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 No. C-11-571 (On Remand)

Decision No. CR2574

Date: July 27, 2012

DECISION ON REMAND

Petitioner, Columbus Nursing and Rehabilitation Center, 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).[1] The following enforcement remedies are reasonable: a $3,050 per day civil money penalty (CMP) from June 4 through June 13, 2007; a $200 per day 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 June 26, 2009, based on substandard quality of care and imposition of a CMP in excess of $5,000.

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[1] 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.

My decision as set forth above, originally issued on September 13, 2010,[2] is unchanged after my review on remand. The bases for my decision are also unchanged. My opinion discussing the bases for my Conclusions of Law in the September 13, 2010 decision that were affirmed by the Departmental Appeals Board (the Board) in its decision dated June 30, 2011,[3] are set forth in this opinion unchanged from my September 13, 2010 opinion and are set forth here for the convenience of the Board and the reader. My opinion discussing the Findings of Fact and Conclusions of Law contested by the Centers for Medicare and Medicaid Services (CMS) and remanded by the Board are reorganized and elaborated upon as necessary to permit meaningful review by the Board.

I. Procedural History

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.

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 Petitioner 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.

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[2] *Columbus Nursing and Rehab. Ctr.*, DAB CR2241 (September 13, 2010).

[3] *Columbus Nursing and Rehab. Ctr.*, DAB No. 2398 (June 30, 2011).

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 (Tr.) was prepared. CMS offered exhibits 1 through 6, 13 through 49, 60 through 72, and 75 through 80. CMS Exs. 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 to propose 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 were 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.

On September 13, 2010, I issued a decision in which I concluded as follows:

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.

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.

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.

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. § 483.25(i)(1) posed immediate jeopardy was not clearly erroneous.

9. Petitioner returned to substantial compliance 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.

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

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; a $200 per day 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.

CMS requested review by the Appellate Division of the Board. Petitioner did not request review.[4] On June 30, 2011, the Board remanded the case to me for clarification of my factual findings, legal conclusions, and analysis regarding the findings of fact and conclusions of law contested by CMS. *Columbus Nursing and Rehab. Ctr.*, DAB No. 2398, at 1. The Board remanded for further findings, conclusion, and analysis on my Conclusions of Law 1, 2, 4, 9, 10, 12, and 13, as listed above (the remanded Conclusions of Law). The Board affirmed my Conclusions of Law 3, 5 through 8, and 11, and they are treated as law of the case and not subject to change by me. *Id.*, at 2, 19.

The parties were offered the opportunity to file additional briefing following the remand. Both parties declined the offer.

II. Discussion

A. Issues

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 of a SNF in Medicare are found at section 1819 of the Social Security Act (Act) and at 42 C.F.R. Part 483. Section 1819(h)(2) of the Act authorizes the Secretary of Health and Human Services (Secretary) 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.[5] The Act requires that the Secretary terminate the Medicare participation of any

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[4] Either party dissatisfied with an ALJ decision may request review by the Board. 42 C.F.R. §§ 498.80, 498.82(a)(1).

[5] Participation of a NF in Medicaid is governed by section 1919 of the Act. Section 1919(h)(2) of the Act gives enforcement authority to the states to ensure that NFs comply
(Continued next page.)

SNF that does not return to substantial compliance with participation requirements within six months of being found not to be in substantial compliance. Act § 1819(h)(2)(C). The Act also requires that the Secretary deny payment of Medicare benefits for any beneficiary admitted to a SNF, if the SNF fails to return to substantial compliance with program participation requirements within three months of being found not to be in substantial compliance – commonly referred to as the mandatory or statutory denial of payments for new admissions (DPNA). Act § 1819(h)(2)(D). The Act grants the Secretary discretionary authority to terminate a noncompliant SNF's participation in Medicare, even if there has been less than 180 days of noncompliance. The Act also 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).[6]

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. Noncompliance refers to any deficiency

(Continued from preceding page.)

with the participation requirements established by sections 1919(b), (c), and (d) of the Act.

[6] Congress granted the Secretary authority to impose enforcement remedies against a SNF to ensure that a facility that fails to comply with the conditions for participation promptly returns to and maintains substantial compliance, or its participation in Medicare is terminated. Act § 1819(h)(2); 42 C.F.R. § 488.402(a); 59 Fed. Reg. 56,116, 56,175-176 (Nov. 10, 1994); *Carrington Place of Muscatine*, DAB No. 2321, at 23 (2010); *Embassy Health Care Ctr.*, DAB No. 2299, at 11 (2010); *Taos Living Ctr.*, DAB No. 2293 (2009). CMS has no more authority under the Act than the authority granted to the Secretary that is delegated by the Secretary to CMS. The statutory purpose authorized for imposition of enforcement remedies was satisfied in this case when Petitioner was found by CMS to have returned to substantial compliance. Petitioner does not contest the noncompliance at the level of immediate jeopardy found by me and affirmed by the Board. Thus, it is not clear by what authority or why CMS continues to pursue the greater enforcement remedies; what interest CMS seeks to vindicate; or why the parties cannot come to some resolution without wasting further resources of the government and Petitioner. Nevertheless, I am obliged to comply with the Board's directions on remand.

that causes a facility not to be in substantial compliance. 42 C.F.R. § 488.301. State survey agencies survey facilities that participate in Medicare on behalf of CMS to determine whether the facilities are complying with federal participation requirements. 42 C.F.R. §§ 488.10-.28, 488.300-.335. The regulations specify the enforcement remedies that CMS may impose if a facility is not in substantial compliance with Medicare requirements. 42 C.F.R. § 488.406.

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 CMPs, $50 per day to $3,000 per day, is reserved for deficiencies that do not pose immediate jeopardy, but either cause actual harm to residents, or cause no actual harm but have the potential for causing more than minimal harm. 42 C.F.R. § 488.438(a)(1)(ii).

Petitioner was notified in this case that it was ineligible to conduct a NATCEP for two years. Pursuant to sections 1819(b)(5) and 1919(b)(5) of the Act, SNFs and NFs may only use nurse aides who have completed a training and competency evaluation program. Pursuant to sections 1819(f)(2) and 1919(f)(2) of the Act, the Secretary was tasked to develop requirements for approval of NATCEPs and the process for review of those programs. Sections 1819(e) and 1919(e) of the Act impose upon the states the requirement to specify what NATCEPs they will approve that meet the requirements that the Secretary established and a process for reviewing and re-approving those programs using criteria the Secretary set. The Secretary promulgated regulations at 42 C.F.R. Part 483, subpart D. Pursuant to 42 C.F.R. § 483.151(b)(2) and (e)(1), a state may not approve and must withdraw any prior approval of a NATCEP offered by a SNF or NF that has been: (1) subject to an extended or partial extended survey under sections 1819(g)(2)(B)(i) or 1919(g)(2)(B)(i) of the Act; (2) assessed a CMP of not less than $5,000; or (3) subject to termination of its participation agreement, a DPNA, or the appointment of temporary management. Extended and partial extended surveys are triggered by a finding of "substandard quality of care" during a standard or abbreviated standard survey and involve evaluating additional participation requirements. "Substandard quality of care" is identified by the situation where surveyors identify one or more deficiencies related to participation requirements established by 42 C.F.R. § 483.13 (Resident Behavior and Facility Practices), § 483.15 (Quality of Life), or § 483.25 (Quality of Care) that are found to constitute either immediate jeopardy, a pattern of or widespread actual harm that does not amount to immediate jeopardy, or a widespread potential for more than minimal harm that does not amount to immediate jeopardy 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. *The Residence at Salem Woods*, DAB No. 2052 (2006); *Cal Turner Extended Care*, DAB No. 2030 (2006); *Beechwood Sanitarium*, DAB No. 1906 (2004); *Emerald Oaks*, DAB No. 1800, at 11 (2001); *Anesthesiologists Affiliated*, DAB CR65 (1990), *aff'd*, 941 F.2d 678 (8th Cir. 1991). A facility has a right to appeal a "certification of noncompliance leading to an enforcement remedy." 42 C.F.R. §§ 488.330(e), 488.408(g)(1), 498.3. However, the choice of remedies, or the factors CMS considered when choosing remedies, are not subject to review. 42 C.F.R. § 488.408(g)(2). A facility may only challenge the scope and severity level of noncompliance 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 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 evidence and making a prima facie showing of a basis for imposition of an enforcement remedy. Petitioner bears the burden of persuasion to show by a preponderance of the evidence that it was in substantial compliance with participation requirements or any affirmative defense. *Batavia Nursing & Convalescent Inn*, DAB No. 1911 (2004); *Batavia Nursing & Convalescent Ctr.*, DAB No. 1904 (2004), *aff'd, Batavia Nursing & Convalescent Ctr. v. Thompson*, 129 F. App'x 181 (6th Cir. 2005); *Emerald Oaks*, DAB No. 1800; *Cross Creek Health Care Ctr.*, DAB No. 1665 (1998); *Hillman Rehab. Ctr.*, DAB No. 1611 (1997), *aff'd, Hillman Rehab. Ctr. v. United States*, No. 98-3789 (GEB), 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.[7] Tr. at 32-38. Therefore, only the deficiencies cited by the June 27 and August 14 surveys have ever been at issue before me.

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,[8] s/s G;[9] 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

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[7] 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.

[8] 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.

[9] 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.

483.20(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; 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.

The conclusions of law from my prior decision, *Columbus Nursing and Rehab. Ctr.*, DAB CR2241 affirmed by the Board, establish that Petitioner was not in substantial compliance with program participation requirements from June 4 through August 2, 2007. Therefore, based on the Board's decision, it is now not subject to dispute 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 (Tag F309); 483.25(c) (Tag F314); and 483.25(i)(l) (Tag F325). It is also not subject to dispute that the noncompliance based on the violations of 42 C.F.R. §§ 483.25(c) (Tag F314) and 483.25(i)(l) (Tag F325) posed immediate jeopardy for Petitioner's residents from June 4 through June 13, 2007. Accordingly, there is a basis for the imposition of an enforcement remedy based solely upon the affirmed conclusions of law, from at least June 4 through August 2, 2007. The affirmed conclusions of law authorize a CMP in the upper range from $3,050 to $10,000 per day for the period June 4 through June 13, 2007, as proposed by CMS; a CMP in the lower range from $50 to $3,000 per day for the period June 14 through August 2, 2007; and a DPNA from July 20 through August 2, 2007. Accordingly, it is not necessary to review any of the other deficiency citations from the June 2007 survey, as I also concluded in my prior decision.

In my prior decision, I concluded that Petitioner returned to substantial compliance on August 3, 2007, contrary to the CMS allegation that Petitioner continued to be noncompliant based upon violations of 42 C.F.R. §§ 483.10(b)(11) (Tag F157) and 483.25 (Tag F309). CMS did not appeal and the Board affirmed my conclusion that Petitioner did not continue to violate 42 C.F.R. § 483.25 (Tag F309) after August 2, 2007, and that deficiency citation is no longer before me. The Board did not affirm, but remanded my Conclusion of Law 10 that Petitioner did not violate 42 C.F.R. § 483.10(b)(11) (Tag F157). Therefore, whether or not there is a basis for the imposition of an enforcement remedy for the period August 3 through September 4, 2007, remains and turns on the single remaining deficiency cited by the revisit survey on August 14, 2007,

i.e., whether or not Petitioner was in violation of 42 C.F.R. § 483.10(b)(11) (Tag F157) during that period. Because the Board did not affirm my conclusions of law as to the reasonable remedies for this case, the reasonableness of all the remedies also remains an issue.

I have carefully considered all the evidence and the arguments of both parties, even though not all may be specifically discussed in this decision. I discuss the credible evidence given the greatest weight in my decision-making.[10] I also discuss the evidence that I find not credible and weighty and the reasons I find the evidence not credible or weighty. 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. The fact that a particular document or specific testimony is not discussed in this decision indicates that evidence was not considered as probative as the evidence discussed. There is no requirement for me to discuss the weight given every piece of evidence offered and admitted 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 (On Remand).

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

The surveyors allege that Petitioner violated 42 C.F.R. § 483.13(c) because Petitioner failed to ensure that Resident 3 "was free of neglect." CMS Ex. 13, at 14. The regulation 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). As discussed hereafter, Petitioner had the required policy. The issue is whether or not the instances when Petitioner failed to deliver goods and services to Resident 3, show that Petitioner failed to implement its policy. I conclude that the instances of neglect identified do not show that Petitioner failed to implement its policy prohibiting neglect.

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[10] "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.

a. Facts

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.

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

On January 20, 2007, Resident 3 was admitted to Petitioner. Resident 3, a woman, was 86 when the survey was done. 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 no improvement in Resident 3's cognition or her ability to engage in activities of daily living. She remained severely cognitively impaired for daily decision-making; range of motion had improved in her neck and arm; but 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, 13 days after the survey that concluded on June 27, 2007, with a cause of death listed as end-stage dementia. P. Ex. 1, at 2-4.

From her admission on January 20 through June 5, 2007, Petitioner's clinical records show that Resident 3 received extensive care and services. Physician orders for the period January 20, 2007 through June 5, 2007, include: treatment for a sore on Resident 3's buttocks with changes in treatment; occupational therapy evaluation and treatment to

improve ADLs and eating skills; physical therapy evaluation and treatment; psychiatric consults; changes in her medication; treatment for left knee 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 psychiatric consultations 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 risks for elopement and wandering were assessed. CMS Ex. 27, at 292. The care and services 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.

Additional care and services received by Resident 3 are described in this decision under Tags F309, F314, and F325. All the care and services received by Resident 3 that are specifically mentioned in this decision and all the care and services reflected by the contemporaneous clinical records in evidence even though not summarized in this decision, are relevant and material to my conclusion that Petitioner did not fail to implement its policy prohibiting neglect of its residents.

b. Analysis

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 term neglect as used in the Secretary's regulations is the "failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness." 42 C.F.R. § 488.301. The Board has concluded in several cases that "multiple or sufficient examples of neglect, even if related to only one resident may support a reasonable inference that a facility has failed to develop or implement policies and procedures that prohibit neglect." *Woodland Oaks Healthcare Facility*, DAB No. 2355, at 11 (2010) (citations omitted); *Dumas Nursing and Rehab., L.P.*, DAB No. 2347, at 14 (2010); *Columbus Nursing & Rehab. Ctr.*, DAB No. 2247, at 27 (2009); *Emerald Shores Health & Rehab. Ctr.*, DAB No. 2072 (2007); *Liberty Commons Nursing and Rehab. Ctr. — Johnston*, DAB No. 2031, at 18 (2006), *aff'd, Liberty Commons Nursing and Rehab Ctr. — Johnston v. Leavitt*, 241 F. App'x 76 (4th Cir. 2007); *Barn Hill Care Ctr.*, DAB No. 1848, at 10 (2002); *Emerald Oaks*, DAB No. 1800, at 18 (2001).

There is no dispute that Petitioner had a policy, though as discussed hereafter, CMS originally espoused a theory, abandoned on appeal, regarding the specific language of the policy. The significant issue before me is whether there are examples of neglect of Resident 3 of such quantity or quality to trigger a reasonable inference that Petitioner failed to implement its policy prohibiting neglect. I conclude that the instances of neglect are not sufficient in number or significance to trigger a reasonable inference that Petitioner failed to implement its policy prohibiting neglect.

(i) Allegations by Surveyors

The surveyors allege in the SOD that Petitioner violated 42 C.F.R. § 483.13(c) 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 specific 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":

> Coordinate and monitor Resident 3's total health care needs. Assess, plan, implement, evaluate and modify Resident 3's care needs using a multidisciplinary approach to include input from the primary care provider, physical and occupational therapies, nursing and the dietitian to minimize Resident 3's decline. Provide prompt interventions to prevent further deterioration, e.g., acute/chronic pain, weight loss, range of motion and skin integrity changes. Maintain her highest

> practical level of physical, mental and psychosocial well being.

CMS Ex. 13, at 14. The surveyors allege that Petitioner's neglect of Resident 3 resulted in "significant weight loss, frequent episodes of unresolved pain, decline in activities of daily living and acquired pressure ulcers." CMS Ex. 13, at 14-15. The surveyors further allege that the failure of facility staff to provide necessary services to avoid physical harm and mental anguish resulted in high levels of pain, the development of an eschar-covered pressure ulcer, and an unplanned weight loss of 17 percent between January 2007 and June 2007. CMS Ex. 13, at 15. The surveyors allege three examples of neglect under Tag F224 in support of the general allegations of noncompliance.[11]

(aa) First Example – June 13, 2007, 9:55 a.m. – **Not Neglect**

The first example is based upon Surveyor Lubick's observations on June 13, 2007 at 9:55 a.m. The CMS evidence is inconsistent and potentially misleading.

The SOD states that a surveyor was standing outside Resident 3's room and heard Resident 3 moaning loudly and continuously. The SOD alleges that the surveyor observed five staff members walk by the room and none entered or offered assistance. The SOD alleges that after about five minutes a therapy staff member entered the room; offered Resident 3 food; and then left – whereupon Resident 3 began moaning loudly again. Another staff member was observed to pass the room and not stop. The therapy staff member returned and advised Resident 3 that a nurse would be in shortly. When the therapy staff member left the room Resident 3 started yelling that she needed help and the yelling continued for about three minutes until the nurse arrived. The nurse then left and returned with juice and cookies. The SOD does not state that Resident 3 continued to moan or yell after receiving the juice and cookies. CMS Ex. 13, at 16.

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[11] The Board expressed concern that in my original decision I discussed "neither the number nor nature of any instances of neglect" or what circumstances surrounded the instances I thought relevant. *Columbus Nursing and Rehab. Ctr.*, DAB No. 2398, at 12. I regret any lack of clarity that resulted in this remand. In my original decision, as in this decision on remand, I considered all the instances of neglect alleged as such in the SOD. All are relevant because they were alleged by CMS to be the basis for the imposition of enforcement remedies, though not all are well-founded. In this decision I have attempted to carefully flag or signal the failures to deliver care and services necessary to prevent harm, physical or mental, i.e., neglect.

Surveyor Tina Lubick testified that she made the observations related to Resident 3 and drafted the deficiency citation. Tr. at 44. Surveyor Lubick testified that at 9:55 a.m. on June 13, 2007, she stood outside Resident 3's room; Resident 3 was moaning very loud; and during a five minute period she observed five different staff members walk by without checking on Resident 3. After about five minutes a therapy staff member entered Resident 3's room and offered assistance and asked Resident 3 if she was hungry. Surveyor Lubick did not testify that she entered the room or that she heard Resident 3's response. She testified the therapy staff member left and Resident 3 started moaning again. The therapy staff member returned and told Resident 3 that the nurse would be in. Surveyor Lubick did not testify as to whether she entered the room, whether the staff member then left, or whether the resident continued to moan. When the nurse arrived she asked Resident 3 if she was hungry, the nurse left, and then returned with cookies, juice, and a banana. Surveyor Lubick did not testify that she entered the room but she testified to additional information not contained in the SOD, specifically that the nurse gave the resident cookies, but placed the juice and banana out of the resident's reach. Surveyor Lubick did not testify whether or not the resident ate the cookies, but she testified that Resident 3 continued to moan, though on cross-examination she stated that the resident was making noises but not loud noises (Tr. at 180). She testified that she did not see the nurse assess the resident for the cause of her moaning or provide any pain medication but she also failed to testify whether or not she was in a position to observe. She opined that the nurse failed to properly assess the resident but a foundation for her opinion, including her ability to observe is not specified in the SOD and was not developed during examination. Tr. at 49-51.

The notes Surveyor Lubick made during the survey are also in evidence. Her notes indicate that at 9:55 a.m. she heard Resident 3 moaning loudly. The notes do not indicate whether Surveyor Lubick was inside or outside the room, but she records that she saw five staff walk by the room. The surveyor's notes show that a therapy staff member entered Resident 3's room and asked if the resident needed anything. The therapy staff member offered to remove the breakfast tray or some other food that was in the room. The resident started moaning loudly again when the therapy staff member departed, which causes me to infer that the resident stopped moaning while the therapy staff member was present. The notes indicate that another staff member passed the room without stopping and then the therapy staff member returned and advised the resident that the nurse would be in. According to Surveyor Lubick's notes, when the therapy staff member left the room the second time, the resident started yelling "I need help, I need some help, I need help." The note shows that at 10:00 a.m., five minutes into the observation, a registered nurse entered the resident's room and asked the resident what she needed help with. The nurse asked if the resident was hungry and said she was going to get the resident something to snack on and the nurse left. The surveyor notes do not say that the resident continued to moan or yell at that point. The notes show that the nurse returned with cookies and juice and put them in the room. The note then states that the resident was feeding herself the cookies, that the juice was not accessible, and the

resident requested a banana. I infer that at some point the surveyor entered Resident 3's room to observe the resident eating cookies and the location of the juice, but when she entered is not clear. The nurse fetched a banana but the surveyor recorded that it was not left accessible to the resident. CMS Ex. 25, at 12-13. The surveyor notes do not reflect that the resident was moaning or calling out after the interaction with the nurse and the eating of cookies by the resident.

The surveyor's testimony is inconsistent with her recording of her observations in both the SOD and her surveyor notes. The surveyor notes and SOD are mostly consistent, though the notes include additional details. I conclude that the surveyor's recordings of her observations at the time of the survey on June 13, 2007, are a more reliable source for the facts than the surveyor's recollection of events at the time of trial on February 3, 2009, more than 19 months after the events she observed – recollection that may have been adversely impacted by her preparation for trial. I do not find credible her recollection that the resident continued to moan after the nurse's intervention. In fact, the surveyor did not recall in her testimony that she recorded that the resident was actually feeding herself cookies and asked for a banana, both facts that are inconsistent with pain having any significant impact upon the resident at the time. I infer, based upon the observations of the surveyor recorded in the SOD and in her notes, that Resident 3's behavior was inconsistent with significant pain. I further infer that the resident's yelling and moaning were behavioral rather than due to pain because the yelling and moaning of the resident was resolved by the intervention of the nurse with cookies, which the resident ate without assistance according to the surveyor's notes. The facts show that the resident's yelling and moaning were effectively remedied, without the need for her prescribed pain medications, Tylenol and Vicodin.[12] CMS Ex. 13, at 15-16; CMS Ex. 25, at 12-13; Tr. at 180. I conclude that Surveyor Lubick's conclusion that the resident was manifesting symptoms of pain (Tr. at 52) between 9:55 a.m. and 10:00 a.m. on June 13, 2007, is simply incorrect and inconsistent with the evidence in the record. Indeed,

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[12] The SOD states that the surveyor interviewed Resident 3's roommate who characterized Resident 3 as behaving like a five-month old, describing the resident as sleeping, mumbling, screaming when staff performed her hygiene and dressed her, and screaming in the dining room. Even if I fully credit this hearsay evidence, it provides no insight as to the cause of the resident's conduct, i.e., whether it was related to pain or a behavioral manifestation of the resident's dementia. The roommate's statement that Resident 3 slept does show, however, that Resident 3's pain was not always so severe and unrelenting as to prevent sleep.

Surveyor Lubick pointed to no signs or symptoms of pain except moaning and yelling, which are also signs and symptoms of a behavioral problem.[13]

Surveyor Lubick does not specifically allege in the SOD which of the activities that she observed on June 13, 2007, amounted to neglect. Thus, it is necessary to analyze each of the activities she observed to decide whether or not there was neglect. The broad regulatory definition of neglect includes two elements: (1) any "failure to provide goods and services." and (2) the goods and service are "necessary to avoid physical harm, mental anguish, or mental illness." 42 C.F.R. § 488.301. The definition of neglect does not include an element of knowledge or notice, and the definition of neglect may be satisfied whether or not staff was aware that the resident was in need of goods and services to avoid physical harm, mental anguish, or mental illness. The definition of neglect does not consider the intent of Petitioner's staff. Neglect may occur even if the failure to deliver necessary goods and services was unintended. Under a strict application of the definition of neglect, neglect is complete the instant that staff fails to deliver care or services necessary to avoid physical harm, mental anguish, or mental illness. The definition of neglect does not specifically permit a period for a facility to assess and intervene to meet the need for goods and services. However, it has been noted by the Board in a number of different SNF enforcement cases that SNF's are generally not treated as being "strictly liable" for violations of statutory and regulatory requirements for participation. *See, e.g., Tri-County Extended Care Ctr.*, DAB No. 1936, at 7 (2004), *aff'd, Tri-County Extended Care Ctr. v. Leavitt*, No. 04-04199 (6th Cir. Dec. 14, 2005); *Cherrywood Nursing and Living Ctr.*, DAB 1845 (2002). A limited number of defenses have been recognized for specific noncompliance related to adequate showings of unavoidability, foreseeability, reasonableness of action, and the like. The Board has recognized, based mostly on interpretation of the regulations, that SNFs are not subject to

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[13] For all deficiency citations for which Surveyor Lubick was responsible and about which she testified, I accept her testimony as credible only to the extent that it is corroborated by her recording of her observations. This limitation is appropriate as her testimony to facts that are not recorded in either the SOD or her surveyor notes raises a significant issue regarding the reliability of her recollection of her observations and the facts and how her recollection was impacted by preparation for trial. I generally give little weight to her conclusions or inferences expressed in the SOD, in her notes, and at hearing, as her testimony related to her observations of Resident 3 between 9:55 a.m. and 10:00 a.m. on June 13, 2007, shows that she was willing to express conclusions or draw inferences based upon an insufficient factual basis, without considering all the facts, and/or without considering other possible conclusions or inferences based on the same facts. The credibility of Surveyor Lubick's conclusions is in doubt not due to any lack of truth and veracity, but rather due to an apparent lack of objectivity.

enforcement remedies for unavoidable negative outcomes, or unforeseen or unpreventable circumstances that produce a risk for or an actual negative outcome. *Tri-County Extended Care Ctr.*, DAB No. 1936, at 7; *Woodstock Care Ctr.*, DAB No. 1726, at 21, 25, 40 (2000), *aff'd, Woodstock Care Ctr. v. Thompson*, 363 F.3d 583(6th Cir. 2003).

Furthermore, not all regulatory or statutory violations, including instances of neglect, are subject to the imposition of enforcement remedies by CMS. Noncompliance occurs and CMS is authorized to impose an enforcement remedy, only if a statutory or regulatory violation poses a risk for more than minimal harm. 42 C.F.R. §§ 488.301, 488.402(b).

I conclude that Surveyor Lubick's observation that multiple staff passed the resident's room without intervening during the first five minutes of the observation is not neglect within the meaning of 42 C.F.R. § 483.13(c). Certainly the staff that passed without intervening did not provide care and services to the resident, the first element of the definition of neglect. However, according to the SOD and the CMS evidence, within the next three minutes the care and services necessary to avoid any physical harm, mental anguish, or mental illness were delivered by a therapy staff member and a nurse. The therapy staff member entered the room, spoke to the resident, made an assessment of the situation and then left, apparently to locate assistance. The nurse entered the room, made some assessment of the situation, and decided that a snack was the appropriate intervention, which proved to be correct. Surveyor Lubick alleges that Petitioner did not thoroughly assess the Resident's pain so that an appropriate intervention could be implemented. I conclude that the surveyor's conclusion is unsupported. The evidence shows that at the beginning of the observation it is most likely that Surveyor Lubick was outside the resident's room. The evidence does not specifically show that Surveyor Lubick ever moved into the room where she could have observed an assessment by the nurse. Furthermore, the evidence shows that the nurse asked the resident at least one question about what she needed help with. Surveyor Lubick did not record the answer by the resident or other questions by the nurse. However, there is no dispute that after the nurse entered the resident's room and spoke to the resident the nurse determined to obtain a snack for the resident. The nurse correctly determined that a snack would satisfy or distract the resident as the chosen intervention, the cookies, were effective without the need for pain medication or other interventions to address pain.

I further conclude that even if one concluded that neglect occurred in this example, the evidence does not show a risk for more than minimal harm. As discussed above the facts are more consistent with the resident's moaning and yelling being behavioral rather than due to pain. Further, the resident's behavior was remedied within 10 minutes by giving her cookies that she ate. If the event observed by Surveyor Lubick did not pose a risk for more than minimal harm, then that event did not constitute noncompliance and no enforcement remedy would be authorized based on that incident.

The surveyor alleges that facility staff administered and adjusted the resident's psychoactive medications on the theory that her behaviors were related to her dementia rather than pain. The surveyor also alleges that staff failed to monitor the resident's behaviors. Clearly staff was aware of the resident's behaviors in the circumstance observed and cited by the surveyor and staff intervened successfully with cookies. I construe the surveyor's allegation to be that Petitioner did not have a behavioral care plan for the resident that involved monitoring, tracking, and analyzing her behaviors and devising, implementing, and adjusting interventions to address the behaviors. This allegation, as I have construed it, is discussed in more detail under Conclusion of Law 3. Conclusion of Law 3 is that Petitioner violated 42 C.F.R. § 483.25 (Tag F309) and the violation posed a risk for more than minimal harm and amounted to noncompliance. The noncompliance discussed under Tag F309, constitutes neglect as it is defined in 42 C.F.R. § 483.301 and within the meaning of 42 C.F.R. § 483.13(c).

(bb) Second Example – Right Foot Eschar Discovered June 12, 2007 – **Neglect**

The second example cited by the surveyor related to the discovery of an eschar on the plantar region of Resident 3's right foot on June 12, 2007. The surveyor alleges that a nurse admitted to her that she failed to check the bottom of Resident 3's foot during a full body skin assessment following a shower on June 11, 2007. The nurse also admitted that she failed to call the resident's physician prior to being questioned by the surveyor. CMS Ex. 13, at 18. As discussed hereafter under Tag F314 (Conclusion of Law 5), I have concluded that Petitioner was not in substantial compliance with the program participation requirement at 42 C.F.R. § 423.25(c) due to the resident's development of bilateral mushy heels in April 2007 and the plantar eschar in June 2007. This failure to deliver necessary care and services to prevent potential harm amounted to neglect within the meaning of 42 C.F.R. § 483.13(c).

(cc) Third Example – Unplanned Weight Loss – **Neglect**

The third example cited by the surveyor is based upon Resident 3's unplanned weight loss. Under Tag F325 (Conclusion of Law 7), I discuss in detail that Petitioner was not in substantial compliance with 42 C.F.R. § 483.25(i)(l) due to the care and services related to the resident's weight loss. This failure to deliver necessary care and services to prevent potential harm amounted to neglect within the meaning of 42 C.F.R. § 483.13(c).

(ii) CMS Arguments

(aa) The Abandoned Theory

CMS argued two theories in its post-hearing brief 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. 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 objected 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 and no further remedy need be crafted for Petitioner.[14]

In its Request for Review filed with the Board on November 15, 2010 (Request for Review) CMS abandoned its theory that Petitioner's policy was inadequate in its prohibition of neglect. Request for Review at 11 n.4. I include my analysis of this theory from my prior decision only to avoid the need for the reader to refer to my prior decision.

CMS did not argue to me that Petitioner did not have a policy but that Petitioner's policy pertained only to the investigation and reporting of incidents of neglect and did not specifically prohibit neglect. CMS Br. at 7. The 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

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[14] The Board expressed concern that I discussed the merits of the CMS arguments, even though, I recognized the merit in Petitioner's position that CMS had potentially engaged in sharp practice and violation of my Prehearing Order by not disclosing its theory of the case in advance of trial. *Columbus Nursing and Rehab. Ctr.*, DAB No. 2398, at 10. Rather than inquire as to the reason why CMS did not raise the arguments prior to hearing or attempt to fashion a remedy for Petitioner if I concluded there was prejudice and that a remedy was necessary, I found it more consistent with judicial economy to simply analyze the CMS theories, which I found to be without merit anyway. I further recognized that in the case of review by the Board, the Board could disagree with my conclusion regarding CMS's conduct of its case finding an error of law, in which case the Board would either act as the finder of fact or remand for further record development. The cases cited clearly show that the Board has recognized that due process requires adequate notice but inadequate notice is tested by the Board for prejudice. Petitioner suffers no prejudice in this instance as CMS does not prevail on its fresh theory.

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 its 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 regulations 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 did not explain to me how this argument was pertinent to the case before me. Petitioner clearly had a policy that prohibited neglect and included 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, i.e., no noncompliance is cited on such grounds. 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 potentially result in such harm would not be neglect under the regulation. The regulatory definition turns upon the impact of the failing, error, or omission, while Petitioner's expanded definition turns upon the cause. 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).[15]

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[15] CMS also refers in it Request for Review to a prior "extensive history of noncompliance" and the fact that the Board has twice upheld findings and remedies imposed as a result of surveys conducted in the year immediately preceding the surveys at issue before me in this case. Request for Review at 1. Counsel's purpose for emphasizing Petitioner's history of noncompliance in its brief before me (CMS Br. at 7 n.1) and in the introduction to its request for review is not clear from the context. The prior surveys and findings of noncompliance are not at issue before me. Presumably CMS found that Petitioner corrected any noncompliance from the prior surveys to which CMS refers or CMS would have complied with the Act and Petitioner would have been terminated from participation in Medicare prior to the surveys that are at issue before me.
(Continued next page.)

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* (DAB No. 2247) 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).

(bb) The Failure to Implement Theory

CMS's second theory is that Petitioner violated 42 C.F.R. § 483.25(c) by failing to implement its policy prohibiting neglect. CMS argues that the failure to implement the policy is shown by many staff members failing on multiple occasions to provide Resident 3 with "services to meet her needs related to the prevention of pain, pressure sores, and weight loss." CMS Br. at 7, 8. CMS cited to the allegations in the SOD (CMS Ex. 13, at 13-20) in support of its arguments. CMS cites to no other examples from the evidence in support of its argument. CMS Br. at 8-9.

On appeal to the Board CMS conceded that I recognized the legal standard applied by the Board in *Columbus Nursing & Rehab. Ctr*., DAB No. 2247. But CMS argued to the Board that I erred when I concluded that the noncompliance I concluded existed under Tags F309, F314, and F325, did not trigger the reasonable inference that Petitioner failed to implement its policy prohibiting neglect. Request for Review at 9-12.

CMS takes issue with the analytic approach in my decision. CMS recognized that in my decision I listed some of the many instances where the clinical records show that the

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(Continued from preceding page.)

Act § 1819(h)(2)(C). Petitioner's history of noncompliance is only relevant in this case to the issue of the reasonableness of the remedies to be imposed and my only consideration of Petitioner's history of noncompliance is related to that issue.

facility adequately delivered necessary care and services for Resident 3. CMS did not acknowledge in its Request for Review that the summary of the evidence showing care and services adequately delivered, clearly shows the complicated nature of Resident 3's many health issues. Request for Review at 10. CMS focuses upon my conclusions that Petitioner was noncompliant with program participation requirements based on violations of 42 C.F.R. §§ 483.25(Tag F309), 483.25(c) (F314), and 483.25(i)(l) (F325). CMS argues I committed error by "balancing the evidence of the care that the resident did receive against the evidence of care that she did not receive." Request for Review at 10 (emphasis in original). CMS argues that I erred by considering the many instances when the resident received care and treating those instances as cancelling-out the multiple instances in which staff failed to provide necessary care and services. Request for Review at 10.

CMS is correct that I considered all the treatment received by Resident 3 as reflected by the contemporaneous clinical records in evidence, some of which is summarized throughout my initial decision and this decision on remand. I also considered that "neglect" as defined by the Secretary is any "failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness." 42 C.F.R. § 488.301. I further considered that, as discussed under Conclusions of Law 3, 5, and 7, Petitioner's staff failed to provide Resident 3 services and that failure posed a risk for physical harm, mental anguish, or mental illness. The Board stated in the prior case involving this Petitioner, that the issue "is whether the circumstances presented, viewed as a whole, demonstrate a systemic problem in implementing policies and procedures." *Columbus Nursing & Rehab. Ctr*., DAB No. 2247. at 27 (citation omitted). By considering all the clinical evidence related to Resident 3 and considering both the adequate delivery of care and services and Petitioner's deficiencies, I viewed the circumstances presented as a whole. Contrary to the assertion of CMS there is no simple balancing. Rather, having viewed the circumstances as a whole, I conclude that Petitioner's deficiencies in delivering care and services to Resident 3 were not symptomatic of a failure to prohibit neglect by a policy. Rather, I conclude that the evidence, when viewed as a whole, showed that that an earnest and significant effort was made to deliver necessary care and service to a resident who had an extremely complicated clinical course that required much care and many services. The instances of noncompliance discussed hereafter, clearly meet the definition of neglect in 42 C.F.R. § 488.301. However, I conclude that the instances of neglect discussed in this decision are not sufficient to trigger a reasonable inference that Petitioner failed to implement its policy prohibiting neglect.

Accordingly, I conclude that Petitioner did not violate 42 C.F.R. § 483.13(c) based upon the facts related to Resident 3. Because there was no deficiency, 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 (Affirmed).

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

The Board affirmed my Conclusion of Law that Petitioner violated 42 C.F.R. § 483.25 but remanded for clarification of my determination that the declaration of immediate jeopardy was clearly erroneous. *Columbus Nursing and Rehab. Ctr.*, DAB No. 2398, at 6-10. My factual findings and analysis from my original decision are set forth below followed by my additional findings and analysis to clarify why the declaration of immediate jeopardy was clearly erroneous.

a. Findings and Analysis from Original Decision

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 medication 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, 2007, 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.[16] 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.[17] The resident's psychosocial well-being care plan is dated April 2007, and it indicates that the 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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[16] 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.

[17] 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 instances 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, indicate 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 going to sleep 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 that 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 in the psychiatrist's notes 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, not that she was in pain. 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 did any other assessment of the resident. Tr. at 50-51.[18]

Surveyor Lubick observed Resident 3 again on June 14, 2007 at 7:55 a.m. while a CNA was present providing care and Resident 3 was yelling loudly that her legs hurt. 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. 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 had 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

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[18] This is the event analyzed in detail under Conclusion of Law 1.

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[19] as a result of the violation.

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[19] This finding is consistent with evidence that Resident 3 suffered either pain or mental distress. I make the finding not as a substitute for the surveyor's scope and severity determination but rather to reflect the seriousness of the deficiency, a finding that is required when assessing the reasonableness of the enforcement remedies proposed. 42

(Continued next page.)

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. [20] Thus, there was a medical basis for Resident 3 to complain of pain. The care plan dated 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, 2007, 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

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C.F.R. §§ 488.404(b), 488.438(e) - (f). The finding is made here rather than restating the evidence and analysis in the part of the decision discussing the reasonableness of the enforcement remedies to be imposed.

[20] 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.

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.[21] Dr. Kraus's testimony is also considered not weighty due to his admission 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,

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[21] "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.

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.

b. Additional Findings and Analysis Related to Immediate Jeopardy on Remand[22]

In my original opinion I stated the following regarding immediate jeopardy:

> 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.

I mistakenly thought this conclusion was amply supported by the long recitation and discussion of the evidence and the analysis related to the conclusion that CMS made a prima facie showing of a violation of 42 C.F.R. § 483.25, which Petitioner failed to rebut by attempting to show Resident 3 suffered no pain. Clearly, the Board perceived conflict among my conclusions that:

- There was noncompliance because Petitioner's staff failed to follow care plans and policy in assessing Resident 3's signs and symptoms of pain;

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[22] In post-hearing briefing, CMS did not address immediate jeopardy in detail related to specific allegations of noncompliance, but asserted generally that the declaration of immediate jeopardy had to be upheld unless Petitioner met the heavy burden of showing the declaration was clearly erroneous. CMS Br. at 19-20; CMS Reply at 23-24.

- Resulting in actual harm to Resident 3 in the form of some unresolved or unmitigated pain; but,
- The noncompliance that caused actual harm did not rise to the level of immediate jeopardy as the noncompliance did not cause or was not likely to cause serious injury, harm, impairment, or death.

The Board also expressed confusion about my analysis discussing the weight and credibility accorded to the expert opinions relative to the existence of immediate jeopardy. I discredited the experts' opinions that Resident 3's behaviors were not related to pain but rather her dementia. None of the experts or the surveyor had adequate bases to distinguish the cause of the resident's behaviors that all agree could signal pain or dementia related behaviors. I did not specifically credit or discredit their opinions regarding the care and services delivered to address the resident's signs and symptoms. My error was the presumption that by stating the opinions of the experts without specifically crediting them, the opinions would be understood to have been credited and considered weighty unless specifically rejected or minimized. The purpose of this further analysis is to explain that the expert opinions related to the treatment of the resident's signs and symptoms of pain and the effectiveness of that care and treatment (delete: and other care and treatment), is sufficient to rebut the surveyor's conclusion that there was immediate jeopardy. The clinical evidence is consistent with and supports the opinions of Petitioner's experts in this regard. Further, while the CMS expert opined more should have been done sooner and that pain is severe [serious] harm, his testimony does not bolster the surveyor's opinion that there was immediate jeopardy.

It is first necessary to consider the meaning of immediate jeopardy, what the Act and regulations provide, and the principles adopted by various appellate panels of the Board.

The Act requires that if the state survey agency finds that a facility's deficiencies "immediately jeopardize the health or safety" of the facility's residents, the state is to recommend that the Secretary take action to remove jeopardy and correct the deficiencies through the appointment of temporary management, or terminate the facility's participation. Act § 1819(h)(1)(A). Congress granted the Secretary authority and required that, if a facility was found to no longer meet the conditions for participation and the facility's deficiencies "immediately jeopardized the health or safety of its residents" the Secretary is to remove the jeopardy and correct the deficiencies through the appointment of temporary management or terminate the facility's participation. Act §1819(h)(2)(A)(i) and (4); *see also* Act § 1919(h)(3)(B)(i) and (5) (enforcement procedures for NFs are similar to those for SNFs). The phrase "immediately jeopardize" is not defined in the statutes. However, the context suggests that Congress intended that the phrase be given its plain meaning and apply if there was any potential of instantaneous or proximate, hazard or risk for harm to the health or safety of a long-term care facility resident.

The phrase "immediate jeopardy," which seems to have derived from the statutory "immediately jeopardize," is given a specific and different effect or meaning by the Secretary through regulation. "*Immediate jeopardy"* under the regulations refers to 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, 489.3 (emphasis in original). Thus, "immediate jeopardy" under the regulations refers only to serious injury, serious harm, serious impairment, or death; whereas the statutory "immediately jeopardize" refers to any imminent risk to a resident no matter how severe. In the context of survey, certification, and enforcement related to SNFs and NFs under the regulations, a conclusion by the state agency and CMS that noncompliance with program participation requirements poses immediate jeopardy to a facility resident's, triggers specific regulatory provisions that require enhanced enforcement remedies, including authority for CMS to impose a larger CMP than may be imposed when there is no declaration of immediate jeopardy. 42 C.F.R. §§ 488.408(e), 488.438(a)(1)(i), (c), and (d). The regulations also require termination of the facility's provider agreement on an expedited basis or the removal of the immediate jeopardy through appointment of temporary management. 42 C.F.R. §§ 488.410, 488.440(g), 488.456, 489.53(d)(2)(B)(ii).

Pursuant to 42 C.F.R. § 498.3(d)(10) a finding by CMS that deficiencies pose immediate jeopardy to the health or safety of a facility's residents is not an initial determination that triggers a right to request a hearing by an ALJ or that is subject to review. A finding of noncompliance that results in the imposition of an enforcement remedy, except the remedy of monitoring by the state, does trigger a right to request a hearing and is subject to review. 42 C.F.R. §§ 488.408(g); 498.3(b)(8) and (13). Furthermore, the level of noncompliance, i.e. scope and severity, is subject to review only if a successful challenge would: (1) affect the amount of CMP that may be imposed, i.e. the higher range of CMP authorized for immediate jeopardy; or (2) affect a finding of substandard quality of care that rendered the facility ineligible to conduct a NATCEP. 42 C.F.R. § 498.3(b)(14) and (15). Pursuant to 42 C.F.R. § 498.60(c)(2), in reviewing a CMP, the ALJ must uphold the CMS determination of the level of noncompliance (i.e. scope and severity), unless it is clearly erroneous. The phrase "clearly erroneous" is not defined by the Secretary.

Many appellate panels of the Board have addressed "immediate jeopardy."[23] Recently in *Mississippi Care Ctr. of Greenville*, DAB No. 2450, at 14 (2012), the Board commented:

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[23] Some of the often cited decisions are: *Lakeport Skilled Nursing Ctr.*, DAB No. 2435, at 6 (2012); *Liberty Health & Rehab. of Indianola, LLC*, DAB No. 2434, at 12, 19 (2011); *Yakima Valley School*, DAB No. 2422, at 7 (2011); *Lutheran Home at Trinity Oaks*, DAB No. 2111 (2007); *Daughters of Miriam Ctr.*, DAB No. 2067 (2007);
(Continued next page.)

> CMS's determination that a deficiency constitutes immediate jeopardy must be upheld unless the facility is able to prove that the determination is clearly erroneous. 42 C.F.R. § 498.60(c)(2); *Woodstock Care Center*. The "clearly erroneous" standard means that CMS's immediate jeopardy determination is presumed to be correct, and the burden of proving the determination clearly erroneous is a heavy one. *See, e.g.*, *Maysville Nursing & Rehabilitation Facility*, DAB No. 2317, at 11 (2010); *Liberty Commons Nursing and Rehab Center — Johnston*, DAB No. 2031, at 18 (2006), *aff'd*, *Liberty Commons Nursing and Rehab Ctr. — Johnston v. Leavitt*, 241 F. App'x 76 (4th Cir. 2007). When CMS issued the nursing facility survey, certification, and enforcement regulations, it acknowledged that "distinctions between different levels of noncompliance . . . do not represent mathematical judgments for which there are clear or objectively measured boundaries." 59 Fed. Reg. 56,116, 56,179 (Nov. 10, 1994). "This inherent imprecision is precisely why CMS's immediate jeopardy determination, a matter of professional judgment and expertise, is entitled to deference." *Daughters of Miriam Center*, DAB No. 2067, at 15 (2007).

The Board's statement that the CMS immediate jeopardy determination is entitled to deference is subject to being misunderstood to limit ALJ and Board review of immediate jeopardy beyond what was intended by the drafters of the regulations. In the notice of final rulemaking on November 10, 1994, the drafters of 42 C.F.R. § 498.60(c)(2), discussing the merits of the reviewability of deficiency citations, selection of remedy, and scope and severity, commented:

> We believe that a provider's burden of upsetting survey findings relating to the level of noncompliance should be high, however. As we indicated in the proposed rule, distinctions between different levels of noncompliance, whether measured in terms of their frequency or seriousness,

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Britthaven of Havelock, DAB No. 2078 (2007); *Koester Pavilion*, DAB No. 1750 (2000); *Woodstock Care Ctr.* DAB No. 1726 (2000).

> do not represent mathematical judgments for which there are clear or objectively measured boundaries. Identifying failures in a facility's obligation to provide the kind of high quality care required by the Act and the implementing regulations most often reflect judgments that will reflect a range of noncompliant behavior. Thus, in civil money penalty cases, whether deficiencies pose immediate jeopardy, or are widespread and cause actual harm that is not immediate jeopardy, or are widespread and have a potential for more than minimal harm that is not immediate jeopardy does not reflect that a precise point of noncompliance has occurred, but rather that a range of noncompliance has occurred which may vary from facility to facility. While we understand the desire of those who seek the greatest possible consistency in survey findings, an objective that we share, the answer does not lie in designing yardsticks of compliance that can be reduced to rigid and objectively calculated numbers. Survey team members and their supervisors ought to have some degree of flexibility, and deference, in applying their expertise in working with these less than perfectly precise concepts. **For these reasons, we have revised the regulations to require an administrative law judge or appellate administrative review authority to uphold State or HCFA findings on the seriousness of facility deficiencies in civil money penalty cases unless they are clearly erroneous.**

59 Fed. Reg. at 56,179 (emphasis added). It is clear from this regulatory history that the drafters of 42 C.F.R. § 498.60(c)(2) ensured that the state agency or CMS determination that there was immediate jeopardy would receive deferential consideration, by adopting the clearly erroneous standard of review. Thus, caution must be exercised to ensure that the Board's decision in *Mississippi Care Ctr. of Greenville, Daughters of Miriam Ctr.*, and other decisions that have mentioned deference relative to immediate jeopardy not be read to require deference for the determination that there was immediate jeopardy beyond that imposed by adoption of the clearly erroneous standard. Giving or requiring that the immediate jeopardy determination be given deference in addition to applying the "clearly erroneous standard" would be contrary to the intent of the drafters of the regulation; would significantly limit the review of the determination by an ALJ and the Board; and would impermissibly deny an affected party the due process right to review intended by the drafters of the regulation.

In the foregoing quotation from *Mississippi Care Ctr. of Greenville,* that panel of the Board states that the clearly erroneous standard means that "the immediate jeopardy

determination is presumed to be correct, and the burden of proving the determination clearly erroneous is a heavy one." *Id*. at 14. Similar formulations have been used in other Board decisions when referring to the "clearly erroneous standard." However, the Board's characterization of the "clearly erroneous standard" in *Mississippi Care Ctr.* and other cases does not define the standard. The "clearly-erroneous standard" is described in Black's Law Dictionary as a standard of appellate review applied in judging the trial court's treatment of factual issues, under which a factual determination is upheld unless the appellate court has the firm conviction that an error was committed. *Black's Law Dictionary* 269 (18th ed. 2004). The Supreme Court has addressed the "clearly erroneous standard" in the context of the Administrative Procedures Act (APA). The Court described the preponderance of the evidence standard, the most common standard, as requiring that the trier of fact believe that the existence of a fact is more probable than not before finding in favor of the party that had the burden to persuade the judge of the fact's existence. *In re Winship*, 397 U.S. 358, 371-72 (1970); *Concrete Pipe and Products of California, Inc. v. Construction Laborers*, 508 U.S. 602, 622 (1993). The "substantial evidence" standard considers whether a reasonable mind might accept a particular evidentiary record as adequate to support a conclusion. *Consolidated Edison*, 305 U.S. 197, 229 (1938); *Dickinson v. Zurko*, 527 U.S. 150, 162 (1999). Under the "clearly erroneous" standard a finding is clearly erroneous even though there may be some evidence to support it if, based on all the evidence, the reviewing judge or authority has a definite and firm conviction that an error has been committed. *United States v. United States Gypsum Co.*, 333 U.S. 364, 395 (1948); *Dickinson*, 527 U.S. at 162; *Concrete Pipe*, 508 U.S. at 622. The clearly erroneous standard has been characterized by the Court as being stricter than the substantial evidence test and significantly deferential.[24] The Court stressed in discussing the clearly erroneous standard the importance of not simply rubber-stamping agency fact-finding. The Court also commented that the APA requires meaningful review. *Dickinson*, 527 U.S. at 162 (citations omitted); *Concrete Pipe and Products of California*, 508 U.S. at 622-23.

Various panels of the Board have recognized other principles applicable to the review of the immediate jeopardy issue. A finding of immediate jeopardy does not require a finding of actual harm, only a likelihood of serious harm. *Dumas Nursing and*

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[24] The Board's characterization of the clearly erroneous standard as being highly deferential to the fact finding by the state agency surveyor and CMS and even triggering a rebuttal presumption is entirely consistent with the Supreme Court's characterization of the standard. However, the Court's cautions about ensuring meaningful review rather than rubber-stamping agency decisions shows it is important for the ALJ and the Board not to be tempted to simply defer to the surveyor, the state agency, or CMS on the immediate jeopardy issue.

Rehabilitation, L.P., DAB No. 2347, at 19 (2010), *citing Life Care Center of Tullahoma*, DAB No. 2304, at 58 (2010), *aff'd, Life Care Center of Tullahoma v. Sebelius*, No. 10-3465 (6th Cir., Dec. 16, 2011). The definition of immediate jeopardy at 42 C.F.R. § 488.301, does not define "likelihood" or establish any temporal parameters for potential harm. *Agape Rehabilitation of Rock Hill*, DAB No. 2411, at 18-19 (2011). The duration of the period of immediate jeopardy is also subject to the clearly erroneous standard. *Brian Ctr. Health and Rehab./Goldsboro*, DAB No. 2336, at 7-8 (2010). There is a difference between "likelihood" as required by the definition of immediate jeopardy and a mere potential. The synonym for likely is probable, which suggest a greater degree of probability that an event will occur than suggested by such terms as possible or potential. *Daughters of Miriam Ctr.*, DAB No. 2067 at 10. Jeopardy generally means danger, hazard, or peril. The focus of the immediate jeopardy determination is how imminent the danger appears and how serious the potential consequences. *Woodstock Care Ctr.*, DAB No. 1726 (2000).

What is the meaning of serious injury, harm, or impairment as used in the definition of immediate jeopardy found in 42 C.F.R. § 488.301? How does serious injury, harm, impairment compare with "actual harm?" On the first question the Board recognized in *Yakima Valley School*, DAB No. 2422, at 7 (2011), that the regulations do not define or explain the meaning of the term "serious" as used in the definition of immediate jeopardy.[25] The Board suggested that the definitions may be unimportant as the Board has held that under the clearly erroneous standard that once the state agency or CMS declares immediate jeopardy, there is a presumption that the actual or threatened harm was serious and the facility can only rebut the presumption of immediate jeopardy by showing that the harm or threatened harm meets no reasonable definition of the term "serious." *Id., citing Daughters of Miriam Ctr.*, DAB No. 2067, at 9. In *Daughters of Miriam Ctr*, the Board discussed that the ALJ attempted to define "serious" finding meanings such as dangerous grave, grievous, or life-threatening. The Board notes that

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[25] Appendix Q of the State Operations Manual (SOM) also fails to provide surveyors a working definition of the term "serious" that they can use to determine whether harm, injury, or impairment is serious when deciding whether or not to declare immediate jeopardy. The Act does not define the phrase immediately jeopardize as previously discussed in this decision and does not introduce the concept of serious harm, injury, or impairment as the basis for finding immediate jeopardy. Thus, one is not in error concluding that absent a definition of the term "serious" in the Act, the regulations, the SOM, or decisions of the Board, it is essentially up to individual surveyors and whatever unpublished guidance they receive from their superiors or CMS officials, to exercise their individual discretion and judgment to decide that there was immediate jeopardy, which subjects a facility to the maximum imposable CMPs.

the ALJ stated that serious harm is outside the ordinary, requiring extraordinary care, or having lasting consequences. The Board further noted that the ALJ stated that a serious injury may require hospitalization, or result in long-term impairment, or cause severe pain as opposed to harm, injury, or impairment that is temporary, easily reversible with ordinary care, does not cause a period of incapacitation, heal without special medical intervention, or does not cause severe pain. The Board did not endorse or adopt the ALJ's definitional exercise but concluded that it was simply unnecessary in the context of that case. The Board reasoned, as already noted, that the facility bore the burden to rebut the presumption by showing that the actual or threatened harm met no reasonable definition of serious. *Daugthers of Miriam Ctr.*, DAB No. 2067, at 9.

Applying the clearly erroneous standard to the record before me related to the noncompliance I have found based on the violation of 42 C.F.R. § 483.25 (Tag F309), I have a definite and firm conviction that the declaration of immediate jeopardy was in error. My conclusion is based on my finding that while the evidence does show actual harm in the form of pain or mental distress, the evidence does not show actual serious harm, injury, or impairment or death, or a likelihood of serious harm, injury, or impairment or death.

Surveyor Lubick alleged in the SOD that:

> Petitioner did not adequately or consistently:
>
> - Assess Resident 3 when she repeatedly moaned and cried out in pain during rest periods and activity (transfers, eating)
> - Provide prescribed medications prior to transfers and cares to promote comfort;
> - Assess the effectiveness of its pain treatment regimen;
> - Assess if pain was a contributing factor for the increased anxiety, behaviors, constipation, significant weight loss and skin breakdown that Resident 3 was experiencing;
> - Review the frequency of the need of prn (as needed) pain medications for breakthrough pain.
>
> As a result, Resident 3 experienced frequent episodes of pain that were unresolved by pain medications.
>
> The above failures created an Immediate Jeopardy situation which began on 6/4/07.

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. On admission, Resident 3 was assessed as complaining of excruciating pain that was assessed to be soft-tissue pain. CMS Ex. 27, at 5-9. 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. 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. The resident was assessed for pain and received pain medications. CMS Ex. 27, at 164-232. 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. CMS Ex. 27, at 153; P. Ex. 1, at 266.

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. The April 2007 MDS assessed Resident 3 as complaining of periods of mild pain occurring less than daily. The April 2007 MDS shows that she continued 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 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. Thus, the evidence shows improvement of the resident's pain and pain control as of April 2007.

The clinical record, though inconsistent in the reporting of instances 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 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 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. 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. 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 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. CMS Ex. 27, at 167; P. Ex. 1, at 216. Resident 3's care plan was updated on June 6, 2007, with the intervention to use Vicodin (Acetaminophen and the narcotic Hydrocodone) as necessary if pain is severe. 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 care plan was updated on June 15, 2007, with the intervention to administer narcotics as ordered. CMS Ex. 27, at 153; P. Ex. 1, at 266.

The foregoing clinical evidence from January 2007 to the survey in June 2007 shows that Petitioner's care planning, assessment, and treatment of Resident 3's pain was not

perfect. However, the clinical evidence shows that the resident was repeatedly assessed for pain, alternative interventions including increasingly significant pain medications were implemented, the effect of interventions was assessed and recorded, there was a period of improved pain control, the resident's treating physician was actively involved in care planning and treatment, and psychiatric consults were ordered and performed.

Dr. Kraus testified that Resident 3's case was complicated in the last few months and that he or his physician assistant called facility staff daily to follow the resident's case. Tr. at 435-41. He testified that due to the resident's reduced ability to communicate it was difficult to determine whether her agitation was due to pain or her dementia. Testing and examination was done to attempt to determine a source for pain but there was no trauma or change in physical condition that explained her increased complaints of pain. Tr. at 459-63. He opined that the resident was treated consistent with the standard of care and there was no risk for serious harm or injury or death and there was no potential for more than minimal harm. Tr. at 470-71. Dr. Kraus's opinion that there was no risk for more than minimal harm is consistent with his diagnosis that there was no cause for the resident's complaints of pain. I have discounted that opinion as the clinical evidence shows that the resident complained of pain whether or not due to physical or psychological causes. However, Dr. Kraus's opinion that there was no risk for serious harm, injury, or death is consistent with his knowledge of the resident's condition, his regular care of the resident, and the clinical evidence discussed above which shows that there was care planning and interventions to minimize potential pain.

Surveyor Lubick testified to observing Resident 3 on June 12, 2007, when she was yelling she was cold and when prompted by the CNA, the resident said she had back pain. Surveyor Lubick testified to no other signs and symptoms of pain but concluded that the resident was suffering from unresolved pain. Tr. at 45-47. I infer the resident was not suffering from severe pain as she only complained when the CNA asked if she had pain. Surveyor Lubick again observed the resident approximately three hours later on June 12, and the resident was moaning and calling out very loudly. She testified she asked Resident 3 what was the matter and the resident replied that her legs were breaking. Tr. at 47. Survey Lubick testified she told a staff member who advised her that the resident was on scheduled pain medication, which was being adjusted. Surveyor Lubick opined that staff should have assessed the resident and used available pain medication or other interventions. Tr. at 47-49. Surveyor Lubick is correct that the staff member should have responded to Surveyor Lubick's concern by assessing the resident and then making an informed judgment about whether some intervention was appropriate rather than dismissing the surveyor as she did. However, I recognize, as no doubt the staff member did, that Resident 3's complaint was exaggerated. Clearly, the resident's legs were not breaking and she was regularly being given pain medication for her complaints of pain. Surveyor Lubick next saw the resident during the morning on June 13, this is the incident discussed under Tag F224, which I inferred was behavioral and not related to pain and which caused me to conclude that Surveyor Lubick's opinion as to the existence

of pain and its severity was not weighty. On June 14, 2007, Surveyor Lubick observed the resident yelling loudly that her legs hurt while staff was providing care. The staff member consulted with a nurse and was told that the resident had been given a dose of Vicodin approximately two hours before and the nurse instructed the staff member to get the resident up and she would be in to speak to her. Surveyor Lubick did not dispute that the resident received Vicodin two hours in advance of the incident or opine that the Vicodin was inadequate for pain control in advance of care. Rather, Surveyor Lubick opined that the nurse should have assessed the resident. Tr. at 54-55. Again I agree with Surveyor Lubick that the nurse should have personally assessed the resident rather than simply relying upon the report of the CNA, her knowledge that the resident had received Vicodin, and her knowledge of the resident. Surveyor Lubick observed Resident 3 approximately 25 minutes later when staff was lifting the resident out of bed and moving her to the bathroom with a mechanical lift. Resident 3 was screaming or yelling. The DON ordered staff to stop and the resident was given another half Vicodin. Surveyor Lubick opined that the resident had been crying out for half an hour. Tr. at 55-56. The extra half of a Vicodin tablet was not effective to stop the resident's yelling as a nurse's note for June 14, 2007, at 8:40 a.m. shows that the physician had to be contacted for additional instructions and new orders.[26] CMS Ex. 27, at 57, 131. The evidence does not show that Surveyor Lubick did not observe the resident in pain. Rather, the evidence shows that when the resident's complaints of pain were not resolved, Petitioner's staff consulted with the treating physician to determine the appropriate treatment. Rather than simply sedate the resident with higher doses of pain or psychotropic medications during a time when staff and physician were working to assess the cause of the complaints, the care planning team continued to work to find the best treatment modality. Selection of the best treatment modality in this complicated case was a matter for the treating physician and Petitioner's staff, not the surveyor, the state agency, CMS, or me. While it is more likely than not that the resident experienced some pain as Surveyor Lubick

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[26] The Nurse's Notes entry for June 14, 2007 at 8:40 a.m. shows that Dr. Kraus was advised that Resident 3 continued to call-out despite scheduled Vicodin; she called-out when no one was around; and she called-out with any movement. Sometimes the resident complained of pain and sometimes she denied pain. The note indicates that Dr. Kraus gave new orders and that Petitioner's staff was waiting for the psychiatric consult notes to send to him. CMS Ex. 27, at 131. The new orders received on June 14, 2007 at 8:40 a.m. were for 10 milligrams of Oxycontin by mouth every 12 hours for pain; an additional 5 milligrams of Oxycontin by mouth every six hours as needed for breakthrough pain; and to increase the residents Seroquel to 50 milligrams to address her agitation related to Alzheimer's. CMS Ex. 27, at 57. This evidence supports Dr. Kraus testimony regarding on-going efforts to evaluate the cause of the resident's complaints and behaviors and to adjust medication appropriately.

concluded, I have a firm conviction based upon the contemporaneous medical evidence and the testimony of the treating physician, Dr. Kraus, that the resident's pain was not actual or potential harm that met any reasonable definition of serious harm, injury, or impairment, or that was likely to cause her death. Common definitions, synonyms for serious and related words found at oxforddictionaries.com, merriam-webster.com, and dictionary.com, respectively, are: significant or worrying because of possible danger or risk; having important or grave possible consequences, grave, severe; and dangerous, grave, severe, life-threatening, grievous.

The CMS expert witness, Dr. 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. Dr. Berlowitz 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. Tr. at 350-58; CMS Ex. 80, at 2. Dr. Berlowitz is without a doubt an expert in geriatric medicine. In weighing his opinions, however, it is important to recognize that his knowledge of Resident 3 was based upon his review of the clinical records and not upon any examination of the resident. His opinion that Resident 3 was not as free of pain as possible is worthy of weight and consistent with my conclusion that the resident did suffer actual harm in the form of pain. His opinion that the resident could have been advanced to narcotic pain medication sooner is clearly correct. However, the decision to increase medication is a medical decision that is best left to the judgment of the treating physician who has been examining the resident and treating the resident and is more familiar with the resident's case, including the care plan and goals. The clinical evidence shows improvement of the resident's complaints of pain and pain symptoms in April 2007. Tr. at 415. The clinical evidence shows that the resident continued to receive relief from pain through the use of non-narcotics in the first half of May. The evidence shows that the resident did not require medication on a daily basis. The resident's pain was clearly monitored and assessed as reflected by the clinical evidence, though the documentation of assessment and monitoring was not perfect. Therefore, Dr. Kraus's judgment not to advance to narcotics earlier than he did has some support in the clinical evidence. I do not find that Dr. Berlowitz's opinion that Resident 3's pain

amounted to serious harm merits any weight. Dr. Berlowitz was not asked to clarify and did not offer any characterization, definition, or description for what he considered to be "serious harm." Rather, Dr. Berlowitz simply said that in his opinion there was no need for a person on comfort care to experience any pain. He testified "based on the surveyor's notes" that the resident's complaints of pain were often ignored. Tr. at 354, 415. The clinical evidence and even the surveyor's testimony and notes do not support his conclusion that the resident's complaints of pain were often ignored or that she was not given pain medications in advance of cares. The evidence shows that the resident's complaints were assessed and addressed in most instances and that she did receive pain medication on a scheduled and as needed basis.

Dr. Kurt Hansen, Petitioner's expert, 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. Dr. Hansen's opinion that Resident 3 was receiving care consistent with the standard of practice is entitled to weight. His opinion is consistent with and supported by the clinical evidence. His opinion that the resident's moaning was likely not caused by pain, at least in some instances, is consistent with the fact that the moaning was not resolved by significant pain medication in some instances. However, he also acknowledged that the resident's osteoarthritis could cause some pain with movement. Dr. Hansen was also not asked to elaborate upon his understanding of the phrase "severe injury or harm" in the context of immediate jeopardy and that opinion is no more or less weighty than Dr. Berlowitz's opinion on the same topic.

Weighing the opinions of the treating physician, Dr. Kraus, against those of the CMS expert, Dr. Berlowitz, I conclude that the opinions of Dr. Kraus should be given greater weight in determining the seriousness of the potential harm, injury, or impairment to Resident 3. Dr. Berlowitz, never clearly articulated how he defined "serious harm" though his testimony indicated that in his opinion any pain was both serious and unnecessary in the case of Resident 3. Dr. Kraus was the treating physician for Resident

3 for approximately six months prior to the survey, the evidence shows he or his physician's assistant regularly saw her, that he was regularly updated by Petitioner's staff and that he was actively involved in the care and treatment of the resident. Based on his knowledge of the resident it was not unreasonable for him to conclude that the resident's complaints of pain were exaggerated, possibly due to psychiatric causes such as dementia rather than a physical cause. It was not unreasonable, given the clinical record, for the physician to determine it was appropriate to permit some complaints of pain while attempting to adjust interventions rather than to simply sedate the resident to prevent her complaints. Dr. Kraus's testimony supports my conclusion that Resident 3 was receiving sufficient care and treatment that there was no probability or likelihood that unresolved pain had the potential to cause serious harm, injury, impairment, or death.

Surveyor Lubick alleged in the SOD that Resident 3 experienced frequent episodes of pain that were unresolved by pain medication, due to Petitioner's failure to: assess the resident when she moaned and cried out; provide prescribed medication prior to transfers and cares; assess effectiveness of pain treatment regimen; and review the effectiveness of medication for her breakthrough pain. Surveyor Lubick alleged that these failures posed immediate jeopardy, i.e., a potential for serious harm, injury, impairment, or death. CMS Ex. 13, at 55, 72. I have a definite and firm conviction that the declaration of immediate jeopardy was in error in this case. My conclusion is based on my finding that while the evidence does show actual harm in the form of pain or mental distress, the evidence does not show actual serious harm, injury, or impairment or death or a likelihood of serious harm, injury, or impairment or death. The clinical record and the testimony of Dr. Kraus show that the resident received treatment for pain; was frequently assessed; and closely monitored. The evidence shows that the resident's complaints of pain likely involved both a physical and a psychiatric cause. Based on the contemporaneous clinical records, pain was not resolved in some instances by significant pain medication supporting an inference that the complaints of pain were not due to a physical cause. The records show that in other instances complaints of pain were resolved by more mild analgesics or even distracters such as cookies, indicating that pain was physical but not as significant as the surveyor and CMS argue. Most importantly, the clinical record shows that the care planning team, including Dr. Kraus, was actively involved in the care of Resident 3. The records are not perfect, the assessments not as frequent or thorough as Surveyor Lubick and CMS might prefer, and narcotics were not implemented as early as Dr. Berlowitz would have had Resident 3 been his patient. Nevertheless, I am convinced that it was not likely or probable that Resident 3 was going to suffer serious harm, injury, impairment or

death.[27] Accordingly, I conclude that the declaration of immediate jeopardy was clearly erroneous.

The Board expressed concern that I did not address whether the bases alleged for immediate jeopardy under Tag F309 had the potential for causing serious injury, harm, impairment, or death to any other resident. *Columbus Nursing and Rehab. Ctr.*, DAB No. 2398, at 9-10. Surveyor Lubick stated in the SOD that she considered five other residents related to the delivery of care and services for pain. CMS Ex. 13, at 55. Surveyor Lubick did not specifically allege that any of the other five residents were in immediate jeopardy. She did not allege facts, specifically or generally, that suggest that the declaration of immediate jeopardy extended to other residents in Petitioner's facility. CMS Ex. 13, at 54-72. Surveyor Lubick stated that immediate jeopardy was abated on June 14, 2007, at which time Petitioner had reviewed the case of all residents with scheduled pain medication using Petitioner's current assessment tool; staff had been instructed to call the nurse if a resident seemed to be experiencing significant pain; and physicians would be adjusting pain management regimens as necessary. CMS Ex. 13, at 72. Surveyor Lubick does not indicted that any of the interventions implemented to abate immediate jeopardy were new or not already standard practice in Petitioner's facility. Rather, the assessment of the residents using the current pain assessment tool was a method for Surveyor Lubick to confirm that there were no deficiencies related to other

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[27] The Board noted that on appeal CMS argued that Resident 3's pain contributed to other serious consequences. The Board specifically noted the argument related to pressure sores and weight loss. The Board failed to mention that CMS advanced the argument related to pressure sores and weight loss without the benefit of supporting evidence. *Columbus Nursing and Rehab. Ctr.*, DAB No. 2398, at 9 n.4. Not even Surveyor Lubick alleged that unresolved pain caused or was a contributing factor to weight loss or pressure sores. Rather, Surveyor Lubick alleged that Petitioner failed to assess and attempt to determine whether the resident's pain was a contributing factor. The Board affirmed my Conclusions of Law 5 through 8 that there was noncompliance related to pressure ulcers and weight loss that amounted to immediate jeopardy. I see no legal need to engage in an analysis of whether the resident's pain may have been a contributing factor to weight loss or the development pressure ulcers, particularly where there is no evidence urged by CMS as supporting the argument and given that I have already concluded that there was immediate jeopardy related to the actual weight loss and the development of pressure sores. I also conclude that it is not necessary given the posture of this case to determine whether there was any colorable basis for the CMS argument or whether it was frivolous. CMS made the argument to the Board and not to me and I will not exercise my jurisdiction to inquire as to a potential offense to the Board absent some specific direction by the Board to do so.

residents. The instruction to staff to call the nurse and the reminder that physicians would adjust pain management approaches are simply reminders to staff. Even if Surveyor Lubick had alleged that immediate jeopardy extended to other residents, I would have a definite and firm conviction that the declaration of immediate jeopardy was in error based upon Surveyor Lubick's lack of objectivity demonstrated in the example of Resident 3.[28]

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

6. The determination that Petitioner's violation of 42 C.F.R. § 483.25(c) posed immediate jeopardy was not clearly erroneous (Affirmed).

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

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[28] The Board directed that I address whether or not CMS gave timely and adequate notice that it alleged that Resident 3 suffered "severe" pain. *Columbus Nursing and Rehab. Ctr.*, DAB No. 2398, at 9 n 4. It is clear from the regulations and the prior decisions of the Board that the fact issue to be resolved in addressing immediate jeopardy is whether there is actual or a potential for "serious" harm, "serious" injury, or "serious" impairment. Petitioner had sufficient notice based on the SOD that CMS alleged that there was a potential for serious harm, injury, or impairment to Resident 3 or that Resident 3 had suffered serious harm, injury, or impairment related to the noncompliance alleged under Tag F309. The Board, CMS, and Petitioner do not state what legal significance if any the term "severe" has in context of Tag F309 or the allegation of immediate jeopardy related thereto. To the extent "severe" may be viewed as meaning "serious," Petitioner had adequate notice. Otherwise, the term "severe" has no legal significance and there is no requirement that I have found that requires CMS to give notice prior to using a legally insignificant term to describe Resident 3's pain.

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 necessary care and services" for attainment or maintenance of the highest practicable resident well-being. 42 C.F.R. § 483.25 (emphasis supplied). The regulation then goes on to provide that a resident with pressure sores must receive "necessary treatment and services" for healing, prevention of infection, and prevention of yet more pressure sores. 42 C.F.R. § 483.25(c)(2) (emphasis supplied). We therefore reject Clermont's contention that the standard is "nowhere in the regulation." That argument is belied by the plain language of the regulation.

> Moreover, as we explained in *Koester Pavilion*, in the preamble to the final regulation, CMS expressly declined to use "less demanding" language with respect to a facility's obligation to "ensure" outcome of treatment for pressure sores. *Koester Pavilion* at 30, quoting 56 Fed. Reg. 48,826, at 48,850 (Sept. 26, 1991). CMS recognized that factors beyond required treatment and services, such as disease process and resident compliance, affect care outcome. *Id.* However, CMS also recognized that the regulation allows a facility to put forward "available clinical evidence" to show that "a negative resident care outcome was unavoidable." *Id.* The preamble further provides that facilities "should <u>always</u> furnish the <u>necessary</u> treatment and services" for pressure sore prevention or healing. *Id.* at 30-31(emphasis supplied). Thus, a facility may provide necessary treatment and services to ensure the prevention or healing of pressure sores, yet still be confronted with a negative outcome. In that instance, the facility may put forward clinical evidence to show that the outcome was unavoidable.

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

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,[29] as blisters on both heels 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 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

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[29] 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.

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, 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 monitor 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 Petitioner 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 a 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 were 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 dies 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 was 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 plantar surface of the resident's 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, and 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.[30] There is no dispute that the pressure 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).

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[30] 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.

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 (Affirmed).

8. The determination that Petitioner's violation of 42 C.F.R. § 483.25(i)(1) posed immediate jeopardy was not clearly erroneous (Affirmed).

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 the 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 resident's psychotropic medications to reduce her lethargy, changing her to

a mechanical soft diet, and 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. Petitioner 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(i) 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 lose 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.[31]

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[31] The Board specified that I was to address this Conclusion of Law only if my Conclusion of Law 10 changed on remand. *Columbus Nursing and Rehab. Ctr.*, DAB

(Continued next page.)

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 Messer, a licensed RN and nursing home administrator, was called to testify by Petitioner. Ms. Messer 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. Messer 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.

(Continued from preceding page.)

No. 2398, at 9 n.8. My Conclusion of Law 10 is unchanged though I have added discussion to address the issues raised by the Board.

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 (On Remand).

a. Text From Original Decision

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. 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. 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 one centimeter from the vaginal opening 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 was 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 because 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 Messer, 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.

b. Additional Analysis On Remand

The Board expressed concern in the remand decision that I did not conduct a complete analysis. To the contrary, my analysis was complete and correct, but like the anxious math student at the end of a long examination, I simply failed to show all my work to arrive at the correct answer.

There is no dispute that on August 9, 2007 at 12:30 p.m., nursing staff discovered and documented that Resident 2 had a two by one centimeter[32] hard, rough mass protruding one centimeter from the vaginal opening 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. Staff called the resident's physician about 1:05 p.m., but had to leave a message with the physician's nurse. 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 was taking minimal water with meals with minimal urinary output; but she had no complaint of pain or discomfort. CMS Ex. 68, at 4.

The first step in the analysis under the regulation is to determine whether or not the foregoing facts describe:

- An accident with injury that has a potential to require physician intervention:
- A significant change in physical, mental, or psychosocial status;
- A situation that requires significant alteration of treatment; or
- A situation where a decision is made to transfer or discharge the resident.

If any one or more of the conditions was met on August 9, 2007, the facility's duty to consult with the resident's physician under 42 C.F.R. § 483.10(b)(11)(i) was triggered. The surveyors and CMS do not allege that the facts described show that an accident occurred or that a decision was made to transfer or discharge the resident.

The surveyor, Ann Angell, alleged in the SOD that the duty to consult was triggered by a "significant change of condition" that was observed at approximately 12:30 p.m. on August 9, 2007. CMS Ex. 63, at 2, 7. Surveyor Angell opined that the mass was a significant change because it is not normal for such a mass to be in that location, it was painful to touch, there was drainage which she felt might indicate an infection, and the resident was at risk for infection. Tr. at 546, 549. I do not find Surveyor Angell's opinion to be weighty as it is not based upon either the regulatory definition or the SOM explanation of the regulatory standard discussed hereafter. Furthermore, Surveyor Angell also opined that the physician should be consulted for any change in condition. Tr. at 552. However, she agreed that not every call to a physician is related to a significant change. Tr. at 582-83. Surveyor Angell's testimony indicates that she did not understand

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[32] The diameter of a U.S. penny is approximately two centimeters.

the regulatory standard or the SOM guidance when citing the deficiency, which further undermines the weight of her opinions and conclusions.

CMS argued to me that there was a significant change in condition as alleged by the surveyor. CMS also argued the additional ground that there was a need for significant alteration of treatment evidenced by the fact the resident was sent to the emergency room on August 10, 2007. [33] CMS's position is that the change in physical status and need to significantly alter treatment occurred at approximately 12:30 p.m. on August 9, 2007. CMS Brief at 21-22; CMS Reply at 25-27.[34] The CMS arguments are not persuasive.

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[33] The Board directed that I address whether or not CMS timely raised the issue of whether there was need for a significant change in treatment. *Columbus Nursing and Rehab. Ctr*, DAB No. 2398, at 15 n.9. The surveyor alleged only that the facility failed to consult with the physician when there was a significant change in condition. CMS Ex. 63, at 2, 7. CMS did not raise the issue of whether there was a need for a significant change in treatment in its prehearing brief dated May 9, 2008. CMS Prehearing Brief at 41-42. CMS did not raise the issue in its opening statement at trial. Tr. at 32-34. CMS first advanced the additional grounds for a violation of 42 C.F.R. § 483.10(b)(11)(i) in post-hearing briefing. Although I gave the parties the opportunity to address the Boards Remand decision, they declined to do so and CMS has waived the opportunity to comment upon the issue. CMS did not timely raise the issue of whether or not there was a need for a significant change of treatment; the government failed to give Petitioner timely and sufficient notice of the alternate theory for liability; and the CMS allegation could be rejected for that reason. However, out of an abundance of caution I addressed the merits of the argument for the Board.

[34] CMS also argues that Petitioner's staff failed to record the resident's vital signs on August 9, 2007. There is no dispute that vital signs are not recorded. However, the surveyors did not allege any deficiencies based on a failure to properly assess Resident 2 or deliver necessary care and services on August 9, 2007. CMS also argues that Petitioner failed to follow its own policy. However, there is no regulatory requirement that Petitioner issue or implement a policy related to the identification and reaction to significant changes. To the extent that CMS cites the facility policy as evidence of a standard of care, Petitioner was not cited for failure to deliver professional services or to deliver necessary care and services. The charge by the surveyor only alleges a violation of 42 C.F.R. § 483.10(b)(11). CMS Ex. 63, at 1. CMS has the very low burden of proceeding by showing a prima facie case of the noncompliance as alleged in the SOD. However, CMS is responsible to ensure that its proof actually relates to the cited noncompliance. If CMS was not satisfied with the citation of noncompliance in the SOD,
(Continued next page.)

The regulation describes a significant change as "deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications." 42 C.F.R. § 483.10(b)(11)(B).[35] The regulation describes a need to alter treatment significantly as "a need to discontinue an existing form of treatment due to adverse consequences, or to commence a new form of treatment." 42 C.F.R. § 483.10(b)(11)(C). The same definitions appear in the SOM, App. PP, Tag F157. CMS further elaborates in the SOM that **"**life-threatening conditions are such things as a heart attack or stroke;" and "[c]linical 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." CMS explains in the SOM that the need to alter treatment "significantly" means a need to stop a form of treatment because of adverse consequences such as an adverse drug reaction, or commence a new form of treatment to deal with a problem, such as the use of any medical procedure, or therapy that has not been used on that resident before.

The evidence shows that on August 9, 2007 at 12:30 p.m., staff observed a two by one by one centimeter mass protruding from the resident's vaginal opening; it was very painful with slight touch; a yellow-white discharge was noted; and a foul odor was noted. CMS Ex. 68, at 4; P. Ex. 2, at 89. The contemporaneous medical record is the most credible description of the mass and the resident's clinical presentation. Comparing the description of the mass and the resident's signs and symptoms with the definitions of the regulation and the further policy guidance of CMS in the SOM, I conclude that the mass was not of the same significance as a heart attack or stroke, the development of a stage II pressure sore, the onset or recurrence of periods of delirium, recurrent urinary tract infection, or the onset of depression. I also conclude that on August 9, 2007, the mass did not require, on an emergency or immediate basis, a new form of treatment, medical procedure, or therapy that had not been used before within the meaning of the regulation. Resident 2 was already being treated for major depression. P. Ex. 2, at 73-74. Resident 2 had also had a prior urinary tract infection diagnosed on about June 29, 2007, which cleared after a ten day course of antibiotic. P. Ex. 2, at 76, 79-81, 265.

(Continued from preceding page.)

CMS certainly had authority to reopen and revise its determination at any time prior to the hearing and give Petitioner proper notice thereof.

[35] The drafters of the regulation used the abbreviation "i.e." which indicates that the quoted language, which appears in parentheses in the regulation, was intended to clarify the meaning of the provisions rather than simply provide examples, which would have been indicated by use of the abbreviation "e.g."

On August 10, 2007, the resident was transported to the hospital where the mass could be removed under anesthesia to minimize the resident's pain associated with the contractures that limited access to the area without pain. Even if one concluded that the removal of the mass constituted a new medical procedure or that the initiation of antibiotics was a new form of treatment, the evidence does not show that the resident was at risk for more than minimal harm due to the 20-hour delay to remove the mass or begin antibiotics. The evidence shows that on August 9, 2007, the resident reported no complaints of pain or discomfort other than the pain related to the attempt to examine the mass. CMS Ex. 68, at 4-5; P. Ex. 2, at 89-90. The evidence shows that the resident refused her evening meal on August 9 and was taking very little fluid, but that was not a new problem for the resident as she had been refusing meals and had decreased fluid intake and output for some time and interventions had been implemented to address the problems. P. Ex. 2, at 78, 87-89, 106. On August 5, 2007, the resident had complained of nausea which she associated with the protein powder being added to her juice. P. Ex. 2, at 89.

I will not infer from the fact that staff called the physician on August 9, 2007, that staff believed there was a significant change that required consultation with the physician. The Nurse's Notes entry at 1:05 p.m. on August 9, 2007, states that the physician was updated by a message left with his nurse regarding the mass in the vaginal area. CMS Ex. 68, at 4. The note does not indicate that staff expressed a need for an urgent response from the physician or otherwise indicated that immediate medical attention was required, which would have been indicated by a request for new treatment or order to send the resident to the hospital. As Ms. Angell testified on cross-examination physicians are often contacted by staff when there is no significant change. Tr. at 582-83.

I also will not infer from the fact that the on-call physician directed that the resident be sent to the hospital on August 10, 2007, that there was a significant change or need to significantly alter treatment on August 9, 2007. 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, though 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. All the reasons the on-call physician elected to have the resident sent to the emergency room on August 10, 2007, are likely not reflected in the evidence. However, an inference can be drawn that the on-call physician was not the resident's treating physician and he had only the information provided by the staff by telephone, including that the resident was not feeling well; she had a vaginal density or foreign object; a temperature; and though not recorded in the notes, he probably believed that she was old based on the fact she was from the nursing home. The Nurse's Note clearly states however that the resident was being sent to the hospital for evaluation. CMS Ex. 68, at 5. The examination notes from the hospital show that vaginal examination had to be deferred due to excruciating

discomfort trying to position the resident and that the examination would be done under anesthetic or sedative. CMS Ex. 68, at 13-14. Subsequent to the administration of anesthetic, the mass was simply removed by forceps. CMS Ex. 68, at 15. After the procedure, the only ongoing treatment was antibiotics for a urinary tract infection. CMS Ex. 68, at 12. The records related to the procedure to remove the mass and the follow-up with antibiotics to treat a urinary tract infection, do not describe a life threatening situation or clinical complications similar in magnitude to the illustrations of those phrases used by CMS in the SOM. While the addition of an antibiotic to treat the urinary tract infection is a change in treatment, it is not a significant change as the treatment of nursing home residents with antibiotics is common and the evidence shows Resident 2 was treated with antibiotics for a urinary tract infection the month before. The fact that the resident was sent to the hospital is also not persuasive evidence that the on-call doctor thought the resident required emergency care or that the resident was experiencing a significant change. Clearly the resident did not have a prior appointment to see the on-call doctor in his office, if he had an office outside the hospital. It is also not uncommon for nursing home residents to be sent to the hospital for evaluation in the emergency room rather than being directed to a physician's office where there are fewer resources to deal with the many possible complications the residents may have or develop during treatment. If the physician was aware of the extent of the resident's contractures and secondary pain, it would certainly not be unreasonable for him to conclude that examination and treatment under anesthesia could be necessary, which could be more safely done in the hospital rather than a physician's office. Based on all the evidence, I conclude that the simple removal of a foreign object from the resident's vagina was complicated by her comorbidity which necessitated treatment at the hospital rather than the facility or a physician's office. However, the fact removal was required in the hospital, does not elevate the simple removal of a foreign object to the level of a significant change in the resident's condition. The simple removal of the foreign object, though complicated by the resident's comorbidity, did not require a significant change in her treatment. The resident had previously been treated for a urinary tract infection with antibiotics and the fact that she was given antibiotics again for a urinary tract infection related to the foreign object and its removal does not mark a significant change in treatment or show the recurrence of an infection.

Accordingly, I conclude that the evidence does not show a significant change in the resident's physical, mental, or psychosocial status or a need to alter treatment significantly within the meaning of 42 C.F.R. § 483.10(b)(11)(i) and there was no violation of that regulation on August 9, 2007.

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

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 235-45. 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 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 from the June 27, 2007 survey. There 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 (On Remand).

13. Reasonable remedies are a $3,050 per day CMP from June 4 through June 13, 2007; a $200 per day 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 (On Remand).

a. Discussion From Original Decision

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.[36] 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 F309 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

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[36] I did not make the finding as a substitute for the surveyor's scope and severity determination but rather to reflect the seriousness of the deficiency, a finding that is required when assessing the reasonableness of the enforcement remedies proposed. 42 C.F.R. §§ 488.404(b), 488.438(e) - (f).

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; a $200 per day CMP 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.

b. Additional Discussion Following Remand

The Board expressed concern in the remand decision that I had not sufficiently articulated the basis for my reduction of the CMP for the period June 4 through June 13, 2007 from $8,800 per day to $3,050 per day, which is the least amount authorized when there is immediate jeopardy. The reduction in the total amount of the CMP for the period June 4 through June 13, 2007, due to the change from $8,800 to $3,050 per day, was $57,500. I found the remaining enforcement remedies for the period of noncompliance reasonable, including a $200 per day CMP for June 14 through August 2, 2007, a DPNA effective July 20 through August 2, 2007, and ineligibility to conduct a NATCEP, reasonable. My reading of the Board's remand decision is that the remedies I found reasonable with no change require no further analysis. Thus, my additional analysis is limited to the CMP in the upper range for the period June 4 through 13, 2007.

The analysis in my original decision was intentionally brief and as comprehensive as I believed necessary. Although I did not discuss all the relevant evidence, I certainly was aware and considered Petitioner's prior history of noncompliance to the extent it was

supported by evidence in the record or prior decisions of the Board[37] and argued by CMS. CMS Prehearing Brief at 46-49; CMS Brief at 24-29; CMS Reply at 28-30. I clearly considered the severity of the noncompliance, the relationship of the instances of noncompliance and the facts as they related to Resident 3, all of which is reflected under the discussion of the various tags. I specifically mentioned in my original analysis that I considered that I found the evidence proved fewer instances of noncompliance that posed immediate jeopardy than CMS presumably considered when the decision was made to impose an $8,800 per day CMP. I also stated that I specifically considered whether a CMP of lesser amount fulfilled the Congressional purpose for authorizing the Secretary to impose CMPs. I considered the evidence of potential financial hardship posed by the additional penalty totaling $57,500 credible as it was unrebutted and I had no basis to discount the sworn testimony of Mr. Metten.

My authority to review the reasonableness of the CMP is limited by 42 C.F.R. § 488.438(e). The limitations are: (1) I may not set the CMP at zero or reduce it to zero; (2) I may not review the exercise of discretion by CMS in selecting to impose a CMP; and (3) I may only consider the factors specified by 42 C.F.R. § 488.438(f) when determining the reasonableness of the CMP amount. In determining whether the amount of a CMP is reasonable, the following factors specified at 42 C.F.R. § 488.438(f) must be considered: (1) the facility's history of non-compliance, including repeated deficiencies; (2) the facility's financial condition; (3) the seriousness of the deficiencies as set forth at 42 C.F.R. § 488.404(b), the same factors CMS and/or the state were to consider when setting the CMP amount; and (4) the facility's degree of culpability, including but not limited to the facilities neglect, indifference, or disregard for resident care, comfort, and safety and the absence of culpability is not a mitigating factor. The factors that CMS and the state were required to consider when setting the CMP amount and that I am required to consider when assessing the reasonableness of the amount are set forth in 42 C.F.R. § 488.404(b): (1) whether the deficiencies caused no actual harm but had the potential for minimal harm, no actual harm with the potential for more than minimal harm, but not immediate jeopardy, actual harm that is not immediate jeopardy, or immediate jeopardy to resident health and safety; and (2) whether the deficiencies are isolated, constitute a pattern, or are widespread. My review of the reasonableness of the CMP is *de novo* and

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[37] *Columbus Nursing and Rehab. Ctr.*, DAB No. 2273 (2009) (Board affirmed ALJ decision that Petitioner was noncompliant with requirements for the prevention and care of pressure sores and noncompliance posed immediate jeopardy); *Columbus Nursing and Rehab. Ctr.*, DAB No. 2247 (2009) (Board affirmed ALJ decision that Petitioner failed to thoroughly investigate and report abuse or neglect; failed to protect residents during investigation; and failed to implement its abuse and neglect policy and noncompliance posed immediate jeopardy).

based upon the evidence in the record before me. I am not bound to defer to the CMS determination of the reasonable amount of the CMP to impose but my authority is limited by regulation as already explained. I am to determine whether the amount of any CMP proposed is within reasonable bounds considering the purpose of the Act and regulations. *Emerald Oaks*, DAB No. 1800, at 10 (2001); *CarePlex of Silver Spring*, DAB No. 1683, at 14–16 (1999); *Capitol Hill Community Rehab. and Specialty Care Ctr.*, DAB No. 1629 (1997). The regulations do not specify how the ALJ is to weigh each of the regulatory factors but leave that determination to the discretion of the ALJ.

Before addressing the relative weighing of factors, I address issues raised by the Board related to the evidence of financial condition in this case. There is no issue that Petitioner bears the burden of persuasion by a preponderance of the evidence that its financial condition impacts its ability to pay according to prior decisions of the Board. The regulation requires that in determining the amount of the CMP, CMS and the state must consider the facility's financial condition. 42 C.F.R. § 488.438(f)(2). I am also required to consider financial condition when conducting my *de novo* review of the reasonableness of the CMP. The requirement to consider financial condition is a requirement imposed by section 1128A(d) of the Act. The Act and regulation do not specify a point in time that is relevant and must be used for assessing the facility's financial condition. The drafters of the regulation stated:

> Response: As stated above, it is a statutory requirement that a facility's financial condition be considered as a factor to determine the amount of the civil money penalty. **We do not specify in the regulation what we will examine in determining the facility's financial condition, because these factors are unique for each facility.** Therefore, it is the responsibility of the facility to furnish the information it believes appropriately represents its financial status. We consider a facility's financial condition in conjunction with the other factors specified in the rule when determining the amount of a civil money penalty, because it is not our intent to put facilities out of business, and the amount of the civil money penalty is determined on a case by case basis.

59 Fed. Reg. 56,116, 56,205 (Nov. 10, 1994). Thus, the drafters of the regulation intentionally did not specify that some evidence of financial condition may be more relevant or probative than other evidence or specify that only evidence of financial condition at the time of the CMS determination is relevant. A CMP may not be collected until final administrative review is complete and it is only then that the financial impact of the CMP will affect the facility. 42 C.F.R. § 488.442(a). Thus, it is more consistent with the requirement to consider financial condition to consider financial condition at each stage when the financial condition must be considered rather

than only at the point in time when CMS determined to propose a CMP. I find no legal basis to limit the review to which Petitioner is entitled under the section 1128A(d) of the Act to only that evidence of financial condition at the time CMS determined to impose a CMP. The Board requested that I address whether CMS gave adequate notice of its objection to the relevance of testimony about Petitioner's financial condition after the date on which CMS proposed the CMP. *Columbus Nursing and Rehab. Ctr.*, DAB No. 2398, at 18. The CMS objection was timely and could not be expected until such time as Mr. Metten actually began to testify as to what CMS perceived to be objectionable matters. The CMS objection was overruled at hearing and Mr. Metten was permitted to testify but CMS was advised that it could raise the issue in post-hearing briefing where the objection could be more fully addressed by both parties. If not already apparent, I conclude that the CMS objection is without merit and was correctly overruled at hearing for the reasons discussed above.

The Board comments that it has in prior cases permitted an ALJ to disregard testimony regarding financial condition where the facility failed to also submit documentation in support of the testimony. *Columbus Nursing and Rehab. Ctr*, DAB No. 2398, at 17. It is not clear to me whether or not the Board is suggesting that it is unwilling to consider testimonial evidence regarding financial condition absent documents to bolster the testimony.[38] However, I conclude that it would be an abuse of my discretion in this case to disregard the testimony offered regarding financial condition. The Act requires consideration of financial condition before a CMP may be imposed and collected. The regulation includes the same requirement. Neither the Act nor the regulations specify the form of the evidence that must be considered or rule out consideration of testimonial evidence as to financial condition. In this case, there is no dispute that CMS did not attempt to rebut the testimony. The CMS cross-examination was ineffective in creating any concern about the truth and veracity of Martin Metten or the credibility of the evidence he provided. Petitioner listed Mr. Metten on its June 17, 2008 list of witnesses and specifically stated that Mr. Metten would testify about Petitioner's financial ability to pay the proposed CMP. Despite the advance notice, CMS was not prepared at hearing to question Mr. Metten with or introduce as rebuttal evidence any evidence related to Petitioner's financial condition at the time of hearing based on information available to CMS (*see e.g.* SOM § 7516; Tr. at 889; CMS Ex. 5). Mr. Metten testified under oath subject to cross-examination by the government. Mr. Metten was in a position to know

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[38] No adverse inference should be drawn from Petitioner's failure to submit documents as there was no motion for production of such documents by CMS, and no grounds to sanction Petitioner by drawing such an inference. Act § 1128A(c)(4). Although CMS may take the position that it is prohibited from requesting such production by its own regulations, such a prohibition is clearly not consistent with section 1128A of the Act.

and understand the financial condition of Petitioner's owner and operator, Heyde Health System Columbus, LLC, as its vice-president and chief operating officer. Tr. at 877-78. Mr. Metten's credible testimony was that in 2007 and 2008, Petitioner had a combined net operating loss of approximately $830,000 (Tr. at 878), $670,000 in 2007 and $160,000 in 2008 (Tr. at 883-84); Petitioner's census of residents declined from an average of 65 in 2006 to the mid-50s in 2007, and to the mid-40's in 2008 (Tr. at 881-82); Petitioner's cash position was worse at the time of hearing than when CMS proposed the CMP (Tr. at 884); Petitioner does not own the real estate on and in which it operates (Tr. at 887); Petitioner did report a profit in 2005 and an insignificant loss in 2006 (Tr. at 889); average monthly gross revenues were $400,000 (Tr. at 890); Petitioner's total assets amounted to $700,000 to $800,000 (Tr. at 890); Petitioner had no access to credit at the time (Tr. at 891); Petitioner had no cash available at the time of hearing (Tr. at 897); Petitioner was having difficulty making its payroll and paying vendors (Tr. at 897-98); Medicare revenue was insufficient to cover operating costs (Tr. at 898); and Petitioner had a negative net worth at the time of hearing (Tr. at 900). The gist of Mr. Metten's testimony was that given the Petitioner's financial condition at the time of hearing, the payment of any CMP would have a significant negative financial impact upon Petitioner. CMS Ex. 5 confirms that Petitioner reported a net loss of approximately $185,000. CMS Ex. 5 also shows that in 2006 Petitioner reported total assets of $706,890 and total liabilities of $706,890, of which $393,025 was owner equity and current liabilities of $313,865, none of which is inconsistent with Mr. Metten's testimony. I conclude based on all the evidence that Mr. Metten's testimony was relevant, credible, and unrebutted by CMS. I conclude that the evidence shows that it is more likely than not that the imposition and collection of any CMP, specifically a CMP totaling $57,500 more than I found reasonable in my initial decision, would have a significant adverse impact upon Petitioner's ability to continue in business. Petitioner has met its burden to show by a preponderance of the evidence its financial condition and that its financial condition would be adversely impacted by a CMP.

I weighed and considered the factors the Board questioned as follows:

- Seriousness and Relationship of the Deficiencies

The noncompliance under Tag F314 and F325 was serious and posed immediate jeopardy. The noncompliance under Tag F309 was also serious as it caused actual harm to Resident 3. The three deficiencies all relate to the care and treatment of Resident 3 but I do not consider the fact that the impact was upon one resident as a mitigating factor. The authorized CMP must be in the upper range of authorized CMPs during the period June 4 through 13, 2007, due to the existence of immediate jeopardy.

I also note that Petitioner was culpable for its noncompliance related to Resident 3.

● Petitioner's Financial Condition

The evidence of Petitioner's financial condition supports my conclusion that imposing a total CMP of $57,500 more than I found reasonable in my initial decision, would have had a serious negative impact upon Petitioner's ability to pay staff and vendors, to the extent that Petitioner could no longer sustain business operations.

● History of Noncompliance and Other Factors

I have carefully considered the Board's prior decisions in cases involving Petitioner and the Boards prior affirmances of immediate jeopardy-level noncompliance and substandard quality of care. The decisions are available on the Board's website. *Columbus Nursing and Rehab. Ctr.*, DAB No. 2273 (2009) (Board affirmed ALJ decision that Petitioner was noncompliant with requirements for the prevention and care of pressure sores and the noncompliance posed immediate jeopardy); *Columbus Nursing and Rehab. Ctr.*, DAB No. 2247 (2009) (Board affirmed ALJ decision that Petitioner failed to thoroughly investigate and report abuse or neglect; failed to protect residents during investigation; and failed to implement its abuse and neglect policy and the noncompliance posed immediate jeopardy). I conclude in this decision that Petitioner was noncompliant with 42 C.F.R. § 483.25(c) related to prevention and treatment of pressure sores and that the noncompliance posed immediate jeopardy. The Board affirmed the same citation of noncompliance at the immediate jeopardy-level in DAB No. 2273, and I clearly recognize similarity between the two citations. I also recognize that in the prior cases as in this case, Petitioner was not terminated but was determined by CMS to have returned to substantial compliance with program participation requirements, thereby satisfying the statutory purpose for enforcement remedies at the time. I have also considered that the remedies imposed in the prior cases were insufficient to ensure that Petitioner maintained compliance with program participation requirements. However, at the time of the hearing in this case Petitioner had been found to have returned to substantial compliance once again.

● Relative Weight of the Factors and Impact Upon the Amount of the CMP Approved

The regulation sets a floor of $3,050 for a per day CMP for noncompliance that poses immediate jeopardy. 42 C.F.R. § 488.438(a)(1)(i). I am not bound by the CMS proposed CMP of $8,800 per day and may not inquire as to the CMS decision-making regarding the imposition of a CMP or its amount. Rather, I must do a *de novo* review. Petitioner's culpability and history of noncompliance including the repeated noncompliance related to pressure sores supports an increased amount above the $3,050 floor for immediate jeopardy noncompliance. The noncompliance was serious but the fact that the noncompliance posed immediate jeopardy compels a CMP in the upper range of authorized CMPs and I decline to further escalate the amount of the CMP by considering

seriousness twice in this case. The surveyors cited the immediate jeopardy noncompliance as being isolated, a characterization with which I agree. The additional factor for consideration in this case is evidence of Petitioner's unfavorable financial condition at the time of hearing.

There are no formulas provided by the regulation or the Act for weighing the factors. Rather, the weighing of the factors is a matter left to the discretion of the ALJ, who is bound to follow the Act and regulations and ensure the law is applied consistent with the intent of Congress. In this case Petitioner returned to substantial compliance and the purpose for imposing an enforcement remedy was achieved. Considering only Petitioner's history of noncompliance, the seriousness of the noncompliance in this case, and Petitioner's culpability, I would not hesitate to impose a daily CMP at the maximum amount of $10,000 per day. However, given the evidence of Petitioner's financial condition, I conclude that a CMP of no more than $3,050 per day is reasonable for the period of June 4 through 13, 2007.

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, a $200 per day CMP 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