Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	Date: July 29, 2008
Rensselaer Care Center, (CCN: 15-5287),	)	Docket No. C-06-537
	)	Decision No. CR1821
Petitioner,	)	
v.	)	
Centers for Medicare & Medicaid Services.	)	

DECISION

Petitioner, Rensselaer Care Center, violated 42 C.F.R. §§ 483.25, 483.25(c), 483.25(h)(2), and 483.75,[1] as alleged by the Centers for Medicare & Medicaid Services (CMS) based upon the survey of Petitioner's facility completed on May 10, 2006. A civil money penalty (CMP) of $300 per day for the period May 10 through May 22, 2006, a total CMP of $3900, is reasonable.

I. Background

Petitioner, a long-term care facility located in Rensselaer, Indiana, is authorized to participate in the federal Medicare program as a skilled nursing facility (SNF) and the Indiana Medicaid program as a nursing facility (NF). On May 10, 2006, surveyors from the Indiana State Department of Health (the state agency) completed a survey of Petitioner's facility, the fourth survey in a survey-cycle that began on November 23,

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

2005. Joint Stipulation and Joint Statement of Issues Presented for Hearing, dated September 6, 2006 (Jt. Stip.) ¶ A2. The parties stipulated prior to hearing that only the deficiencies alleged by the survey completed on May 10, 2006, and the proposed CMP based upon the May 10 deficiencies, are at issue before me.[2] Jt. Stip. ¶¶ A3-13, B1-2.

CMS notified Petitioner by letter dated May 19, 2006, that based upon Petitioner's continued noncompliance as determined by the May 10, 2006 survey, remedies including termination effective May 27, 2006, a denial of payment for new admissions (DPNA) effective December 7, 2005, and a CMP of $300 per day effective February 16, 2006 would continue. Jt. Stip. ¶ 2; Petitioner's Exhibit (P. Ex.) 2. A revisit survey of Petitioner's facility was completed on May 26, 2006, and Petitioner was determined to have returned to substantial compliance effective May 23, 2006. CMS Exhibit (CMS Ex.) 6, at 5-7. CMS notified Petitioner by letter dated June 14, 2006 that based upon the revisit survey termination would not occur and the other remedies would be discontinued effective May 23, 2006. P. Ex. 6. Thus, the only enforcement remedy remaining in issue is the $300 per day CMP for the 13-day period May 10 through 22, 2006, a total CMP of $3900, which is based upon the findings of the May 10, 2006 survey.

Petitioner timely requested a hearing before an administrative law judge (ALJ) by letter dated June 21, 2006. The request for hearing was docketed as C-06-537, and assigned to me on June 29, 2006 for hearing and decision. A Notice of Case Assignment and Prehearing Case Development Order (Prehearing Order) was issued at my direction on June 29, 2006.

A hearing was convened in Indianapolis, Indiana on November 28 and 29, 2006. A 547-page transcript (Tr.) of the hearing was prepared. CMS offered CMS Exs. 1 through 34. CMS Exs. 1 through 6 and 8 through 34 were admitted (Tr. 22), and CMS Ex. 7 was withdrawn by CMS upon objection by Petitioner and Petitioner's stipulation that Petitioner does not dispute that it has the ability to pay the proposed CMP. Tr. 19-20. Petitioner offered P. Exs. 1 through 77, all of which were admitted. CMS elicited testimony from two surveyors, Linda Campbell, Registered Nurse (R.N.) and DeAnn Mankell, R.N. Petitioner elicited testimony from Michael Louck, M.D., Mary Sabados, Licensed Practical Nurse (L.P.N.), Brenda Stidham, R.N., Petitioner's Director of Nursing (DON), and Michael Carson, R.N. The parties submitted post-hearing briefs and post-hearing reply briefs.

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[2] Petitioner indicates in its June 21, 2006 request for hearing, that it filed requests for hearing related to the prior surveys in the survey-cycle, but the parties reached a settlement agreement as to those surveys and the enforcement remedies based on those surveys.

II. Discussion

A. Findings of Fact

The following findings of fact are based upon the testimony at hearing, the exhibits admitted, and the parties' stipulations. Citations to exhibit numbers related to each finding of fact are in the analysis section of this decision if not indicated here.

1. Facts related to 42 C.F.R. § 483.25 (Tag F309[3]):

   a. On March 24, 2006, Resident B was diagnosed with influenza in a hospital emergency department, and he returned to Petitioner's facility that same day. CMS Ex. 12, at 13, 37, 40, 48.

   b. Resident B's physician ordered treatment on March 24, 2006, that included: oxygen therapy to be administered by nasal cannula continuously at the rate of two liters per minute; 2.5 milligrams of albuterol administered by a small volume nebulizer four times per day; one teaspoon of Phenergan VC, a cough syrup expectorant, administered four times per day after the nebulizer treatment; and two tablets of Tylenol every four to six hours as needed for temperature greater than 100 degrees. CMS Ex. 12, at 16, 38; P. Ex. 10, at 7; P. Ex. 11, at 7.

   c. The standard of care for administration of albuterol by nebulizer to a long-term care facility resident is to assess the resident's lungs before and after the nebulizer treatment.

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[3] This is a "Tag" designation as used in the State Operations Manual (SOM), Appendix PP – Guidance to Surveyors for Long Term Care Facilities. 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, if interpreted clearly, do have such force and effect. *State of Indiana by the Indiana Department of Public Welfare v. Sullivan*, 934 F.2d 853 (7th Cir. 1991); *Northwest Tissue Center v. Shalala*, 1 F.3d 522 (7th Cir. 1993). Thus, while the Secretary of Health and Human Services (Secretary) may not seek to enforce the provisions of the SOM, he may seek to enforce the provisions of the Act or regulations as interpreted by the SOM.

d. The documentary and testimonial evidence does not show that Petitioner's staff assessed Resident B's lungs before and after each administration of albuterol by nebulizer, and the evidence does not permit an inference that they did so.

e. Petitioner's staff failed to administer Phenergan VC as ordered by Resident B's physician on one occasion, on March 27, 2006.

f. Resident B suffered actual harm due to the missed dose of Phenergan VC on March 27, 2006.

g. On March 27, 2006, between 1:30 p.m. and 3:00 p.m., Resident B's temperature escalated from 99 degrees to 102.6 degrees. CMS Ex. 12, at 15; P. Ex. 12, at 5; P. Ex. 14, at 4.

h. Petitioner's policy entitled *Identifying Change in Resident Condition* required, consistent with the standard of care or practice, immediate physician notification whenever a resident's temperature exceeded 102 degrees rectally or 101 degrees orally. CMS Ex. 23, at 2.

i. Petitioner's staff did not immediately contact or consult with Resident B's physician to advise him that the resident's temperature was greater than 101 and 102 degrees on March 27, 2006.

j. On March 27, 2006, at 3:00 p.m., a facility nurse increased the flow rate of Resident B's oxygen from two liters to five liters per minute without notifying the physician of the change, or obtaining his approval immediately after the change. CMS Ex. 12, at 15; P. Ex. 12, at 5.

k. Petitioner's staff failed to administer Tylenol, as ordered by the resident's physician, at any time after 8:00 p.m. on March 27, 2006, even though the resident's temperature was in excess of 100 degrees at 10:00 p.m. that night and at 11:30 a.m. the following morning. CMS Ex. 12, at 15, 17, 44; P. Ex. 10, at 7; P. Ex. 14.

l. Resident B suffered actual harm as a result of increased suffering due to influenza symptoms, development of pneumonia, delayed treatment of pneumonia, and eventual death.

2. Facts related to 42 C.F.R. § 483.25(c) (Tag F314):

a. Resident 57's admission Minimum Data Set (MDS), with an assessment reference date of March 7, 2006 (the last day of a seven day assessment or observation period that began on March 1, 2006), includes a current diagnosis of decubitus ulcers (CMS Ex. 13, at 7; P. Ex. 30, at 4), and Petitioner reported that: Resident 57 had one Stage I pressure ulcer defined as a persistent area of skin redness with no break in the skin, where the redness does not disappear when pressure is removed; she had a history of resolved ulcers; she had pressure relieving devices for bed and chair; she was on a turning and repositioning program; she received ulcer care; she received preventive or protective skin care; and she had preventive or protective foot care. P. Ex. 30, at 5.

b. A physician's order, dated March 15, 2006, reflects a diagnosis of decubitus ulcer coccyx area, and the physician ordered that DuoDerm be applied to the wound and changed every day, and, as needed, to the open area on the coccyx; that the resident be limited to being up in her wheelchair no more than four times per day for one hour; that she be turned from side-to-side when in bed; and that she not lie on her back. CMS Ex. 13, at 25, 31; P. Ex. 4, at 4-5.

c. Resident 57's physician characterized the right gluteal wound near the coccyx as a Stage III decubitus in his progress note dated March 25, 2006.

d. Resident 57's physician characterized the right gluteal wound near the coccyx as not open in an order dated April 21, 2006.

e. A physician's order, dated April 26, 2006, shows that the right upper gluteal wound near the coccyx broke open again and the doctor ordered use of DuoDerm and protective cream to both buttocks. CMS Ex. 13, at 34.

f. A physician's progress note, dated May 16, 2006, states that the Stage III decubitus on Resident 57's right buttock had healed to a Stage II without infection. P. Ex. 47.

g. On May 3, 2006, Surveyor Campbell observed Resident 57 sitting in her wheelchair for more than five hours (CMS Ex. 5, at 13; CMS Ex. 13, at 61; Tr. 132), which was in excess of the one-hour limitation required by Resident 57's physician order and her skin care plan and care plan. CMS Ex. 13, at 31, 36, 42-43.

h. On May 3, 2006, Surveyor Campbell observed Resident 57 in her bed positioned lying on her back in bed with the head of her bed elevated (CMS Ex. 5, at 12; CMS Ex. 19, at 4; Tr. 131), contrary to her physician's orders. CMS Ex. 27, at 9; CMS Ex. 28, at 18; Tr. 131.

i. Petitioner did not follow Resident 57's physician's orders or comply with its own care planned interventions to heal the resident's pressure sore.

j. The evidence prior to May 3, 2006 does not show Resident 57 was noncompliant with interventions to heal her pressure sore.

k. Resident 57's pressure sore was not, as a matter of fact, unavoidable based upon the evidence of record.

3. Facts related to 42 C.F.R. § 483.25(h)(2) (Tag F324):

a. There is no dispute that Resident A was at high risk for falls and had fallen at Petitioner's facility on July 10, 2005, August 19, 2005, August 25, 2005, and December 15, 2005. P. Brief at 17, 26; P. Ex. 77.

b. Resident A's prior falls all involved her attempts to walk unassisted and without supervision of staff, and it was foreseeable that if Resident A attempted to walk without supervision and assistance, she would fall and injure herself, whether she arose from her bed or a chair.

c. The falls on July 10 and August 25, 2005 were from Resident A's bed and, in both instances, a bed alarm [a pressure sensitive pad placed under the resident in the bed] was in place and sounded. P. Ex. 77, at 1.

d. The bed alarm was an intervention listed on Resident A's care plan dated January 19, 2006. CMS Ex. 15, at 48-49; P. Ex. 59, at 10-11.

e. A handwritten entry on Resident A's care plan, dated April 18, 2006, states that the bed alarm was discontinued by a physician's telephone order on February 1, 2006. CMS Ex. 15, at 48-49; P. Ex. 59, at 10-11.

f. There is no evidence other than the April 18, 2006 handwritten entry on the care plan that shows that a physician ordered that the bed alarm be discontinued on February 1, 2006.

g. There is evidence that Resident A set off her motion sensor alarm [a wall-mounted alarm with a beam focused down the right bed rail] with her baby doll and that increased her fidgeting (P. Ex. 61, at 9), but there is no evidence that she set off her bed alarm between January 19 and February 1, 2006.

h. Petitioner does not dispute that Resident A did not have a bed alarm as a fall prevention intervention in March 2006 or April 1 through 9, 2006.

i. By March 2, 2006, Resident A was mostly, if not completely, recovered from her upper respiratory infection and she displayed behaviors similar to those at the time her January 19, 2006 care plan was adopted. CMS Ex. 15, at 48.

j. On April 9, 2006, Resident A got out of bed, the motion sensor did not sound, she fell attempting to ambulate, and she suffered a fracture of her right hip.

k. A pressure sensitive bed alarm such as that listed as an intervention on Resident A's care plan dated January 19, 2006 was not in use on April 9, 2006.

l. There is no dispute that padded side rails were up on Resident A's bed and the motion sensor was in use on April 9, 2006.

m. There is no dispute that interventions such as a low bed or fall mats were not in use as interventions on April 9, 2006.

n. Petitioner did not reassess the need for fall prevention interventions for Resident A after she partially or totally recovered from her upper respiratory infection in late February or early March 2006 and resumed behaviors similar to those at the time her January 19, 2006 care plan was adopted.

o. Petitioner did not assess in February, March, or before April 9, 2006, whether other interventions such as a low bed or fall mats might be more effective interventions to minimize the risk of injury due to falls.

p. Petitioner did not assess in February, March, or before April 9, 2006, whether the intervention of a bed alarm should be implemented.

q. Resident A suffered actual harm.

4. The parties stipulated that the violation of 42 C.F.R. § 483.75 (Tag F490) is based upon the other deficiencies cited. Jt. Stip. ¶ A(8).

5. Three of Petitioner's residents suffered actual harm because Petitioner's staff failed to delivery quality care in the form of necessary care and services.

6. Petitioner's staff failed to comply with facility policy and procedures governing oxygen use, physician notification, and wound care and prevention showing that Petitioner failed to effectively implement those policies. CMS Exs. 23, 24, and 25.

7. Petitioner failed to ensure proper assessment and care planning was done as required by its policy (CMS Ex. 26) and the regulations, to ensure effective fall prevention measures were implemented in the case of Resident A.

8. Petitioner's records related to the three quality of care deficiencies addressed in this decision are inconsistent, incomplete, and unclear, depriving Petitioner of the ability to show the quality of care delivered; and demonstrating a lack of effective administration and supervision of staff in the delivery of care and services.

9. The regulatory violations in this case are serious.

10. The regulatory violations in this case resulted in actual harm to Petitioner's residents.

11. Petitioner was culpable for the violations and harm.

12. Petitioner has the ability to pay the approved CMP.

B. Conclusions of Law

1. Petitioner's request for hearing was timely and I have jurisdiction.

2. Petitioner violated 42 C.F.R. § 483.25.

3. Petitioner violated 42 C.F.R. § 483.25(c).

4. Petitioner violated 42 C.F.R. § 483.25(h)(2).

5. Petitioner violated 42 C.F.R. § 483.75.

6. Petitioner was not in substantial compliance with program participation requirements as Petitioner's residents suffered actual harm due to the violations of 42 C.F.R. §§ 483.25; 483.25(c); 483.25(h)(2); and 483.75.

7. The evidence is not in equipoise and the burden of persuasion does not affect the decision in this case.

8. There is no regulatory or other requirement for the ALJ to review the CMS consideration of the regulatory factors that must be considered when imposing a CMP; rather, the ALJ must provide Petitioner a de novo review of the factors.

9. A CMP of $300 per day for the period May 10 through May 22, 2006, a total CMP of $3900, is reasonable.

C. Issues

The issues in this case are:

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

D. Applicable Law

Petitioner is a long-term care facility participating in the federal Medicare program as a SNF and in the state Medicaid program as a NF. The statutory and regulatory requirements for participation by a long-term care facility are found at sections 1819 and 1919 of the Social Security Act (Act) and at 42 C.F.R. Part 483. Sections 1819 and 1919 of the Act vest the Secretary with authority to impose CMPs against a long-term care facility for failure to comply substantially with federal participation requirements.

Pursuant to the Act, 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 the Secretary through his regulations at 42 C.F.R. Part 483. Facilities that participate in Medicare may be surveyed on behalf of CMS by state survey agencies in order to determine whether the facilities are complying with federal participation requirements. 42 C.F.R. §§ 488.10-488.28, 488.300-488.335. Pursuant to 42 C.F.R. Part

488, CMS may impose a per instance or per day CMP against a long-term care facility when a state survey agency concludes that the facility is not complying substantially with federal participation requirements. 42 C.F.R. §§ 488.406; 488.408; 488.430. The regulations in 42 C.F.R. Part 488 also give CMS a number of other remedies that can be imposed if a facility is not in compliance with Medicare requirements. 42 C.F.R. §§ 488.406; 488.408; 488.430.

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 CMP, of from $3050 per day to $10,000 per day, is reserved for deficiencies that constitute 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). The lower range of CMP, from $50 per day to $3000 per day, is reserved for deficiencies that do not constitute immediate jeopardy, but either cause actual harm to residents, or cause no actual harm but have the potential for causing more than minimal harm. 42 C.F.R. § 488.438(a)(1)(ii). Pursuant to 42 C.F.R. § 488.301, "*(i)mmediate 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." (emphasis in original).

The Act and regulations make a hearing before an ALJ available to a long-term care facility against which CMS has determined to impose a CMP. Act § 1128A(c)(2); 42 C.F.R. §§ 488.408(g); 498.3(b)(13). The hearing before an ALJ is a *de novo* proceeding. *Anesthesiologists Affiliated, et al*, DAB CR65 (1990), *aff'd*, 941 F.2d 678 (8th Cir. 1991); *Emerald Oaks*, DAB No. 1800, at 11 (2001); *Beechwood Sanitarium*, DAB No. 1906 (2004); *Cal Turner Extended Care*, DAB No. 2030 (2006)*; The Residence at Salem Woods*, DAB No. 2052 (2006). A facility has a right to appeal a "certification of noncompliance leading to an enforcement remedy." 42 C.F.R. § 488.408(g)(1); *see also* 42 C.F.R. §§ 488.330(e) and 498.3. However, the choice of remedies by CMS 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 found by CMS if a successful challenge would affect the range of the CMP that could be collected by CMS or impact upon the facility's nurse aide training and competency evaluation program (NATCEP). 42 C.F.R. §§ 498.3(b)(14) and (d)(10)(i). CMS's determination as to the level of noncompliance "must be upheld unless it is clearly erroneous." 42 C.F.R. § 498.60(c)(2). This includes CMS's finding of immediate jeopardy. *Woodstock Care Center*, DAB No. 1726, at 9, 38 (2000), *aff'd, Woodstock Care Center v. Thompson*, 363 F.3d 583 (6th Cir. 2003). The Departmental Appeals Board (the Board) has long held that the net effect of the regulations is that a provider has

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

When a penalty is proposed and appealed, CMS must make a *prima facie* case that the facility has failed to comply substantially with federal participation requirements. "*Prima facie*" means that the evidence is "(s)ufficient to establish a fact or raise a presumption unless disproved or rebutted. *Black's Law Dictionary* 1228 (8th ed. 2004); *see also Hillman Rehabilitation Center*, DAB No. 1611, at 8 (1997), *aff'd*, *Hillman Rehabilitation Center v. U.S. Dept. of Health and Human Services*, No. 98-3789 (GEB) slip op. at 25 (D.N.J. May 13, 1999). To prevail, a long-term care facility must overcome CMS's showing by a preponderance of the evidence. *Batavia Nursing and Convalescent Center*, DAB No. 1904 (2004); *Batavia Nursing and Convalescent Inn*, DAB No. 1911 (2004) *aff'd*, *Batavia Nursing & Convalescent Ctr. v. Thompson*, 143 Fed.Appx. 664 (6th Cir. 2005); *Emerald Oaks*, DAB No. 1800; *Cross Creek Health Care Center*, DAB No. 1665 (1998); *Hillman Rehabilitation Center*, DAB No. 1611.

E. Analysis

The survey completed on May 10, 2006, is the basis for the state agency's and CMS determinations that Petitioner continued not to be in substantial compliance with program participation requirements from May 10 through 22, 2005. Based upon the findings and conclusions of the survey set forth in the Statement of Deficiencies (SOD) dated May 10, 2006, CMS alleges that Petitioner was in violation of four regulatory requirements: 42 C.F.R. §§ 483.25 (Tag F309), 483.25(c) (Tag F314), 483.25(h)(2) (Tag F324), and 483.75 (Tag F490). CMS alleges that the four regulatory violations provide a basis for imposition of an enforcement remedy and that the remedy it proposes is reasonable. Petitioner disagrees.

1. Petitioner violated 42 C.F.R. § 483.25 (Tag F309).

The quality of care regulation at issue here requires that each resident receive, and the participating facility must provide, the necessary care and services to attain or maintain a resident's highest practicable physical, mental, and psychosocial well-being, in accordance with the resident's comprehensive assessment and plan of care. 42 C.F.R. § 483.25.

The SOD alleges that Petitioner failed to ensure that Resident B received necessary care and services related to timely intervention for respiratory distress that resulted in his hospitalization. CMS Ex. 5, at 3. Resident B was an 88-year-old man who suffered from congestive heart failure and other ailments; he developed influenza on or about March 24,

2006, and died from pneumonia on March 30, 2006. Jt. Stip. ¶ A5. CMS argues that Petitioner failed to adequately and regularly assess Resident B who had an influenza diagnosis, and to promptly contact Resident B's physician when he started to exhibit signs of increased respiratory distress which prompted staff to increase his oxygen above the physician-prescribed level. CMS Post-Hearing Brief (CMS Brief) at 2; CMS Ex. 5, at 2-10.

As discussed below, I conclude that Petitioner did violate 42 C.F.R. § 483.25 (Tag F309) by failing to ensure that Resident B received necessary care and services, including failing to assess his lung function before and after nebulizer treatments despite the known risks for pneumonia secondary to influenza or aspiration; failing to administer Phenergan VC and Tylenol as ordered by Resident B's physician to reduce the symptoms associated with influenza (congestion and fever); and failing to consult with Resident B's physician when his temperature increased and his oxygen flow rate was increased. The result of Petitioner's failure to deliver the necessary care and services listed was actual harm in the form of increased suffering due to influenza symptoms and delayed treatment of pneumonia that eventually resulted in death.

a. Petitioner's staff failed to assess Resident B's lungs.

Following examination and testing at a hospital on March 24, 2006 for influenza, Resident B returned to Petitioner's facility that evening with several prescribed treatments,[4] one of which included 2.5 milligrams of albuterol[5] to be administered by a small volume nebulizer[6] four times per day. CMS Ex. 12, at 16, 38; P. Ex. 10, at 7; P. Ex.11, at 7. The surveyors allege in the SOD, and CMS alleges before me, that no documentation was found showing that Resident B's lungs were assessed before and after nebulizer treatments which were administered four times per day. CMS Ex. 5, at 4-5. CMS asserts that standard nursing care requires staff to assess the condition of a resident's lungs right before and right after administration of albuterol treatment. CMS Brief at 6-7.

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[4] Resident B's post-hospitalization treatment included Tamiflu, an antiviral medication used to shorten the course of influenza; oxygen; Tylenol or ibuprofin every 4-6 hours as necessary for fever; cough syrup four times daily; and monitoring of his condition. P. Ex. 10, at 7; P. Ex. 11, at 7.

[5] Albuterol is a generic name for a bronchodilator. CMS Ex. 34, at 4. A bronchodilator serves to open an individual's air passage in order to make breathing easier and thus allow for increased facilitation for coughing up sputum. Tr. 147.

[6] A small volume nebulizer is a machine that is used to turn medication into an aerosol that can be inhaled into the lungs. Tr. 147.

Several witnesses testified at hearing regarding the standard of care. According to CMS's witness, Linda Campbell, R.N., a surveyor with the state agency who investigated this alleged deficiency during the survey, the standard of care for elderly residents receiving albuterol treatment is to assess their lungs and breathing status prior to and after administration of albuterol treatment in order to determine the effectiveness of the treatment:

> I would look at the respiratory rate, I would look at the depth of respiration, are they having problems breathing. I'd look at their skin color, are they having any compromise with oxygenation. I'd listen to their lungs to see if there's any congestion or any fluid in the lungs.

Tr. 148.

Surveyor Campbell further testified that Mosby's Drug Reference is one of several guides accepted in the nursing industry as authoritative on the proper administration of various medications. Tr. 149-50, 263-65; CMS Ex. 34. Under a section referenced as *Nursing Considerations*, Mosby's Nursing Drug Reference states that when using a bronchodilator nurses should assess an individual's respiratory function to include "vital capacity, forced expiratory volume, ABGs [arterial blood gases], lung sounds, heart rate and rhythm." CMS Ex. 34, at 4.

Petitioner's expert witness, Michael Carson,[7] testified that it is standard nursing practice in providing nebulizer treatments to assess the patient before and after administration of albuterol or any medication. Mr. Carson stated that you look at a resident's respiratory status, including pulse, to ensure that the treatment is effective. He further stated that staff should also look at an individual's rate, their rhythm and whether there is audible congestion. Mr. Carson explained that pre- and post- assessment is taught to nurses in school as standard procedure. He opined that there is no requirement to document pre- and post- assessments or to document the assessments in any particular record, but that is good clinical practice. Tr. 480-82.

[7] Mr. Carson was Senior Vice President of the Clinic Services for Life Care of America in Cleveland, Tennessee, and was qualified at hearing to render expert opinions as a registered nurse and a licensed nursing home administrator. Tr. 432-38.

Resident B's physician, Dr. Michael Louck[8], testified that given Resident B's influenza diagnosis, staff would be expected to perform regular lung assessments throughout the day.[9] He further testified that a lung assessment would include listening to lung sounds by auscultation, recording respiratory rate, checking skin color, and recording whether the resident was coughing. Tr. 220-21. Dr. Louck testified that, while it may not be possible to prevent influenza from developing into pneumonia in a nursing home resident as may have been the case with Resident B, regular lung assessments should be conducted by staff. Tr. 198, 220-21.

The March 2006 medication administration record (MAR) for Resident B shows that neubulizer treatments (listed as SVN) were done March 24 through 28, 2006. The MAR does not show whether or not any pre- or post- assessment was done. P. Ex. 11, at 7. Petitioner does not deny the CMS allegation that pre- and post- assessments were not documented. Petitioner's Brief (P. Brief) at 7-8; Petitioner's Reply (P. Reply) at 7-8. Petitioner argues, rather, that documentation of the pre- and post- assessments is not necessary and, if done, need not be maintained in any permanent record. Petitioner cites the testimony of Mr. Carson referred to above to support this contention. Petitioner correctly points out that the Secretary does not prescribe the form for most clinical records and that I should look at all the evidence to determine whether or not pre- and post- assessments were done. Petitioner cites specifically P. Ex. 11, at 7; P. Ex. 12, at 3-5; P. Ex. 14; P. Exs. 21-22. P. Brief at 7. The document at P. Ex. 11, at 7 is the MAR already mentioned which shows that albuterol was administered by nebulizer from March 24 through 28, 2006. Pre- and post- assessments are not documented on the form. The documents at P. Ex. 12, at 3-5, are Nurse's Notes that include entries for March 24 through March 28, 2006. The Nurse's Notes for March 24 contain notes reflecting assessment of various vital signs three times on March 24; one mention of lung sounds at 1:00 p.m.; and one nebulizer treatment at 9:00 p.m., with little relief and with vital signs noted, but no mention of lung sounds. The notes for March 25, 2006 show a nebulizer treatment at 1:30 a.m., vital signs are noted, lung sounds were assessed and noted to be diminished throughout the lung fields; at 5:30 a.m. a nebulizer treatment was given, temperature is noted to be elevated and Tylenol was given, and lung sounds were noted to be diminished; the 2:40 p.m. note lists a nebulizer treatment and diminished lung sounds; 9:00 p.m. and 10:00 p.m. notes indicate elevated temperature and oxygen level, but no mention of lung assessment. A note at 12:30 a.m. on March 26, 2006 includes vital signs, notes that his lungs remained congested, and a nebulizer treatment was given; a 5:30 a.m. note indicates a nebulizer treatment was given, but no vital signs or lung sounds are

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[8] Dr. Louck was not the facility medical director, rather, he was Resident B's personal physician for several years prior to and after Resident B's 2001 admission to Petitioner's facility. Tr. 191-92.

[9] Dr. Louck's testimony was received by telephone. Tr. 186.

recorded; a 10:30 a.m. note includes his temperature, that a nebulizer treatment was given, he had an unproductive cough, but it does not mention lung sounds; a 9:00 p.m. note lists his temperature and that a nebulizer treatment was given, but no other vital signs or lung sounds are indicated. A note from 2:00 a.m. on March 27, 2006 lists vital signs, and that a nebulizer treatment was given, but does not mention lung sounds; the next note, at 1:30 p.m., lists his temperature, that there was rattling in both lungs with frequent coughing, and a nebulizer treatment was given; the next note at 9:00 p.m. includes his temperature and oxygen saturation, that a nebulizer treatment was given and he was noted to be congested. There are only two notes for March 28, 2006, one indicating that Resident B was seen by the doctor who directed his admission to the hospital, and another that he was transmitted to the hospital, and neither note reflects vital signs, lung sounds, or that a nebulizer treatment was given. P. Ex. 12, at 3-5. The documents at P. Ex. 14 are "24 Hour Report Sheets" (24 Hour Reports) dated March 24 through 28, 2006. The 24 Hour Reports do not show pre- and post- assessments for each nebulizer treatment, and although they do include some vital signs, they do not address lung assessments pertaining to Resident B. The 24 Hour Reports are much less detailed than the Nurse's Notes entries I reviewed.

The last exhibits Petitioner points to as evidence that nebulizer treatments were being administered consistent with the standard of practice are the handwritten statements of two members of Petitioner's nursing staff. P. Exs. 21-22. Both indicate that they assess lung sounds before and after giving nebulizer treatments. Neither nurse was called by Petitioner to testify under oath at hearing, and they were not subject to cross-examination. Even if I accept their assertions as true, these two nurses did not administer four nebulizer treatments per day from March 24 through 28, 2006, and they cannot attest to the practices of the other nurses who administered nebulizer treatments.

Petitioner makes the point that the Secretary does not prescribe the form or content of clinical records, with a limited exception. P. Brief at 7. Thus, there is generally no regulatory basis for citing a failure to document. Petitioner seems to recognize however that its failure to point to some evidence that a treatment was in fact delivered and that it was delivered consistent with standards of practice may result in a deficiency finding. Thus, not only is it good clinical practice to document as testified to by Mr. Carson, but it is good legal practice, for when called to defend its delivery of care and services, the availability of contemporaneous documentary proof eliminates the difficulty a facility has proving care and services were delivered as assessed, planned, and ordered.

Petitioner did not present any staff to testify under oath, and subject to cross-examination, that pre- and post- assessments were done. Petitioner's argument, that staff used the facility's 24 Hour Reports to record information pertaining to treatments given to Resident B to pass on from shift to shift, may be accurate based upon the 24 Hour Reports discussed above. But, the argument is misleading because the information contained on

the documents offered is limited and does not include evidence of lung assessment or show that assessments were done before and after nebulizer treatments. Petitioner's expert, Mr. Carson, explained that the 24 Hour Reports are "a professional nurse's communication with the ongoing shift and the next shift after that and ongoing forward . . . to let the professional nursing staff coming on duty know what has occurred with this particular resident." Tr. 481-82. Thus, the 24 Hour Reports have a limited purpose. Indeed, my review of Petitioner's clinical records discussed above reveals that information on the 24 Hour Reports is much more limited than Petitioner's Nurse's Notes entries. The Nurse's Notes contain more of the information that would be necessary for Petitioner's staff and Resident B's physician to assess the effectiveness of nebulizer treatments based upon lung sounds and whether Resident B's condition was improving or deteriorating. However, even Petitioner's Nurse's Notes reviewed above do not include pre- and post- assessment of lung sounds, making it difficult to assess whether albuterol administered via nebulizer had any beneficial effect as a treatment modality, making it impossible to assess the effectiveness of the intervention. It is noteworthy that entries in the Nurse's Notes that do indicate lung sounds show that some of Petitioner's nursing staff considered the Nurse's Notes an appropriate place for such information. The 24 Hour Reports provided do not reflect information on lung sounds, or that such information was actually passed from the nurses on one shift to the next. Furthermore, the few Nurse's Notes entries that mention lung sounds describe them as diminished, congested, or rattling, certainly not normal, and a potential cause for concern in an elderly resident with a confirmed case of influenza and at risk for development of pneumonia.

It is not necessary for me to reach any conclusion regarding the best place to record lung sounds or similar assessments of a resident's condition. The issue that requires a conclusion is whether or not Resident B's lungs were assessed consistent with the standard of practice given his diagnosis and ordered treatment. The documents obtained by the surveyors and presented by CMS do not show that assessment of lung sounds was regularly done, or that it was done before and after nebulizer treatments. Petitioner has not presented evidence that necessary assessments were done. Petitioner would like for me to infer, based upon the evidence presented, that its nursing staff knew the standard of care and, therefore, must have complied. However, the evidence is insufficient to give rise to any such inference that Petitioner's staff actually knew the standard and complied, except possibly for the two who gave written statements, but were not subject to cross-examination.

Based on the record before me, I conclude that the standard of practice requires the assessment of lung sounds both before and after administration of albuterol by nebulizer. Petitioner's records do not show that assessments were actually done, and Petitioner has failed to submit other credible evidence to show the assessments were done. Thus, Petitioner failed to deliver the necessary care and services as required by the Act and regulations.

As for the potential of harm to Resident B, surveyor Campbell testified that a failure to adequately assess a resident who had been prescribed albuterol by a physician may result in "an increased difficulty in breathing . . . [and] difficulty with increased congestion." Tr. 148. Facility staff failed to do necessary respiratory assessments of Resident B before and after administering albuterol treatment, and the clinical record shows that Resident B's medical condition worsened as reflected by Petitioner's own records. The evidence shows Resident B suffered actual harm.

I further note that Resident B's care plan, dated February 27, 2006, lists as a problem that he was at risk for aspiration. One intervention listed was to observe Resident B for signs of choking and aspiration, to listen for lung sounds, take vital signs and temperature as needed, and to call the physician as needed. CMS Ex. 12, at 28. Nurse's Notes entries from March 23 through March 27, 2006 show that Resident B was having difficulty swallowing and was coughing during meals. P. Ex. 12, at 3-5. Dr. Louck stated in his admission report, dated March 28, 2006, that staff had called him because they were concerned that Resident B might have aspirated because his breathing got worse, and they were having trouble keeping his oxygen saturation up.[10] Thus, staff had an additional reason for doing lung assessments during the period in issue.

b. Petitioner's staff failed to administer Phenergan VC.

The surveyors allege that Petitioner also violated 42 C.F.R. § 483.25 (Tag F309) because Petitioner failed to administer Phenergan VC[11] to Resident B at 8:00 p.m. on March 27, 2006, following his nebulizer treatment, as required by the resident's physician's order. Tr. 142-45; CMS Ex. 5, at 6. According to Resident B's March 2006 MAR, and his physician's order dated March 24, one teaspoon of Phenergan VC was to be administered four times per day after Resident B's nebulizer treatment. CMS Ex. 12, at 16, 38; P. Ex. 10, at 7; P. Ex. 11, at 7. A Nurse's Notes entry dated March 27, 2006, at 9:00 p.m. shows that a nebulizer treatment was given. CMS Ex. 12, at 15; P. Ex. 12, at 5. Resident B's MAR does not have staff initials in the block for March 27, 2006, at 8:00 p.m. to show that Phenergan VC was administered after the nebulizer treatment. CMS Ex. 12, at 16; P. Ex. 11, at 7.

Petitioner had admitted, without objection by CMS, handwritten statements from two nurses. P. Ex. 21 (Statement of Nurse Rebecca Pescetto) and P. Ex. 22 (Statement of Anita Ricci, LPN.). Nurse Pescetto states that she administered the 8:00 p.m. dose of Phenergan VC to Resident B on March 27, 2006, but "forgot to sign the MARS on that

[10] I find no contemporaneous clinical records that show Petitioner's staff was having any difficulty maintaining an oxygen saturation above 90 percent for Resident B.

[11] Phenergan VC is an expectorant rather than a cough medicine. Tr. 200.

day." P. Ex. 21. LPN Ricci stated that she "knew proper procedure for administering SVN treatment" to Resident B, and stated "I assess lung sounds administer medication clean equipment reassess lung sounds and document." P. Ex. 22. Both nurses indicate in their statements that they were not interviewed by surveyors.

I do not consider the written statements of Nurse Pescetto and LPN Ricci to be reliable or credible evidence that Phenergan VC was administered. LPN Ricci's statement does not specifically address whether Phenergan VC was administered on March 27, 2006, following the 8:00 p.m. nebulizer treatment. Nurse Pescetto's statement is dated May 17, 2006. Her assertion that she gave the nebulizer treatment is consistent with her Nurse's Notes entry at 9:00 p.m. on March 27, 2006. Her statement that she forgot to sign the MAR to reflect the nebulizer treatment is consistent with the absence of an entry on the MAR. CMS Ex. 12, at 16; P. Ex. 11, at 7. Her statement that she forgot to sign the MAR to show administration of the Phenergan VC is also consistent with the absence of an entry on the MAR at 8:00 p.m. on March 27, 2006. CMS Ex. 12, at 16; P. Ex. 11, at 7. However, her statement that she administered Phenergan VC is inconsistent with the fact that administration of the Phenergan VC is not stated in her Nurse's Notes entry at 9:00 p.m. on March 27, 2006, but the administration of another medication, Tylenol, is mentioned. CMS Ex. 12, at 15; P. Ex. 12, at 5. Her Nurse's Notes entry is detailed and includes information on temperature, the fact she increased oxygen flow to 5 liters, that oxygen saturation was ranging from 91 to 94 percent, Tylenol was given twice, Resident B was not eating well and had only a few bites, and that a nebulizer treatment was given. Despite the detailed note, no mention is made of administration of Phenergan VC. Nurse Pescetto was not called to testify by Petitioner, so there was no opportunity to clarify this obvious inconsistency. There was also no opportunity to inquire as to how Nurse Pescetto could be certain when she made her statement on May 17, 2006, that she actually administered Phenergan VC after the nebulizer treatment around 8:00 p.m. on March 27, 2006, some 51 days earlier. I conclude that Nurse Pescetto's handwritten statement is not sufficiently reliable to rebut the inference raised by the absence of an entry on the MAR or other record related to Resident B, that Phenergan VC was not administered as ordered.

Petitioner argues that CMS has shown no harm to Resident B due to this omission. P. Reply at 4, 8-9. I disagree. The fact that Dr. Louck prescribed Phenergan VC raises the inference that he did so based upon a need of the resident, and that the intent was that the Phenergan VC would have some beneficial impact. The inference is consistent with Surveyor Campbell's testimony that she had experience and training with Phenergan VC, and that a failure to administer the medication in accordance with a physician's order could result in "increased coughing" and "increased congestion." Tr. 143. The record shows that Resident B was experiencing difficulty breathing, and his overall medical condition was deteriorating. Dr. Louck testified that the administration of Phenergan VC to a resident assists "to keep things loose," and functions as an expectorant. Tr. 200. Petitioner has not produced evidence to rebut the inference by showing that the

administration of Phenergan VC would have no beneficial effect, or that a missed dose would have no adverse effect on Resident B. I conclude that Petitioner's staff's failure to provide this necessary treatment to Resident B, as prescribed by his physician, is evidence of harm to the resident. To the extent that the described function of the Phenergan VC was to reduce congestion, which is consistent with making breathing easier, I conclude that the failure to administer Phenergan VC resulted in actual harm to the resident.

c. Petitioner's staff failed to consult Resident B's physician.[12]

The surveyors cite as another example of Petitioner's failure to provide necessary care and services that Petitioner's staff failed to contact and consult Resident B's physician on March 27, 2006, when Resident B's fever exceeded 102 degrees. The surveyors further allege that Petitioner failed to contact Resident B's physician when Petitioner's staff increased the rate of flow of oxygen that was being administered to 5 liters per minute on March 27, 2006. CMS Ex. 5, at 5, 8. The surveyors obtained copies of Petitioner's policies related to physician notification and administration of oxygen. CMS Exs. 23, 24. Petitioner does not deny that its notification policy requires that the attending physician be notified immediately if oral temperature exceeds 101 degrees, or rectal temperature exceeds 102 degrees. CMS Ex. 23, at 2. Petitioner also does not deny that its oxygen use policy provides that oxygen therapy is administered to a resident only upon written order of a licensed physician. CMS Ex. 24, at 1, 4.

Absent evidence to the contrary, I accept Petitioner's policies as reflecting the standard of care. Petitioner's staff violated the standard of care and the regulation.

(1) Failure to consult physician regarding elevated temperature.

The Nurse's Notes entry dated March 27, 2006, at 1:30 p.m. shows that the resident's temperature was 99 degrees, without specifying whether it was taken orally or rectally. The next note is dated March 27, 2006, at 9:00 p.m. The 9:00 p.m. note shows that Resident B's temperature was 102.6 degrees at 3:00 p.m, again with no indication of whether it was oral or rectal. Tylenol was given. The note also indicates that at 3:00 p.m. Resident B's oxygen was increased to 5 liters due to mouth breathing, but his oxygen

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[12] I agree with Petitioner (P. Brief at 21-22), as does CMS (CMS Brief at 5-6), that the surveyors could also have alleged a violation of 42 C.F.R. § 483.10(b)(11)(i) (Tag F157) on the theory that Petitioner failed to consult Resident B's physician on March 27, 2006, when he experienced a significant change in condition. However, this charge was not made and, given my decision on the alleged violation of 42 C.F.R. § 483.25 (Tag F309), I find it unnecessary to do the analysis required under Tag F157.

saturation was noted to be ranging between 91 and 94 percent. The 9:00 p.m. note states that at 8:00 p.m. Resident B's temperature was 101.5 degrees, that Tylenol was given again, and that the resident's oxygen saturation was 92 percent. The 9:00 p.m. note indicates that the resident did not eat well during the shift, that he only took a few bits of his meal, and that the head of his bed was elevated. The Nurse's Notes entry from 10:00 p.m. shows that Resident B's temperature remained at 101.5 degrees, with no indication whether it was an oral or rectal reading, or whether the temperature had dropped due to prior administration of Tylenol and then increased, or whether Tylenol had no effect. Both the 9:00 p.m. and 10:00 p.m. notes on March 27, 2006 are signed by Nurse Pescetto. The next Nurse's Notes entry is dated March 28, 2006, at 2:30 p.m., 16 and a half hours later. CMS Ex. 12, at 15; P. Ex. 12, at 5. The 24 Hour Reports for March 27, 2006, list the temperature of 102.6 and 101.3, but no other details. P. Ex. 14, at 4. Petitioner's clinical records for Resident B do not show that any attempt was made to consult with Petitioner's physician, Dr. Louck, on March 27, 2006. Petitioner's records also do not show that Petitioner made any attempt to consult with Dr. Louck on March 28, 2006, but he did see Resident B at the facility and did direct his admission to the hospital. CMS Ex. 12, at 15; P. Ex. 12, at 5. Dr. Louck testified that he was contacted on March 28, 2006, by Petitioner's staff who told him that Resident B had taken a turn for the worse, he had not had anything to eat other than a few bites, they were having trouble keeping fluids down him, and they were having a hard time keeping his oxygen on. Tr. 203.

Nurse's Notes entries show that Resident B's temperature was over 101 degrees between 3:00 p.m. and 10:00 p.m. on March 27, 2006. Petitioner does not deny that its notification policy requires that the attending physician be notified immediately if oral temperature exceeds 101 degrees, or rectal temperature exceeds 102 degrees. CMS Ex. 23, at 2. Thus, if Resident B's temperature was taken orally the three times the Nurse's Notes show it was checked between 3:00 p.m. and 10:00 p.m. on March 27, 2006, Petitioner's policy required that the physician be notified immediately each time. If Petitioner's staff was taking rectal temperatures, the temperature of 102.6 degrees at 3:00 p.m. on March 27, 2006, required staff to notify Resident B's physician. Petitioner does not deny that Resident B's physician was not contacted or consulted, and that he did not see the resident until 16 and a half hours later.

Petitioner argues that CMS has not shown why Petitioner's policy should be applied as if it was a regulatory standard. P. Reply at 5. CMS does not argue that Petitioner's policy establishes a regulatory standard. Rather, the CMS position is that Petitioner's policy should be accepted as evidence of the standard of care or standard of practice that should be followed in delivering care and services. CMS Post-Hearing Response Brief (CMS Reply) at 5. The Secretary has not directed by regulation what care and services are to be delivered, or how they are to be delivered. The Secretary has dictated that care planning for each resident of a long-term care facility must be by a team of qualified persons, must be delivered by qualified persons in accordance with the plan of care, and the services

delivered must meet professional standards of quality. 42 C.F.R. § 483.20(k)(2)(iii) and (3). Whether or not services delivered meet professional standards of quality, in many instances, may only be determined by considering the professional standards of practice or care applicable. Presumably, Petitioner would not adopt a policy for the guidance of its staff that did not reflect, as a minimum, the standard of care. Thus, it is permissible for CMS to point to Petitioner's policy as evidence of the standard of care without additional evidence to corroborate that the policy reflects the standard of care. *See e.g., Spring Meadows Health Center*, DAB No. 1966 (2005). If Petitioner wishes to establish that its policy does not reflect the standard of care, either because it does not meet the standard of care or because it requires more than a commonly accepted standard of care, then Petitioner is obliged to produce that evidence, not CMS which chooses to rely upon an inference based upon the policy. Petitioner has presented no evidence that its policy on reporting does not meet the standard of care, or that it exceeds the standard of care, and I do not hesitate to draw the inference that its policy reflects the standard of care.

Petitioner also argues that Resident B's physician, Dr. Louck, had made clear not to notify him of such developments as increased fever that staff could control by Tylenol. P. Reply at 5. Petitioner called Dr. Louck to testify at hearing. He is in family practice in Rensselaer, Indiana and Resident B was his patient. Tr. 191-92. He saw the resident on March 24, 2006, when the resident had a temperature of 101degrees and, based upon a influenza swab, determined he had the influenza, but his lungs were clear on an x-ray. Tr. 196-97. He testified that a major risk of influenza in a nursing home resident is the development of pneumonia. Tr. 198. He testified that the hospital was crowded, and he did not want to expose the hospital population to influenza, so he sent Resident B back to the nursing home with an order for Tamiflu (an antibiotic) in an attempt to avoid infection, extra Tylenol, Phenergan VC, breathing treatments with a nebulizer, and supplemental oxygen in the event his oxygen saturation fell below 90 percent. He testified that the expected course for influenza is that one usually has fever and coughing for the next six to seven days. According to Dr. Louck, he would want to be notified of fever of 103 degrees that was not reduced very easily, and that it would be usual for a fever to range between 100 and 102 degrees for three to four days. Tr. 198-99. He testified that he would want to be notified within about six hours of a fever over 103 degrees, a change in mental condition, if the rate of respiration fell below 25 to 30, or if the resident refused to eat or drink, but he would want nursing staff to attempt to intervene first. Tr. 200-01. Dr. Louck reviewed the Nurse's Notes entry from 9:00 p.m. on March 27, 2006, and indicated he was satisfied with the interventions noted and not being contacted immediately. Tr. 201-02. Dr. Louck admitted that he was called to the facility the next day and, after seeing Resident B, he ordered his admission to the hospital. Tr. 204. I have already noted that there were no Nurse's Notes entries for 16 and a half hours from 10:00 p.m. on March 27, to 2:30 p.m. on March 28, 2006. The note on March 28, 2006 does not include any observations related to the resident's condition. However, the note indicates Dr. Louck ordered Resident B admitted to the hospital for suspected

pneumonia. P. Ex. 12, at 5; CMS Ex. 12, at 15. Dr. Louck's admissions note dated March 28, 2006, does not indicate vital signs, but he mentions Resident B continued to run a low grade fever and that he had not eaten anything for breakfast or lunch, it was hard to keep his oxygen on, he seemed more confused than usual, he was not able to sit-up, his chest sounded raspy all over, he had audible wheezes, and he had difficulty coughing. CMS Ex. 12, at 50. Dr. Louck did not explain in his testimony how Resident B's condition was different on March 28 than it was the night before based upon his reading of the Nurse's Notes from March 27, 2006. The only evidence I have found related to Resident B's condition on March 28, 2006 is in the 24 Report dated March 28, 2006. The 24 Hour Reports for March 28, 2006 note recorded temperatures of 100.8 degrees during the 10:00 p.m. to 6:00 a.m. shift, with an oxygen saturation of 94 percent and a temperature of 100.2 degrees at 11:30 a.m. P. Ex. 14, at 5. The Nurse's Notes entry at 2:30 p.m. on March 28, 2006 also adds that Resident B was too weak to sit in a chair, and required a stretcher for transport. CMS Ex. 12, at 15; P. Ex. 12, at 5.

I do not find Dr. Louck's testimony dispositive. Dr. Louck testified that Resident B had influenza and was at risk as a nursing home resident of developing pneumonia.[13] Dr. Louck did not provide any testimony as to the appropriate standard of care for a resident with such a risk, he only testified to his practice, which may or may not be consistent with the standard of care. Clearly, when he was notified by staff on March 28 of Resident B's medical condition, Dr. Louck saw Resident B and ordered that he be directly admitted to a hospital where he was diagnosed with pneumonia and subsequently died. CMS Ex. 5, at 2-10; CMS Ex. 12, at 15-16, 37; Tr. 204. Dr. Louck testified that as soon as facility staff communicated with him it was not very long from the time he received the call to the time he went over. Tr. 203.

I find that there were signs of Resident B's worsening condition, or at least that his condition was not improving, that should have caused staff to call Dr. Louck after he first saw the resident on March 24, 2006, given the known risk for pneumonia. Petitioner's Nurse's Notes include reports between 9:00 p.m. on March 24 and March 27, 2006 that: the resident's temperature remained above 100 degrees on most reports, with a few reports of 98 and 99 degrees, despite administration of an antibiotic, and Tylenol and Motrin; he received little relief from nebulizer treatments; he had a nonproductive cough;

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[13] Dr. Louck testified that Resident B was at risk of developing pneumonia due to both his influenza and his problem with aspiration, and it was not possible to determine the actual cause of the pneumonia that killed him. Tr. 205-06. Given that both Resident B's treating physician and Petitioner could foresee the risk of pneumonia, the obligation to assess, to care plan, to implement interventions, and to assess the effectiveness of interventions was triggered. This alleged violation turns upon Petitioner's failure to implement interventions ordered by the doctor, not the cause of death.

lung sounds were diminished in both fields and congested; his appetite was not good; his skin was withdrawn on touch; and he was reported to be pale. At 1:30 p.m. on March 27, his temperature was down to 99 degrees after being recorded as 101 degrees at 2:00 a.m.; he was coughing frequently; he was noted to have rattling in his lungs; but his appetite was reported to be good, and his family was present. However, at 3:00 p.m. on March 27, 2006, his temperature had again climbed to 102.6 degrees and Tylenol was given, and, his appetite was noted to be poor. Whether or not his temperature dropped due to administration of Tylenol at 3:00 p.m. is not recorded, but at 10:00 p.m. his temperature was at 101.5 degrees. Petitioner's staff did not notify and consult with Dr. Louck about any of the signs and symptoms that indicated this resident's symptoms were not improving but were, in fact, worsening despite antibiotic therapy. Petitioner's failure was a clear failure to deliver a necessary care or service, i.e., Petitioner's staff prevented or delayed the timely delivery of services by Resident B's physician, Dr. Louck, because he was not consulted.

(2) Failure to consult physician regarding increased oxygen flow rate.

The surveyors also note in the SOD that a nurse increased Resident B's oxygen flow rate from two liters per minute to five liters per minute at 3:00 p.m. on March 27, 2006, without consulting with Dr. Louck or obtaining an order for the increase. CMS Ex. 5, at 5, 8.

It is undisputed that at 3:00 p.m. on March 27, the flow rate of Resident B's oxygen was raised from two to five liters per minute. CMS Ex. 12, at 15; P. Ex. 12, at 5.

Petitioner maintains that the decision to increase Resident B's oxygen level was consistent with Dr. Louck's orders, arguing that Dr. Louck's orders allowed staff to increase the oxygen rate as needed if this was required to keep the resident's blood oxygen saturation levels above 90 percent. P. Br. at 6, 9-10; P. Reply at 6. Dr. Louck testified that, when he saw Resident B on March 24, 2006, he ordered that oxygen be administered by nasal cannula if Resident B's oxygen saturation fell below 90 percent. Tr. 199. The order for oxygen on March 24 is recorded in Petitioner's records as oxygen at two liters without any reference to the conditions that it be administered only if Resident B's oxygen saturation fell below 90 percent or that it be administered by nasal cannula. P. Ex. 10, at 7; Tr. 220. A prior order for oxygen dated December 30, 2005, did specify that oxygen was to be administered at a rate of two liters per minute by nasal cannula for shortness of breath or oxygen saturation below 90 percent. P. Ex. 10, at 2. There is no evidence that anyone on Petitioner's staff called for clarification of the March 24, 2006 order. Petitioner's Nurse's Notes, beginning with the 9:00 p.m. note on March 24, 2006 (the first note after Resident B's visit with Dr. Louck), indicate that Resident B was continuously receiving supplemental oxygen, with no indication that he complained of shortness of breath or that his oxygen saturation had fallen below 90 percent. The flow

rate was reported to be two liters per minute until it was increased to five liters per minute at 3:00 p.m. on March 27, 2006, when his oxygen saturation was reported to be ranging between 91 and 94 percent, and he was reported to be congested, but there was no report of shortness of breath. CMS Ex. 12, at 13-15; P. Ex. 12, at 3-5. Dr. Louck's testimony was that he had no problem with the increase from two liters to five liters without him being notified or consulted first. Tr. 202, 209, 225-27. However, he also testified that he expected to be called or notified of such a change. Tr. 209. There is no evidence of any attempt to contact Dr. Louck until the next afternoon.

Dr. Louck did not testify whether it was consistent with a standard of practice for a nurse to increase oxygen flow rate without a specific order of a physician, or without contacting and consulting with a physician first. However, Petitioner's policy entitled *Oxygen Use, General* indicates that "Oxygen therapy is administered to the resident only upon the written order of the licensed physician." CMS Ex. 24, at 1. Absent evidence to the contrary, and for reasons already discussed, I accept Petitioner's policy as reflecting the appropriate standard of practice.

The evidence shows that Dr. Louck was not consulted before the increase in the flow rate of the oxygen from two to five liters at about 3:00 p.m. on March 27, 2006. Further, the evidence shows that he was not consulted until the afternoon of the next day, March 28, 2006. When he did see the resident the next day, Dr. Louck made the decision to have him admitted to the hospital, significantly, because of difficulty keeping the oxygen on the resident and keeping him oxygenated.[14] Tr. 204-05; CMS Ex. 12, at 50. Had Dr. Louck been consulted at 3:00 p.m. on March 27, 2006, he would have had the option to order admission to the hospital at that time, ensuring Resident B would receive the more aggressive treatment at the hospital nearly a whole day sooner than he did.

d. Petitioner's staff failed to administer Tylenol to Resident B.

The surveyors allege that there is no evidence that Petitioner gave Resident B Tylenol on March 28, 2006. CMS Ex. 5, at 6. CMS argues that there is no evidence that Petitioner's staff gave Resident B any Tylenol after 8:00 p.m. on March 27, 2006, though the evidence shows he had a fever in excess of 100 degrees. CMS Brief at 8, n.9; CMS Reply at 3.

[14] At hearing, Dr. Louck could only speculate as to what caused Nurse Pescetto to increase the oxygen flow rate from two to five liters at 3:00 p.m. on March 27, 2006, as he apparently never discussed the matter with her, and the Nurse's Notes are not clear. Tr. 226-28.

The physician's order on March 24, 2006, was recorded by Petitioner as Tylenol every four to six hours, as needed, for fever above 100 degrees. P. Ex. 10, at 7. Resident B's MAR shows that Tylenol was administered one time on March 24, two times on March 25, one time on March 26, and two times on March 27, but not at all on March 28, 2006. P. Ex. 11, at 10; CMS Ex. 12, at 17. Nurse's Notes entries for Resident B show that Tylenol was administered at 5:30 a.m. on March 25 for a recorded temperature of 100.3 degrees; at 2:40 p.m. on March 25 for a recorded temperature of 100.4 degrees; at 3:00 p.m on March 25 for a recorded temperature of 99.8 degrees; at 8:30 p.m on March 25 for a recorded temperature of 100.5 degrees; at 10:30 a.m. on March 26 he was given Motrin for a recorded temperature of 100.9 degrees; at 9:00 p.m. on March 26 he was given Tylenol for a recorded temperature of 101 degrees; Tylenol was given at 3:00 p.m. on March 27 for a recorded temperature of 102.6 degrees; Tylenol was given at 8:00 p.m. on March 27 for a recorded temperature of 101.5 degrees; the two Nurse's Notes entries for March 28 at 2:30 p.m. and 3:30 p.m. do not reflect temperatures or whether Tylenol was administered. The 24 Hour Reports show that Tylenol was administered on the 10:00 p.m. to 6:00 a.m. shift, the 6:00 a.m to 2:00 p.m. shift, and the 2:00 p.m. to 10:00 p.m. shift on March 25; and the 2:00 p.m. to 10:00 p.m. shift on March 26, 2006. The 24 Hour Reports does not show any Tylenol administered on March 27 or 28, 2006. The 24 Hour Reports for March 28, 2006 has recorded temperatures of 100.8 degrees during the 10:00 p.m. to 6:00 a.m. shift and 100.2 degrees at 11:30 a.m. P. Ex. 14.

Petitioner's clinical records for Resident B do not show that Resident B was given Tylenol after 8:00 p.m on March 27, or on March 28, 2006. The absence of any record that Tylenol was administered gives rise to the inference that none was administered. Because there is evidence Resident B's temperature was above 100 degrees during the period referenced, Petitioner's staff failed to comply with the physician's order depriving Resident B of care or services necessary to minimize the impact of having a fever, which is actual harm.

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

The quality of care requirement 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).

The application of this regulation is well-established by decisions of various appellate panels of the Board. *Koester Pavilion*, DAB No. 1750 and *Cross Creek Health Care Center*, 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).

An appellate panel of the Board in *Clermont Nursing and Convalescent Center*, DAB No. 1923, at 9-10 (2004), *aff'd, Clermont Nursing and Convalescent Center 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 always furnish the necessary treatment and services" for pressure sore prevention or healing. *Id.* at 30-31

> (emphasis supplied). Thus, a facility may provide necessary treatment and services to ensure the prevention or healing of pressure sores, yet still be confronted with a negative outcome. In that instance, the facility may put forward clinical evidence to show that the outcome was unavoidable.

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

The surveyors allege in the SOD that Petitioner failed to prevent Resident 57 from developing a Stage II[15] pressure sore. CMS Ex. 5, at 11. CMS alleges that Petitioner failed to take adequate measures to prevent a Stage II pressure ulcer from developing near Resident 57's coccyx after she was admitted to the facility, and then also failed to provide necessary treatment and services as ordered by the resident's physician to heal the wound once it did appear. CMS Brief at 14-20; CMS Reply at 10-15.

Resident 57, who was 80 years-old at the time of the survey, was readmitted to Petitioner's facility on February 23, 2006 with diagnoses of a decubitus ulcer on her heel, polymyalgia rheumata, bipolar disorder, diabetes mellitus (Type II), chronic obstructive

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[15] Following is the instruction given surveyors regarding identifying the stage of a pressure sore:

> **Stage I:** A persistent area of skin redness (without a break in the skin) that is nonblanchable. Redness can be expected to be present for one-half to three-fourths as long as the pressure applied that has occluded blood flow to the areas. For example: If a resident is laying on his right side for 30 minutes and turned to his back, redness may be noticed over his right hip bone. Redness in that area can be expected to remain for up to 20 minutes. The survey team then would check to see if the area is nonblanchable. Just having the redness does not indicate a stage I. To identify the presence of stage I pressure ulcers in residents with darkly pigmented skin, look for changes such as changes in skin color (grayish hue), temperature, swelling, and tenderness or texture.
> **Stage II:** A partial thickness loss of skin layers either dermis or epidermis that presents clinically as an abrasion, blister, or shallow crater.
> **Stage III:** A full thickness of skin is lost, exposing the subcutaneous tissues - presents as a deep crater with or without undermining adjacent tissue.
> **Stage IV:** A full thickness of skin and subcutaneous tissue is lost, exposing muscle and/or bone.

SOM, App. PP, Guidance To Surveyors, Tag F314.

pulmonary disease (COPD), arteriosclerotic heart disease (ASHD), epilepsy, atrial fibrillation, and hemophilia, among others. P. Ex. 23, 25; CMS Ex. 13, at 22, 38. Two different Initial Data Collection Tools dated February 23, 2006 are in the record provided by Petitioner, both are checked for bruises, but not skin tears, lacerations, pressure sores, vascular ulcers, or a history of pressure sores. However, on one, red spots are noted on the right buttock or gluteal area near the coccyx, and on both left and right heels; and, on the other, only a red area is noted on the right gluteal area near the coccyx. P. Ex. 24, at 2; P. Ex. 25, at 3. An Admission/Annual History and Physical form signed by a physician on February 20, 2006, indicates skin "ok." P. Ex. 25, at 1. A pressure sore risk assessment completed on February 24, 2006, rated Resident 57 as at moderate risk. Noted risk factors were a history of pressure ulcers, decreased or impaired bed/chair mobility, episodes of urinary or bowel incontinence, pain, and use of antipsychotics/antidepressants/hypnotics. P. Ex. 26; CMS Ex. 13, at 12-13. A *Pressure Ulcer Prevention Checklist*, dated February 24, 2006, shows that a preventative seat cushion (pressure reduction) was ordered, laboratory testing was ordered on admission, weekly skin integrity assessments were ordered, and Resident 57 was to receive vitamin or mineral supplements, specifically Centrum Silver. CMS Ex. 13, at 14; P. Ex. 35, at 1; P. Ex. 41, at 1. A physician's order dated February 24, 2006, directed the application of "Riley's Butt Cream" to Resident 57's buttocks and perineal area to prevent skin breakdown. CMS Ex. 13, at 35-37, 46; P. Ex. 40, at 1, 3; P. Ex. 42, at 1.

Resident 57's admission MDS, with an assessment reference date of March 7, 2006 (the last day of a seven day assessment or observation period), includes a current diagnosis of decubitus ulcers. CMS Ex. 13, at 7; P. Ex. 30, at 4. Under Section M of the MDS, which is entitled "Skin Condition," Petitioner reported that Resident 57 had one Stage I pressure ulcer, defined as a persistent area of skin redness with no break in the skin and the redness does not disappear when pressure is removed; that she had a history of resolved ulcers; and,that she had pressure relieving devices for bed and chair, she was on a turning and repositioning program, she received ulcer care, she received preventive or protective skin care, and she had preventive or protective foot care. P. Ex. 30, at 5.[16] The MDS also shows that during the seven-day assessment period Resident 57 required extensive assistance of one person for changing position in bed, she did not walk except with a two-person assist, she was totally dependent upon staff for locomotion on and off the unit, she

[16] Counsel must take more care preparing exhibits for hearing. This important exhibit is an excellent example of poor exhibit preparation. The copies of this exhibit offered by both parties are poorly done, and the right-side and bottom of the page of the MDS is partially cut-off in both the CMS and Petitioner's exhibit. On CMS Ex. 13, at 8, the right-side of the form is completely cut-off in the copy so that it is impossible to determine what entries were made by Petitioner's staff. The entries on P. Ex. 30, at 4, are partially cut-off, but the entries by Petitioner's staff are discernable.

required extensive assistance of one person to use the toilet and to perform hygiene, and a wheelchair was her primary mode of locomotion. CMS Ex. 13, at 6-7, 10; P. Ex. 30, at 3-4, 7. She was reported to usually be continent of bowel and bladder. CMS Ex. 13, at 7; P. Ex. 30, at 4.

Petitioner implies or suggests in its briefs (P. Brief at 12-13, 24; P. Reply at 10), and also through testimony at hearing (Tr. 398-99, 408-16 (DON Stidham); Tr. 463-73 (Mr. Carson)) that the wound at issue was caused by Resident 57 being dropped by her daughter on the parking lot of the facility at the time of admission, which caused a bruise or abrasion of the lower buttock near the gluteal fold. Petitioner thus indirectly raises the issue of whether or not 42 C.F.R. § 483.25(c) (Tag F314), which covers only pressure sores[17] and not other types of wounds, is even applicable. I have no difficulty resolving this issue against Petitioner. DON Stidham's testimony regarding the cause of the "wound," and its status or appearance, is inconsistent with the contemporaneous documents discussed above, and is thus not credible. The evidence shows that DON Stidham did not actually observe the wound in either February or March 2006, as she did not begin working at the facility until April 3, 2006. Tr. 398, 417, 424. Mr. Carson, Senior Vice President of Clinical Services for Life Care of America, Petitioner's owner and operator (Tr. 2, 432), testified that he was familiar with the three residents who are the focus of the alleged deficiencies based upon direct observation, records review, and assisting with their care. Mr. Carson was not assigned to work full-time at Petitioner's facility, but due to prior surveys, had been full-time at the facility for six weeks working on clearing prior deficiencies, and he was present during the May 2006 survey. Tr. 439-40. Mr. Carson testified that he observed that Resident 57 had a wound on the lower part of her buttock, not on her coccyx. He did not state specifically when he saw the wound. He testified that he learned through "[a]ssociate interview" that Resident 57 had been dropped on the parking lot upon admission. Tr. 463-67, 472-73. I find the testimony of Mr. Carson regarding the cause of the wound, and his conclusion that it was not a pressure sore, not credible. Mr. Carson did not see the resident at the time of admission or view the wound or injury at that time. Further, Mr. Carson's testimony in this regard is inconsistent with Petitioner's contemporaneous clinical records discussed above. I find more credible the MDS discussed above, which was based upon the assessment period of March 1 through 7, 2006, than the testimony of either Mr. Carson or DON Stidham who

[17] "Pressure sore" means ischemic ulceration and/or necrosis of tissues overlying a bony prominence that has been subjected to pressure, friction or shear. SOM, App. PP, Guidance To Surveyors, Tag F314.

were not present at the time, and who developed their opinions based upon hearsay that was inconsistent with the actual documents in Resident 57's files. The MDS assessment indicated both a current diagnosis of decubitus ulcer and a description of a Stage I ulcer present at the time. The MDS also listed the interventions Petitioner purported to implement to prevent or improve pressure sores.[18]

Petitioner's clinical records for this resident are inconsistent regarding the number and location of the wounds. I resolve these inconsistencies against Petitioner, based on the weight of the evidence. I conclude, based upon the available clinical evidence, with significant weight given to the March 7, 2006 MDS, that Resident 57 was readmitted to Petitioner's facility on February 23, 2006, with a Stage I pressure sore on her coccyx. Petitioner's records contain additional evidence consistent with this conclusion. A Nurse's Notes entry at 10:00 p.m. on February 23, 2006, the day of admission, indicates that Resident 57's heels felt very soft or mushy. A Nurses' Notes entry at 3:30 p.m. on February 24, 2006, indicates that the resident had reddened areas on her heels and coccyx which were blanchable.[19] The February 24 note also lists orders to use bunny boots on the resident at night, and to apply barrier cream on her coccyx. P. Ex. 43, at 1-2; CMS Ex. 13, at 22-23. The Nurse's Notes entries on February 23, 2006 are consistent with the Initial Data Collection Tools dated February 23, 2006 in the records provided by Petitioner, which show on one, red spots on the left buttock near the coccyx and both left and right heels, and on the other only a red area on the coccyx. P. Ex. 24, at 2; P. Ex. 25,

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[18] Between March 15 and May 3, 2006, and June 15 and 22, 2006, a member of Petitioner's staff, LPN L. Hopkins, used a form entitled "Non-Pressure Skin Condition Record." P. Ex. 38, at 1-2, 4-5. The first page of this record indicates that the open area on the right gluteal area was like a blister that opened, and it is also indicated to be an abrasion. P. Ex. 38, at 1. This form was completed once per week, according to the dates, and signed by LPN Hopkins. LPN Hopkins was not called to testify regarding this form or why she chose to characterize the wound as non-pressure. She did include with the entry on March 15, 2006, that the wound looked like shearing, and she listed the physician's orders from that date. She also indicated stages for the wound as if a pressure sore. P. Ex. 38, at 1-2. Absent testimony from LPN Hopkins, I do not find her choice of this form to be worthy of much weight regarding whether or not the wound was a pressure sore. Furthermore, LPN Hopkins also used a "Pressure Ulcer Status Record" for recording observations of the right gluteal wound, from May 10 through June 10, 2006. P. Ex. 39.

[19] DON Stidham described a Stage I pressure sore as being a red spot on the skin that is blanchable. Tr. 411. The SOM states that a Stage I pressure sore is nonblanchable. SOM, App. PP, Guidance To Surveyors, Tag F314. I find it unnecessary to resolve this apparent conflict as there is sufficient other evidence of the Stage I pressure sore.

at 3. The notes are also consistent with a Nutritional Risk Assessment note dated February 28, 2006.[20] P. Ex. 49, at 2. An entry in the Nurse's Notes, at 2:00 or 2:10 p.m. on February 25, 2006 indicates that no bruising or redness from the previous injury was observed, but barrier cream was applied per orders. CMS Ex. 13, at 23-24. A note entered at 10:00 p.m. on February 25, 2006 indicates that Resident 57's buttocks were reddened, without indicating where specifically. P. Ex. 43, at 2-3; CMS Ex. 13, at 23-24. I find this evidence is sufficient to show that when Resident 57 was admitted on February 23, 2006, she had a Stage I pressure ulcer on her coccyx.[21] The evidence also suggests pressure sores on both heels, however, the coccyx sore is the subject of the deficiency, and I make no findings regarding the heels.

Because the gluteal wound was a pressure sore on or near the coccyx that developed prior to Resident 57's admission to Petitioner's facility, the issue is whether Petitioner ensured Resident 57 received "care and services necessary for healing, to prevent infection, and to prevent other sores from developing." 42 C.F.R. § 483.25(c).

No mention of the coccyx pressure sore is made in Nurse's Notes from February 25 through March 13, 2006. However, a Nutritional Progress Notes entry dated March 7, 2006 indicates a reddened area to the coccyx. P. Ex. 49, at 1. A Nurse's Notes entry at 10:00 p.m. on March 14, 2006 indicates that there was a small open lesion on the right buttock, approximately 0.2 cm, which looked like a blister that opened. P. Ex. 43, at 3; CMS Ex. 13, at 24. A March 15, 2006 note, at 2:00 p.m, indicates the physician was called for a treatment order for the buttock wound. A note at 10:45 p.m. on March 15

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[20] Petitioner also submitted Nutrition At Risk Program forms with entries dated from March 3, 2006 through May 23, 2006, the first of which was signed by Mary Hitchings, CDM (Certified Dietary Manager). The remaining entries are unsigned, but the handwriting is consistent with that of Ms. Hitchings. Her note, dated March 3, 2006, indicates decubitus ulcer heel. Entries dated March 15 and 22, 2006 indicate non-pressure area, Stage I, right gluteal. A note dated May 7, 2006 indicates right buttocks Stage I. A note dated May 23, 2006 indicates right gluteal healed as of May 19, 2006. There is no evidence that Ms. Hitchings ever observed the wounds she described, or that she was qualified to make such assessments. Her characterization of the wound is not considered weighty, but she does confirm the reported existence of the wound.

[21] This conclusion does not prejudice Petitioner as it precludes my finding Petitioner responsible for new pressure sores after Resident 57 was admitted. The conclusion also does not prejudice CMS, as CMS prevails on the issue of whether necessary treatment was provided.

states that a treatment order was given for application of DuoDerm[22] to the resident's coccyx wound with other instructions regarding limiting time in her wheelchair and turning her side-to-side while in bed. P. Ex. 4, at 4; CMS Ex. 13, at 25. The physician's order, dated March 15, 2006, reflects a diagnosis of decubitus ulcer coccyx area. He ordered DuoDerm be applied to the wound and changed every day, and as needed, to the open area on the coccyx. He also ordered that the resident be limited to being up in her wheelchair no more than four times per day for one hour, that she be turned from side-to-side when in bed, and that she not lie on her back. P. Ex. 41, at 5. A Skin Care Plan dated March 15, 2006 indicates an open area on the right gluteal measuring 2.2. cm long by 2.0 cm wide by 0.1 cm deep. The form does not indicate where on the right gluteal area the sore appeared, but the right gluteal area includes the area from the coccyx to the gluteal fold at the bottom of the right buttock. The care plan noted 10 preprinted items which included turning and repositioning every two hours, checking for incontinence every two hours, and changing the resident's undergarment as needed. Handwritten entries include use of DuoDerm for the wound, limiting the resident's time up in her chair, turning her side-to-side while in bed, and not placing her on her back. CMS Ex. 13, at 40; P. Ex. 33, at 1. Additional interventions were added on May 10, 12, and June 16, 2006 which appear on the copy of the form provided by Petitioner. P. Ex. 33, at 1. A physician's progress note dated March 25, 2006, characterizes the wound on the right gluteal as a Stage III decubitus. P. Ex. 47. A physician's order dated March 28, 2006, includes the direction to keep the resident off her back in bed and to turn her twice every two hours left to right. CMS Ex. 13, at 32. A physician's order dated April 21, 2006, states "red buttocks–not open," which I construe to mean that the coccyx wound had closed, reflecting healing. CMS Ex. 13, at 33. A physician's order dated April 26, 2006, shows that the right upper gluteal wound broke open again, and the doctor ordered use of DuoDerm and protective cream to both buttocks. CMS Ex. 13, at 34. A physician's progress note dated May 16, 2006, states that the Stage III decubitus on the right buttock had healed to a Stage II without infection. P. Ex. 47. Weekly Skin Integrity Assessment forms dated between March 1, 2006 and May 16, 2006 are, on their face, inconsistent regarding the location of the wound, and they do not consistently indicate a turning schedule of every two hours. P. Ex. 37.

Petitioner's clinical records presented by CMS show that after her admission, Resident 57's Stage I coccyx pressure ulcer became an open wound, which is, at a minimum, a Stage II pressure sore. Tr. 129-30. The additional records presented by Petitioner are consistent and reflect that the area on or near the coccyx became an open wound, healed,

[22] A special dressing often used in the treatment of pressure sores and similar wounds.

reopened, and worsened before healing. There can be no dispute that Petitioner's clinical records show that Resident 57's wound worsened, given the fact that it became an open wound rather than just a red spot. Thus, the issue is whether or not the worsening of the wound was unavoidable. I conclude that Petitioner has failed to show unavoidability.

The surveyors allege that on May 3, 2006, Resident 57 was up in her wheelchair from 7:15 a.m. to until about 1:00 p.m. At 1:15 p.m. on May 3, 2006, Resident 57 was observed by the surveyor to be lying in bed on her back with the head of the bed elevated. On May 4, 2006, at 9:40 a.m., the surveyor also observed Resident 57 lying in bed on her back with the head of the bed elevated. CMS Ex. 5, at 11-12. Surveyor Campbell testified that she made the observations of Resident 57 reported in the SOD, and her testimony was consistent, except she testified that the reported 1:15 p.m. observation on May 3, 2006 actually occurred at 2:15 p.m. Tr. 129-34.

The physician's order from March 15, 2006 is clear that the resident was supposed to be up in her wheelchair no more than four times per day for no more than one hour. P. Ex. 41, at 5. Another physician's order dated March 28, 2006, is also clear that the resident was not to be on her back in bed, and was to be turned left to right, twice, every two hours. CMS Ex. 13, at 32. Petitioner's Skin Care Plan dated March 15, 2006, specifies that the resident's time up in her chair was to be limited, but it does not specify four times for no more than one hour each time. The Skin Care Plan dated March 15, 2006, also specifies that Resident 57 was be turned side-to-side in her bed and not on her back, but it does not state the frequency for turning other than approximately every two hours. P. Ex. 33, at 1. A copy of a different care plan for Resident 57, dated March 13, 2006 and updated with handwritten entries, did not include the physician's order to limit the resident's time up in the chair or to keep her off her back in bed until it was added on May 3, 2006. The care plan stated that staff was to encourage and assist the resident to change position frequently, at least every two hours, and as necessary. The entry dated May 3, 2006, during the survey, states that she was to be encouraged to be up in her chair only one hour, four times per day. The May 3 entry also indicates that Resident 57 was to be reminded why she was not to lay on her backside or sit-up too long. CMS Ex. 13, at 42-43; P. Ex. 32, at 17. Petitioner's care plans for Resident 57 appear to be conflicting and incomplete and, except for a general statement to comply with physicians orders, do not actually contain the detailed orders of the physician from March 15 and 28, 2006. During the survey on May 3, 2006, Petitioner's staff attempted to update the one care plan, but still failed to specifically state the physician's order for Resident 57.

The surveyors' observations on May 3 and 4, 2006, show that Petitioner was not following either Resident 57's physician's orders, or its care plans for Resident 57. Resident 57's MARs for March and April 2006 list the interventions ordered by Resident 57's physician on March 15, 2006. CMS Ex. 13, at 46, 48; P. Ex. 42, at 1, 12. My review of the MARs reveals that initials appear in the block for each shift for each day

from the afternoon of March 15, 2006 through April 30, 2006. While Petitioner's excellent documentation on the MAR would normally give rise to an inference that staff was actually implementing the interventions ordered, the inference is lost because the surveyor actually observed that the interventions were not being followed. Petitioner's failure to ensure staff was consistently following physician's orders, and its care plans, and the undisputed facts that the wound healed partially and then worsened during the period March 15 through April 26, 2006 (CMS Ex. 13, at 32-34), runs counter to Petitioner's position that worsening of the wound was unavoidable.

Petitioner argues that Resident 57 was noncompliant with limitations on sitting up in her chair and lying on her back in bed. P. Brief at 2, 15, 24-25; P. Reply at 10-11. The care plans mentioned above do not indicate any problem with noncompliance until entries during and after the survey regarding encouraging compliance. P. Ex. 33, at 1; P. Ex. 32, at 17; CMS Ex. 13, at 43. Petitioner also provided a care plan dated May 24, 2006, after the survey, that addresses a history of noncompliance with doctors orders.[23] P. Ex. 32, at 4-8. Prior to the survey, specifically May 3, 2006, I find no evidence that Petitioner care planned to address noncompliance by Resident 57. Monthly nursing summaries for March and April 2006 show that Resident 57 was being treated for a pressure ulcer, but neither mention any noncompliance with orders or resistance to care. P. Ex. 36, at 1-4. Further, there is no mention in Nurse's Notes entries from February 23, 2006 to May 3, 2006 that Resident 57 was noncompliant in any respect. A 4:30 p.m. entry on May 3, 2006, after Surveyor Campbell's observations on that date, states that the nurse demonstrated to Resident 57 the way she should lay in bed and turn side-to-side, using pillows for positioning. The note further indicates that Resident 57 stated she preferred to lay on her back, but that she would try to lie on her side. P. Ex. 43, at 1-7. Petitioner points to 24 Hour Reports entries at P. Ex. 45 as evidence of noncompliance. P. Brief at 15. However, neither report indicates noncompliance, rather, they merely state that the resident was to be encouraged to limit time up in her wheelchair, to lay on her sides, and to report to the nurse if the resident was noncompliant. Petitioner points to no other documents that indicate noncompliance. The absence of any entry regarding noncompliance is inconsistent with Petitioner's theory that the resident's wound was unavoidable due to her noncompliance with turning or being up in her wheelchair.[24] DON Stidham testified that she spoke with Resident 57 about the need to stay off her

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[23] I recognize that Petitioner may have offered this care plan to demonstrate its plan of correction for the alleged deficiency. I do not construe this document to be evidence that Petitioner admitted it failed to properly care plan. Rather, I mention this care plan only in the interest of being thorough in addressing all the evidence of record.

[24] I note that the Nurse's Notes entries during the period reflect that the resident was frequently up in her wheelchair to attend therapy and meals, without any mention of difficulty complying with the physician's order that the time in her chair be limited.

buttocks, but she could not say when the conversation occurred, or whether it was before or after the survey. She did state in response to a leading question from counsel for Petitioner, that she began speaking with the resident sometime after beginning work in April 2006. Tr. 403-05. DON Stidham did not testify that she was Resident 57's primary caregiver and, as DON, it is doubtful she was. She testified she was aware that nursing staff explained the interventions to the resident based upon Nurse's Notes and nurse's documents (Tr. 406), but the documents submitted by Petitioner show that those discussions occurred at the time of the survey as already discussed, with the possible exception of the 24 Hour Reports for which the dates are not readable. P. Ex. 45. Mr. Carson opined that the resident was pretty much noncompliant at times. Tr. 466. However, he identified no specific documents dated prior to the survey showing noncompliance consistent with that opinion. Mr. Carson also opined that the right gluteal pressure ulcer was unavoidable and adequately treated. Tr. 472. I conclude that his opinion is not consistent with the evidence already discussed that shows Petitioner did not document implementation of the interventions ordered by Resident 57's physician, and that the resident's clinical record is devoid of references to noncompliance. His testimony that the right gluteal wound was never treated as a pressure ulcer, and that it was never at Stage II (Tr. 473), is not credible given all the evidence in the clinical record for Resident 57.

I conclude that Petitioner has not demonstrated that Resident 57's pressure sore was unavoidable. Accordingly, I conclude that Petitioner violated 42 C.F.R. § 483.25(c) (F-314).

3. Petitioner violated 42 C.F.R. § 483.25(h)(2) (Tag F324).

The regulation requires that a facility ensure "[e]ach resident receives adequate supervision and assistance devices to prevent accidents." 42 C.F.R. § 483.25(h)(2). Section 483.25(h)(2) does not make a facility strictly liable for accidents that occur, however, it does require the facility to take all reasonable or practicable steps to ensure that a resident receives supervision and assistance devices that meet his or her assessed needs and mitigate foreseeable risks of harm to residents from accidents. *Woodstock Care Center v. Thompson*, 363 F.3d. 583, 590 (6th Cir. 2003); *Clermont Nursing and Convalescent Center*, DAB No. 1923 (2004), *aff'd, Clermont Nursing and Convalescent Center. v. Leavitt,* 142 Fed.Appx. 900 (6th Cir. 2005). Although a facility can choose the method of supervision it uses to prevent accidents, the method chosen needs to be "adequate." *Id*. To determine if the supervision is "adequate," one must look at the resident's ability to protect himself or herself from harm. *Id*.[25] An "accident" is "an

[25] Appellate panels of the Board have extensively discussed facilities obligations (continued...)

unexpected, unintended event that can cause a resident bodily injury," excluding "adverse outcomes associated as a direct consequence of treatment or care (e.g., drug side effects or reactions)." SOM, App. PP, Tag F324; *Woodstock Care Center*, DAB No. 1726, at 4.

The surveyors cited this deficiency based upon their conclusion that Petitioner failed to provide Resident A adequate supervision to prevent her from falling and fracturing a hip on April 9, 2006. CMS Ex. 5, at 17. CMS argues that Petitioner failed to provide adequate supervision and assistance devices, including mats, a pressure sensitive alarm, or a low bed to prevent Resident A from falling and fracturing her right hip on April 9, 2006. CMS Brief at 28; CMS Reply at 16-21.

Resident A was initially admitted to Petitioner's facility on February 19, 2003, and readmitted on July 12, 2005, after being discharged to the hospital on July 10, 2005, following a fall. CMS Ex. 15, at 30; P. Ex. 51; P. Ex. 77, at 2. She was 88 at the time of her fall on April 9, 2006. CMS Ex. 15, at 30; P. Ex. 51. Her MDS, with an assessment reference date of January 10, 2006 (the last MDS prior to the April 9 fall), indicates that her decisions were poor and she required cues/supervision; she was easily distracted, had periods or altered perception or awareness of surroundings, episodes of disorganized speech; and periods of restlessness. She was limited to making concrete requests, and was sometimes understood and she sometimes understood others, and could respond to simple direct communication. She required limited assistance of one person for bed mobility; extensive assistance of one for transfers, walking in her room, and for locomotion off the unit; she was rated as being independent for locomotion on the unit; and she required partial physical support while attempting to stand or to maintain position while sitting. CMS Ex. 15, at 30-32; P. Ex. 56, at 2-3. She was also noted to be in an Alzheimer's/dementia special care unit. CMS Ex. 15, at 33; P. Ex. 56, at 4.

Petitioner does not dispute that Resident A was predisposed to falls (P. Brief at 26) and had fallen before in July, August, and December 2005 (P. Brief at 17). Petitioner's records show that Petitioner's staff rated Resident A at high risk for falls seven times between April 26, 2005 and January 9, 2006.[26] CMS Ex. 15, at 27-28; P. Ex. 52; Tr. 448.

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[25](...continued)
under 42 C.F.R. § 483.25(h)(2) in many cases, including in the following: *Estes Nursing Facility Civic Center*, DAB No. 2000 (2005); *Northeastern Ohio Alzheimer's Research Center*, DAB No. 1935 (2004); *Guardian Health Care Center*, DAB No. 1943, at 17-18 (2004); *Woodstock Care Center*, DAB No. 1726, at 28 , *aff'd, Woodstock Care Center v. Thompson*, 363 F.3d 583 (6th Cir. 2003).

[26] A Fall Risk Assessment dated April 9, 2006, the day of the fall in question, determined that Resident A was at high risk for falls. However, her score on the
(continued...)

Resident A's physician, Dr. Ahler, commented in his progress note of August 24, 2005 that the resident was totally demented, she should not be up and walking; therapy was not going to be successful, and was a waste of effort and money; the resident needed restraint because she forgets she cannot walk, and falls when she tries; and she needs a belt restraint, side rails up, and anything to remind her not to get up to try to walk. CMS Ex. 15, at 73. The doctor's observations and comments clearly support my conclusion that this resident was not able to care for herself. His opinion that she should not be attempting to walk without assistance is consistent with Petitioner's own assessments in the MDS from January 2006.

Resident A's prior falls all involved her attempts to walk unassisted and without supervision of staff. Thus, it was foreseeable that if Resident A attempted to walk without supervision and assistance, she would fall and injure herself. Furthermore, prior falls for which I have evidence, were from her bed and from a chair. Thus, it was foreseeable that whether in a chair, wheelchair, or regular chair, or bed, Resident A was at risk for falling and injury if she tried to leave the chair or bed and walk unsupervised and unassisted. The facts of the early falls are reported in the contemporaneous nursing notes.

A Nurse's Notes entry for July 10, 2005, at 7:45 a.m., indicates that the nurse was called to the resident's room by a CNA, the bed alarm[27] was sounding, and the resident was on the floor at the foot of the bed on her right side. P. Ex. 77, at 1-2. The Post-Fall Assessment indicates that the resident wandered without regard to fatigue, she had impaired vision, she had a history of multiple falls, and she had loss of coordination.

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[26](...continued)
assessment was lower than it had been for the past year, partly due to the fact she had not had a fall in the preceding three months. I note that Resident A's last reported fall occurred on December 15, 2005. Coincidentally, Petitioner had also completed a fall risk assessment on that day and erroneously scored her as having three or more falls in the preceding three months when her last reported fall occurred on August 25, 2005. CMS Ex. 15, at 28; P. Ex. 52, at 2. Petitioner's Incident/Accident Data Entry Questionnaire suggests that the April 9, 2006 Fall Risk Assessment was actually done after the April 9 fall. P. Ex. 66, at 7-8.

[27] LPN Sabados testified that the bed alarm used was a mat that was placed under the resident that sounded an alarm when the resident got out of bed. Tr. 379. She described the bed alarm that was discontinued on February 1, 2006 in the same way. Tr. 384. Mr. Carson described the motion sensor as a box placed on the wall at the head of the bed that was focused down one side of the bed toward the foot board and that there was another box to the alarm on the opposing wall. If anything passed between the two boxes on opposing walls, the alarm sounded. Tr. 454-56.

Interventions listed as in place prior to the fall were a velcro alarming seat belt, I presume for her wheelchair, and a bed alarm. The new intervention was to get the resident up early to avoid her getting up on her own. P. Ex. 77, at 3, 4.

A Nurse's Notes entry for August 19, 2005, at 7:55 a.m., indicates that, on that day, Resident A left her stationery chair in the dining room, walked out, and then fell on her buttocks. A CNA was not close enough to prevent the fall. P. Ex. 77, at 5. There is no indication that the velcro alarm belt from her wheelchair was used on her stationery chair. The Post-Fall Assessment dated August 19, 2005, shows Resident A had a history of falls and that she had a loss of coordination. The form states that no interventions were in place to prevent her from falling. The new intervention was to monitor the resident more closely when she was using a stationery chair in the dining room. P. Ex. 77, at 6.

A Nurse's Notes entry for August 25, 2005, at 7:05 p.m., states that staff heard the bed alarm at 5:40 p.m. Resident A was observed in her doorway where she tripped on a blanket before staff could reach her. A note dated August 26, 2005, at 2:50 a.m., shows the resident was sleeping in bed with both padded side rails up, with a bed alarm and a motion sensor in place. P. Ex. 77, at 7, 8. A Falls Prevention Strategies form and a Post-Fall Assessment form, both dated August 25, 2005, confirm that a motion sensor was placed in the resident's room. P. Ex. 77, at 9-10.

I do not have Nurse's Notes that describe the fall on December 15, 2005. However, the Accident/Incident Committee Review form entry dated December 16, 2005, indicates that the fall was from bed on December 15, 2005, at 4:55 a.m., when Resident A attempted to get out of bed without assistance. P. Ex. 67, at 1; Tr. 376-77. There is no indication in the note as to whether the bed alarm sounded. The intervention listed is for one-on-one teaching to be done by CNAs. What was to be taught is not mentioned, and there is no indication that Resident A's demented state and difficulty communicating and understanding were considered. However, given all the evidence regarding Resident A's condition, teaching or reminding clearly was unlikely to be an effective intervention.

The Nurse's Notes related to the falls on July 10 and August 25, 2005 show that in both instances a bed alarm was in place and sounded. Although the notes show that the alarm did not prevent a fall in either case, the bed alarm effectively alerted staff in both instances that the resident was getting out of bed. A more prompt response by Petitioner's staff might have prevented the actual fall, particularly the August 25 incident, given the fact the resident had the chance to get to the door before she tripped on her blanket.

The bed alarm continued to be listed as an intervention in Resident A's care plan dated January 19, 2006. In the January 2006 care plan, Petitioner identified as a problem that Resident A had a potential for fall related injury. The goal stated was to ambulate safely with staff assistance and have no fall- related injury for 90 days. Eleven interventions were listed on the care plan when it was printed:[28] (1) two-person assist for ambulation and verbal cues as needed; (2) observe for any declines and scheduling of therapy screens as needed; (3) ensure that items are in their normal location in the room and not in anyone's way; (4) escort the resident to see her husband; (5) complete the fall assessment quarterly and as needed; (6) velcro seatbelt alarm when she was unattended in the wheelchair; (7) observe closely while using a stationery chair in the dining room and the alarm in the dining room was to be used; (8) take to the toilet on a schedule and as needed; (9) bed alarm; (10) awaken early to avoid her getting up by herself; and (11) a motion sensor in her room. Handwritten entries on the care plan show that the bed alarm was discontinued on February 1, 2006, based upon a telephone order from her physician, but this entry is dated April 18, 2006 — nine days after the April 9 fall.[29] Other handwritten entries indicate changes after the April 9, 2006 fall which is in issue. CMS Ex. 15, at 48-49; P. Ex. 59, at 10-11. A Physician's Progress Note dated February 1, 2006, signed by Dr. Ahler, includes diagnoses of acute bronchitis, probable early pneumonia, profound dementia, and early anoxia from respiratory failure. Dr. Ahler states his plan, but does not mention discontinuing her bed alarm. CMS Ex. 15, at 74.

Nurse's Notes admitted by Petitioner for the period December 16, 2005 through April 9, 2006 do not reflect any order to discontinue Resident A's bed alarm. P. Ex. 61. The notes do show that the resident's family visited on January 10, 2006, she became agitated at times, and when she was up in her wheelchair the velcro alarm belt was in place. When in bed, her padded side rails were up and the bed alarm was used. The next note, at 1:06 p.m. on January 14, 2006, shows Resident A had signs and symptoms of an upper respiratory infection, Dr. Ahler was contacted, and a new order was received. P. Ex. 61, at 3. The notes show that her symptoms worsened after January 14, 2006, and that she received much nursing attention. An entry at 3:00 a.m. on January 23, 2006 reflects that Resident A was fidgety, she was holding and caring for her "baby doll" that she believed was a real baby, and with which she repeatedly set off the "motion sensor" in the room and that increased her fidgeting. P. Ex. 61, at 9. There is no indication that there was

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[28] Petitioner provided me an earlier care plan dated October 20, 2005. The interventions listed on that care plan are the same as on the January 19 care plan, except that the two-person assist with ambulation was added on December 12, 2005. P. Ex. 58, at 8-9.

[29] The termination of the bed alarm is also noted on February 1, 2006 in the MAR, with no reference to a physician's order or a date indicating when the change was made. P. Ex. 75, at 5.

any discussion with Dr. Ahler, or that any order was given to discontinue the motion sensor. Contrary to the arguments of Petitioner, there is no indication in any of the Nurse's Notes that Resident A set off her bed alarm.[30]

Significant improvement in Resident A's upper respiratory infection is reflected by February 13 and 14, 2006. P. Ex. 61, at 3-19. The notes from February 16, 2006 show that Resident A was engaging in increased mobility, and propelling herself in her wheelchair in the hallways. P. Ex. 21, at 20. The note from 3:30 a.m. on March 2, 2006, shows that Resident A had increased strength, was able to reposition herself in bed between rounds, and ambulated short distances with assistance of staff. It was also noted on March 2 and 9, 2006 that fall prevention measures were in use at all times, but there is no indication what those measures were. P. Ex. 61, at 21. A note at 2:30 a.m. on March 22, 2006 states that padded side rails and a motion alarm were in use. P. Ex. 61, at 22. On April 2, 2006, at 2:00 p.m,. it was noted that Resident A was up in her wheelchair daily with the velcro alarm belt, she ambulated short distances with staff assistance, and she attended activities of choice. P. Ex. 61, at 23. A "Nursing Observation Summery" form dated April 3, 2006, indicates that Resident A could self-release from her velcro alarm belt. P. Ex. 62, at 4. Thus, staff was aware as early as March 2 that interventions were necessary to alert staff of any attempt by Resident A to rise and walk unassisted or without supervision, or to prevent her from attempting to do so.

Nevertheless, on April 9, 2006, Resident A was reported by staff to have fallen with a resulting hip fracture. A Nurse's Notes entry on April 9, 2006, at 7:05 p.m., reflects that another resident called out that a person was on the floor, staff found Resident A laying on her left side with noticeable facial grimacing, and when she was placed in a wheelchair, she complained of pain in her right hip or leg area. Dr. Ahler and the family were notified. Resident A was transported to the hospital where she was admitted and it was determined that she had a hip fracture. P. Ex. 61, at 23-24. A Nurse's Note entry dated April 9, 2006 at 7:20 p.m., signed by LPN Catlin, states that she found the resident lying on her left side in the West hall, the resident was assessed, placed in a wheelchair, she did some facial grimacing but she did the same prior to the fall with movement, she was toileted and when returned to her wheelchair began crying and grimacing. P. Ex. 65, at 1. A statement from Ken Denta, offered by Petitioner and admitted, states that before the fall Resident A had been taken to the toilet, washed, dressed in night clothes for bed, placed in bed with her side rails up, the sensor light was on and her room door was left

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[30] Mr. Carson testified that you do not want an alarm going off all the time with an "Alzheimer's type of client" because you do more harm than good. Tr. 451-52, 509-10. Mr. Carson never testified to any instances of Resident A's bed alarm sounding. He also never mentioned the one documented instance where Resident A set off the motion sensor with her baby doll.

open. Mr. Denta states that after awhile the resident was seen on the floor just outside the room, and staff went to assist. P. Ex. 65, at 2. LPN Sabados testified that no alarm was heard prior to Resident A being found on April 9. Tr. 368. Records from Jasper County Hospital dated April 9 and 10, 2006, show that Resident A had a comminuted intertrochanteric fracture of the right hip. An open reduction and internal fixation was done on April 10, 2006. P. Ex. 69; P. Ex. 70.

An Incident Follow-up and Recommendation Form dated April 10, 2006 indicates the resident was found in the middle of the hallway on April 9, 2006. P. Ex. 64, at 1. The form also indicates that Resident A's care plan and fall assessment were both updated on April 9, 2006, but the form does not indicate whether that was before or after the fall. P. Ex. 64, at 2. The handwritten changes to the January 2006 care plan, including the deletion of the bed alarm, are all dated April 18 and 19, 2006, more than a week afer the Incident Follow-up and Recommendation Form was signed by the administrator and DON. CMS Ex. 15, at 48-49; P. Ex. 59, at 10-11.

Petitioner's Incident/Accident Data Entry Questionnaire indicates that the accident occurred on April 9, 2006 at 7:05 p.m., and states that Resident A climbed out of bed and was found in the hallway on April 9, 2006. The Questionnaire identifies CNA Ken Denta as Resident A's assigned caregiver at the time of the accident. The Questionnaire states that side rails and other bed devices were in use at the time; that Resident A's care plan was updated following the incident; and that her last Fall Risk Assessment Score was 14.[31] The statement of CNA Denta, referred to above, is also summarized. P. Ex. 66. Mr.

Carson testified that during his interviews of staff he learned that they concluded Resident A climbed over the foot of the bed because the motion sensor was working, but did not sound. Tr. 457.

Petitioner argues several theories in its defense, all of which are without merit. Petitioner argues that Resident A was properly assessed as at high risk for falls, the care plan was updated, and interventions were appropriate. P. Brief at 17. Given the facts that Resident A had repeated falls when attempting to ambulate unassisted and without supervision

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[31] The Fall Risk Assessment completed by Petitioner, dated April 9, 2006, scored the resident as a 10. P. Ex. 52, at 2. Petitioner's Incident/Accident Data Entry Questionnaire entry that the last fall assessment scored Resident A at 14, is consistent with my conclusion that the assessment on April 9 was actually done after the fall, and possibly after the Questionnaire was completed. I note that the assessments for January 9, 2006 and April 9, 2006 are in adjacent columns, limiting the possibility that the form was simply misread by Petitioner's administrator or DON.

from July through December 2005, there is a significant question as to the adequacy of the interventions listed on care plans for the resident and/or whether the interventions listed were adequately implemented during that period. Other than the addition of the motion sensor, there was little change in the care plans.

However, the focus of the deficiency citation is the April 9, 2006 fall. In that regard, it is significant that a bed alarm was in use from July 2005 to February 1, 2006, and that alarm had effectively alerted staff to the resident's attempts to get out of bed and ambulate, although staff's reaction was too slow to actually prevent falls. Petitioner argues, contrary to what its records show, that the bed alarm was discontinued on February 6, 2006, because Resident A had not had any falls for two months. P. Brief at 17; P. Reply at 14. Petitioner's witness did not testify consistent with that theory. Rather, LPN Sabados testified that the note at P. Ex. 67 indicated that the resident had been discharged from the fall safety program and, although what the discharge meant is not explained in the document, LPN Sabados testified that the discharge meant simply that Resident A would no longer be discussed in fall safety program meetings. Tr. 375-76. Clearly some interventions continued after the February 6 note that Resident A was discharged from the fall safety program, including the use of padded bed rails, the motion sensor, toileting on a schedule, and others. Petitioner's records actually state the bed alarm was discontinued on February 1 due to physician orders. However, the credibility of the notation on Petitioner's records that the physician ordered that the bed alarm be discontinued on February 1, 2006 is suspect due to the fact it was apparently not entered on the care plan until April 18, long after the fall. P. Ex. 59, at 11. Petitioner has produced no other document that records a telephone order from a physician to discontinue the bed alarm on or about February 1, 2006.

I do not find credible or weighty Mr. Carson's opinion that eliminating the bed alarm as an intervention before the April 9, 2006 fall was acceptable. Tr. 449-52. His testimony about P. Ex. 67 is not consistent with that of LPN Sabados who actually made the entry indicating that Resident A was dismissed from the fall safety program. His testimony about what the care planning team did or did not do is not based upon any documentary evidence and, as he was not part of the team in February 2006, his only basis for knowledge would be some document or staff interviews to which he made no reference in his testimony. He was apparently incorrectly informed that Resident A's bed alarm had been sounding and creating agitation or other problems with the resident, when the evidence only shows that the motion sensor had sounded when the resident was moving her baby doll.[32] Mr. Carson also failed to account for the facts that bed side rails were in

[32] I note that Petitioner does not specifically allege in its brief that the bed alarm had sounded and increased the resident's agitation. Rather, Petitioner states that "one of

(continued...)

use at the time of the July 10, 2005, August 25, 2005, and December 15, 2005 falls, but the side rails were not effective to deter a fall. He failed to mention any consideration of the fact that the bed alarm was effective in sounding and alerting staff of the July 10 and August 25, 2005 falls. He pointed to no evidence that the motion sensor was ever effective for alerting staff of a fall by Resident A. Furthermore, Mr. Carson admitted that the motion sensor was positioned in such a manner that the resident's movements would not likely trigger the alarm if she crawled out over the end of her bed rather than over its side. Tr. 508. Resident A's improved physical condition beginning about March 2, 2006 made it possible for her to climb out of bed, including over the foot of the bed.

Petitioner has failed to produce any document from between about February 1 and April 9, 2006 that shows the effectiveness of the bed alarm as an intervention was assessed, or that a decision was made by the care planning team to discontinue the alarm. Furthermore, Petitioner has presented no evidence that the care planning team ever assessed the effectiveness of the bed alarm or any of the existing interventions about March 2, 2006 when staff was clearly aware that Resident A was recovered from her respiratory infection to the extent that she was active again. Petitioner has produced no evidence that shows any difference in Resident A's condition on or after March 2, 2006, and before the fall on April 9, 2006, that might have been a basis for a decision by the care planning team that the resident required less aggressive fall prevention interventions than she required on January 9, 2006, when her last MDS and care plan were completed. Petitioner has produced no evidence that the care planning team ever considered whether interventions such as a low bed with fall mats and without side rails, with or without alarms, might have been more effective between July 2005 and April 9, 2006 to prevent injuries from falls, and without the agitation that Petitioner associated with the use of alarms. Petitioner's expert, Mr. Carson, testified that fall mats and a low bed would lessen the impact of any fall. Tr. 507. However, there is no evidence Petitioner ever considered such obvious interventions.

Petitioner also alludes to, without arguing and while admitting that it is highly speculative, a theory that Resident A did not fall and break her hip, but suffered a spontaneous fracture and crawled out of bed to advise staff. P. Brief at 19-20; P. Reply at 13, n.9. Petitioner indicates that this theory arises from the testimony of Mr. Carson, Petitioner's expert witness. Tr. 458-60. I conclude that Petitioner's suggestion that the resident did not fall but developed a spontaneous fracture and crawled out of bed is not

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[32](...continued)
the alarms had been noted to be increasing the Resident's agitation." P. Brief at 17.

supported by competent evidence, as even Petitioner's expert admitted that it was entirely speculative. Tr. 460. Furthermore, Petitioner stipulated prior to hearing that Resident A "suffered several falls while under Petitioner's care, including a fall in which she suffered a fractured hip." Jt. Stip. ¶ 7.[33]

In *Clermont*, the Board held that for a facility to establish that they are in substantial compliance with 42 C.F.R. § 483.25(h)(2) the facility "must eliminate or reduce the *risk* of accident to the greatest degree practicable." (Emphasis in original). *Clermont Nursing and Convalescent Center,* DAB No. 1923, at 21. In this case, Petitioner did not take all practicable measures to reduce the foreseeable risk Resident A would suffer from another fall with injuries when she attempted to leave her bed and ambulate unassisted. Petitioner's staff stopped using the bed alarm and there is no evidence the care planning team ever evaluated eliminating that intervention. There is no evidence that the care planning team ever assessed the effectiveness of other interventions that might have been more appropriate for Resident A's condition, such as fall mats or a low bed.

I conclude that Petitioner did not do what was practicable or reasonable and violated 42 C.F.R. § 483.25(h)(2). Resident A suffered actual harm as a result.

4. Petitioner violated 42 C.F.R. § 483.75 (Tag F490).

The regulation at 42 C.F.R. § 483.75 addresses standards of administration, and provides that a facility must be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident. The regulation requires a facility's management to both assure that its staff identify and address resident needs and that staff follow established procedures and protocols.

The surveyors allege that this regulatory requirement was violated based upon the violations of 42 C.F.R. §§ 483.25, 483.25(c), and 483.25(h)(2) discussed above. CMS Ex. 5, at 25, 31-32; Jt. Stip. ¶ A(8). CMS argues that three residents suffered actual harm due to the three deficiencies already discussed, a sufficient basis alone for finding a Tag F490 deficiency. CMS also argues that the evidence shows that Petitioner's staff failed to comply with facility policy and procedures governing oxygen use, physician notification, and wound care and prevention, and that Petitioner failed to effectively implement those policies. CMS Brief at 28-29; CMS Reply at 22; CMS Exs. 23, 24, and 25. CMS also alleges that the system for monitoring Resident A for falls broke down, indicating a failure of administration. CMS Brief at 22; CMS Ex. 26.

[33] Petitioner has not sought leave to withdraw from this stipulation of fact.

Appellate panels of the Board have approved derivative deficiencies cited under 42 C.F.R. § 483.75 in prior cases. *See Cross Creek Health Care Center*, DAB No. 1665; *Asbury Center at Johnson City*, DAB No. 1815 (2002); and *Eastwood Convalescent Center*, DAB No. 2088 (2007).

Petitioner argues that even if it is found to have violated 42 C.F.R. §§ 483.25, 483.25(c), and 483.25(h)(2), CMS has failed to show a nexus between those violations and effective, efficient administration. P. Brief at 29; P. Reply at 16.

I have no difficulty finding the common sense connection or nexus between the deficiency findings I have addressed, and the allegation that those deficiencies establish that Petitioner was not being administered effectively and efficiently. Careful review of Petitioner's records related to the three deficiencies above revealed systemic failures to deliver quality care and/or to document care was delivered as planned or ordered, not singular errors by individual staff. The evidence is sufficient to raise the inference that Petitioner was not administered effectively and efficiently, and the evidence is unrebutted.

I conclude that Petitioner violated 42 C.F.R. § 483.75, and that violation contributed to the actual harm suffered by the three residents discussed above.

5. The evidence is not in equipoise and the burden of persuasion does not control the decision in this case.

In my Prehearing Order and during the opening of the hearing (Tr. 3-4), I advised the parties that I had determined that the burden of going forward with the evidence and the burden of persuasion would be as described by the Board in *Hillman* and its progeny. *See Hillman Rehabilitation Center*, DAB No. 1611, at 8, *aff'd*, *Hillman Rehabilitation Center v. U.S. Dept. of Health and Human Services*, No. 98-3789 (GEB) slip op. 25 (D.N.J. May 13, 1999); *Cross Creek Health Care Center*, DAB No. 1665; *Emerald Oaks*, DAB No. 1800; *Batavia Nursing and Convalescent Center*, DAB No. 1904 (2004); *Batavia Nursing and Convalescent Inn*, DAB No. 1911, *aff'd*, *Batavia Nursing & Convalescent Ctr. v. Thompson*, 143 Fed.Appx. 664 (6th Cir. 2005); *Emerald Oaks*, DAB No. 1800 (2001). Petitioner objects to bearing the burden of persuasion. Petitioner's Prehearing Brief at 23.

The United States Supreme Court has concluded that in cases subject to the federal Administrative Procedure Act (APA) the phrase "burden of proof" as used in section 7(c) of the APA (5 U.S.C. § 556(d)) means the burden of persuasion, which must be distinguished from the burden of production (also know as the burden of going forward with the evidence). *Department of Labor v. Maher Terminals, Inc.*, 512 U.S. 267, 272 (1994). The Court stated the burden of persuasion is "the notion that if the evidence is evenly balanced, the party that bears the burden of persuasion must lose." *Id*. The U.S.

Court of Appeals for the Seventh Circuit refused to address the rule for the allocation of the burden of proof adopted by the Board in *Hillman*, because in the case before the Seventh Circuit the evidence was not in equipoise and *Hillman* was not, by its own terms, operative; and, because the Board had not addressed the application of the rule in any comprehensive manner. *Fairfax Nursing Home, Inc. v. HHS*, 300 F.3d 835, 840, n.4, *cert. denied*., 537 U.S. 1111 (2003). In the case before me, as in *Fairfax*, the evidence is not evenly balanced or in equipoise; accordingly, it is not necessary to decide this case based upon which party bears the burden of persuasion or proof.

6. The CMP imposed in this case is reasonable.

If a facility is not in substantial compliance with program requirements, CMS has the authority to impose one or more of the enforcement remedies listed in 42 C.F.R. § 488.406, including imposing a CMP. CMS may impose a CMP for the number of days that the facility is not in compliance or for each instance that a facility is not in substantial compliance. 42 C.F.R. § 488.430(a). In this case, CMS chose to impose a per day CMP. CMS is authorized to impose a CMP from $50 per day to $3000 per day, as immediate jeopardy is not alleged or established. 42 C.F.R. § 488.438(a)(1)(ii). Pursuant to 42 C.F.R. § 488.438(e), because I have found there is a basis for imposition of a CMP, my authority on review of the reasonableness of the CMP is limited: (1) I may not set the penalty at or reduce it to zero; (2) I may not review the CMS or state decision to use a CMP as an enforcement remedy; and (3) I may only consider the factors specified at 42 C.F.R. § 488.438(f). The factors listed in 42 C.F.R. § 488.438(f) that I must consider in determining whether the amount of the CMP is reasonable are: (1) the facility's history of noncompliance, including repeated deficiencies; (2) the facility's financial condition; (3) the seriousness of the deficiencies as set forth at 42 C.F.R. § 488.404; and (4) the facility's degree of culpability. Petitioner objected in its prehearing brief that CMS should be required to show that it actually considered the factors listed in 42 C.F.R. §§ 488.438(f) and 488.404. Petitioner's Prehearing Brief at 23. Petitioner does not cite any authority in support of its argument. Certainly the regulations impose upon me no such requirement. The CMS consideration of the factors is not controlling in the ALJ hearing. Rather, I provide Petitioner a de novo review of the factors that includes any submissions of relevant evidence Petitioner chooses to submit for my consideration.

I conclude that there is no evidence of a history of noncompliance. Tr. 18. However, there is evidence, that during prior surveys in the same survey cycle, the surveyors made allegations of violations of 42 C.F.R. §§ 483.25(c) and 483.25(h)(2) similar to those at issue in the case before me. CMS Ex. 3. The allegations from the prior surveys and enforcement remedies based upon the deficiencies cited in those surveys were resolved without a hearing and without admission of fault. While I do not consider evidence of those prior surveys as evidence of a history of noncompliance, I do find evidence that Petitioner's administration was on notice of the surveyors' allegations from the prior

surveys, but failed to remedy the deficiencies in quality of care that are similar to those in the case before me. I conclude Petitioner was more clearly culpable given this prior notice than it might have been without such prior knowledge. The parties stipulated at hearing that Petitioner does not dispute it's ability to pay the proposed CMP. Tr. 19-20. Petitioner concedes that the CMP is relatively small. P. Brief at 29. All four of the deficiencies are serious failures on the part of Petitioner that resulted in actual harm to its residents. Petitioner failed in this case to deliver quality care to its residents.

I find reasonable the CMP proposed by CMS: $300 per day effective May 10, 2006 through May 22, 2006. Petitioner was found to be back in substantial compliance effective May 23, 2006. Petitioner's defense was that it was always in substantial compliance. Therefore, Petitioner has not argued that, if found out of compliance, it returned to substantial compliance before May 23, 2006. The total CMP is $3900. Jt. Stip ¶ A(12).

III. Conclusion

For the foregoing reasons, I conclude that Petitioner violated 42 C.F.R. §§ 483.25, 483.25(c), 483.25(h)(2), and 483.75. I further conclude that a CMP of $300 per day for the period of May 10 through May 22, 2006, a total CMP of $3900, is reasonable.

/s/
Keith W. Sickendick
Administrative Law Judge