Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Columbus Nursing and Rehabilitation Center
(CCN: 52-5445),

Petitioner

v.

Centers for Medicare and Medicaid Services.

Docket Nos. C-07-682, C-07-729, C-08-56, and C-08-183

Decision No. CR2241

Date: September 13, 2010

DECISION

Petitioner, Columbus Nursing and Rehabilitation Center,[1] was not in substantial compliance with program participation requirements from June 4, 2007 through August 2, 2007, due to violations of 42 C.F.R. §§ 483.25, 483.25(c), and 483.25(i)(1) (2006).[2] The following enforcement remedies are reasonable: a $3,050 per day civil money penalty (CMP) from June 4 through June 13, 2007; a $200 CMP from June 14 through August 2, 2007; a denial of payment for new admissions (DPNA) effective from July 20 through August 2, 2007; and withdrawal of authority to conduct a nurse aide training and competency evaluation program (NATCEP) for two years from June 27, 2007 through

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[1] This case was incorrectly docketed as "Columbus Nursing and Rehab Center." The correct name is "Columbus Nursing and Rehabilitation Center." Tr. at 9-10.

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

June 26, 2009, based on substandard quality of care and imposition of a CMP in excess of $5,000.

I. Background

Petitioner, located in Columbus, Wisconsin, is authorized to participate in Medicare as a skilled nursing facility (SNF) and in the Medicaid program as a nursing facility (NF). Petitioner was subject to surveys by the Wisconsin Department of Health and Family Services (the state agency) completed on June 27, 2007; July 5, 2007; August 14, 2007; and September 14, 2007.

The Centers for Medicare and Medicaid Services (CMS) notified Petitioner by letter dated July 10, 2007, that the June 27, 2007 recertification and complaint survey determined that Petitioner violated 42 C.F.R. §§ 483.13(c), 483.25, 483.25(c), and 483.25(i)(1); and that the violations of these regulations posed immediate jeopardy and amounted to substandard quality of care. CMS advised Petitioner that immediate jeopardy lasted for ten days from June 4, 2007 through June 13, 2007 and was abated on June 14, 2007. CMS advised that the survey concluded that Petitioner had numerous continuing deficiencies, none of which posed immediate jeopardy, and that Petitioner continued not to be in substantial compliance on and after June 13, 2007. CMS advised Petitioner that it accepted the following state agency recommendations: to impose a CMP of $8,800 per day for ten days from June 4, 2007 through June 13, 2007; a CMP of $200 per day beginning on June 14, 2007 and continuing until Petitioner returned to substantial compliance; a discretionary DPNA beginning on July 20, 2007 and continuing until Petitioner returned to substantial compliance; a directed plan of correction effective July 20, 2007; termination of Petitioner's provider agreement on December 27, 2007, if Petitioner did not return to substantial compliance before that date; and CMS advised Petitioner that its authority to conduct a NATCEP was withdrawn. CMS Exhibit (CMS Ex.) 1.

CMS notified Petitioner by letter dated July 25, 2007, that a complaint survey completed on July 5, 2007 found that Petitioner violated 42 C.F.R. § 483.25(h)(1) and that the violation posed immediate jeopardy from January 29, 2007 to June 14, 2007. However, CMS advised that the remedies previously imposed continued unchanged. CMS Ex. 2.

CMS notified Petitioner by letter dated October 24, 2007, that a revisit survey completed on August 14, 2007, found continuing noncompliance. CMS advised Petitioner that the previously imposed enforcement remedies continued. CMS also advised Petitioner that a revisit survey completed on September 14, 2007 concluded that Petitioner returned to substantial compliance effective September 5, 2007; the $200 per day CMP stopped accruing on September 4, 2007; the total CMP due was $104,600; the DPNA ended on September 4, 2007; and termination of Petitioner's provider agreement was rescinded. CMS Ex. 3.

Petitioner requested a hearing by letters dated August 29, 2007; September 14, 2007; October 22, 2007; and December 20, 2007. The requests for hearing were docketed as C-07-682, C-07-729, C-08-56, and C-08-183, respectively, and assigned to Judge Jose Anglada for hearing and decision. The cases were consolidated by orders dated November 16, 2007, December 4, 2007, and February 5, 2008, under the docket number C-07-682. The consolidated case was reassigned to me for hearing and decision on January 28, 2009, due to Judge Anglada's assignment to another agency.

A hearing was convened in Madison, Wisconsin on February 3 through 6, 2009, and a 1023-page transcript was prepared. CMS offered exhibits 1 through 6, 13 through 49, 60 through 72, and 75 through 80. CMS exhibits 1 through 6, 13 through 18, 22 through 34, 37, 39, 41, 45 through 49, 60 through 65, 67 through 72, and 75 through 80 were admitted. Petitioner offered exhibits (P. Ex.) 1 through 37 and all were admitted. CMS called the following witnesses: Surveyor Tina Lubick, RN; Surveyor Cheryl Bott, MSW; Daniel Berlowitz, MD; and Surveyor Ann Angell, RN. Petitioner elicited testimony from the following witnesses: Bruce Kraus, MD, Petitioner's Medical Director; Donna Elford, LPN; Kurt Hansen, MD; Janet Lutze, RN; Roberta Messer, Petitioner's Administrator during the surveys in issue; Martin Metten, Executive Vice-President and Chief Operating Officer for Petitioner's owner and operator, Heyde Health System Columbus, LLC (Tr. at 877); Susan Cary; and Mary Widner, Vice-President for Clinical Services for Petitioner's owner and operator. The hearing adjourned *sine die* on February 6, 2009, upon the agreement of the parties that Petitioner would file written direct examination for its remaining witnesses. The parties were directed to file a joint status report after the filing of Petitioner's additional direct testimony to advise me whether CMS requested cross-examination of Petitioner's remaining witnesses and proposing dates to continue the hearing, if necessary. Tr. at 1005-09. On March 25, 2009, Petitioner filed the declarations of Brian Phillips, Barbara Yohn, and Stephanie Foxx, which I have marked as P. Exs. 38, 39, and 40, respectively. On April 15, 2009, the parties filed their joint status report in which CMS waived cross-examination of Brian Phillips, Barbara Yohn, and Stephanie Foxx and the parties proposed three dates to reconvene the hearing to receive testimony from one additional witness for Petitioner. Subsequently, Petitioner waived further witness testimony and requested a decision based on the current record by a letter dated April 24, 2009. P. Exs. 38, 39, and 40 are admitted into evidence.

The parties filed post-hearing briefs on June 15, 2009 (CMS Br. and P. Br., respectively) and post-hearing reply briefs (CMS Reply and P. Reply, respectively) on July 31, 2009.

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 (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.[3] 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, 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

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[3] 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.

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).

In this case, the state agency was required to withdraw Petitioner's approval to conduct a NATCEP. 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 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 skilled nursing or nursing facility 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) that 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 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. *Cal Turner Extended Care*, DAB No. 2030 (2006); *The Residence at Salem Woods*, DAB No. 2052 (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 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 Ctr.*, DAB No. 1904 (2004), *aff'd*,*Batavia Nursing & Convalescent Ctr. v. Thompson*, 129 F. App'x. 181 (6th Cir. 2005); *Batavia Nursing & Convalescent Inn*, DAB No. 1911 (2004); *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

The parties stipulated prior to hearing that no enforcement remedies were imposed based on deficiencies cited by a Life Safety Code survey completed on June 13, 2007. Therefore, no Life Safety Code deficiencies are at issue before me. Tr. at 10; Stipulation to Limit Scope of Hearing dated May 9, 2008. CMS stated during the hearing that the deficiency cited by a complaint survey that ended on July 5, 2007, was not the basis for an enforcement remedy and that the deficiency cited is not at issue before me. Petitioner

agreed that no enforcement remedy was imposed based on the deficiency and that the deficiency was not at issue before me.[4] Tr. at 32-38.

The Statement of Deficiencies, CMS-2567 (SOD) for the survey that ended on June 27, 2007 cites the following deficiencies at the scope and severity (s/s) indicated: 42 C.F.R. §§ 483.10(b)(11), Tag F157,[5] s/s G;[6] 483.13(c), Tag F224, s/s J; 483.13(c)(1)(ii)-(iii), (c)(2)-(4), Tag F225, s/s D; 483.15(3)(1), Tag F246, s/s D; 483.15(h)(2), Tag F253, s/s D; 483.20 and 483.20(b), Tag F272, s/s D; 483.20(b)(2)(ii), Tag F274, s/s D; 483.20(d) and 483.20(k)(1), Tag F 279, s/s E; 483.25, Tag F309, s/s J; 483.25(c), Tag F314, s/s J; 483.25(e)(2), Tag F318, s/s D; 483.25(i)(1), Tag F325, s/s J; 483.25(l), Tag F329, s/s D;

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[4] Petitioner did not disagree with my assertion that I have no jurisdiction to address issues related to Petitioner being placed on a "special focus" list due, in part, to Petitioner being cited for a deficiency by the survey completed on July 5, 2007. Tr. at 37.

[5] This is a "Tag" designation as used in CMS Publication 100-07, State Operations Manual (SOM), Appendix PP – Guidance to Surveyors for Long Term Care Facilities (http://www.cms.hhs.gov/Manuals/IOM/list.asp). The "Tag" refers to the specific regulatory provision allegedly violated and CMS's guidance to surveyors. 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. *State of Indiana by the Indiana Dep't of Pub. Welfare v. Sullivan*, 934 F.2d 853 (7th Cir. 1991); *Northwest Tissue Ctr. v. Shalala*, 1 F.3d 522 (7th Cir. 1993). 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.

[6] Scope and severity levels are used by CMS and a state when selecting remedies. The scope and severity level is designated by an alpha character, A through L, selected by CMS or the state agency from the scope and severity matrix published in the SOM, Chap. 7, § 7400E. A scope and severity level of A, B, or C indicates a deficiency that presents no actual harm but has the potential for minimal harm, which is an insufficient basis for imposing an enforcement remedy. Facilities with deficiencies of a level no greater than C remain in substantial compliance. 42 C.F.R. § 488.301. A scope and severity level of D, E, or F indicates a deficiency that presents no actual harm but has the potential for more than minimal harm that does not amount to immediate jeopardy. A scope and severity level of G, H, or I indicates a deficiency that involves actual harm that does not amount to immediate jeopardy. Scope and severity levels J, K, and L are deficiencies that constitute immediate jeopardy to resident health or safety. The matrix, which is based on 42 C.F.R. § 488.408, specifies which remedies are required and optional at each level based upon the frequency of the deficiency.

483.35(d)(1)-(2), Tag F364, s/s E; 483.40(b), Tag F386, s/s D; 483.75(e)(8), Tag F497, s/s E; 483.75(j)(2)(i), Tag F504, s/s D; and 483.75(o)(1), Tag F520, s/s E. CMS Ex. 13.

A revisit survey was conducted on August 14, 2007, and the surveyors concluded that Petitioner had corrected all the alleged deficiencies cited by the June 7 survey as of August 14, 2007, except the deficiencies cited under 42 C.F.R. §§ 483.10(b)(11), Tag F157 and 483.25, Tag F309. CMS Ex. 62. The revisit survey completed on August 14, 2007, cited Petitioner for the following deficiencies at the scope and severity indicated: 42 C.F.R. §§ 483.10(b)(11), Tag F157, s/s G; and 483.25, Tag F309, s/s G. CMS Ex. 63. Petitioner disputes all the deficiencies from both surveys but argues, in the alternative, that Petitioner corrected by August 3, 2007 any deficiency that I may find was correctly cited by the June 27 survey. Tr. at 38-40.

I conclude that Petitioner was not in substantial compliance with program participation requirements based upon the deficiencies cited by the survey completed on June 27, 2007, as discussed hereafter. I conclude that Petitioner returned to substantial compliance on August 3, 2007. I conclude that the deficiencies discussed in this decision are a sufficient basis for the imposition of reasonable enforcement remedies. Thus, I conclude in the interest of judicial economy, that it is not necessary to discuss all the deficiencies cited by the June 27, 2007 survey. My conclusions of law are set forth in bold followed by a statement of the pertinent facts and my analysis.

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 in this decision the credible evidence given the greatest weight in my decision-making. 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 did not violate 42 C.F.R. § 483.13(c), Tag F224, as alleged by the survey completed on June 27, 2007.

2. The declaration of immediate jeopardy related to the alleged violation of 42 C.F.R. § 483.13(c), Tag F224, was clearly erroneous.

The surveyors allege that Petitioner violated 42 C.F.R. § 483.13(c) because it failed to ensure that Resident 3 was not neglected. The surveyors allege that the violation posed immediate jeopardy. CMS Ex. 13, at 14. The surveyors alleged more specifically that Petitioner did not coordinate and monitor Resident 3's total health care needs; assess, plan, implement, evaluate, and modify care-planned interventions; promptly intervene to

prevent pain weight loss, loss of range of motion, and changes in skin integrity; and maintain Resident 3 at the highest practical level of well-being. The surveyors allege that the immediate jeopardy situation began on June 4, 2007 and was abated on June 14, 2007, but the deficiency continued at a scope and severity of D because Petitioner had not fully implemented its plan of correction. CMS Ex. 13, at 14-15. The surveyors state in the SOD that Petitioner had 54 residents at the time of the survey (CMS Ex. 13, at 1) and that Resident 3 was the only resident out of 15 sampled for which they identified any neglect. CMS Ex. 13, at 14.

Resident 3,[7] a woman, was 86 when the survey was done. She was admitted to Petitioner's facility on January 20, 2007. Her diagnoses included dementia and Alzheimer's disease, depression, hypertension, generalized anxiety disorder, psychological pain disorder, myofascial pain, and osteoarthritis CMS Ex. 27, at 1-2, 7; P. Ex. 1, at 1, 170. According to her Minimum Data Set (MDS) with an assessment reference date of January 29, 2007, Resident 3's cognitive skills for daily decision-making were severely impaired; at times she complained of excruciating pain that was assessed to be soft-tissue pain; she was five feet and six inches tall and weighed 194 pounds; she had a pressure ulcer and had pressure relieving devices for bed and chair and was on a turning schedule; she was frequently incontinent of bowel and bladder; she had unsteady gait; had loss of range of motion of her neck, one arm, and one leg; she used a wheelchair as her primary mode of locomotion; and she required staff assistance with most activities of daily living (ADLs). CMS Ex. 27, at 5-9. A quarterly MDS with an assessment reference date of April 15, 2007, shows she remained severely cognitively impaired for daily decision-making; range of motion had improved in her neck and arm; she continued to require staff assistance with ADLs; she remained frequently incontinent of bowel and bladder; she continued to complain of periods of mild pain occurring less than daily; she had experienced weight loss; and she was reported to have no pressure ulcers. CMS Ex. 27, at 14-16; P. Ex. 1, at 162-63. Resident 3 was assessed as at high risk for falls on January 21, 2007 and April 15, 2007. CMS Ex. 27, at 25. Resident 3 died on July 10, 2007, with a cause of death listed as end-stage dementia. P. Ex. 1, at 2-4.

Physician orders for the period January 20, 2007 through June 5, 2007, include: treatment for a sore on her buttocks with changes in treatment; occupational therapy evaluation and treatment to improve ADLs and eating skills; physical therapy evaluation and treatment; a psychiatric consult; changes in her medication; treatment for left knee

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[7] Resident 3 was the subject of all four alleged violations that allegedly posed immediate jeopardy from the June 27, 2007 survey. The facts stated here are pertinent to my discussion of Tags F309, F314, and F325.

pain and swelling; hip x-rays twice; ointment and drops for her eyes; orders for laboratory testing for a possible urinary tract infection (UTI); audiologist consult; authorization to catheterize due to urinary incontinence; speech therapy consult for oral dysphagia; dental care; diet change to mechanical soft with ground meat due to pocketing her food and decreased ability to chew; and treatment for ulcers on her heels. CMS Ex. 27, at 42-82. Resident 3 was seen for a psychiatric consultation on January 25, 2007 (CMS Ex. 27, at 83) and May 3, 2007 (CMS Ex. 27, at 88). She received psychotropic medications for her mood. CMS Ex. 27, at 249-64. Nursing assessments and nursing notes reflect the care and services Resident 3 received. CMS Ex. 27, at 98-132. The evidence includes Resident 3's care plan. CMS Ex. 27, at 146-61. The resident was assessed for pain and received pain medications. CMS Ex. 27, at 164-232. Her sleep was assessed. CMS Ex. 27, at 233-48. Her risk for pressure sores was assessed. CMS Ex. 27, at 269-73, 276-77, 283-85. Nurse's notes include entries for weekly wound assessments from February 6, 2007 through March 20, 2007 and April 28, 2007 through June 12, 2007. CMS Ex. 27, at 288-91. Her risk for elopement and wandering were assessed. CMS Ex. 27, at 292. The care Resident 3 received, including ADLs, continence care, and meals and snacks, were regularly recorded. CMS Ex. 27, at 307-18. Resident 3 received physical, occupational, and speech therapy. CMS Ex. 27, at 332-93.

There is no dispute that Petitioner had a policy entitled "Investigation and Reporting of an Allegation of Misconduct (defined as Abuse, Neglect, or Misappropriation of a Client's Property) and Injuries of Unknown Source, with an effective date of April 1, 1992 and revised through January 11, 2007. P. Ex. 9. I refer to this policy hereafter as Petitioner's neglect and abuse policy.

The Act requires that long-term care facilities that participate in Medicare or Medicaid "protect and promote the rights of each resident" including "[t]he right to be free from physical or mental abuse, corporal punishment, involuntary seclusion, and any physical or chemical restraints imposed for purposes of discipline or convenience and not required to treat the resident's medical symptoms." Act §§ 1819(c)(1)(A)(ii) (SNFs) and 1919(c)(1)(A)(ii) (NFs). The Secretary has promulgated regulations to implement the requirements of the Act including 42 C.F.R. § 483.13(c), which provides in pertinent part:

> (c) Staff treatment of residents. The facility must develop and implement written policies and procedures that prohibit mistreatment, neglect, and abuse of residents and misappropriation of resident property.

The regulation explicitly requires that Petitioner "develop and implement written policies and procedures that prohibit mistreatment, neglect, and abuse of residents and misappropriation of resident property." 42 C.F.R. § 483.13(c). The surveyors allege in the SOD that Petitioner violated the regulation but the surveyors make no specific

reference to Petitioner's neglect and abuse policy; they make no allegations that the policy is insufficient; and they make no allegations that the policy was not implemented. The surveyors do not specifically allege that the alleged errors and omissions related to Resident 3 show that Petitioner failed to implement its neglect and abuse policy. CMS Ex. 13, at 13-20. The surveyors' allegations are that Petitioner neglected Resident 3 because Petitioner failed to "adequately or consistently": (1) coordinate and monitor her total health care needs; (2) assess, plan, implement, evaluate, and modify her care plan to minimize her decline; (3) provide prompt interventions to prevent deterioration; and (4) maintain her highest practical level of well-being. CMS Ex. 13, at 14.

CMS argues two theories for why Petitioner violated 42 C.F.R. § 483.13(c): (1) Petitioner failed to develop a sufficient policy to prohibit neglect; and/or (2) the fact that many staff members failed to deliver necessary care and services to Resident 3 on multiple occasions shows that Petitioner failed to implement its policy prohibiting neglect. CMS Br. at 7. As already noted, the surveyor did not allege that Petitioner did not have the policy required by the regulation, that the policy was inadequate, or that it was not implemented. Rather, Surveyor Lubick testified that the deficiency was cited because she concluded that Petitioner failed to deliver necessary care and services to Resident 3. Tr. at 157-58. CMS did not allege either theory that it now advances in its prehearing brief but rather cited only the allegations from the SOD. CMS Prehearing Brief at 12-15. Petitioner objects to CMS arguing for the first time post hearing, new grounds for a violation of 42 C.F.R. § 483.13(c). P. Reply at 5, 10-11. Petitioner's objection is well taken. *Spring Meadows Health Care Ctr.*, DAB No. 1966 (2005); *Livingston Care Ctr.*, DAB No. 1871 (2003). However, considering the substance of the CMS theories reveals that they are without merit at any rate.

CMS does not argue that Petitioner did not have a policy but, argues that Petitioner's policy pertains only to the investigation and reporting of incidents of neglect and does not specifically prohibit neglect. CMS Br. at 7. This argument is belied by the policy document itself. The first sentence of the policy states that Heyde Health System, Petitioner's management company, will not tolerate misconduct by employees or contractors. Misconduct is defined in the title of the policy as including abuse, neglect, or misappropriation of client property. P. Ex. 9, at 1. Although it might have been stated more clearly, the plain meaning of the language of the policy is that Petitioner will not tolerate and thus prohibits neglect of it residents. CMS further argues that the definition of neglect set forth in Petitioner's policy is inconsistent with the regulatory definition. CMS Br. at 7. "Neglect" is defined by the regulations as "failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness." 42 C.F.R. § 488.301. Petitioner's policy includes the definition from the regulation but expands upon that definition. CMS complains that the policy excludes from the definition of neglect "mere inefficiency, unsatisfactory conduct or failure in good performance as the result of inability, incapacity, inadvertency or ordinary negligence in isolated instances, or good faith errors in judgment or discretion." P. Ex. 9, at 5; CMS Br. at 7-8. CMS

does not explain to me how this argument is pertinent to the case before me. Petitioner clearly has a policy that prohibits neglect and includes the regulatory definition of neglect. The fact that Petitioner elaborated upon the definition of neglect in its policy is not alleged to have caused a failure to deliver services to any resident or posed the potential for more than minimal harm. Therefore, there is no issue before me related to the sufficiency of Petitioner's definition of neglect. I note however, that the regulatory definition of neglect is limited and neglect exists under the regulatory definition only if a failure to deliver goods and services could result in physical harm, mental anguish, or mental illness, a failure that would not result in such harm, would not be neglect under the regulation. The regulatory definition turns upon the impact of the failing while Petitioner's expanded definition turns upon the cause of the failing. Therefore, depending upon the facts of any given case, Petitioner's policy may be inconsistent with the regulation. However, that issue is not raised by the facts before me and it is not for me to give an advisory opinion.

CMS refers to a prior decision of the Board that specifically considered the very policy of Petitioner at issue before me, *Columbus Nursing & Rehab. Ctr*., DAB No. 2247 (2009). In that case the Board affirmed the ALJ's conclusions that Petitioner failed to adequately investigate a possible incident of abuse (*id*. at 7); that Petitioner failed to adequately document its investigation and conclusions (*id*. at 14); that Petitioner failed to implement adequate measures to protect the resident in that case from further abuse (*id*. at 16); that Petitioner failed to comply with requirements for reporting abuse (*id*. at 19); and that Petitioner failed to implement its policy based on facts that multiple staff failed to follow the policy and that one staff member alleged she never received training on the policy (*id*. at 26-27). Contrary to the suggestion of CMS, the Board did not find Petitioner's policy defective or insufficient. Rather, the Board in *Columbus* upheld the ALJ's conclusions that Petitioner fell short of its own policy for investigating and documenting investigations of suspected abuse or injuries of unknown origin and failed to show that it otherwise met the requirements of the Act and regulations. *Id*. at 12, 15-16. In upholding the ALJ's conclusion that Petitioner failed to implement its policy, the Board commented that it has never required multiple examples of failure to follow a policy to establish that the policy was not implemented. The Board stated that the issue "is whether the circumstances presented, viewed as a whole, demonstrate a systemic problem in implementing policies and procedures." *Id*. at 27 (citation omitted).

CMS argues to me in this case that the multiple failures to deliver goods and service to Resident 3 supports a conclusion that Petitioner failed to implement its policy prohibiting neglect. Applying the Board's test of whether the circumstances presented when viewed as a whole demonstrate a systemic problem in implementing policies and procedures, I conclude that the allegation that Petitioner failed to implement its policy is unsupported in this case. As already noted the surveyor alleged the violation of 42 C.F.R. § 483.13(c), Tag F224, because she concluded that Petitioner neglected Resident 3 not because Petitioner did not have or implement a required policy. Tr. at 157-58. Furthermore, the

clinical record for Resident 3 admitted as evidence and summarized above shows that there was an extensive effort to deliver goods and services to Resident 3. Although the deficiency citations discussed hereafter reflect my conclusions that Petitioner was not in substantial compliance with some program participation requirements related to its care of Resident 3, I do not conclude that the deficiencies reflect a systemic problem with Petitioner implementing its policy prohibiting the neglect or abuse of residents.

Accordingly, I conclude that Petitioner did not violate 42 C.F.R. § 483.13(c) in the case of Resident 3, and the declaration of immediate jeopardy related to the alleged violation was clearly erroneous.

3. Petitioner violated 42 C.F.R. § 483.25, Tag F309, as alleged by the survey completed on June 27, 2007.

4. The determination that Petitioner's violation of 42 C.F.R. § 483.25 posed immediate jeopardy was clearly erroneous.

The regulation requires that:

> Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and pyschosocial well-being, in accordance with the comprehensive assessment and plan of care.

42 C.F.R. § 483.25. The surveyors allege in the SOD that Petitioner violated the regulation in the case of Resident 3 because Petitioner did not deliver care and services necessary for Resident 3 to be as free of pain as possible. The surveyors allege more specifically that Petitioner did not adequately or consistently: assess Resident 3 when she moaned or cried out in pain; provide prescribed pain medication prior to transfers and care; assess the effectiveness of its pain treatment; assess whether pain contributed to the resident's increased anxiety, behaviors, constipation, weight loss, and skin breakdown; or review the frequency of the need for mediation for breakthrough pain; all of which resulted in Resident 3 suffering unresolved instances of pain. The surveyors allege that the deficiency posed immediate jeopardy on June 14, 2007, that the immediate jeopardy was abated on that date, and that the deficiency continued to pose a risk for more than minimal harm. CMS Ex. 13, at 55.

Resident 3's diagnoses on admission on January 20, 2007, included psychological pain disorder, myofascial pain, and osteoarthritis. CMS Ex. 27, at 1-2, 7; P. Ex. 1, at 1, 170. According to her admission MDS with an assessment reference date of January 29, 2007, Resident 3's cognitive skills for daily decision-making were severely impaired and at times she complained of excruciating pain that was assessed to be soft-tissue pain. The

MDS indicates that she asked repetitive questions; voiced repetitive anxious complaints or concerns; and displayed a sad, pained, worried facial expression on a daily basis. She was also noted to withdraw from activities and to have reduced social interactions. CMS Ex. 27, at 5-6; P. Ex. 1, at 168-69. The narrative to the January MDS indicates that Resident 3 had repetitive anxious concerns about wanting to go home but she was easily redirected. P. Ex. 1, at 177; CMS Ex. 27, at 19. A quarterly MDS with an assessment reference date of April 15, 2007, shows she remained severely cognitively impaired for daily decision-making and she continued to complain of periods of mild pain less than daily. She was noted to withdraw from activities and to have reduced social interaction but there was no indication of repetitive questions, anxious complaints or concerns, or a sad and pained expression. CMS Ex. 27, at 14-16; P. Ex. 1, at 162-63.

A care plan dated February 1, 2007, addressed Resident 3's diagnosis of arthritis with approaches of assessing the resident's pain every shift and as necessary; administering Tylenol (Acetaminophen) as ordered; and observing her for non-verbal pain indicators, with the goals of the resident being pain free or at an acceptable level of pain and able to participate in ADLs without pain. The care plan was updated on June 6, 2010, with the intervention to use Vicodin (Acetaminophen and the narcotic Hydrocodone) as necessary if pain is severe. The care plan was further updated on June 15, 2007, with the intervention to administer narcotics as ordered. CMS Ex. 27, at 153; P. Ex. 1, at 266. A Care Conference Checklist dated April 24, 2007, indicates that the resident should be repositioned as needed for pain and that the resident seemed more awake due to reduction of her psychotropic medication. P. Ex. 1, at 256.

Resident 3 had care plans addressing depression and anxiety with agitated features and her Alzheimer's dementia, dated February 1, 2007. Interventions for the depression and anxiety included daily assessment of mood, administering medication as ordered, monitoring, and updating the physician with the goal that her mood remains stable until May 2007, July 2007, and October 2007. Interventions for her dementia included encouraging the resident to attend activities, maintaining a routine, one-on-one intervention, and medication as ordered with the goal of maintaining cognitive stability through May, July, and October 2007. There is no indication that either care plan was updated except by the addition of new goal dates. P. Ex. 1, at 266; CMS Ex. 27, at 153. A care plan dated April 2007 with goal dates of July 2007 and October 2007, lists as problems depression and anxiety that is not easily altered. Undated additions to the list of problems on the preprinted plan include deterioration in mood, calling-out, and repetitive physical movements. Interventions include monitoring, medication as ordered, including the resident in activities, encouraging the family to visit, reminiscing with the resident, allowing the resident to ventilate her feelings, and using validation. Listed goals were keeping her mood stable for three months and keeping her free from side effects of

medication for 90 days. There are no dates written on the care plan to indicate that the problem or interventions were updated after April 2007 and before the survey.[8] P. Ex. 1, at 261; CMS Ex. 27, at 155. Resident 3's dementia care plan dated April 2007 with goal dates of July and October 2007, lists problems that she is not easily altered, deterioration in behavioral symptoms, socially inappropriate, and resists cares. The following interventions are listed: distract, use validation, encourage participation in activities, socialization, encourage family visits, administer medication as ordered, use a behavior log, psychiatric consults as necessary, psychotropic medication as ordered, monitor for side-effects, and approach at a later time as necessary. The plan appears to have been updated on June 26, 2007, but the meaning of the entry "T.G. #2 added 6/26/07" is not clear. P. Ex. 1, at 262; CMS Ex. 27, at 156.[9] The resident's psychosocial well-being care plan is dated April 2007, and it indicates that resident is adjusting to the nursing home. Interventions include introducing the resident to other residents, including her in activities, encouraging family visits, use of validation, and changing the subject. Goals include adjustment to the facility and a new roommate with target dates of July 2007. P. Ex. 1, at 262; CMS Ex. 27, at 156.

Petitioner's pain assessment policy required that a pain assessment be completed on each resident who had acute, chronic, or suspected pain, on admission, upon return from the hospital, if there was a significant change, quarterly for each resident on analgesics, or on

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[8] The copy of the document placed in evidence by Petitioner includes additional entries that do not appear on the copy introduced by CMS that was obtained by the surveyor during the survey. For example, the document obtained by the surveyor only listed depression but the copy introduced by Petitioner includes the notation "[with] anxiety" with an unreadable date and initials next to the notation. Other additions are the entries that there was deterioration in mood, calling out, and repetitive physical movements but they are undated. I infer that the subsequent entries were added during or after and in response to the survey. I do not consider subsequent remedial measures adversely to Petitioner.

[9] Comparison of Petitioner's exhibit and the CMS exhibit reveals that this care plan was also altered after CMS obtained its copy during the survey. Additions include reference to additional problems of deterioration in behavioral symptoms, socially inappropriate behavior, and resisting care. The intervention "T.B. #2 added 6/26/07" was clearly added during the survey between two interventions that are on both copies. The intervention of re-approaching also appears only on Petitioner's copy and is undated. I infer that the entries that are not present on the copy obtained by the surveyor were added during or after and in response to the survey. I do not consider subsequent remedial measures adversely to Petitioner.

order of the physician or clinical manager. The policy provided that a "Pain Management Flow Sheet" could be used for follow-up until the pain was under control. The policy also required that the interdisciplinary team address pain management on the care plan and that pain management be addressed in the weekly summary. CMS Ex. 27, at 162.

Pain assessments by Petitioner's staff show that the resident suffered pain. A pain assessment form dated January 20, 2007, indicates that Resident 3 had generalized pain characterized as a dull ache in all joints due to osteoarthritis and myofascial pain. The severity of her pain is not indicated but an acceptable level of pain is marked as three on a scale of one to ten with ten being worst. Medications indicated for pain are Celebrex (a nonsteroidal anti-inflammatory drug (NSAID)) and Darvocet (Acetaminophen and a narcotic). CMS Ex. 27, at 164; P. Ex. 1, at 217. A pain assessment dated April 15, 2007, describes Resident 3 as having chronic, generalized joint pain due to osteoarthritis, which was worse in the morning. Non-verbal indicators that Resident 3 was experiencing pain were guarding and grimacing. The form indicates that Resident 3 was unable to respond to the question of what level of pain was acceptable, but a note indicates that the resident denied discomfort or pain. APAP (Acetaminophen) 500 mg is listed as the medication used. CMS Ex. 27, at 166; P. Ex. 1, at 215. A follow-up/quarterly assessment summary dated June 12, 2007, indicates that Resident 3 had increased complaints of discomfort and pain at different times in different areas. Resident 3 had prescriptions for Vicodin and Tylenol to be used as necessary for facial grimacing and complaints of pain. The note indicates that she had a recent reduction in her Clonazepam and that the "[t]eam is wondering if yelling out/behaviors may be related to this." CMS Ex. 27, at 167; P. Ex. 1, at 216. Though this seems to be a pertinent question and important to Petitioner's defense in this case, I find no evidence that prior to the survey Petitioner developed a care plan for addressing the behavior or for systematically assessing and tracking the behavior to attempt to distinguish between behaviors due to pain and those due to dementia or some other cause. A Pain Assessment form dated June 15, 2007 indicates that the resident was unable to assess the severity of her pain but she was crying. The narrative indicates that when the resident was approached she started crying out and when asked if she hurt, she responded that she wished she did. The note indicates that Resident 3 calls out with any interaction and sometimes when no one is present. The note states that both staff and the physician are monitoring closely and that pain and psychotropic medications are being adjusted to address progressing dementia and "failed dose reduction." P. Ex. 1, at 188-89.

The clinical record, though inconsistent in the reporting of instance of pain and behaviors and incomplete in recording the effectiveness of interventions, shows that Resident 3 obtained relief of pain from medication and non-pharmacological interventions. Resident 3's Medication Administration Form (MAR) for April and May 2007 show that she received a daily dose of Acetaminophen, two tablets of 500 milligrams once a day for arthritis, however the order was discontinued on May 30, 2007. P. Ex. 1, at 328, 340, 356. Nurse's Notes and 24-Hour Reports for April 2007 show that Resident 3

complained of a headache on April 6, leg pain on April 7, leg pain on April 9, and leg pain and bilateral ankle pain on April 12, 2007. The report shows that each complaint of pain in April 2007 was addressed with Tylenol with relief of the pain. P. Ex. 6, at 1-6, 133-34. Nurse's Notes and a 24-Hour Report dated April 14, 2007, indicates that Resident 3's family wanted her Clonazepam reduced and her Zoloft increased. P. Ex. 6, at 5, 135. Nurse's Notes record a complaint of bilateral foot pain on April 30, 2007. P. Ex. 1, at 135. Nurse's Medication Notes for April 2007, show that Resident 3 was given Tylenol or Acetaminophen ten times on seven days, April 6, 9, 11, 18, 26, 29, and 30, 2007, for headache, leg, ankle, or foot pain. There is no indication of whether or not the pain medication was effective in three instances but entries show it was effective in six instances and ineffective in one instance with no indication other interventions were attempted. P. Ex. 1, at 355. A MAR for April 2007 lists Acetaminophen for pain as needed every four hours and shows administration on April 6, 7, 9, 11, 12, twice on 13, twice on 19, 28, and 30. P. Ex. 1, at 354. A pain assessment flow sheet for May 2007, records complaints of pain on ten days (11 instances), eight days the pain was in her legs, one day she was unable to state where the pain was, and one day just has a question mark. The indicators of pain are verbalization on one occasion, verbalization and moaning on four occasions, moaning on two occasions, moaning and yelling on two occasions, and moaning and crying on two occasions. She was given Tylenol or the generic Acetaminophen seven times, Vicodin four times, and a Tylenol and Vicodin on one occasion. Non-medication interventions listed are repositioning, rest, one-on-one time, and fluid. I note that only repositioning is listed as an intervention in the care plan. Six events are noted to have resulted in decreased moaning, quiet, or the resident was asleep after interventions. However, five events do not indicate whether the interventions were successful. CMS Ex. 27, at 222; P. Ex. 1, at 136-38, 346. A Nurse's Medication Notes form for May 2007 shows that Acetaminophen was administered on May 1, 2, and 8 for moaning and complaints of leg pain and that the medication was effective. Vicodin was administered on May 23, 27, and 28 for moaning and yelling and complaints of leg pain, and the drug was noted to be effective in one instance but there was no note for the other two instances. P. Ex. 1, at 349. A MAR for May 2007 shows Acetaminophen prescribed to be administered as needed for pain was given on May 1, 2, 3, 21, 23, and 28 and Vicodin was given on May 23, 27, and 30. P. Ex. 1, at 348. A 24-Hour Report entry on May 21, 2007, contains the request that something be ordered for Resident 3's pain as she had only Tylenol 500 mg and that was not enough, the report indicates that the morning nurse called but the afternoon nurse noted that no call-back was received. P. Ex. 6, at 14. A 24-Hour Report entry from the night-shift on May 22, 2007, reflects that Resident 3 was "crying out <u>all</u> night" and there was no call back from the physician. CMS Ex. 6, at 15 (emphasis in original). However, an entry from the day-shift indicates a new order for Vicodin, half-tablet by mouth every six hours as needed for pain. CMS Ex. 6, at 15. Entries on the 24-Hour Report on May 28 and June 3, 2007 show that she was given Tylenol and Vicodin for complaints of leg pain and leg cramps. A note also suggests that Resident 3 be monitored at night related to her calling out but I find no evidence that a plan for doing so was developed or implemented prior to the survey. CMS Ex. 6, at 16-

18. An entry on June 4, 2007, indicates that the resident was crying out all night and she was given Vicodin; a day-shift note indicates that she cried out with any movement and that her left shoulder, arm, hip, and leg would be x-rayed to rule out fractures. A note from the second-shift indicates that the left hip was x-rayed and that the power of attorney wanted Resident 3's Clonazepam increased. P. Ex. 6, at 19. Entries in the 24-Hour Report forms continue to show that Resident 3 was moaning loudly and/or crying on June 5, 6, 7, and 14, 2007. The notes reflect that on June 7 she complained specifically of leg pain and was holding her right inner thigh and she was sent to the hospital for x-rays of the right hip, which were negative. P. Ex. 6, at 20-25. Nurse's Notes are consistent with the 24-Hour Reports. P. Ex. 6, at 138-43. The Nurse's Notes record that on June 5, 2007, the physician increased Resident 3's Clonazepam back to its prior dose. On June 6, 2007, a new order for an increased dose of Vicodin was obtained to address the resident's increased moaning. A note dated June 14, 2007 records that the physician was updated that Resident 3 continues to call-out despite increased Vicodin, sometimes verbalizing pain and sometimes not. P. Ex. 1, at 139. An Analgesic Record/Pain Flow Sheet for June 2007 reflects complaints of leg pain on June 1, 2, 4, and 6; a complaint of shoulder pain on June 10; complaints of pain on June 9 and 11, the location of which could not be determined. The form shows that Resident 3 was given her scheduled Hydrocodone or a half-tablet of Vicodin with evidence of pain relief in four instances but no notation of whether the medication was effective in four instances. CMS Ex. 27, at 231; P. Ex. 1, at 332. A Nurse's Medication Notes form shows that Hydrocodone was administered on June 1, 2, 3, 5, and 6 for moaning and/or crying rather than pain; with the notation on June 3 and 6 that the medication was not helpful; but no indication of effectiveness on June 1, 2, and 5. P. Ex. 1, at 331. Resident 3's MAR for June 2007 indicates that the Hydrocodone could be given every six hours as needed for pain, with entries showing administration on June 1, 2, 3, 4, 5, 6, and 9, 2007. P. Ex. 1, at 330. Nurses' Progress Note forms for April and May 2007 do not include any discussion of Resident 3's complaints of pain. The June 2007 Nurses' Progress Note lists a new order for Vicodin by mouth every six hours on a routine basis for pain and also notes that staff was awaiting results of a second set of x-rays. P. Ex. 1, at 125-30.

A physician's note by Bruce Kraus, MD, dated May 24, 2007, indicates that nursing staff raised questions as to whether Resident 3 may have been having pain but he states that he is not certain that there is significant pain; he notes that he gave her a prescription for Vicodin; and that he would try to find a proper balance for pain medication, psychotropic medication, and anti-anxiety medication. P. Ex. 1, at 106.

A psychiatric consultation was done on January 25, 2007. Resident 3 was reported to have a history of senile dementia, generalized anxiety disorder, generalized myofascial pain, osteoarthritis, and major depression. Her depression was evaluated as being under relatively good control with Zoloft. P. Ex. 1, at 277-79; CMS Ex. 27, at 83-85. A psychiatric consultation was also done on May 3, 2007, to consider her extreme lethargy. She was noted to have partially treated depression. The psychiatrist recommended

tapering her dose of Seroquel as there was no evidence that she suffered psychosis or bipolar disorder. She was noted to have a history of dementia, depression, generalized anxiety, and myofascial pain. She was assessed as obviously demented with short and long-term memory deficits, a low mood, insight diminished, possibly with thoughts of hopelessness and helplessness, and poor judgment. Staff reported her to be extremely lethargic and she told the examiner that she was very tired. P. Ex. 1, at 274-76; CMS Ex. 27, at 88-90. There is no indication that staff complained of agitation or crying out. A third psychiatric consult was done by the same psychiatrist on July 5, 2007, following the survey. The psychiatrist indicates in his report that he was asked to consult as the state surveyors suggested regarding whether Resident 3's complaints of pain were being ignored. He concurred with Dr. Kraus that Resident 3 did not appear to be in any pain at all, though he notes that she continues to seem tired and lethargic. He opined that her discomfort was secondary to dementia rather than any actual pain. The psychiatrist does not discuss the basis for his conclusion in this regard; he does not mention any testing or specific evaluation that he did or how he overcame the resident's clear communication deficits; his report does not mention whether he assessed the resident while she was under the influence of narcotic pain medication; and the record contains no information regarding the psychiatrist's qualification to develop a credible opinion on this issue. I further note that the first two evaluations lasted 40 and 45 minutes respectively, while the post-survey evaluation lasted no more than 25 minutes. His plan was to stop her Seroquel but continue her on the other psychotropic drugs. He notes he discussed his plan with staff, though there is no evidence of a change to the care plan. P. Ex. 1, at 271-72, 487.

On February 15, 2007, Resident 3 was assessed by Social Services as suffering severe "anxiety; anxious expression, rumination, worring (sic)" and mild to intermittent complaints of physical pain. P. Ex. 1, at 292. Behavior/Intervention Monthly Flow Record forms for February through May 2007 show that the only behavior being monitored was Resident 3's making paranoid statements. P. Ex. 1, at 284-91. It was not until June 25, 2007, that Petitioner began tracking Resident 3's behavior of "unredirectable," repetitive, calling-out. The flow record for June 2007 records on three days the interventions of redirection and one-on-one. P. Ex. 1, at 282.

Surveyor Tina Lubick testified that she made the observations of Resident 3 between June 12 and 14, 2007. Tr. at 43-45. She testified that when she observed Resident 3 at 12:25 p.m. on June 12, 2007, the resident was yelling that she was cold. A Certified Nursing Assistant (CNA) escorted the resident to her room and helped her put on a sweater. The CNA asked Resident 3 if she was having pain and she said she had back pain. The CNA told a licensed staff member that Resident 3 was complaining of pain, but nothing was done. Surveyor Lubick testified that the nurse should have assessed Resident 3 and offered pain medication or another intervention. Surveyor Lubick opined that Resident 3 was suffering from unresolved pain. Tr. at 45-47. Surveyor Lubick testified that she observed Resident 3 at 3:35 p.m. on June 12 and the resident was

moaning and calling out very loudly. Surveyor Lubick testified she asked Resident 3 what was the matter and she replied that her "legs were breaking." Tr. at 47. Surveyor Lubick testified that she spoke with a staff member who explained that the facility was not certain whether Resident 3 was suffering pain or whether her complaining was just a behavior. The staff member also advised that Resident 3 was on a scheduled pain medication and her medications were being adjusted. Surveyor Lubick opined that the staff should have assessed Resident 3 and determined whether pain medication or other intervention was appropriate. Surveyor Lubick testified based upon Resident 3's MAR (CMS Ex. 27, at 230-31) that as needed medication was available for Resident 3 but none was administered at the time the surveyor made her observation. Tr. at 47-49.

Surveyor Lubick observed Resident 3 again on June 13, 2007, at 9:55 a.m. when Resident 3 was moaning loudly. She observed five staff members pass the resident's room and none offered assistance. A therapy staff member did enter the room and ask the resident if she was hungry and then left the room. A nurse came to the room with cookies, a banana, and juice but she did not leave the banana and juice in reach of Resident 3. She testified that the nurse never asked about the resident's moaning or do any other assessment of the resident. Tr. at 50-51.

Surveyor Lubick observed Resident 3 again on June 14, 2007 at 7:55 a.m. and she was yelling loudly that her legs hurt while a CNA was present providing care. The CNA stopped and stated she would find a nurse but returned and indicated that she could not find a nurse. When the CNA started providing care the resident again yelled out and the CNA left again stating that she would find a nurse. The CNA returned and stated the nurse told her that Resident 3 had Vicodin at 6:00 a.m. and that the nurse instructed her to get the resident up and that she would be in to speak to the resident. The surveyor opined that the nurse should have assessed the resident. Tr. at 54-55.

Surveyor Lubick observed Resident 3 again at 8:20 a.m. on June 14, 2007. Petitioner's staff was using a mechanical lift to get the resident out of bed and Resident 3 was screaming or yelling while staff moved her from bed to bathroom. The surveyor asked her supervisor to observe too. Petitioner's director of nursing (DON) also entered the room and ordered staff to stop care stating that they could not allow the resident to be uncomfortable. The DON went for pain medication and another nurse came and gave the resident half of a Vicodin. The surveyor estimated that Resident 3 had been crying out for a half-hour. Tr. at 55-56. Surveyor Lubick opined that Resident 3 was experiencing pain due to the efforts of staff to move her despite the fact that she had received her scheduled pain medication. She could not opine that the half-Vicodin was effective at relieving the resident's pain as she did not see her again until seven hours later. Tr. at 58-60. However, the surveyor testified based upon the Nurse's Notes for June 14 at 8:40 a.m. (CMS Ex. 27, at 131) that the Vicodin did not relieve the resident's pain as she continued to yell and her physician needed to be contacted for additional instructions. Tr. at 60-61.

Surveyor Lubick testified that licensed staff did not assess Resident 3 for pain when alerted by staff; licensed staff did not intervene when they walked by Resident 3's room and she was moaning; and licensed staff did not assess whether the resident's pain medication was effective. Tr. at 62-63. She also opined that the fact the facility was not tracking as a behavior Resident 3's moaning and crying out, was consistent with her conclusion that the yelling out was due to pain and not a behavior. Tr. at 64. She opined that the care plan for managing the resident's pain was not adequate as it did not address her discomfort with activity or address the use of Vicodin. Tr. at 65-66. She testified regarding instances when pain medication was not effective that Petitioner's staff needed to assess the resident to see if the medication was effective and, if not, then other interventions needed to be implemented. Tr. at 67. She cites as an example entries in Nurse's Notes for April 7, 2007, at 6:45 a.m. that show that Resident 3 was given one 500 milligram Tylenol at 4:30 a.m., at 5:15 a.m. the resident continued to complain of pain and there was swelling of her left ankle; but there is no indication of the action taken by the nurse. She testified that a Nurse's Notes entry for April 12, 2007, shows the resident complained of pain at 11:45 p.m. on April 11, a Tylenol was given, later at 12:15 a.m. the resident was checked and she continued to complain of pain, but another Tylenol was not given until 5:15 a.m. when the resident was found to have an elevated temperature. Tr. at 67-70; CMS Ex. 27, at 123. Surveyor Lubick testified to entries in the Nurse's Notes that showed that Resident 3 received Vicodin but that it was not effective to stop her signs of possible pain; the physician was not advised or the notification was delayed regarding the effectiveness of the pain medication; and the physician continued to order the same medication and dosing. Tr. at 76-83; CMS Ex. 27, at 127-29. She opined that Petitioner violated the regulation and that the violation caused Resident 3 serious harm. Tr. at 83.

CMS called Daniel Berlowitz, MD who was accepted as an expert in geriatrics and pressure sores. Tr. at 330-31. Doctor Berlowitz opined that Resident 3 did not receive the necessary care and services to be as free of pain as possible. He testified that the clinical record shows the resident had chronic pain that required narcotic therapy to relieve the pain. He testified that the record shows that Resident 3 specifically stated that she was in pain on numerous occasions. Her treatment was limited to Tylenol until May and he opined that she should have been started on stronger medication sooner. He testified that systematic monitoring of the pain and the effect of pain medication is not reflected in the clinical record and that monitoring should have been done. He testified that using Tylenol, then escalating to narcotics as needed, and then to scheduled narcotics was fine, but there was an unduly long time in the transition to the stronger medication which he attributed to the absence of adequate monitoring of the resident's pain and the effectiveness of the medication. He testified that pain has both physical and psychological components and the fact that she was diagnosed with a chronic pain syndrome does not mean she did not have real pain. The fact she had pain is reflected by the fact that she had some relief from pain medication. He opined that pain is serious

harm and that there was no need for someone on comfort care measures such as Resident 3 to be in pain. He testified that Zoloft and Seroquel have no significant pain relieving properties. He testified that Lorazepam is an anti-anxiety medication and while it has no pain relieving effect it does have a sedating effect. Tr. at 350-57.

Petitioner called Bruce Kraus, MD, to testify. Dr. Kraus is board certified in internal medicine. He is Petitioner's Medical Director. He testified that he has 30 to 40 nursing home residents as patients in multiple facilities and he has been caring for long-term care residents for 30 years. He was Resident 3's treating physician. He testified that Resident 3 was a complicated case, particularly in the last couple months of her life. He testified that he or his physician assistant called the facility on a daily basis to check on his patients, including Resident 3. He testified that Resident 3 was in the late-stage of Alzheimer's, initially he could communicate with her, but subsequently she became confused and did not respond appropriately to questioning. She also had increasing agitation after about two or three months, the cause of which was the subject of considerable discussion. Her ability to eat and her mobility also declined. Tr. at 435-41. He testified that when the resident started falling asleep at meals it was determined to reduce her anti-anxiety medication due to concern that she was over sedated. He testified that when her medication was reduced there was an increase in agitation, anxiety, and moaning at times. He testified that there was concern related to whether the agitation was due to dementia or pain. The resident would call out but could not articulate whether she was in pain or not. He testified that there was no change in condition such as trauma or a broken bone, x-rays were done, but he was never able to determine that she was actually experiencing a painful condition and he concluded she had no significant cause for pain. Tr. at 459-63. He conceded however that osteoarthritis could be a cause for pain but it is usually slow developing and he did not feel the resident had a significant pain problem during the first couple months at the facility. Tr. at 464. He did not explain why he discounted the psychological pain disorder and myofascial pain as possible causes of pain related behavior. He opined that the care Resident 3 received at Petitioner for her moaning and agitation was consistent with the standard of practice and in some cases above and beyond. Tr. at 466. He testified that the care and services provided to the resident were not likely to lead to serious injury, harm, or death. He opined that there was no potential for more than minimal harm. Tr. at 470-71. Dr. Kraus testified that he was reasonably certain that Resident 3 was suffering from agitation due to her dementia rather than pain. Tr. at 501-02.

Kurt Hansen, MD, was called to testify by Petitioner and the parties agreed that he was qualified to render opinions as an expert in the area of geriatric care. Tr. at 661. He opined that the treatment of Resident 3's pain was consistent with standards of practice. He opined that her moaning was related to agitation and behavioral problems secondary to dementia rather than pain. He testified that the resident's primary care physician and a consulting psychiatrist were addressing her symptoms, there were multiple medication changes to address behavioral symptoms, x-rays were done, psychotropic medications

were used, and pain medication was increased. He opined that the fact increased pain medication did not stop the resident's moaning supports his conclusion that the moaning was not the result of pain. He opined that the resident's mild osteoarthritis would not cause pain consistent with the resident's behaviors rather the osteoarthritis would have caused pain with movement but the resident would cry-out whether moving or not. He opined that Petitioner's care plan was appropriate and not likely to cause serious injury, harm, death, or more than minimal harm. Tr. at 679-85. Dr. Hansen testified on cross-examination that he did not know what problems the resident was having with pain prior to her admission to Petitioner. Tr. at 734. He agreed that he could not rule out that the resident's moaning and crying out was due to pain rather than agitation. Tr. at 735-36.

Mary Widner, RN and Vice-President of Clinical Services for Heyde Health Systems, testified that she was responsible for overseeing the clinical services provided by all the company's skilled nursing facilities, including regulatory compliance. Tr. at 928. During the June and August 2007 surveys of Petitioner, she was the administrator of another skilled nursing facility owned by Heyde but she collaborated on the plan of correction for Petitioner. Tr. at 930-31. She testified that she reviewed Resident 3's chart and she opined that Petitioner did all it could consistent with the family's wishes for treating the resident. Tr. at 974. She testified that the resident was receiving narcotic pain medication but her crying out was more likely due to her dementia than pain. Tr. at 975. She testified that to the extent there was a deficiency it was not likely to cause serious harm or death or more than minimal harm. Tr. at 975.

I conclude that CMS has made a *prima facie* showing of a violation of 42 C.F.R. § 483.25 that Petitioner has failed to rebut. I conclude that Petitioner has failed to establish an affirmative defense to the violation. I further conclude that the evidence shows that Resident 3 suffered actual harm as a result of the violation.

Resident 3's clinical record that has been admitted as evidence shows that she had diagnoses that included a psychological pain disorder, myofascial pain, and osteoarthritis. Petitioner has not presented credible medical evidence that rules out either a psychological pain disorder or myofascial pain syndrome as a basis for pain. [10] Thus, there was a medical basis for Resident 3 to complain of pain. The care plan dated

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[10] There is no evidence before me that Petitioner developed and implemented a care plan to address the resident's diagnoses of psychological pain disorder and myofascial pain. While Petitioner's failure to deliver care and services pursuant to a properly implemented care plan for the resident's psychological pain disorder and myofascial pain would be an independent basis to find a violation of 42 C.F.R. § 483.25, the surveyors and CMS did not give Petitioner notice of that deficiency and I do not find a violation for that reason.

February 1, 2007, addressed Resident 3's diagnosis of arthritis, required that the resident's pain be assessed every shift and as necessary; required that Tylenol (Acetaminophen) be administered as ordered; required observation of the resident for non-verbal pain indicators; and established the goals that the resident be pain free or at an acceptable level of pain and able to participate in ADLs without pain. The care plan was updated on June 6, 2010, with the intervention to use Vicodin as necessary if pain was severe. The care plan was further updated on June 15, 2007, with the intervention to administer narcotics as ordered. CMS Ex. 27, at 153; P. Ex. 1, at 266. The care plan did not include non-pharmacological interventions for pain. However, a Care Conference Checklist dated April 24, 2007, indicates that the resident should be repositioned as needed for pain. P. Ex. 1, at 256. Thus, not only did Resident 3 have diagnoses that established a medical basis for her pain, Petitioner had adopted and modified a care plan to address the resident's pain secondary to her arthritis. Surveyor Lubick's unrebutted testimony shows that during the survey there were instances when Resident 3 acted as though she might be in pain, but staff did not respond as required by the care plan. The Board has repeatedly concluded that a facility's failure to follow its care plan is a violation of 42 C.F.R. § 483.25. *Venetian Gardens*, DAB No. 2285, at 5 (2009).

Petitioner's attempt to rebut the CMS *prima facie* case on the theory that the resident was not suffering pain must fail as the evidence simply does not support such a finding. From her admission to the time of the survey, Petitioner's staff and the resident's treating physician treated the resident as if she had pain, including care planning to address pain due to arthritis. The clinical record shows that from the resident's admission in January 2007 to the time of the survey, there were many instances when the resident complained of pain or displayed behaviors consistent with pain, and the resident apparently received relief from pain medications. The record shows that Dr. Kraus continued to treat the resident as if she had pain, despite his testimony at hearing that he had come to believe that the resident's calling out and agitation were due to dementia rather than pain. The documents show that prior to the survey he questioned whether the resident's behavior was due to pain or dementia, but he elected to attempt to find an appropriate mix of pain, anti-anxiety, and psychotropic medication. P. Ex. 1, at 106. Thus, Dr. Kraus's testimony that the resident's behaviors were due to dementia rather than pain, at least to the extent that he suggested that that was his opinion during and before the survey, is not weighty or persuasive.[11] Dr. Kraus's testimony is also considered not weighty due to his admission

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[11] "Credible evidence" is evidence that is worthy of belief. *Black's Law Dictionary* 596 (18th ed. 2004). The "weight of evidence" is the persuasiveness of some evidence compared to other evidence. *Id*. at 1625. Thus, while Dr. Kraus's testimony may be credible, particularly given his admission that he did not review the clinical record prior to testifying, his opinions at hearing are simply not as persuasive as the contemporaneous recordings in the clinical record because he did not review those records prior to hearing.

that he had not reviewed the resident's clinical record prior to the hearing.

I find that the post-survey psychiatric opinion that the resident was behaving due to dementia rather than pain (P. Ex. 1, at 271-72, 487) is not persuasive. Two prior psychiatric consultations were done by the same psychiatrist, and neither addressed any problem behavior the resident was having due to dementia. It was only after the survey that the psychiatrist opined that the resident was not suffering pain and I have no evidence that the psychiatrist did any evaluation or testing or was even qualified to render such an opinion.

I find that the testimony of Petitioner's expert, Dr. Hansen, is not weighty as he admitted that he was not aware of the resident's history of pain prior to her admission to Petitioner. Furthermore, he failed to resolve the inconsistency between the fact that pain medication had been effective in the past with his opinion that the resident was not in pain but was behaving due to her dementia.

Mary Widner's opinion that the resident was behaving due to her dementia is not given weight as the basis for the opinion and her qualification to develop the opinion is not established. Her opinion that the facility did all it could is simply not credible as it is based on her review of the clinical record, which shows that the resident's care plan for pain only provided for monitoring and assessing pain and administering pain medication, and a separate document that required repositioning. The clinical record does not show that other possible interventions for pain were attempted and assessed for effectiveness.

Accordingly, I conclude that Petitioner violated 42 C.F.R. § 483.25 in the case of Resident 3. However, the violation does not support a determination of immediate jeopardy and the determination is clearly erroneous as it relates to this deficiency. Immediate jeopardy is present if a provider's noncompliance caused or is likely to cause a resident serious injury, harm, or impairment, or death. The evidence supports a conclusion that the resident, more likely than not, suffered pain that was not promptly relieved. I have no difficulty concluding that pain amounts to actual harm. However, given the resident's history of pain and the treatment she did receive for pain, it was not "likely" that she would suffer serious injury, harm, impairment, or death due to Petitioner's failure to assess, monitor, and treat her pain given the facts of this case.

5. Petitioner violated 42 C.F.R. § 483.25(c), Tag F314, as alleged by the survey completed on June 27, 2007.

6. The determination that Petitioner's violation of 42 C.F.R. § 483.25(c) posed immediate jeopardy was not 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 care 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 are to be applied by surveyors 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. "Friction" is the mechanical force exerted on skin that is dragged across any surface. "Shearing" results when layers of the skin rub against each other or the underlying tissue rubs against the skin resulting in tissue damage. Friction and shearing are not primary causes of pressure ulcers but they are considered to be contributing factors. "Eschar" is a thick, leathery, black or brown colored, necrotic or devitalized tissue that has lost its normal physical properties and biological activity and it may be loose or firmly adhered to a wound. 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; *see also Meadow Wood Nursing Home*, DAB No. 1841 (2002) (loose dressing contaminated with fecal matter constitutes violation); *Ridge Terrace*, DAB No. 1834, at 15-16 (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.

An appellate panel of 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.Appx. 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 <u>necessary</u> 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 and CMS contend that Petitioner failed to render necessary treatment and services to Resident 3 to prevent the development of pressure sores on both of Resident 3's heels that were discovered April 28, 2007 and the pressure sore on Resident 3's right foot that was discovered on June 12, 2007. CMS Ex. 13, at 73-91. It is alleged that the violation posed immediate jeopardy beginning on June 12, 2007; that the jeopardy was abated on June 14, 2007; but that the deficiency continued as Petitioner had not implemented its complete action plan.

A Nursing Admission Assessment of Resident 3 was completed upon her admission on January 20, 2007, and documents a small Stage II decubitus ulcer on her coccyx. CMS Ex. 27, at 270. A Resident Assessment Protocol (RAP) form dated February 2, 2007 assessed the resident as at risk for pressure ulcers due to her current ulcer on her coccyx,

impaired bed mobility, and incontinence. It was noted on the form that she had diagnoses of dementia and osteoarthritis; that she was working with therapy to increase strength and mobility; that she was at low risk for nutritional depletion; and that she would benefit from toileting every two hours. P. Ex. 1, at 177. A Weekly Pressure Ulcer Progress Report shows that the ulcer was healed by February 28, 2007, the form notes that there was a risk for the ulcer to return due to incontinence of urine and there was an instruction to use a barrier cream to help prevent a new ulcer. CMS Ex. 27, at 278; P. Ex. 1, at 243, 246, 527.

Resident 3's initial care plan dated January 21, 2007, required that she be repositioned every two hours and that a weekly skin assessment be done and recorded. The plan for incontinence required that she be toileted every two hours or as necessary, that her perineal area be assessed, and that a protective cream be applied. P. Ex. 1, at 593. Resident 3's care plan dated February 6, 2007, listed as problems small sores on the resident's buttocks. There is no evidence that the care plan was changed when the sores on her buttocks were reported to be healed on February 28, 2007, contrary to the argument of Petitioner (P. Reply at 7-8). The care plan also listed a problem dated April 28, 2007,[12] as blisters of both heels that had hardened and were turning to eschar. A problem dated June 12, 2007 indicates an eschar on the right, fifth plantar surface. The individual interventions listed on the care plan are generally not dated. The interventions include: pad, protect, and/or apply skin preparation to fragile skin; position body with pillows/support devices and protect bony prominences; apply cream after each episode of incontinence, keep skin clean and dry, and perform peri-care after each incontinent episode; pressure reduction to be used for sitting and there was a direction that therapy review current type of pressure reduction which was noted not to be effective; staff was to inspect her skin daily; licensed staff was to perform weekly skin assessments; and weekly wound progress assessments and documentation were to be done, with treatment as ordered. The intervention of a dietary referral to review nutrition is dated February 13, 2007. The intervention of a physical therapy referral for ankle flexion therapy, I infer was related to the blisters discovered on the heels on April 28, 2007, which is consistent with the intervention dated May 1, 2007 that required placing Thera-Boots on both feet

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[12] Petitioner asserts that the mushy heels were actually discovered on April 23, 2007, but concedes that the handwriting on the facility's records could be read as either April 23 or 28, 2007. P. Brief at 6-7 (citing P. Ex. 1, at 247, 412). Petitioner's argument reveals a preference for April 23 in support of Petitioner's argument that staff did not fail to do a weekly skin assessment. However, if April 23 was the correct date there is no explanation for a five day delay in updating the resident's care plan to address the mushy heels. My reading of Petitioner's clinical record is that the mushy heels were discovered on April 28, 2007.

for protection. I also infer that the intervention of placing sheep skin padding between the Thera-Boot and the right foot by the little toe relates to the eschar discovered on the plantar surface of the right foot near the little toe on June 12, 2007. Although the care plan includes the intervention of elevating heels off the bed, it was never checked and, I infer, never planned or ordered. CMS Ex. 27, at 160; P. Ex. 1, at 258. Another care plan that appears to address eating, nutrition, hydration, oral and dental care, and skin condition with dates from February 1 to July 2007, includes the following interventions: a cushion in the wheel chair for pressure relief (undated); weekly assessment of the skin with a report of any redness to the RN (undated); updating the MD as necessary (undated); providing Thera-Boots (noted to be discontinued on an unreadable date in June 2007); and the use of an air mattress (June 15, 2007). P. Ex. 1, at 264. Petitioner also submitted as evidence a form for the period May 1, 2007 through May 31, 2007, on which staff recorded their initials to indicate that certain interventions were performed each shift with the following interventions that do not appear on another care plan document: skin barrier twice each day to both heels dated April 28, 2007; Thera-Boots on at all times with checks every two hours dated April 28, 2007; and the undated intervention to cover the right heel with telfa and to wrap with cling if drainage was present. P. Ex. 1, at 338.

Petitioner provided copies of weekly wound assessments for February 6, 13, 20, 28, and March 6, 13 and 20, 2007. The assessments show that the resident's buttocks ulcers healed as of February 28, 2007. The wound nurse recommended that due to the resident's ongoing urinary incontinence that a barrier cream be used following incontinence episodes. P. Ex. 1, at 245-46, 529-30. The next weekly wound assessment is dated a month later on April 28, 2007, when it was discovered during a shower assessment (P. Ex. 1, at 412) that the resident had bilateral spongy heels, with intact skin. The assessment indicates that a skin barrier was applied, the Thera-Boots were initiated, and the nurse would continue to monitor on the weekly wound assessment. The May 1 assessment shows that there was a problem with the fitting on the left boot that was adjusted to fit without discomfort. Nevertheless the nurse had the physician agree to a physical therapy consult to address the resident's dorsal flexion. In the May 8, 2007 assessment the nurse notes that the right heel is draining, that the staff continued to apply the Thera-Boot with skin barrier to the heels; and therapy had worked to improve the resident's ankle flexion so that the fit of the Thera-Boot was improved. Weekly wound assessment notes for the period May 15 through July 3, 2007, show that the heel ulcers healed but that a new sore formed on the resident's coccyx or buttocks. P. Ex. 1, at 245-50, 526, 531-34.

Brian Phillips, Physical Therapist, testified that he was requested on about May 1, 2007 to assist with obtaining a better fit with the Thera-Boot and a program was initiated to improve the range of motion in the resident's ankles. Although the resident never completely cooperated, the fit of the Thera-Boots was improved and the heel ulcers were healing. P. Ex. 38, at 3-4. Mr. Phillips also testified that in mid-June 2007, a nurse asked

him to check a small eschar on the plantar region of Resident 3's right foot at the edge of the boot. The nurse suggested that the sore was caused by rubbing of the skin against the boot. Mr. Phillips testified that he checked the boot and determined that it still fit properly but, he added a piece of gauze between the boot and the eschar as added protection. P. Ex. 38, at 5-7. Mr. Phillips Therapy Progress Notes dated June 14, 2007 show that the eschar on the plantar surface was discovered on June 11, 2007, that it appeared to be from the edge of the foot plate on the boot, and that he placed extra padding that he did not secure to the boot, but left loose. P. Ex. 1, at 524.

A pressure sore risk assessment, referred to as a "Braden Scale" was completed on April 15, 2007. The assessment scored the resident at mild risk for the development of new sores, but the assessment form that Petitioner used with the Braden Scale shows that the assessment did not consider the contributing diagnosis of Alzheimer's dementia and her history of having a pressure ulcer. The assessment also did not consider that the resident was cognitively impaired, that she had contractures, that she required assistance with ADLs, that she used psychotropic drugs, that she had repeatedly complained of lower extremity pain when lying in bed (P. Ex. 1, at 256), or that she had edema in her feet and ankles, a possible sign or symptom of venous insufficiency (P. Ex. 1, at 583). The interventions listed on the assessment form included the following: to turn and reposition the resident every two hours; to monitor laboratory findings and weight; to keep linen dry and wrinkle free; to keep skin clean and dry; to do peri-care after each incontinent episode; to apply barrier cream after each incontinent episode; to encourage mobility and ambulation; to have a nurse conduct weekly skin assessments; to monitoring for pain and to administer pain medication as ordered. CMS Ex. 27, at 284-85. A care plan dated April 23, 2007 that listed the problem of potential skin breakdown, listed the following interventions: (1) to assist the resident every two hours with repositioning, if needed (which is significantly different than the intervention recommended by the assessment to turn and reposition every two hours); (2) a weekly skin assessment; and (3) the requirement to report any open areas to a nurse. CMS Ex. 27, at 159; P. Ex. 1, at 595. An undated entry on the copy of the plan introduced as evidence by Petitioner indicates that it was discontinued because it was carried over to a skin care plan. P. Ex. 1, at 595. However, the care plan for alteration in skin integrity, a copy of which was introduced as evidence by both parties, does not include an intervention to turn and reposition every two hours or to assist the resident in doing so. The skin integrity care plan also does not include several other interventions identified by the April 15, 2007 assessment, including monitoring of laboratory findings and weight; keeping linen dry and wrinkle free; encouraging mobility and ambulation; or to monitor for pain and to administer pain medications as ordered. CMS Ex. 27, at 160; P. Ex. 1, at 258. There is also evidence that before the survey concluded Petition added the interventions of an air mattress and floating the heels. P. Ex. 1, at 259.

Resident 3's MDS with an assessment reference date of January 29, 2007 indicated that Resident 3 could walk with limited assistance and could reposition herself in bed with the

assistance of one person. P. Ex. 1, at 169-70. The April 15, 2007 MDS indicated that she was no longer ambulatory and required extensive assistance to reposition herself in bed and to transfer from a wheelchair or a bed. CMS Ex. 27, at 15; P. Ex. 1, at 162. Surveyor Lubick testified that Resident 3 was admitted to Petitioner with a pressure ulcer on her coccyx and she was assessed in January 2007 as at risk for pressure ulcers due to her existing ulcer and her impaired bed mobility and incontinence. Tr. at 86; CMS Ex. 27, at 19. She testified that when the resident was next assessed in April 2007, she was no longer ambulatory but she no longer had a pressure ulcer. She opined that the decline in Resident 3's ability to ambulate increased her risk for pressure sores. However, she did not find evidence that Petitioner added interventions to address prevention of pressure sores in light of the residents decline in ability to ambulate. Tr. at 87-88. She testified that the initial care plan dated January 21, 2007 that addressed skin integrity was inadequate, for while it provided for assessing and recording weekly, repositioning every two hours, and treatment as ordered, the plan did not address nutritional needs, the specific treatments to be provided for the existing ulcer, and it did not address therapy needs to attempt to increase mobility. Tr. at 89-90; P. Ex. 1, at 593. I note that the nutrition and hydration sections on the plan are not completed, however the mobility plan indicates that the resident is to be evaluated for therapies and encouraged to participate. I further note that the initial care plan included a plan to check the resident for incontinence every two hours, to assess her perineal area, to apply protective cream, and to toilet her every two hours. P. Ex. 1, at 593. Surveyor Lubick testified that Resident 3's care plan dated April 23, 2007 also required that the resident be repositioned every two hours but that she found no record that turning was actually done every two hours. Tr. at 91-96; CMS Ex. 27, at 159. She testified that the interventions listed on the care plan dated February 6, 2007 were insufficient as the plan did not list encouraging mobility, pressure reduction for the bed, elevating heels, dietary interventions, monitoring and medicating for pain, or a wound care consultant. Tr. at 97; CMS Ex. 27, at 150-51. She opined that the discovery of such large spongy areas on the resident's heels recorded on April 28, 2007 (CMS Ex. 27, at 290) was inconsistent with daily skin checks having been done. Tr. at 98. The care plan dated February 6, 2007, required daily skin inspections. CMS Ex. 27, at 160. She also testified that there was no evidence that staff was elevating the resident's heels. Tr. at 99. I note that the intervention of elevating the heels is not checked on the February 6, 2007 care plan. CMS Ex. 27, at 160. A Shower Day Worksheet/BodyAudit shows no skin issues on April 14, 2007, but shows blisters or sores on both heels and the coccyx on April 28, 2007. Tr. at 99-100; CMS Ex. 27, at 282. She opined that the spongy heels would have developed due to the resident having her heels on the bed and possibly due to friction from sliding the resident, and before blistering the skin would have appeared to be red. Tr. at 103. On April 9, 2007, the physician ordered that "skin barrier preps" be applied to both heels twice a day and for Thera-Boots to be used for both legs. CMS Ex. 27, at 52. Surveyor Lubick testified that Thera-Boots are a splinting device that keeps the heels elevated. Tr. at 103. A Repositioning Assessment completed by a physical therapist on May 2, 2007 specified

that the Thera-Boots were to be on securely at all times and checked every two hours for pressure. CMS Ex. 27, at 234; Tr. at 103-04. Surveyor Lubick testified that she was concerned about a Nutritional Progress Notes entry dated April 28, 2007 that states that the resident's skin was intact when it is documented that the resident had spongy heels. She also testified that she located no documents that indicated that the dietician was ever notified that Resident 3 had heel ulcers. She opined that the dietician should have reassessed the resident for nutritional needs. Tr. at 104-05; CMS Ex. 27, at 134. She testified that on May 29, 2007, Resident 3 had bilateral heel eschar, which is necrotic tissue. She testified that a wound covered with eschar is "unstageable." Tr. at 106-07. A Shower Day Worksheet/Body Audit dated June 11, 2007, did not indicate an area of eschar on the plantar surface of the right foot, only the sores on both heels. P. Ex. 1, at 404. Surveyor Lubick testified that on June 12, 2007 she observed an area of eschar on the plantar surface of the resident's right foot, on the ball or pad of the foot where the hard plastic edge of the Thera-Boot met the foot. She testified that Resident 3 had a downward flexion on her right foot which increased the probability of the pressure sore where the Thera-Boot met the foot. Surveyor Lubick testified that on June 13, 2007, she observed the eschar on Resident 3's heels. She testified that on June 13, 2007 the wound treatment nurse told her that the physician had not yet been notified of the new area of eschar on the plantar aspect of the right foot. A Nurse's Notes entry shows that the physician was notified at 1:20 p.m. on June 13, 2007. She opined that it was an error for staff not to have notified the physician on June 12 when the eschar was discovered. She also noted that staff had failed to document in the Nurse's Notes the discovery of the new eschar on June 12, 2007 (CMS Ex. 27, at 291). She opined that if staff had been checking the Thera-Boots every two hours as ordered and planned, they would have noticed that there was redness, irritation or other change before the new area of eschar developed. She opined that the new eschar could have been avoided had staff done the planned examinations and monitored the foot, particularly because Petitioner's records show that in May 2007, Resident 3 was assessed as having plantar flexion contractures of the right foot and had received physical therapy to address that problem. Tr. at 108-16. She opined that Petitioner violated 42 C.F.R. § 483.25(c) in the case of Resident 3 and that the violation was likely to cause serious injury, harm, impairment or death because Resident 3 was at high risk for ulcer development. Tr. at 121-22.

CMS called Daniel Berlowitz, MD who opined that the pressure sores that developed on Resident 3's heels were avoidable. Tr. at 333. He testified that the pressure sore on the resident's buttock at admission indicated that she was at risk for the development of pressure ulcers regardless of the score determined using an assessment instrument. He opined that given her limited mobility he assessed Resident 3 at moderate risk for developing other pressure ulcers. He opined that the pressure sore was avoidable as there were interventions available that were not used by Petitioner, including elevating the resident's heels or using a boot to keep the heels off the mattress. He noted that the issue of pressure on the heels was not addressed by the care plan in effect prior to development of the mushy heels. Tr. at 334-35. He opined that the ulcer that was discovered on the

plantar surface of Resident 3's foot on June 12, 2007 was also avoidable because there was some success at resolving the plantar flexion through physical therapy but the restorative program was not continued and the evidence does not show that the resident's skin was being monitored every two hours as directed. He testified that some evidence of skin damage would have been evident before eschar developed. Tr. at 338-40. He testified that the presence of eschar indicates that there is a stage three or four ulcer which is a deep tissue injury but they are generally treated as being unstageable. Tr. at 341. He opined that the deep tissue injury had the potential to cause serious harm, including serious infection. Tr. at 342. He opined that Petitioner did not do what was necessary to avoid pressure sores as the evidence does not show that turning and repositioning were accomplished, that heels were elevated or otherwise kept off the mattress, and the care plan was not changed to reflect the resident's loss of mobility. Regarding the eschar on the plantar surface of the right foot, he opined that Petitioner did not do what was necessary to address the contracture of the foot and to ensure monitoring. Tr. at 343-44. He testified that he saw no evidence of peripheral vascular disease that might have caused the heel ulcers. He opined that the plantar ulcer was more likely caused by rubbing on the boot than vascular disease. He opined that the ulcers on the feet were not Kennedy Terminal Ulcers and they were not part of the normal progression of Alzheimer's disease. Tr. at 348-50. He testified on cross-examination that, while a low-pressure mattress is an accepted intervention, the mattress alone is often not enough. Tr. at 379. He testified that Resident 3 entered the facility with a pressure ulcer in January 2007 and that Petitioner had done a good job healing that ulcer. He testified that after the pressure ulcer healed in March 2007, Resident 3 became progressively less mobile. Tr. at 387-88. He testified on cross-examination that pressure ulcers do commonly occur in people with advanced Alzheimer's disease. However, the fact that a person with advanced Alzheimer's developed pressure ulcers does not mean the ulcers are attributable to the disease rather than a failure to reposition, to relieve pressure, or to address incontinence problems. Tr. at 401-02. He opined that if skin assessments were being done as planned and the Thera-Boot was being removed every few hours as planned, skin changes would have been noted before the eschar formed on the plantar surface of the foot. Tr. at 422-23. I find that Dr. Berlowitz's testimony is fully credible and persuasive.

Resident 3's physician, Dr. Krause, could not recall whether Resident 3 had a pressure ulcer on her coccyx or buttock when she entered the facility in January 2007 or whether she had a history of a healed ulcer. He testified that he had not had time to review the details of the resident's clinical record prior to being called to testify, which causes me to find his testimony less weighty than the testimony of Dr. Berlowitz who did review the clinical record. Dr. Krause acknowledged that at some time the resident developed mushy heels. He testified that he believed that interventions were in place to prevent pressure sores. He opined that despite the interventions the pressure sores on Resident 3's heels occurred anyway. He opined that Resident 3's care plan was adequate and appropriate. Tr. at 442-45. He testified that he believed the interventions he ordered were being followed, although he did not state how he knew and he was not always

present at the facility. Tr. at 447. He testified that he believed that the treatment for Resident 3's heel pressure sores was "adequate, appropriate, and consistent with good standards of care." Tr. at 448. He opined that Resident 3's Alzheimer's played a significant role in the development of the pressure ulcers due to her increased confusion, decreased ability to ambulate, and increasing difficulty eating, maintaining good nutrition, and her weight loss. He testified that it is a known risk that conditions such as those experienced by Resident 3, place a person at significant risk for skin problems including ulcerations. Tr. at 448-49. He testified that Resident 3 developed a pressure sore from her Thera-Boot and he opined that it was unavoidable because the boot was necessary to prevent further damage to the heels. Tr. at 468. He testified that the care the resident received was consistent with the standards of care and did not put the resident at risk for serious harm or death. Tr. at 469. He testified that there was no potential for more than minimal harm. Tr. at 472. He agreed on cross-examination that skin would appear red before eschar formed. Tr. at 497. I do not find persuasive Dr. Krause's opinion that Resident 3's pressure sores were unavoidable. He readily admitted that he had not reviewed the resident's records prior to the hearing, thus his recollection of the various interventions recorded in multiple documents in the clinical records is suspect if not incredible. Further, Dr. Krause's awareness of whether interventions were being performed by staff as ordered is also suspect given the facts that he was not always at the facility and he had not reviewed the record prior to the hearing. He recognized that the resident's decreased ability to ambulate may have contributed to her heel ulcers, but he did not explain why there was no new interventions added to the care plan to address the decreased ambulation after the April MDS was done. His testimony that the ulcer caused by the Thera-Boot was unavoidable is also not persuasive given the testimony of Mr. Phillips that he remedied the problem by adding a loose piece of gauze and the notation in the clinical record that a piece of lamb's wool was added to relieve the pressure and shearing or friction. His opinion that there was no risk for serious harm or death or even minimal harm is not credible. Dr. Berlowitz's testimony that deep tissue injuries pose the risk for serious infections that can cause death or serious harm is more persuasive.

Dr. Hansen testified that the eschar on the plantar area of Resident 3's right foot might not have been caused by unrelieved pressure. He testified that he was no expert in the type of boot used but he opined that the eschar may have been caused by rubbing or scraping. He stated he did not consider the eschar significant as the resident had larger pressure sores on her heels. He testified that it would not be a standard of care to elevate the heels of a resident assessed as at low risk for pressure sores, otherwise virtually all nursing home residents would have their heels elevated. He testified that a weekly skin assessment would be the standard of care for a resident at low risk for pressure sores. He opined that the eschar on the plantar surface of Resident 3's foot likely developed as a blister from friction that then broke and became eschar. He opined that when the eschar was found, it was properly treated, that it was not likely to cause serious injury, harm, or death, or that it would have posed more than minimal harm. He opined that the heel ulcers were properly treated with the Thera-Boot, physical therapy, and weekly skin

assessments, and the heel ulcers were healing and improving. Tr. at 662-70. He opined that the heel sores were unavoidable because staff was doing screening and they developed anyway. He opined that the heels were appropriately treated and were not more likely than not to cause serious harm, injury, or death, but they were likely to cause more than minimal harm. Tr. at 673. He testified in response to my questions that there is no doubt that the resident's mushy heels were caused by pressure on her heels. He agreed that it was foreseeable that a resident who was often in bed would develop pressure sores on her heels. Tr. at 700-01. He also admitted in response to my question that the contracture of the resident's foot and contact with the edge of the Thera-Boot may have been enough pressure to cause the eschar on the plantar surface of the resident's foot within a few days. Tr. at 709-11. Dr. Hansen testified on cross-examination that he opined that Resident 3 was at low risk for pressure sores based upon an assessment done by Petitioner. However, he admitted that because the resident had a pressure sore before, she was at risk to develop another pressure sore. He testified however that the fact the resident had a prior pressure sore on her coccyx would not cause him to order elevation of her heels. Tr. at 714-17. He testified that rotating the resident in the bed to protect her coccyx and weekly skin assessments would be appropriate interventions. Tr. at 719. Regarding the eschar on the plantar surface, he explained that a pressure sore is caused by squeezing the blood out of the tissue until the tissue died which is different from rubbing the skin and causing trauma, though both will have a similar appearance and in either case the injury was caused by the Thera-Boot. He agreed that if staff had been checking the skin under the boot, they would have noticed some type of mark before the eschar formed. Tr. at 721-22. He agreed that padding the Thera-Boot would have avoided the problem. Tr. at 726. Dr. Hansen's testimony is found to be credible and persuasive and it supports my findings and conclusions set forth hereafter.

Janet Lutze, RN, a wound care specialist, testified that it would be unusual for the Thera-Boot to cause a pressure ulcer on the resident's plantar surface of her foot. She opined that the development of the eschar was not foreseeable. She opined that the eschar on the plantar surface could have developed quickly with little prior indication. Tr. at 748-50. She opined that the heel ulcers likely would have led to serious injury, harm, or death but they were treated with the Thera-Boots. She opined that the eschar on the plantar surface did not have the potential for even minimal harm. She opined that inadequate nutrition leads to skin breakdown. Tr. at 757-59. She testified on cross-examination that she saw the eschar on the plantar surface of Resident 3's foot on June 26, 2007, she opined that it was healing. She admitted that she was not aware that physical therapy had difficulty fitting the Thera-Boot and agreed that pressure on the foot caused by the resident's flexion of the foot could cause a pressure sore. Tr. at 760-61. She testified that the Thera-Boot should have come off so the skin could be checked every two hours if ordered and at least every four hours if not ordered for more frequent checks. She agreed that it would be surprising, if the Thera-Boot was being removed and the skin was checked every two hours, that the first sign of injury to the plantar surface was the eschar. Tr. at 765. Nurse Lutze agreed with me that development of a pressure sore is a

significant change that requires that the care planning team get together to reassess the care plan. But she testified that a spongy heel is not necessarily a pressure ulcer, rather it is an indication that something may develop. Tr. at 770-72. She testified that when she saw the resident's heels in June 2007, the sores were static. Tr. at 772.
Mary Widner opined that Resident 3's care plan for pressure ulcers was adequate, that staff followed the plan and that the resident's mushy heels and the eschar on the plantar aspect of the right foot were due to her medical condition and unavoidable. She testified that the pressure sores were not likely to lead to serious injury, harm, or death as they were treated. She agreed that the ulcers were actual harm. Tr. at 976-82. She agreed on my examination that Thera-Boots are not intended to cause eschar so the Thera-Boot used for Resident 3 was either used incorrectly or it was not an appropriate intervention. Tr. at 990-91. On cross-examination she agreed that the deficiency cited under Tag F314 had the potential for more than minimal harm but she felt staff did all they could. Tr. at 997-98.

I conclude that Petitioner violated 42 C.F.R. § 483.25(c) (Tag F314) because it failed to deliver necessary care and services to Resident 3 to prevent the development of new pressure ulcers. I further conclude that the determination that the deficiency posed immediate jeopardy is not clearly erroneous.

The gist of the deficiency citation in the SOD is that Petitioner failed to deliver necessary care and services to ensure that Resident 3 did not develop new pressure sores, after the pressure sore she had on admission was healed. CMS Ex. 13, at 73-74. There is no dispute that when Resident 3 was admitted to the facility on January 20, 2007, she had at least one Stage II pressure sore on her buttocks.[13] There is no dispute that the pressure

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[13] Petitioner's clinical records are not clear regarding whether the resident had one or two pressure ulcers when she was admitted. The MDS with an assessment reference date of January 29, 2007, appears to indicate two ulcers, one a Stage I and one a Stage II. P. Ex. 1, 171. However, a Weekly Pressure Ulcer Progress Report dated February 6, 2007 only describes one Stage II ulcer. But, an entry on the same form dated February 13, 2007 indicates there were two Stage II ulcers. A diagram on the form also shows two ulcers, one on each buttock. CMS Ex. 27, at 278; P. Ex. 1, at 243. Nurse's Notes that record the weekly wound assessment are similarly confusing. P. Ex. 1, at 245. An undated assessment indicates a Stage II ulcer on the right gluteal cheek. P. Ex. 1, at 222. The Skin Integrity care plan indicates an ulcer on the right gluteal area on February 6, 2007, and an ulcer on the left gluteal area on February 13, 2007. P. Ex. 1, at 258. Whether or not the resident had one or two ulcers when she was admitted does not affect this decision as it is clear that she had a least one on admission.

sores on Resident 3's buttocks healed by February 28, 2007. There is no dispute that Resident 3 remained a resident in the facility. There is no dispute that on April 28, 2007, staff discovered that Resident 3 had developed spongy or mushy spots on her heels and that such spots are considered to be pressure ulcers. Thus, CMS has satisfied the burden of coming forward with sufficient evidence to make a *prima facie* showing of a violation of 42 C.F.R. § 483.25(c)(2).

Petitioner argues that there is no violation of 42 C.F.R. § 483.25(c)(1) in this case because the resident was admitted to Petitioner with a pressure sore. Petitioner also argues that there can be no violation of 42 C.F.R. § 483.25(c)(2) because the resident did not have a preexisting pressure sore when the mushy heels developed and, according to Petitioner, a resident must have another sore already present for 42 C.F.R. § 483.25(c)(2) to be triggered by the development of a new pressure ulcer. P. Reply at 5-6. Petitioner's interpretation of the regulation and the Board's prior decisions addressing the regulations is in error. A facility will generally not be found in violation of 42 C.F.R. § 483.25(c)(1) for the development of a pressure sore prior to admission of a resident to a facility. However, as the Board has addressed repeatedly, 42 C.F.R. § 483.25(c)(2) clearly obligates a facility to deliver necessary treatment and services to promote healing and to prevent infection of an existing pressure ulcer, and to prevent the development of new sores. Petitioner cites no authority in support of its interpretation of 42 C.F.R. § 483.25(c)(2) that when a facility resolves a preexisting sore, the facility may not be found in violation of the regulation based on the development of a new pressure ulcer. The only sensible reading of the regulation and the clear intent of the regulation is that a facility must provide treatment and services necessary to heal a pressure ulcer that existed when a resident is admitted and to prevent the development of any new sore while the resident is under the facility's care. The regulation establishes one defense for a facility and that is that the development of new sores was unavoidable. *Clermont Nursing and Convalescent Ctr.*, DAB No. 1923, at 10.

Petitioner argues that the "appearance of a pressure sore after admission is a deficiency only if it is not demonstrated to be unavoidable." P. Br. at 6. Petitioner's statement reflects understanding that when CMS has made a *prima facie* showing of a violation, the burden to show unavoidability is upon Petitioner. Petitioner argues that the development of the heel ulcers and the plantar ulcer was unavoidable. Petitioner argues that after the buttocks sores healed staff continued to assess the resident; that the April 15 assessment showed the resident at low risk for new sores; that the resident's care plan continued to provide for a turning schedule and weekly skin assessments; that the standard of care did not require floating the resident's heels; that the plantar eschar was not a pressure sore because it was probably caused by friction; and that the plantar eschar was caused by the Thera-Boots which were prescribed as an intervention of the heel ulcers and should thus be considered unavoidable. P. Br. at 6-10. Based on my review of the clinical records and Petitioner's arguments, I conclude that Petitioner has failed to show that the resident's heel and plantar sores were unavoidable.

Petitioner cannot show that the heel ulcers were unavoidable in this case because Petitioner's evidence does not show that the care planned interventions were implemented. Petitioner's care plan for Resident 3 related to skin integrity and the avoidance of pressure sores is not found in one consolidated care plan. Rather, interventions are found in various documents executed during the approximate five month period from the resident's admission to the survey. Resident 3's initial care plan dated January 21, 2007, required that she be repositioned every two hours. Her care plan dated February 6, 2007, required daily skin inspections and to position her body with pillows/support devices and to protect bony prominences. The pressure sore assessment on April 15, 2007, specified that the resident should be turned and repositioned every two hours. The April 23, 2007 care plan required that the resident be assisted with repositioning every two hours if needed. But it is not clear whether the as needed language of the April 23 plan referred to a need for assistance with repositioning or the need to reposition. The April 23 care plan is nonsensical given that the April 15, 2007 MDS reflected a significant decrease in mobility, including bed mobility with extensive assistance needed for repositioning in bed (CMS Ex. 27, at 15; P. Ex. 1, at 162), and that the April 15 pressure sore assessment identified the need to turn and reposition the resident every two hours (CMS Ex. 27, at 284). In fact, the copy of the April 23, 2007 care plan introduced by Petitioner shows on its face that it was discontinued and that the skin care plan controlled.

Petitioner has failed to show in this case that the resident was turned and repositioned every two hours as required by her care plan. Petitioner has failed to show that daily skin inspections were done. Petitioner has failed to show that staff protected bony prominences, such as the resident's heels, by elevating her heels or otherwise. Petitioner argues regarding turning that the April 23 care plan eliminated the need to turn and reposition the resident every two hours (P. Reply at 8), but I find that argument neither meritorious nor credible for the reasons already noted. Petitioner points to no evidence that staff took any action to protect Resident 3's bony prominences. Petitioner's argument that elevating the heels in a case like that of Resident 3 is not standard of care is belied by the fact that Resident 3's care planning team, including presumably Dr. Kraus, adopted the intervention to protect bony prominences which includes the heels. Petitioner also fails to identify evidence that shows that daily skin inspections were actually completed for the Resident.

Regarding the development of the plantar eschar, Petitioner suggests first that it was not a pressure sore at all. P. Brief at 8-9. However, that theory is inconsistent with the testimony of Petitioner's witness Dr. Hansen who agreed that contracture of the resident's foot and contact with the edge of the Thera-Boot may have been enough pressure to cause the eschar after a few days. Dr. Hansen also agreed that if staff had been checking the skin under the boot they should have seen some evidence prior to formation of the eschar. Finally, he agreed that simply padding the boot would have

avoided the problem. Nurse Lutze, another of Petitioner's experts, agreed that pressure caused by the flexion of the resident's foot causing contact with the boot could result in pressure that would cause an ulcer and that the Thera-Boot should have been removed every two to four hours so that the skin could be inspected. Nurse Lutze was also skeptical that skin inspections were being done every two hours as ordered given that the first sign discovered by staff was the eschar. Petitioner's argument that initials entered on a form each shift support an inference that the skin under the Thera-Boot was checked every two hours as ordered (P. Reply at 8-9) fails due to the testimony of its own experts that if checks were done as ordered, staff would have seen some sign of skin trauma prior to the discovery of the eschar. Furthermore, the testimony of the physical therapist and the documents show that the pressure caused by the contact between the plantar surface and the boot was easily addressed after the eschar was discovered by simply adding gauze or lambs wool as additional padding.

Accordingly, I conclude that CMS made a *prima facie* showing of a violation of 42 C.F.R. § 483.25(c)(2) and that Petitioner has failed to show that the development of pressure ulcers was unavoidable.

I further conclude that the declaration of immediate jeopardy was not clearly erroneous. Dr. Berlowitz opined that the heel ulcers posed the risk for serious harm, including the risk for serious infection. Nurse Lutze opined that the heel ulcers would likely lead to serious injury, harm, or death if not treated. Mary Widner agreed that all ulcers are at least actual harm. The evidence supports the conclusion that Petitioner's violation of 42 C.F.R. § 483.25(c) posed immediate jeopardy and Petitioner has failed to meet the burden of showing that the determination of immediate jeopardy was clearing erroneous.

7. Petitioner violated 42 C.F.R. § 483.25(i)(l), Tag F325, as alleged by the survey completed on June 27, 2007.

8. The determination that Petitioner's violation of 42 C.F.R. § 483.35(i)(1) posed immediate jeopardy was not clearly erroneous.

This regulation requires that, based on a resident's comprehensive assessment, a facility must ensure that a resident maintains acceptable parameters of nutritional status, such as body weight and protein levels, unless the resident's condition demonstrates that this is not possible. 42 C.F.R. § 483.25(i)(1).

The SOM instructs surveyors that the intent of the regulation is that a resident maintain acceptable nutrition, to the extent possible, and requires that the facility: provide nutritional care and services consistent with the resident's comprehensive assessment; recognize, evaluate, and address residents' needs for nutrition; and provide a therapeutic diet considering the resident's condition and preferences when there is an assessed need. The SOM indicates that weight is a parameter of nutrition and that

unplanned or unintended weight loss may indicate a nutritional problem. The SOM cautions that ideal body weight charts have not been validated for the institutionalized elderly and weight loss is only a guide for determining nutritional status. The SOM provides some suggested parameters for surveyors to consider when evaluating the significance of weight loss. Significant loss is weight loss of five percent in one month, seven and one-half percent in three months, or ten percent in six months. Severe weight loss is loss greater than five percent in one month, seven and one-half percent in three months, or ten percent in six months. SOM, App. PP, Tag F325.

The Board has stated that weight loss alone does not support a deficiency but weight loss does trigger an inference of inadequate nutrition. *Carehouse Convalescent Hosp.*, DAB No. 1799, at 21–22 (2001). If a facility shows by a preponderance of the evidence that it "provided the resident with adequate nutrition" or that the weight loss was due to non-nutritive factors, it can rebut a *prima facie* case based on such an inference. *Carehouse*, DAB No. 1799, at 22. The Board's interpretation of the regulation is that a facility is not strictly liable for a resident's weight loss (*Carehouse*, DAB No. 1799, at 21) but a "facility is responsible for taking all reasonable steps to ensure that the resident receives nutrition adequate to his or her needs." *Windsor House*, DAB No. 1942, at 18 (2004). The "clinical condition exception" is narrow and applies only when a facility demonstrates that it cannot provide nutrition adequate for the resident's overall needs so that weight loss is unavoidable. *Carrington Place of Muscatine*, DAB No. 2321, at 5 (2010); *Carehouse*, DAB No. 1799; *Windsor House*, DAB No. 1942. The Board has indicated that the presence of a significant clinical condition alone does not prove that maintaining acceptable nutrition is unavoidable. *Windsor House*, DAB No. 1942, at 18. In *Windsor House*, the Board found that surveyor observations that a resident was not properly assisted with eating or that the facility was slow to react to a resident's weight loss was sufficient evidence that the facility failed to provide the resident with adequate nutrition. *Id*.

The surveyors allege that Petitioner violated 42 C.F.R. § 483.25(i)(1) in the case of Resident 3 and that the violation posed immediate jeopardy to the resident. CMS Ex. 13, at 99-113. The surveyors allege that Resident 3 experienced a severe weight loss of 17 to 23 percent from January 2007 through June 14, 2007, with the note that the survey team was unable to make an accurate determination of weight loss due to discrepancies in the facility records regarding the resident's weight. The surveyors allege that Petitioner failed to notify the registered dietician and physician of the weight loss; failed to assess the cause of the weight loss; and failed to update the care plan with interventions to prevent weight loss. The surveyors allege that immediate jeopardy began on June 4, 2007 and continued until immediate jeopardy was removed on June 14, 2007, but that the deficiency remained and continued to pose a risk for more than minimal harm without actual harm or immediate jeopardy. CMS Ex. 13, at 100.

The evidence shows that Resident 3 was admitted to the facility on January 20, 2007. Her MDS with an assessment reference date of January 29, 2007, shows that she was 66 inches tall and weighed 194 pounds. CMS Ex. 27, at 5-6. Surveyor Lubick testified that Resident 3 had a 10.6 pound weight loss at the beginning of April 2007 based upon Petitioner's weight records. She testified that Resident 3 had lost 23 pounds as of June 4, 2007. CMS Ex. 27, at 141-43; Tr. at 125. Petitioner's records reflect the following weights for Resident 3 with the gains or losses I have calculated from one weighing to the next:

Date	**Weight**	**Gain (+)/Loss (-)**	**% Change**	
1/21/2007	193.6	Admission		
2/6/2007	194.0	+0.4		
2/9/2007	199.3	+5.3		
3/4/2007	200.6	+1.3		
4/1/2007	190.5	-10.1	5.03%	
4/1/2007	192.1	-8.5	4.24%	Reweigh – Compared to 200.6#
5/1/2007	193.6	+1.5		
6/4/2007	170.6	-23.0	11.88%	
6/13/2007	148.7	-21.9	12.84%	
6/14/2007	168.4	-2.2	1.29%	Reweigh – Compared to 170.6#
Overall Change	1/21/2007 to 6/14/2007	-25.2	13.02%	

CMS Ex. 27, at 134-44. Thus, depending upon which weight is used for the calculation, Resident 3 lost either 10.1 pounds or 8.5 pounds between the March 4 and April 1 weighings. Petitioner's records show that Resident 3 lost more than twenty pounds between May 1, 2007 and June 13 or 14, 2007, a loss of more than eleven percent. The evidence also shows that Resident 3 had lost more than thirteen percent of her body weight in the five month period, January to mid-June 2007. Petitioner concedes that Resident 3 experienced a 11.9 percent to a 13 percent weight loss between January and June 2007. P. Br. at 3. Petitioner also concedes a twenty pound weight loss between May weighing and the June weights. P. Br. at 4. Although the evidence shows that Resident 3 was overweight when admitted, the evidence does not show that the weight loss between January and June 2007 was planned weight loss. Accordingly, the weight loss of more than five percent between May and June 2007, or the ten percent weight loss between January and June 2007 raises an inference and amounts to a *prima facie* showing of a lack of adequate nutrition. Thus, Petitioner has the burden of showing that the

weight loss was not due to a failure to provide adequate nutrition or that the failure to maintain adequate nutrition was unavoidable.

Petitioner argues that the April reweigh showed only a 4.2 percent weight loss, which is not considered significant under the SOM. Petitioner argues that it nevertheless intervened by ordering a swallow study, ordering an occupational therapy assessment, adjusting the residents psychotropic medications to reduce her lethargy, by changing her to a mechanical soft diet, and by moving her to a second feeding. P. Br. at 4; P. Ex. 1, at 96, 98, 444, 446-47, 449, 454-56. An Interdisciplinary Resident Screen form dated April 16, 2007, that reflects the results of the occupational therapy and speech-language therapy screens, shows that Resident 3 had experienced the following changes in condition: she formerly required supervision for eating but was assessed as requiring assistance with eating; and she had been pocketing food. P. Ex. 1, at 440. Petitioner argues that the resident had a small increase in weight between the April and May 2007 weighings and that the significant loss occurred in May and June 2007. After the weight in June confirmed a significant weight loss, Petitioner's power of attorney declined to approve tube feeding of the resident on two occasions. Petitioner argues that a supplement was ordered but that the resident would have lost weight without tube feeding no matter what other interventions were attempted due to her advanced Alzheimer's disease. Petitioner argues that it took all reasonable measures but that the resident's weight loss was clinically unavoidable. P. Br. at 4-5. Petitioner also argues that the change in Resident 3's consumption was not sufficient to give staff notice of a nutrition problem for the resident. Petition cites the testimony of its expert, Dr. Hansen, in support of its position. Dr. Hansen testified that he had reviewed the resident's intake records. He testified that the records would not have alerted the staff that the resident was in the process of losing twenty pounds because the oral intake was recorded and, while she was not eating 100 percent of meals, she was recorded to eat fifty to seventy-five percent for some meals. He opined that based on what the record showed she was eating, she should have been experiencing a gradual weight loss of about ten pounds per month rather than a twenty pound weight loss in one month. Tr. at 675-78. Dr. Hansen did not and could not vouch for the accuracy of Petitioner's intake records for the resident. The records show that in March 2007, the resident consistently ate fifty to 100 percent of her meals with only three or four instances when she ate twenty-five percent. P. Ex. 1, at 397; CMS Ex. 27, at 311. The record for April 2007 shows fewer instances of 100 percent meal consumption and many more instances of only twenty-five percent consumption. P. Ex. 1, at 398; CMS Ex. 27, at 313. The record for May 2007 shows few instances of 100 percent consumption; many instances of twenty-five percent consumption, and many instances of no consumption. P. Ex. 1, at 400; CMS Ex. 27, at 315. I do not require an expert to determine that the intake records for March, April, and May 2007 show that Resident 3 was experiencing a significant decline in her intake of nutrition at meals. Furthermore, Dr. Hansen's testimony supports an inference that Petitioner's recording of meal consumption, particularly in late April and May, was probably overstated since even the reweigh on June 13, 2007 shows a weight loss of more than twenty pounds, which is

twice the loss Dr. Hansen testified is supportable by the amount recorded as consumed by the resident. I find no evidence, and Petitioner points to none, of any assessment of the effectiveness of the interventions implemented in April. Petitioner cites no evidence of any additional interventions, such as supplements, encouragement from staff, or weekly weighings, implemented in late April and May despite the obvious reduction in the resident's consumption.

After reviewing all the evidence, I conclude that Petitioner failed to show that it provided Resident 3 adequate nutrition to meet her needs beginning in April 2007 or that the resident's weight loss was unavoidable.

Surveyor Lubick testified that she was told by a member of the dietary department that interventions for weight loss implemented in April included moving Resident 3 to an assisted table and changing the resident's diet. Tr. at 126. A Nutrition Progress Notes entry dated April 17, 2007, shows that the dietician concluded that the resident had less than or equal to a five percent weight change; that the resident's intake was seventy-five percent; that medications should be reviewed; and that the physician was to be notified of the weight change. CMS Ex. 27, at 134. Nutrition Recommendations dated April 17, 2007, lists a weight loss of 10.6 pounds, which would have been a 5.28 percent weight loss from the March 4 weight; notes that Resident 3 is sleeping through some meals; recommends evaluation of the resident's psychotropic medications; and recommends notification of the physician. CMS Ex. 27, at 135-37. Physicians orders for April 18, 2007 are for speech therapy to evaluate the resident for oral dysphagia (CMS Ex. 27, at 50), and dose reductions in her Seroquel and Clonazepam with a psychiatric consultative examination (CMS Ex. 27, at 51). On April 19, 2007 the physician ordered a diet change to mechanical soft with ground meat due to pocketing of food and decreased chewing at times; an occupational therapy evaluation of ability to self-feed and training in feeding skills (CMS Ex. 27, at 51, 157). The eating care plan dated February 1, 2007 (CMS Ex. 27, at 152) was not updated to include the interventions from April 2007, except the occupational therapy interventions including self-feeding training and upper extremity exercises were included on a separate therapy plan (CMS Ex. 27, at 157). Tr. at 139-40. Surveyor Lubick testified that staff did not notify Resident 3's physician of weight loss revealed by the weighing done in early June until she inquired during the survey. Tr. at 128-29; P. Ex. 1, at 78. The Nutrition At Risk Summary dated June 14, 2007, reflects that Resident 3 suffered significant weight loss and pressure ulcers. The form also reflects that it was faxed on June 14 and again on June 15 and that the physician noted receipt on June 16, 2007. P. Ex. 1, at 78. Surveyor Lubick testified that she concluded that ten days elapsed between the identification of the weight loss and the attempt to notify the physician on June 14, 2007. Tr. at 129. She further testified that when she interviewed the resident's physician, he stated that he was not aware of the weight loss identified in early June. Tr. at 131. She testified that she interviewed the dietician who told her that she was unaware of Resident 3's weight loss in May and June 2007. Tr. at 136. Surveyor Lubick opined that when the twenty-three pound weight loss was identified on

June 4, 2007, there should have been notification of the physician, a nutritional assessment, and the use of supplements. Tr. at 134. She testified that she found no evidence that Resident 3 had been placed on a weight loss plan. Tr. at 137-38. She opined that staff did not timely notify the physician in April 2007, when Resident 3 experienced an 8.5 to 10.1 pound weight loss. Tr. at 139. She opined that the interventions record in April 2007 were inadequate because they did not include supplements, address hydration, or require that staff encourage eating. Tr. at 140. She opined that the nutrition assessment done at admission (CMS Ex. 27, at 133) was insufficient as it did not address hydration needs. Tr. at 140-41. Surveyor Lubick testified that Petitioner's records for Resident 3 record declining consumption of food at meals during the period March through June 13, 2007. Tr. at 142-45; CMS Ex. 27, at 311, 313, 315, 317. She testified that she found no evidence that Resident 3's physician was notified of the decreased food intake. She testified she found no evidence that the dietician was advised of the decreased food intake or a dietary assessment related to the decreased intake. Tr. at 145. She testified that Resident 3 made progress with occupational therapy but she found no evidence that a restorative program was continued after May 14, 2007, as recommended by the May 14, 2007 occupational therapy discharge summary. Tr. at 147-49; CMS Ex. 27, at 377. She opined that Petitioner was in violation of 42 C.F.R. § 483.25(c) in the case of Resident 3 and that violation was likely to cause serious injury, harm impairment, or death. Tr. at 149-50.

Dr. Berlowitz testified that Resident 3's approximate twenty pound weight loss between May and June 2007 and her nutrition were not adequately addressed. Her documented decrease in intake beginning late April and early May should have been addressed right away. A diet change in April 2007 was followed by continued inadequate intake without intervention by Petitioner. Given the resident's documented inadequate intake and her weight loss, he testified that he would be concerned about the adequacy of the resident's nutrition. He testified that he could not testify as to what interventions might have been successful as interventions were not done. He opined that an assessment should have been done to discover why Resident 3 was not eating; and then interventions should have been attempted to improve her eating, including different food preparations and supplements. He opined that inadequate nutrition could adversely affect pressure ulcers and psychosocial well-being. Tr. at 361-66. On cross-examination Dr. Berlowitz opined that Petitioner took appropriate first steps by having a speech therapist evaluate her swallowing, changing her to a ground diet, and changing her eating schedule so that she would have more assistance. But Petitioner did not follow-up and there was no documentation of the effect of the changed interventions or that interventions were changed when they did not work. He agreed that when a resident will no longer swallow and the resident's family will not authorize tube feeding that there is little a facility can do, but a facility needs to assess and try alternative interventions such as more liquid foods and supplements and do so in a systematic way. The facility needs to communicate with the physician to determine what further evaluations may be required. Tr. at 394-98.

Dr. Berlowitz testimony is based upon the clinical record, it is credible, and I consider his testimony weighty.

Dr. Kraus, Resident 3's treating physician, testified that the resident was obese on admission; that she was known to enjoy eating goodies and sweets; that it was not unexpected that when her access to goodies and sweets was limited she would lose weight; and that her weight loss was not medically inappropriate at the rate of about a pound per week. He did not testify that he had approved or ordered a weight reduction program for the resident, however. He recalled being notified by staff regarding the resident's weight loss in April 2007. He testified he issued orders to reverse or slow the weight loss, including changing the time for her seating in the dining area, supplements between and with meals, a speech therapy evaluation of swallowing, occupational therapy evaluation, and a change in diet to modify food texture. Tr. at 450-55. He testified that her anti-anxiety medication was adjusted due to concern that the resident was being over-sedated to the extent that she was even falling asleep at meals. I note that Dr. Kraus did not specify which interventions were ordered in April 2007 and which were ordered in June 2007, for example there is no evidence that supplements were ordered prior to June 2007. He testified that he believed his orders were followed, though it is undisputed that he was not at the facility all the time and he did not review the clinical record prior to the hearing. Tr. at 455-56. He opined that it is very common in late-stage Alzheimer's disease for people to lose their ability to receive adequate nutrition related to impaired ability to swallow. Death ultimately results absent artificial nutrition and Resident 3's daughter had decided that tube feeding should not occur. Tr. at 456-59. He opined that the weight loss was unavoidable. Tr. at 459. He testified that he was aware of the resident's weight loss but attributed it to her advancing dementia. Tr. at 467. He opined that the care provided for weight loss and nutrition was consistent with the standard of care, did not place the resident at risk for serious harm or death, and did not pose a risk for minimal harm. Tr. at 468-72. The physician's opinion that those suffering late-stage Alzheimer's disease often have difficulty with nutrition is not disputed, but it is also not the issue. The issue is whether or not Resident 3 was receiving adequate nutrition. Dr. Kraus's opinions that Petitioner was doing all it could to ensure that the resident was receiving adequate nutrition, particularly in April and May 2007, is not weighty. Dr. Kraus did not review the clinical record prior to the hearing. His testimony reveals that he was not aware of when he ordered particular interventions. He was not in a position to assess whether or not his interventions were implemented as ordered. He did not explain how the effectiveness of the April interventions was assessed by the care planning team. He also did not address why other interventions – e.g., supplements, encouragement, and weekly weighings – were not attempted in April and May when the resident's consumption was documented to continue to decline.

Doctor Hansen testified that it is common for an Alzheimer's patient to stop eating and, unless they are properly supplemented, they pass away. He explained that pocketing food is common for an Alzheimer's patient. He testified that poor nutrition is a risk

factor for the development of pressure sores. Tr. at 671-72. He opined that Resident 3's weight loss was unavoidable because Petitioner did intervene with a speech therapy evaluation, occupational therapy, and changing her feeding so that she could have more assistance. He opined that the weight-loss was unavoidable as the resident continued to loose weight after interventions were changed following the survey. However, he did not comment upon Petitioner's failure to offer supplements in April and May 2007, despite his testimony regarding the importance of supplements. Tr. at 674. He opined that Resident 3 was not end-stage until after the survey. He testified that he would have considered her terminal in April 2007, when she started losing weight. Tr. at 694-95. He testified on cross-examination that he did not believe that the weight records for Resident 3 accurately reflected her weight. He agreed that a twenty pound weight loss in one month would be significant and the physician should be informed. He testified that he believed that Resident 3 did suffer a twenty pound weight loss between April and June 2007. He agreed that prior to the survey, the resident was not receiving nutritional supplements except with her medications. Tr. at 727-32. Dr. Hansen's testimony is credible and it supports my conclusion that Petitioner should have attempted additional interventions such as supplements in April and May 2007.

Mary Widner testified that the weight loss was unavoidable as there was an adequate plan to address nutrition and staff was attempting to feed the resident, her diet was modified, and staff was attempting to address the resident's nutritional needs. She opined that the alleged deficiency was not likely to cause serious injury, harm, or death. Tr. at 981-83. Ms. Widner did not specify whether she thought that the interventions in April 2007 were adequate or whether her opinion was based upon the interventions finally implemented in June and July 2007. Thus, her opinion is not helpful. Her opinion that a failure to ensure a resident's nutritional needs are met, is not likely to cause serious injury, harm, or death, is not credible. Obviously, as a qualified nurse with long experience in the field of long-term care, Ms. Widner was aware that resident's can suffer serious harm or death due to malnutrition. To the extent that Ms. Widner was opining that Resident 3 received the care and services necessary to avoid serious harm, injury, or death, I do not find that opinion weighty as to the period April and May 2007 when the resident's intake continued to decline but the evidence does not show that new interventions such as supplements, more frequent weighing, or encouragement to eat were implemented.

Accordingly, I conclude that Petitioner has not shown by a preponderance of the evidence that it provided the resident with adequate nutrition or that the weight loss was due to non-nutritive factors, or that it did all it could reasonably do to prevent weight loss, which I conclude was indicative of inadequate nutrition in this case. I further conclude that Petitioner has not addressed and has not met its burden to show that the determination of immediate jeopardy was clearly erroneous in this case. Indeed, it is not disputed that failure to receive adequate nutrition may cause serious harm, injury, or death.

9. Petitioner returned to substantial compliance effective August 3, 2007.

Petitioner alleged in its plan of correction for the survey that ended on June 27, 2007, that all elements of the plan would be implemented not later than August 3, 2007. CMS Ex. 15. The plan of correction was accepted by CMS on August 2, 2007. CMS Ex. 15, at 1, 2. A revisit survey on August 14, 2007, resulted in findings that all the deficiencies from the June 27, 2007 survey were corrected except for Tags F157 and F309, as of the date of the revisit, August 14, 2007. CMS Ex. 62. The evidence does not show that the surveyors considered any earlier date for correction, such as August 3, 2007, the date Petitioner alleges it completed all corrective action for all deficiencies cited by the June 27, 2007 survey and returned to substantial compliance. CMS argues that Petitioner continued not to be in substantial compliance based upon continuing deficiencies under Tags F157 (42 C.F.R. § 483.10(b)(11)) and F309 (42 C.F.R. § 483.25) and, therefore Petitioner did not return to substantial compliance on August 3, 2007. The deficiencies under Tags F157 and F309 as found by the survey completed on August 14, 2007, are discussed hereafter. CMS did not discuss in briefing and does not appear to dispute Petitioner's assertion that it corrected all other deficiencies by August 3, 2007.

Roberta Messner, a licensed RN and nursing home administrator, was called to testify by Petitioner. Ms. Messner testified that she was Petitioner's interim nursing home administrator from May to August 2007, and that she was involved in developing and implementing the plans of correction. Tr. at 801-03. She testified that she was the overall coordinator for the plans of correction and that the plans were accepted by CMS and the state agency. She testified that the plans of correction for the survey completed on June 27, 2007, were fully implemented on August 3, 2007. Tr. at 803-04.

Janet Lutze, RN, testified that she was hired by Petitioner as a wound care consultant to help develop and implement the plan of correction related to wound care and she completed training staff in July 2007. Tr. at 746-47.

The testimony of Ms. Messner and Nurse Lutze is unrebutted. I conclude that Petitioner completed correction of the deficiencies cited by the June 27 survey as listed on CMS Ex. 62, not later than August 3, 2007. As discussed hereafter, I also conclude that there was no continuing violation under Tags F157 or F309. Accordingly, I conclude that Petitioner returned to substantial compliance with program participation requirements effective August 3, 2007.

10. Petitioner did not violate 42 C.F.R. § 483.10(b)(11), Tag F157, contrary to the allegations of the August 14, 2007 revisit survey.

During the revisit survey of August 14, 2007, Petitioner was found to be in violation of 42 C.F.R. § 483.10(b)(11) and the surveyors alleged the violation caused actual harm. Section 483.10(b)(11)(i) of 42 C.F.R. entitled, "Resident rights," requires:

> (11) Notification of changes. (i) A facility must immediately inform the resident; consult with the resident's physician; and if known, notify the resident's legal respresentative (sic) or an interested family member when there is --
>
> > (A) An accident involving the resident which results in injury and has the potential for requiring physician intervention;
> >
> > (B) A significant change in the resident's physical, mental, or psychosocial status (i.e., a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications);
> >
> > (C) A need to alter treatment significantly (i.e., a need to discontinue an existing form of treatment due to adverse consequences, or to commence a new form of treatment); or
> >
> > (D) A decision to transfer or discharge the resident from the facility as specified in Sec. 483.12(a).

The regulatory requirements are clearly stated. The regulation requires that a facility "**must immediately . . . consult with the resident's physician** . . . when there is a significant change in the resident's physical, mental, or psychosocial status" (meaning a deterioration in the resident's condition). 42 C.F.R. § 483.10(b)(11) (emphasis added). The requirement is not discretionary and it requires more than merely informing or notifying the physician, which is evident from the plain language of the regulation. The drafters chose the language carefully. The regulation is specific that the facility is required to **immediately** "**inform** the resident; **consult** the physician; and . . . **notify** the legal representative or an interested family member." *Id.* (emphasis added). The preamble to the final rule indicates the drafters' specific intention that the facility should "inform" the resident of the changes that have occurred but should "consult with the physician about actions that are needed." 56 Fed. Reg. 48,826, 48,833 (Sept. 26, 1991). Thus, it is clear from the language of the regulation and its history that the requirement of the regulation to consult means more than to simply notify. Consultation requires a

dialogue with and a responsive directive from the resident's physician as to what actions are needed; it is not enough to merely notify the physician of the resident's change in condition. Nor is it enough to leave just a message for the physician. Also, the facility must provide the physician with all the information necessary to properly assess any changes to the resident's condition and to determine what course of action is necessary.

The regulation also requires consultation "immediately" upon discernment of a significant change in condition of the resident. The use of the term "immediately" in the regulatory requirement indicates that consultation is expected to be done as soon as the change is detected, without any intervening interval of time. It does not mean that the facility can wait hours or days before consulting with the physician. The preamble to the final rule indicates that originally the proposed rule granted the facility up to 24 hours in which to notify the resident's physician and the legal representative or family. However, after the receipt of comments that time is of the essence in such circumstances, the final rule amended that provision to require that the physician and legal representative or family be consulted/notified immediately. 56 Fed. Reg. at 48,833. The point of using the word "immediately" was the recognition that in such situations a delay could result in a situation where a resident is beyond recovery or dies. Furthermore, when we balance the relative inconvenience to a physician and the facility staff to consult about a resident's change in condition with the possibility for dire consequences to the resident if the physician is not consulted, it seems that any inconvenience certainly is inconsequential and outweighed by the potential for significant harm if the facility fails to consult the physician. It is better to err on the side of consulting a physician regarding a change in a resident's condition rather than not or debating about whether the change is significant, particularly since nursing home staff may not be qualified or competent to identify the significance of signs and symptoms. This regulatory requirement is included in the regulation entitled "Resident rights" and the requirements of this specific regulation provide that every resident has the right to a dignified existence and access to and communication with persons and services inside and outside the facility. Therefore, the regulatory requirements make inconsequential any inconvenience under the regulation to the resident's physician or to the facility staff when compared to the protection and facilitation of the rights of the resident. *See* 56 Fed. Reg. at 48,834.

The SOM instructs surveyors as to the CMS policy related to this deficiency, as follows:

> For purposes of §483.10(b)(11)(i)(B), life-threatening conditions are such things as a heart attack or stroke. Clinical complications are such things as development of a stage II pressure sore, onset or recurrent periods of delirium, recurrent urinary tract infection, or onset of depression. A need to alter treatment "significantly" means a need to stop a form of treatment because of adverse consequences (e.g., an adverse drug reaction), or commence a new form of treatment to deal

> with a problem (e.g., the use of any medical procedure, or therapy that has not been used on that resident before).

SOM, app. PP, Tag F157.

The August 14, 2007 revisit survey alleges that Petitioner violated 42 C.F.R. § 483.10(b)(11) (Tag F157) and that the violation caused actual harm to Resident 2. Resident 2 had a diagnosis of Muscular Sclerosis (MS); she suffered from severe contractures; she had a history of urosepsis; and a history of septic shock. CMS Ex. 63, at 3. On August 9, 2007 at 12:30 p.m., nursing staff documented that Resident 2 had a two by one centimeter hard, rough mass protruding from the vaginal opening one centimeter that was "grey in color, painful [with] slight touch" and a white discharge was noted. Resident 2's vital signs were not recorded in the Nurse's Note recording the examination. CMS Ex. 68, at 4; Tr. at 542. Thirty five minutes later, at 1:05 p.m., the staff called Resident 2's physician and left a message with the physician's nurse regarding this mass. CMS Ex. 68, at 4. There was no evidence that Resident 2's physician returned the call. Tr. at 543. A Nurse's Notes entry at 9:30 p.m. on August 9, 2007 shows that Resident 2 refused her evening meal despite being offered different choices at different times; that she as taking minimal water with meals with minimal urinary output; but she had no complaint of pain or discomfort. CMS Ex. 68, at 4. On August 10, 2007 at 9:45 a.m., Resident 2 had a temperature of 100 degrees and complained that she did not feel well, but she denied pain or discomfort. CMS Ex. 68, at 5. The physician on call was contacted and updated on the mass in the resident's vagina, the fact that she had a temperature, and the fact that she had refused food and fluids. The on-call physician ordered that Resident 2 be sent to the emergency room. CMS Ex. 68, at 5. Approximately 20 hours elapsed from the first call to Resident 2's physician at 1:05 p.m. on August 9 and 9:45 a.m. on August 10 when the on-call physician was notified. Nurse's Notes reflect that it was not uncommon for the resident to refuse meals and fluids except for taking a little water. CMS Ex. 68, at 1-4.

Resident 2 arrived at the hospital awake and alert, in moderate distress, and with a temperature of 100.7 degrees Fahrenheit. A vaginal examination was deferred due to excruciating discomfort from trying to position her for the examination and it was determined to do the examination under sedation. Urinalysis revealed the resident was suffering from a urinary tract infection. CMS Ex. 68, at 13. After Resident 2 was sedated, a large foreign mass was extracted from her vagina that appeared to be stool. The physician speculated that the mass of stool had either built-up in her vagina or entered her vagina through a fistula, but he did not determine a cause. The physician observed ulcerations in the vagina but found no fistula or perforation of the rectum into the vagina. The physician ordered intravenous antibiotics due to a severe urinary tract infection and to "avoid septic complications" due to the mass with a 24-hour hospital stay followed by a course of antibiotics on return to the nursing facility. CMS Ex. 68, at 15.

On August 11, 2007, Resident 2 was discharged from the hospital and returned to the facility. Tr. at 549.

CMS alleges that at 1:05 p.m. on August 9, 2007, Petitioner obtained knowledge of a significant change of condition that required immediate consultation with the physician but the consultation did not occur. CMS also argues that the condition required a significant change in treatment as evidenced by the fact that the order was given for the resident to go to the emergency room. CMS Br. at 21-22; Tr. at 542.

Surveyor Ann Angell testified that Resident 2 was dependent upon staff for all cares except that she could use an adaptive cup and obtain her own water. She testified that the resident had severe contractures of her arms and legs and her care plan required the use of splints for both upper and lower extremities. Tr. at 522; CMS Ex. 34, at 5, 25. Surveyor Angell testified that she participated in the survey of Petitioner's facility that ended on August 14, 2007 and she made the findings under Tag F157 related to Resident 2. Surveyor Angell testified that she was concerned that when the mass was found, the resident's vital signs were not recorded. She was also concerned that the resident had a history of septicemia and the discharge could have been a sign of infection. She opined that Resident 2 required immediate medical attention. She testified that the clinical record showed that the resident had vague complaints of nausea and not feeling well and she did not eat at times. She testified that the evidence shows the physician was called and staff left a message but the physician did not return the call. Surveyor Angell testified that she was concerned that the record showed that the resident did not eat the evening meal on August 9, drank little water, and had little urine output, but there was no assessment of the mass, no indication that the physician was called again, and no report that vital signs were assessed. She testified that the resident was listed on the facility 24-hour report for August 9, with the indication that the physician had been updated. She testified that the record shows that the physician on call was contacted and updated on August 10 and he ordered that the resident be sent to the emergency room. Tr. at 541-45. She testified that on August 9, the physician should have been called again after a reasonable time of an hour, if there was no contact with the treating physician the on-call physician or the medical director should have been contacted, and the resident's vital signs should have been monitored for possible indication of infection. She opined that the circumstances reflected a significant change in condition that required consultation with the physician, because the mass was not supposed to be there, it was painful to light touch, the discharge indicated a possible infection, and the resident's history of sepsis. She opined that the resident had a significant change of condition within the meaning of Petitioner's policy at P. Ex. 11 and there was a need for a significant change in the resident's treatment. She opined that staff failed to follow facility policy regarding the change in condition. She opined that the resident suffered actual harm due to the pain she experienced and the delayed treatment. Tr. at 546-60. However, she admitted in response to my questioning that she did not know whether the pain was secondary to the mass or due to her contractures and her examination. Tr. at 576. She admitted on cross-

examination that throughout the day on August 9, 2007, there is no evidence of the resident complaining of pain and when the resident was examined the next morning and she was found to have an elevated temperature the physician was called immediately. Tr. at 584. She testified that the mass in the vagina caused ulcerations that might have been lessened had the mass been removed more promptly. Tr. at 585, 593.

Roberta Messner, Petitioner's Administrator during the surveys, testified that there was no significant change in the resident's condition that required consultation with the physician. She opined that the resident's problem with her contractures was chronic and that the pain was due to her contractures not the mass that was discovered. She also opined that the resident was not exposed to a risk for significant harm due to the delay in sending her to the hospital because she was being monitored. She further attributed the fact that resident had a fever to the fact that she had a urinary tract infection, which was not uncommon for her due to her neurogenic bladder and catheter. Tr. at 844-47.

Mary Widner opined that staff timely consulted with the physician for Resident 2 by consulting him in less than 24 hours. She opined that there was no acute change in condition that required immediate consultation. She opined that there was no emergency as the mass had obviously been present for some time and there was no change in the resident's condition. She opined that the delay in consulting with the physician did not pose a risk for even minimal harm. Tr. at 985-87.

I am convinced based upon the policy guidance of the SOM that the facts do not amount to a violation of the regulation because there was no significant change in the condition of the resident or need to significantly alter care within the meaning of the regulations on August 9, 2007. When on August 10, 2007, Resident 2 manifested signs and symptoms consistent with a possible infection, staff immediately consulted with the on-call physician who ordered that the resident be sent to the emergency room for treatment. Accordingly, I conclude that Petitioner did not violate 42 C.F.R. § 483.10(b)(11) and the alleged violation is no basis for the imposition of an enforcement remedy.

11. Petitioner did not violate 42 C.F.R. § 483.25, Tag F309, contrary to the allegation of the August 14, 2007 revisit survey.

The surveyors allege in the SOD for the survey completed on August 14, 2007, that Petitioner violated 42 C.F.R. § 483.25 and that the violation caused actual harm to Resident 22. More specifically, the surveyors allege that Petitioner failed to ensure that pain management interventions were consistently applied to effectively address Resident 22's pain. The surveyors allege that on August 7, 8, 10, and 12, 2007, staff did not administer pain medication or implement any other interventions when they assessed Resident 22 as suffering pain at a level of four on a scale of zero to five, with five being the worst pain. The surveyor's allegations are that scheduled pain medication was given,

but pain medication ordered to be administered as needed was not administered. CMS Ex. 63, at 8-14.

The regulation requires that:

> Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and pyschosocial well-being, in accordance with the comprehensive assessment and plan of care.

42 C.F.R. § 483.25.

Surveyor Cheryl Bott testified that she drafted the deficiency citation under Tag F309 for the survey that concluded on August 14, 2007. Tr. at 233; CMS Ex. 60, at 7. She testified that Resident 22 was admitted to Petitioner's facility on June 20, 2007, following removal of a brain tumor, which left him with partial paralysis on his right side. She testified that a pain assessment at admission showed that he could not verbalize the location or level of his pain but he did have nonverbal signs of pain including restlessness, fidgeting, pulling on his feeding tube, and crying. She testified that his MDS dated July 3, 2007, assessed him as having short and long-term memory deficits; severe cognitive impairment; total dependence for ADLs; repetitive physical movement; restlessness; resistance to cares; and mild pain less than daily. His care plan reflected that he was not ambulatory; his speech was mumbled at times; and he required extensive assistance for all ADLs. His care plan required Tylenol for pain as needed, assessment of pain level every shift, to update the physician, and to provide one-to-one staff intervention as necessary. The goal of the care plan for pain was that the resident be free of pain. A new MDS done on July 24, 2007, assessed the resident as having a decline in his behaviors related to repetitive verbalizations in addition to the continuing repetitive physical movements and his pain was assessed as daily and moderate. The MDS reflected the addition of an anti-anxiety medication. Surveyor Bott testified that she observed the resident on August 14, 2007 and when she approached him and asked a question his speech was garbled and he began to cry. She testified that according to the resident's records he was to have a Lidoderm patch for pain during the day and he was also to receive Oxycodone four times each day. She testified that the resident also had orders for Zoloft, beginning August 13, 2007, Seroquel, and Lorazepam. Tr. at 235-245. She testified that Resident 22 had orders for Acetaminophen and Acetaminophen with Codeine as needed for pain or elevated temperature. Tr. at 250. She testified that the order for Lorazepam was for administration as necessary for anxiety. Tr. at 251-53. She testified that she cited the deficiency because Resident 22 was assessed on four occasions, August 7, 8, 10 and 12, 2007, as having pain at a level of four on a five point scale, pain she characterized as significant, but there is no evidence that staff used an available pain medication or other interventions to address the pain, but rather, elected to

wait until the next scheduled pain medication one and one-half hours later. She testified that she concluded that Resident 22 suffered actual harm as a result. Tr. at 277-79. She agreed on cross-examination that the clinical records show that on both August 7 and 8 the treating physician was called by a nurse and reportedly opined that Resident 22 was likely displaying increased agitation rather than pain and he prescribed an increase in Seroquel on August 8. Tr. at 287-89, 298-99. She also acknowledged that she did not know whether the resident's crying when she asked him a question evidenced pain or some other circumstance. She agreed that physical displays such as fidgeting, crying, and grimacing could be signs of pain, depression, or agitation, and that she stated that she could not understand the resident's response to her question of whether or not he was experiencing pain. Tr. at 291-94.

Dr. Kraus was also the treating physician for Resident 22. He testified that the resident had a stroke following brain surgery that caused paralysis of his right arm and leg. He testified he saw the resident at least once a month. When he first arrived at Petitioner's facility, Resident 22 was somnolent, minimally alert, with minimal ability to vocalize, and easily agitated. He required tube feeding and had severe neurological deficits, and evidence of altered cognition. Over time he showed improvement, he seemed to be waking to his environment, with eye contact, and he gained some movement in his arm or leg. Later he regained the ability to talk and interact, but he believed that was after the August 2007 survey. Resident 22 was frequently agitated as he was becoming more aware of his surroundings around August 2007. There was a question about whether the brain injury or pain caused the agitation. He knew of no trauma or injury that would have caused pain. However, the resident said the word arm or shoulder and Dr. Kraus speculated that there might be pain in the shoulder. However he testified that in retrospect he believes that the resident became more agitated when he realized that he could not move his arm or shoulder. He did order pain medication and sedating medication. A psychiatric consultant assisted to adjust the medication. However, he concluded that the agitation was really related to his organic brain injury and frustration with the loss of use of his limbs rather than pain. Tr. at 472-80. He opined that the decision of a nurse to provide an "as needed" pain medication was within the standard of nursing practice, as he had discussed with staff his belief that the signs and symptoms indicated agitation rather than pain. He testified that he did not cancel the order for pain medication as he was trying to determine whether the signs and symptoms indicated pain or agitation. He testified that the failure of a nurse to administer pain medication would not have caused more than minimal harm. Tr. at 481. Dr. Kraus testified that he was reasonably certain that Resident 20 was suffering from agitation due to his anxiety or frustration related to his paralysis rather than pain. Tr. at 501-02. The testimony of Dr. Kraus is unrebutted and I find it fully credible and weighty.

Donna Elford, LPN, testified that on the occasions she rated Resident 22 as having pain of four on a scale of one to five, and she did not administer the as needed pain medication because she spoke with Dr. Kraus and he indicated that he believed the problem was

agitation not pain and he adjusted the resident's psychotropic medication. Tr. at 629-33. She testified that she misunderstood the surveyors to be asking her when she charted her pain assessment rather than when she did the pain assessment. She testified that she assessed pain when coming on shift and throughout the shift, but she charted the score at the end of the day when she usually did her charting. She did not intend to suggest to the surveyors that she only did a pain assessment at the end of her shift. Tr. at 634-35. She testified on cross-examination that it is a matter of nursing judgment whether or not to give medication ordered to be administered as necessary. Tr. at 646-48. The testimony of LPN Elford is unrebutted and I find it fully credible and weighty.

The gist of the deficiency citation is that Petitioner's staff violated the regulation and caused actual harm to Resident 22 in the form of unrelieved pain during the morning shift on four days, August 7, 8, 10, and 12, when LPN Elford assessed the resident as having pain but she failed to deliver pain medication ordered to be given as necessary. CMS Ex. 63, at 10-12; CMS Ex. 72, at 31. The allegations are based upon a record review rather than the surveyor witnessing the resident in pain. CMS argues that the evidence shows that LPN Elford assessed Resident 22 as having level-four pain at 2:30 p.m. on each of the four days but she decided not to give Resident 22 pain medication authorized to be administered on an as needed basis because the resident was scheduled for pain medication at 4:00 p.m. CMS Br. at 23. The CMS analysis of the evidence is in error. The CMS view of the evidence is based in part upon a misunderstanding of the response of LPN Elford to a question posed by Surveyor Bott during the survey related to when LPN Elford assessed and/or recorded pain. LPN Elford's testimony at trial is credible and clarifies that she assessed pain of residents throughout her shift, but that she recorded the highest level of pain observed during the shift at the end of her shift. Thus, the CMS argument that Resident 22 suffered level-four pain on each of the four days from 2:30 p.m. until 4:00 p.m. is erroneous. It is not disputed however, that on each of the four days, LPN Elford observed signs and symptoms consistent with pain that she assessed to be at level-four but she elected not to give pain medication in addition to the pain medication that had already been administered as scheduled. Consideration of the clinical evidence is necessary.

When he was admitted to Petitioner's facility on June 20, 2007, Resident 22 had an order for Acetaminophen elixir every four hours as needed for pain or elevated temperature. P. Ex. 3, at 3. On June 29, 2007, an order was issued for Morphine as needed for pain but the drug was discontinued on July 3, 2007, because it caused a rash. P. Ex. 3, at 9. Dr. Kraus's progress note dated July 19, 2007, shows that Resident 22 appeared to have discomfort of unknown etiology, when moving his right arm so the doctor ordered Acetaminophen with Codeine elixir as needed for pain. P. Ex. 3, at 4, 11, 187. On July 24, 2007, a Lidoderm patch was ordered to be applied during the day for pain. P. Ex. 3, at 12. On July 27, 2007, Tylenol 3 was scheduled for three times per day for pain. P. Ex. 3, at 4, 12. On August 3, 2007, Dr. Kraus discontinued the Tylenol 3 and ordered Oxycodone every six hours. He also ordered a psychiatric evaluation and an x-ray of the

right arm and shoulder. P. Ex. 3, at 14. An order dated August 8, 2007 shows Dr. Kraus increased the dose of Seroquel, an antipsychotic used to reduce agitation. P. Ex. 13, at 15. Resident 22 also had orders for Zoloft (an anti-depressant) and Lorazepam (Ativan) (an anti-anxiety medication). CMS Ex. 72, at 27, 31; P. Ex. 3, at 1, 3, 8, 11.

A Nurse's Notes entry dated August 3, 2007, shows that the x-ray of the resident's right upper extremity showed no fracture but that the resident did have arthritis in the arm. P. Ex. 3, at 68; CMS Ex. 72, at 3. A Nurse's Note late-entry on August 8, 2007 for August 7, 2007, states that Nurse Elford updated Dr. Kraus on a pain audit and that Dr. Kraus felt that Resident 22's non-verbal symptoms were really related to agitation and not pain and that Resident 22 was to be monitored for changes. The Nurse's Notes entries for August 8, 2007 state that Nurse Elford updated Dr. Kraus on her concerns for Resident 22's comfort and the doctor changed the afternoon dose of Seroquel but kept the morning dose the same. CMS Ex. 72, at 6; P. Ex. 3, at 71. Nurse's Notes entries by LPN Elford for August 10 at 7:30 a.m. show that the resident was out of bed and went to the dining room for breakfast where he ate 75 percent of his meal. At 11:20 a.m. on August 10 he was reported to be in bed, very agitated, constantly moving his legs, rolling his body back and forth, and pushing staff away, and he was given Ativan. At 1:00 p.m. on August 10, Resident 10 was out of bed for lunch and he received a new bed. At 1:45 p.m. he was back in bed rolling back and forth and pillows were placed under his mattress to keep him from rolling out. A Nurse's Notes late-entry by LPN Elford on August 12, 2007 for August 11 indicates that when the resident was rolling back and forth on August 11 at 8:15 a.m. he was asked if he was in pain and he was given Tylenol with Codeine which calmed him in about 30 minutes. Nurse's Notes entries for LPN Elford on August 12, 2007 show that the resident was restless, tearful and sobbing at 7:00 a.m. and when asked he stated that he could not move his arm. He was given Ativan and was comforted by staff. At 8:15 a.m. the resident was reported to be calmer and was out of bed to go to breakfast. An order to increase the resident's Zoloft due to his increased crying episodes was received at 3:30 p.m. The remainder of the notes for August 12, 2007, show that the resident was calm and resting if not up for meals. P. Ex. 3, at 71-73; CMS Ex. 72, at 6-8. Review of the Nurse's Notes entries prior to August 3, 2007, reveals many instances of reported anxiety and agitation. P. Ex. 3, at 45-70.

A Nurses' Progress Note continuation sheet with an entry dated August 9, 2007, states that Resident 22's analgesic schedule was changed and that there was an on-going evaluation of effectiveness with the physician being updated on frequency of agitation, type of body movement, and calling out. The note also records that the right shoulder x-ray showed no fracture or dislocation. P. Ex. 3, at 43.

The Nurse's Notes entries for August 7, 8, 10, and 12, do not reveal any instance of possible increased pain or anxiety to which LPN Elford and staff did not respond. On August 7 and 8 the evidence is consistent with the testimony of Dr. Kraus and LPN Elford that Dr. Kraus ordered a change in psychotropic medication. The change in

psychotropic medication is consistent with Dr. Kraus's testimony that he suspected the resident's agitation was due to anxiety rather than pain and it is also consistent with the evidence that there was an on-going plan to evaluate the effectiveness of the resident's analgesic regime. The Nurse's Notes show that on August 10, 11, and 12, LPN Elford and staff intervened to address signs of increased agitation and the interventions appear to have been successful. The evidence shows that LPN Elford acted under guidance of Dr. Kraus when she decided to implement interventions other than the administration of pain medication ordered on an as needed basis. However, the decision not to administer as needed pain medication is well within the discretion of the nurse, which is the purpose of authorizing medication to be administered as needed. I note that the case of Resident 22 is significantly different from that of Resident 3 who was the subject of the same deficiency citation by the June 27, 2007 survey. This is no evidence for Resident 22 that he had preexisting diagnoses that could be a cause of pain, unlike Resident 3 who had three diagnoses that were possible sources of pain.

The regulation requires that a facility deliver necessary care and services for each resident to attain or maintain the highest practicable physical, mental, and pyschosocial well-being in accordance with the comprehensive assessment and plan of care for the resident. Delivery of necessary care and services not only includes treating and minimizing suffering from pain, it also requires constant assessment of whether there is pain and the development and implementation of interventions necessary to control the pain without negatively impacting the resident's quality of life. In this case, the evidence does not indicate a failure to deliver necessary care and services. Rather, the evidence indicates that the physician and staff were working to assess the effectiveness of interventions to control pain and anxiety to ensure that Resident 22 attained the highest practicable physical, mental, and psychosocial well-being. Accordingly, I conclude that Petitioner did not violate 42 C.F.R. § 483.25 as alleged by the August 14, 2007 revisit survey and there is no basis for the imposition of an enforcement remedy.

12. The remedies proposed by CMS are not reasonable.

13. Reasonable remedies are a $3,050 per day CMP from June 4 through June 13, 2007; $200 from June 14 through August 2, 2007; a DPNA effective from July 20 through August 2, 2007, and withdrawal of approval to conduct a NATCEP.

I have concluded that Petitioner was not in substantial compliance with program participation requirements from June 4 through August 2, 2007, due to violations of 42 C.F.R. §§ 483.25, 483.25(c), and 483.25(i)(1). I have concluded that the violations of 42 C.F.R. §§ 483.25(c) and 483.25(i)(1) posed immediate jeopardy from June 4 through June 13, 2007, while the violation of 42 C.F.R. § 483.25 caused actual harm. My conclusion that there was immediate jeopardy from June 4 through June 13, 2007, requires that any CMP imposed for that period be in the upper range of authorized CMPs.

The continuing violation of these regulations after the immediate jeopardy was abated and until Petitioner returned to substantial compliance with program participation requirements on August 3, 2007, is a sufficient basis for imposition of a CMP in the lower range in the amount of $200 as proposed by CMS. Therefore, for purposes of assessing a reasonable remedy, I need not consider the non-immediate jeopardy deficiencies cited by the June 27, 2007 survey.

In its letter dated July 10, 2007, CMS proposed a CMP of $8,800 per day for ten days from June 4 through June 13, 2007. CMS based the proposed CMP on the understanding that the state agency had cited four violations at an immediate jeopardy level. I have concluded the determination of immediate jeopardy was clearly erroneous for Tag 309 and that there was no deficiency under Tag F224 and no associated immediate jeopardy. Accordingly, I conclude that a CMP at a rate of $8,800 per day for the ten days from June 4 through June 13, 2007 is unreasonable and I must determine a reasonable CMP for the period of June 4 through June 13, 2007.

I must determine a reasonable CMP by considering the factors listed in 42 C.F.R. § 488.438(f): (1) the facility's history of noncompliance; (2) the facility's financial condition; (3) factors specified in 42 C.F.R. § 488.404; and (4) the facility's degree of culpability, which includes neglect, indifference, or disregard for resident care, comfort or safety. The absence of culpability is not a mitigating factor. The factors in 42 C.F.R. § 488.404 include: (1) the severity of the deficiency; (2) the relationship of the deficiency to other deficiencies resulting in noncompliance; and (3) the facility's prior history of noncompliance in general and specifically with reference to the cited deficiencies. 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 neither bound to defer to CMS's factual assertions, nor free to make a wholly independent choice of remedies without regard for CMS's discretion. *Barn Hill Care Ctr.*, DAB No. 1848, at 21 (2002); *Community Nursing Home*, DAB No. 1807, at 22 (2002); *Emerald Oaks*, DAB No. 1800, at 9; *CarePlex of Silver Spring*, DAB No. 1638, at 8 (1999).

Petitioner produced credible oral testimony from Martin Metten, executive vice president and chief financial officer of Heyde Companies which owns and operates the facility. The unrebutted evidence shows that Petitioner's financial condition is poor and that the imposition of a large CMP would likely put Petitioner out-of-business. Tr. at 878-86. I consider Mr. Metten's oral testimony in determining a reasonable CMP to impose against Petitioner. I have considered evidence of Petitioner's prior history of noncompliance. I have considered Petitioner's culpability regarding its deficiencies related to Resident 3. Based on my consideration of all the required factors in the context of this case, I conclude that reasonable remedies are: a $3,050 per day CMP from June 4 through June 13, 2007; $200 from June 14 through August 2, 2007; a DPNA effective July 20 through

August 2, 2007; and a withdrawal of authority to conduct a NATCEP for two years from June 27, 2007 through June 26, 2009, based on substandard quality of care and the fact that a CMP of over $5,000 has been assessed against Petitioner.

III. Conclusion

For the foregoing reasons, I conclude that Petitioner was not in substantial compliance with program participation requirements from June 4, 2007 through August 2, 2007, due to violations of 42 C.F.R. §§ 483.25, 483.25(c), and 483.25(i)(1). Reasonable enforcement remedies are: a $3,050 per day CMP from June 4 through June 13, 2007, $200 from June 14 through August 2, 2007, a DPNA to be imposed from July 20 through August 2, 2007, and withdrawal of authority to conduct NATCEP for two years.

/s/
Keith W. Sickendick
Administrative Law Judge