applied every shift. CMS Ex. 5, at 22-23; Tr. 306.

Dr. Rao opined that Resident 1's pressure sores became chronic, and worsening was unavoidable and inevitable, about December 9, 2008, four to six weeks after the pressure ulcers developed. Tr. at 230-32, 263. Dr. Rao did not opine that the pressure ulcers were unavoidable when they formed on about November 4, 2008. She also did not opine that the ulcer on Resident 1's sacrum or left heel were unavoidable. I do not accept Dr. Rao's

opinion that worsening or infection of the pressure sores was unavoidable, as her opinion is based on the unsupported assumption that all ordered care and services were provided and the evidence shows that Petitioner failed to deliver care planned care and services necessary to prevent pressure ulcers or to promote their healing.

Petitioner also offered the testimony of Mildred Canlas, its DON since November 2003. Tr. at 568-69. DON Canlas knew Resident 1 from visiting him on her rounds and visits to his room in the mornings or on her way home but she did not provide care to him or participate in his care planning. Tr. at 577, 580, 607-08. She testified that she did review his clinical chart. Tr. at 571. DON Canlas testified that when visiting Resident 1, she noticed the way his foot was positioned, saw pillows on the floor of his room, knew that he had to have a pillow between his legs, and she told staff to ensure the pillows were not on the floor but in the correct position between his legs. Tr. at 578-80. According to DON Canlas, Dr. Rao spoke to the nurses and was receptive to their suggestions. Tr. at 575-76. She testified that she believed that Petitioner's nursing staff properly kept Dr. Rao informed of Resident 1's condition. Tr. at 576. She testified further that staff presented Dr. Rao with various alternatives for the treatment of Resident 1. Tr. at 603. However, she was unable to recall what suggestions staff made to Dr. Rao for alternative interventions. Tr. at 604. DON Canlas did not testify that staff delivered all care planned care and services and she did not opine that Resident 1's pressure ulcers were unavoidable. DON Canlas' testimony was forthright and credible regarding her limited involvement with the care and treatment of Resident 1, and her limited involvement greatly limits the weight of her opinions regarding the thoroughness of staff in complying with the resident's care plan or quality of care and services actually delivered.

I conclude based upon my review of all the evidence that CMS made a *prima facie* showing of a violation of 42 C.F.R. § 483.25(c) that caused actual harm to Resident 1. I further conclude that Petitioner has failed to establish that Resident 1's pressure ulcers were unavoidable because Petitioner has not produced evidence to show that it implemented care planned interventions; that it monitored the impact of interventions implemented; and that it took appropriate action to revise interventions as necessary.

### 4. A PICMP of $4,050 is a reasonable enforcement remedy.

I have concluded that Petitioner was not in substantial compliance with program participation requirements due to its violation of 42 C.F.R. § 483.25(c), which caused actual harm to Resident 1, and there is a basis for the imposition of an enforcement remedy for that period. Petitioner did not specifically challenge the reasonableness of the proposed PICMP, if I found a deficiency. P. Reply at 27-28. I nevertheless review the reasonableness of the proposed remedy.

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 (or the CMS selection of any other authorized remedy); 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 noncompliance, 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), noting the same factors CMS and/or the state considers 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, or safety, and 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 (i) no actual harm but had the potential for minimal harm, (ii) no actual harm but had the potential for more than minimal harm, but not immediate jeopardy, (iii) actual harm that is not immediate jeopardy, or (iv) immediate jeopardy to resident health or 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. In reaching a decision on the reasonableness of the CMP, I consider whether the evidence supports a finding that the amount of the CMP is at a level reasonably related to an effort to produce corrective action by a provider with the kind of deficiencies found, and in light of the above factors. 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 14–16 (1999); *Capitol Hill Cmty. Rehab. & Specialty Care Ctr.*, DAB No. 1629 (1997).

The proposed enforcement remedy at issue is the $4,050 PICMP.[13] The authorized range for a PICMP is $1,000 to $10,000 for a PICMP. 42 C.F.R. § 488.438(a)(2). The PICMP proposed is in the middle of the authorized range. Petitioner does not deny the history of

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[13] CMS notified Petitioner that it could not be authorized to conduct a NATCEP and that any prior approval would be withdrawn. CMS Ex. 14. However, no DPNA was imposed, the CMP was not $5,000 or more, no extended survey was conducted, and none of the other events occurred that would have triggered the ineligibility. Accordingly, there was no loss of approval to conduct NATCEP and that is not an issue before me.

noncompliance that CMS urges me to consider. CMS Br. at 27; CMS Ex. 8. Petitioner does not allege an inability to pay the modest PICMP. The deficiency did cause actual harm to Resident 1. I also conclude that Petitioner was culpable in its failure to comply with Resident 1's care plans. Accordingly, I conclude that a PICMP of $4,050 is reasonable.

**5. The CMS post-hearing motion to strike P. Ex. 3 is denied.**

**6. The CMS post-hearing motion to strike the declaration of Robin Curley, R.N. (P. Ex. 5), is granted.**

The resume of Robin Curley, R.N. (P. Ex. 3) and her declaration, dated November 3, 2009 (P. Ex. 5), were admitted at hearing without objection from CMS. Tr. at 37-43. Petitioner elected not to call RN Curley to testify at hearing. Tr. at 641-42, 692. CMS did not make any objection at hearing to my consideration of P. Exs. 3 and 5 based on the fact that RN Curley did not appear at hearing. CMS did not request a subpoena to compel the attendance and testimony of RN Curley. Tr. at 692. On March 5, 2010, after the hearing had adjourned, CMS filed "Objections to the Admission of Petitioner's Exhibits 3 and 5." Because both exhibits were already admitted to the record at hearing, I construe the CMS motion to be a motion to strike the exhibits. Counsel for CMS argues that he did not object to P. Exs. 3 and 5 at hearing, as he assumed that Petitioner would call RN Curley to testify and CMS would then have the opportunity to cross-examine. CMS asserts that Petitioner made RN Curley unavailable for cross-examination by failing to call her as a witness. CMS makes the general assertion that the conduct of Petitioner was both unfair and prejudicial.

The CMS motion to strike P. Ex. 3 is denied. CMS waived any objection to the admissibility or my consideration of P. Ex. 3 by failing to preserve the objection by raising it prior to the hearing (Prehearing Order, ¶ II.4.b; II.12.e). CMS has not stated good cause for why no objection was made to the admissibility of P. Ex. 3, before RN Curley was called to testify at hearing. CMS has failed to articulate any specific prejudice to the government due to the admission of P. Ex. 3.

The CMS motion to strike P. Ex. 5 is granted pursuant to Prehearing Order, ¶ II.12.h. The Prehearing Order, ¶ II.12.h permits a party to offer a written witness statement in the form of an affidavit or declaration, in lieu of live, direct testimony at hearing. However, the Prehearing Order requires that a party produce for purposes of cross-examination the witness whose written testimony is offered. The Prehearing Order provides that if the witness is not produced for cross-examination, the written statement will be stricken upon motion of opposing counsel. There is no requirement for opposing counsel to specifically articulate prejudice under the Prehearing Order, ¶ II.12.h, because deprivation of the right to cross-examination is presumed to be prejudicial. The Prehearing Order is clear that all that is required is for opposing counsel to object to the written witness statement, and it

will be stricken if there was no opportunity for cross-examination. The Prehearing Order is clear that the party offering the written testimony is obligated to ensure that the witness is present and available for cross-examination, if that party wants the written testimony considered. Accordingly, P. Ex. 5, the declaration of RN Curley, is stricken and not considered as substantive evidence.

## III. Conclusion

For the foregoing reasons, I conclude Petitioner violated 42 C.F.R. § 483.25(c); the violation caused actual harm to Resident 1; Petitioner was not in substantial compliance; there is a basis for the imposition of an enforcement remedy; and a PICMP of $4,050 is a reasonable enforcement remedy.

/s/
Keith W. Sickendick
Administrative Law Judge