Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Plott Nursing Home
(CCN: 05-5619),

Petitioner

v.

Centers for Medicare and Medicaid Services.

Docket Nos. C-09-189, C-09-357

Decision No. CR2326

Date: February 17, 2011

DECISION

Petitioner, Plott Nursing Home, was not in substantial compliance with program participation requirements from September 24, 2008 through December 15, 2008, due to violations of 42 C.F.R. §§ 483.25(c)[1] (Tag F314) and 483.25(d)(2) (Tag F315). There is a basis for the imposition of enforcement remedies. The following enforcement remedies are reasonable: a civil money penalty (CMP) of $500 per day from September 24 through December 3, 2008 and $100 per day from December 4 through 15, 2008, a total CMP of $36,700; and a denial of payments for new admissions (DPNA) from November 22, 2008 through December 15, 2008.

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

I. Background

Petitioner is located in Ontario, California, and participates in Medicare as a skilled nursing facility (SNF) and the state Medicaid program as a nursing facility (NF). On September 24, 2008, the California Department of Public Health (state agency) surveyed Petitioner and concluded that Petitioner was not in substantial compliance with program participation requirements. The Centers for Medicare and Medicaid Services (CMS) notified Petitioner by letter dated November 7, 2008, that it was imposing the following enforcement remedies: a $500 per day CMP effective September 24, 2008 and a DPNA effective November 22, 2008. The state agency completed a revisit survey on December 4, 2008, but Petitioner was not found to have returned to substantial compliance. CMS notified Petitioner by letter dated February 10, 2009, that Petitioner returned to substantial compliance with participation requirements on December 16, 2008 and that the CMP was reduced to $100 per day for the period December 4 through December 15, 2008. Joint Stipulation of Undisputed Facts.

Petitioner requested a hearing before an administrative law judge (ALJ) by letters dated January 2, 2009 and March 24, 2009, which were docketed as C-09-189 and C-09-357, respectively. The cases were assigned to me for hearing and decision. On April 13, 2009, I ordered that the cases be consolidated. On December 7 through 10, 2009, a hearing was convened in San Bernardino, California and a 1058-page transcript (Tr.) of the proceedings was prepared. CMS offered CMS exhibits (CMS Exs.) 1 through 64 and 66 through 73 that were admitted as evidence. Tr. at 31-32, 581-82. Petitioner offered Petitioner exhibits (P. Exs.) 1 through 53, and P. Exs. 1 through 40, page 3 of 41, and 42 through 53 were admitted as evidence. Tr. at 36-55, 819. CMS called the following witnesses: Lieutenant Commander (LCDR) Kelly Valente, Pharm.D., US Public Health Service; Surveyor Michelle Renee Buell, RN; Surveyor Charmaine DeBay, RN; Surveyor Eleanor Pruitt, RN; Surveyor Linda Walton, RN; Surveyor Janine Nichols, RN; Surveyor Deanna Wali, RN; and Surveyor Napoleon Imperio, RN. Petitioner called the following witnesses: Anthony Scarpelli, Petitioner's Administrator; Rasmy Nambela, RN, Petitioner's Director of Nursing (DON); Wendy Perez, LVN, Petitioner's Director of Staff Development; Carol Wagner, RN; John Randolph, MD; Thomas Woodbury, DO, Petitioner's Medical Director; Elizabeth Sterling, Pharm.D., Petitioner's consultant pharmacist; and William Simonson, Pharm.D., FASCP. The parties filed post-hearing briefs (CMS Br. and P. Br., respectively) and post-hearing reply briefs (CMS Reply and P. Reply, respectively).

II. Discussion

A. Issues

The issues in this case are:

Whether there is a basis for the imposition of an enforcement remedy; and

Whether the remedies proposed are reasonable.

B. Applicable Law

The statutory and regulatory requirements for participation by a long-term care facility are found at sections 1819 (SNF) and 1919 (NF) of the Act and at 42 C.F.R. Part 483. Section 1819(h)(2) of the Act vests the Secretary of Health and Human Services (Secretary) with authority to impose enforcement remedies against a SNF for failure to comply substantially with the federal participation requirements established by sections 1819(b), (c), and (d) of the Act.[2] Pursuant to 1819(h)(2)(C), the Secretary may continue Medicare payments to a SNF not longer than six months after the date the facility is first found not in compliance with participation requirements. Pursuant to 1819(h)(2)(D), if a SNF does not return to compliance with participation requirements within three months, the Secretary must deny payments for all individuals admitted to the facility after that date – commonly referred to as the mandatory or statutory DPNA. In addition to the authority to terminate a noncompliant SNF's participation in Medicare, the Act grants the Secretary authority to impose other enforcement remedies, including a discretionary DPNA, CMPs, appointment of temporary management, and other remedies such as a directed plan of correction. Act § 1819(h)(2)(B).

The Secretary has delegated to CMS and the states the authority to impose remedies against a long-term care facility that is not complying substantially with federal participation requirements. "*Substantial compliance* means a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm." 42 C.F.R. § 488.301 (emphasis in original). A deficiency is a violation of a participation requirement established by sections 1819(b), (c), and (d) of the Act or the Secretary's regulations at 42 C.F.R. Part 483, subpart B. State survey agencies survey facilities that participate in Medicare on behalf of CMS to determine whether the facilities are complying with federal participation requirements. 42 C.F.R. §§ 488.10-.28, 488.300-.335. The regulations specify the enforcement remedies that CMS may impose if a facility is not in substantial compliance with Medicare requirements. 42 C.F.R. § 488.406.

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

The regulations specify that a CMP that is imposed against a facility on a per day basis will fall into one of two ranges of penalties. 42 C.F.R. §§ 488.408, 488.438. The upper range of a CMP, $3,050 per day to $10,000 per day, is reserved for deficiencies that pose immediate jeopardy to a facility's residents and, in some circumstances, for repeated deficiencies. 42 C.F.R. § 488.438(a)(1)(i), (d)(2). "*Immediate jeopardy* means a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301 (emphasis in original). The lower range of a CMP, $50 per day to $3,000 per day, is reserved for deficiencies that do not constitute immediate jeopardy but either cause actual harm to residents, or cause no actual harm but have the potential for causing more than minimal harm. 42 C.F.R. § 488.438(a)(1)(ii).

The Act and regulations make a hearing before an ALJ available to a long-term care facility against which CMS has determined to impose an enforcement remedy. Act §§ 1128A(c)(2), 1866(h); 42 C.F.R. §§ 488.408(g), 498.3(b)(13). The hearing before an ALJ is a *de novo* proceeding. *The Residence at Salem Woods*, DAB No. 2052 (2006); *Cal Turner Extended Care*, DAB No. 2030 (2006); *Beechwood Sanitarium*, DAB No. 1906 (2004); *Emerald Oaks*, DAB No. 1800 at 11 (2001); *Anesthesiologists Affiliated*, DAB CR65 (1990), *aff'd*, 941 F.2d 678 (8th Cir. 1991). A facility has a right to appeal a "certification of noncompliance leading to an enforcement remedy." 42 C.F.R. §§ 488.408(g)(1), 488.330(e), 498.3. However, the choice of remedies or the factors CMS considered when choosing remedies are not subject to review. 42 C.F.R. § 488.408(g)(2). A facility may only challenge the scope and severity level of noncompliance CMS determined if a successful challenge would affect the range of the CMP that may be imposed or impact the facility's authority to conduct a nurse aide training and competency evaluation program. 42 C.F.R. § 498.3(b)(14), (d)(10)(i). The CMS determination as to the level of noncompliance, including the finding of immediate jeopardy, "must be upheld unless it is clearly erroneous." 42 C.F.R. § 498.60(c)(2). *Woodstock Care Ctr.*, DAB No. 1726 at 9, 38 (2000), *aff'd*, 363 F.3d 583 (6th Cir. 2003). The Departmental Appeals Board (the Board) has long held that the net effect of the regulations is that a provider has no right to challenge the scope and severity level assigned to a noncompliance finding, except in the situation where that finding was the basis for an immediate jeopardy determination. *See, e.g.*, *Ridge Terrace*, DAB No. 1834 (2002); *Koester Pavilion*, DAB No. 1750 (2000). Review of a CMP is subject to 42 C.F.R. § 488.438(e).

The standard of proof or quantum of evidence required is a preponderance of the evidence. CMS has the burden of coming forward with the evidence and making a prima facie showing of a basis for imposition of an enforcement remedy. Petitioner bears the burden of persuasion to show by a preponderance of the evidence that it was in substantial compliance with participation requirements or any affirmative defense. *Batavia Nursing & Convalescent Inn*, DAB No. 1911 (2004); *Batavia Nursing*

& Convalescent Ctr., DAB No. 1904 (2004), *aff'd, Batavia Nursing & Convalescent Ctr. v. Thompson*, 129 F. App'x 181 (6th Cir. 2005); *Emerald Oaks*, DAB No. 1800; *Cross Creek Health Care Ctr.*, DAB No. 1665 (1998); *see Hillman Rehab. Ctr.*, DAB No. 1611 (1997), No. 98-3789, 1999 WL 34813783 (D.N.J. May 13, 1999).

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

My conclusions of law are set forth in bold text followed by my findings of fact and analysis. Based upon the surveys that ended September 24, 2008 and December 4, 2008, CMS alleges that Petitioner was not in substantial compliance with program participation requirements from September 24, 2008 through December 15, 2008, based upon the following regulatory violations: 42 C.F.R. §§ 483.10(b)(11) (Tag F157,[3] scope and severity (s/s) [4] D); 483.13(a) (Tag F 221, s/s D); 483.15(g)(1) (Tag F250, s/s D); 483.15(h)(2) (F253, s/s E); 483.20(g)-(j) (Tag F278, s/s D); 483.20(d), (k)(1) (Tag F279,

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[3] This is a "Tag" designation as used in CMS Publication 100-07, State Operations Manual (SOM), Appendix PP – Guidance to Surveyors for Long Term Care Facilities (http://www.cms.hhs.gov/Manuals/IOM/list.asp). The "Tag" refers to the specific regulatory provision allegedly violated and CMS's related guidance to surveyors. Although the SOM does not have the force and effect of law, the provisions of the Act and regulations interpreted clearly do have such force and effect. *Northwest Tissue Ctr. v. Shalala*, 1 F.3d 522 (7th Cir. 1993); *State of Ind. by Ind. Dep't of Pub. Welfare v. Sullivan*, 934 F.2d 853 (7th Cir. 1991). Thus, while the Secretary may not seek to enforce the provisions of the SOM, she may seek to enforce the provisions of the Act or regulations as interpreted by the SOM.

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

s/s E); 483.25 (F309, s/s D); 483.25(a)(1) (F311, s/s D); 483.25(c) (Tag F314, s/s D); 483.25(d) (Tag F315, s/s H); 483.25(e)(2) (F318, s/s D); 483.25(h) (Tag F323, s/s D); 483.25(i) (Tag F325, s/s D); 483.25(l) (F329, s/s G); 483.35(d)(3) (Tag F365, s/s D); 483.35(e) (Tag F367, s/s D); 483.35(i) (Tag F371, s/s D); 483.40(c)(3)-(4) (Tag F388, s/s D); 483.60(c) (Tag F428, s/s D); 483.60(b), (d), (e) (Tag F431, s/s E); 483.65(a) (Tag F441, s/s F); 483.70(f) (Tag F463, s/s D); 483.70(h) (Tag F465, s/s E); 483.75(f) (Tag F498, s/s F); 483.75(i) (Tag F501, s/s F); 483.75(j)(3)(ii) (Tag F505, s/s D); and 483.75(o)(1) (Tag F520, s/s F).[5] The December 4, 2008 survey cited only a violation of 42 C.F.R. § 483.25(d) (Tag F315) as posing a risk for more than minimal harm and only that deficiency citation may be the basis for an enforcement remedy (42 C.F.R. §§ 488.301, 488.402(b), 498.3(b)(13)) and is subject to my review (42 C.F.R. § 488.408(g)).

I conclude that Petitioner violated 42 C.F.R. § 483.25(c) (Tag F314) and that the violation resulted in actual harm to Petitioner's residents, as alleged by the September 24, 2008 survey. I also conclude that Petitioner violated 42 C.F.R. § 483.25(d) (F315) as alleged by the surveys completed September 24 and December 4, 2008. The deficiencies under Tags F314 and F315 establish that Petitioner was not in substantial compliance during the period September 24 through December 15, 2008. The deficiencies also provide a sufficient basis for the enforcement remedies that CMS proposes. Thus, I conclude it is not necessary to address all the other alleged deficiencies from the September 2008 survey. The enforcement remedies proposed by CMS are reasonable.

I have carefully considered all the evidence, including the documents and the testimony at hearing, and the arguments of both parties, though not all may be specifically discussed in this decision. I discuss in this decision the credible evidence given the greatest weight in my decision-making.[6] The fact that evidence is not specifically discussed should not be considered sufficient to rebut the presumption that I considered all the evidence and assigned such weight or probative value to the credible evidence that I determined appropriate within my discretion as an ALJ. There is no requirement for me to discuss the weight given every piece of evidence considered in this case, nor would it be consistent with notions of judicial economy to do so.

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[5] The parties stipulated at hearing that CMS was not proceeding upon certain deficiencies cited by the September 24, 2008 survey. Tr. at 647-50.

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

1. Petitioner violated 42 C.F.R. § 483.25(c) (Tag F314), as determined by the survey completed on September 24, 2008, and that violation caused actual harm.

The quality of care regulation includes the requirement that a facility ensure that a resident who enters the facility without a pressure sore does not develop one unless clinically unavoidable. The regulations also require that a resident entering with a pressure sore receives care and services necessary to: promote healing; prevent infection; and prevent other sores from developing. 42 C.F.R. § 483.25(c).

The application of the regulation has been extensively discussed in decisions of various appellate panels of the Board, including *Koester Pavilion*, DAB No. 1750 and *Cross Creek Health Care Ctr.*, DAB No. 1665. The Board has recognized that the pressure sore regulation has 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. Regarding prevention and treatment, 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." *See 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). If CMS establishes a *prima facie* case, the facility bears the burden of showing that the development or deterioration of a pressure sore was clinically unavoidable.

An appellate panel of the Board in *Clermont Nursing & Convalescent Ctr.*, DAB No. 1923, at 9-10 (2004), *aff'd, Clermont Nursing & Convalescent Ctr. v. Leavitt*, 142 F. App'x 900 (6th Cir. 2005), provided the following analysis:

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

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

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

The SOM defines avoidable and unavoidable pressure ulcers as:

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

> and evaluated the impact of the interventions; and revised the approaches as appropriate.

SOM, app. PP, Tag F314.

The surveyors allege in the Statement of Deficiencies (SOD) for the September 24, 2008 survey that Petitioner violated 42 C.F.R. § 483.25(c) (Tag F314) because Petitioner failed to provide necessary treatment and services to prevent healed pressure sores from reopening and to prevent the development of new sores in the case of Resident 6. CMS Ex. 1, at 49.

a. Facts

Resident 6 had a care plan for skin breakdown dated June 2007, with the following interventions: check skin daily during care; turn and reposition every two hours; provide good perineal care with each episode of incontinence; keep skin clean and dry as possible; the resident should be up in her geriatric chair each day; and the resident was to have a pressure relief mattress. The care plan was updated on November 21, 2007, without additional interventions being added. P. Ex. 11, at 256. A continuation sheet for the care plan for skin breakdown indicates that Resident 6 slid down in her bed, was non-compliant with turning and repositioning, and refused to be turned. The interventions added on March 18, 2008, were to assist the resident with positioning in bed, monitor her for turning and repositioning, and assess her skin during activities of daily living. P. Ex. 11, at 258.

Wound Care Evaluation Records from December 26, 2007 through February 29, 2008, show that Resident 6 developed an ulcer over her sacrum[7] that was closed as of February 29. P. Ex. 11, at 283-85, 298, 307-08. A Wound Care Evaluation Record dated March 13, 2008, shows that a coccyx wound had reopened and that it closed by March 20, 2008. P. Ex. 11, at 309. Wound Care Evaluation Records from May 23, 2008 through May 30, 2008, show that Resident 6 had an open ulcer on her coccyx. P. Ex. 11, at 301-302.

A physician's order dated June 5, 2008, states that Resident 6, who was 81 years old, was readmitted to Petitioner's facility with diagnoses of MRSA in her scalp wound; left ankle sprain, aphasia, cognitive disorder secondary to a craniotomy, hypertension, and

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[7] Petitioner's records refer to ulcers over both the sacrum and the coccyx. Because the sacrum and coccyx are adjacent, I recognize the possibility that the terms are being used interchangeably. Whether Resident 6 had an ulcer over the coccyx or the sacrum or both does not affect my decision.

allergies. P. Ex. 11, at 222-25. An admission Minimum Data Set (MDS) for Resident 6 with an assessment reference date of June 18, 2008, shows she was readmitted to Petitioner's facility on June 5, 2008 from an acute care hospital. The MDS shows she was previously a resident of Petitioner's facility. Her diagnoses listed included hypertension, arthritis, osteoporosis, Alzheimer's disease, dementia other than due to Alzheimer's, depression and anxiety, anemia, cancer, antibiotic resistant infection, septicemia, a history of urinary tract infection in the last 30 days, a history of a malignant neoplasm of the brain, dysphagia, malnutrition, gastrointestinal distress, and expressive aphasia. She was assessed as severely impaired for daily decision-making; she rarely understood others but could sometimes be understood; she was totally dependent upon staff for activities of daily living including bed mobility; she was incontinent of bowel and bladder; she had one Stage 2 pressure ulcer; she was noted to have a pressure relieving device for both bed and chair, to be on a turning/repositioning program, to have nutrition or hydration interventions, to be receiving ulcer care and surgical wound care, to receive the application of dressings and ointments and medication, and other preventive or protective skin care. P. Ex. 11, at 269-75.

Wound Care Evaluation Records from June 5 to June 18, 2008, show that Resident 6 had a pressure ulcer over her coccyx that resolved. P. Ex. 11, at 288-89. Wound Care Evaluation Records show that Resident 6 developed a pressure ulcer over her coccyx on June 26, 2008 that resolved by August 21, 2008. P. Ex. 11, at 290-93, 297. A Wound Care Assessment dated July 31, 2008, reflects a healing lower sacrum pressure ulcer, 0.5 by 0.3 centimeters, with no measurable depth, with a scab, and no exudate. Orders were to discontinue hydrocolloid dressing, apply skin prep to wound and surrounding tissue, keep wound open to air, reposition per facility protocol, and a revisit in one week. P. Ex. 11, at 230-31. A Wound Care Assessment dated August 7, 2008, indicates that the lower sacrum pressure ulcer measured 1.0 by 0.3 centimeters with a scab and no exudate, the wound was improving and the increased size reflected the inclusion in the measurement of healing skin that was around the wound. Orders were to clean the wound daily with normal saline, apply skin preparation to the wound and surrounding skin, repositioning per facility policy, and **continue use of low air loss mattress** (the first reference to such a mattress in the evidence before me). P. Ex. 11, at 234-35. A Wound Care Assessment dated August 14, 2008, shows a new healing pressure sore, 1.5 by 0.5 centimeters with no measurable depth, no exudate, with a note that the previous sacral wound had resolved with only very superficial excoriation remaining. Orders were to continue repositioning per facility protocol, **continue use of low air loss mattress**, clean daily with normal saline, apply skin preparation to sacral area, and leave the sacral area open to air. P. Ex. 11, at 232-33. A wound care assessment dated August 21, 2008, shows that all sacral wounds were resolved. P. Ex. 11, at 236-37.

Wound Care Evaluation records reflect that on August 27, 2008, the coccyx wound was reopened. The ulcer was reflected on Wound Care Evaluation records through September 22, 2008. P. Ex. 11, at 295-96. The presence of this ulcer and the

development of the new ulcer on the resident's left lower buttock triggered the significant change MDS of September 18, 2008.

Resident 6's significant change MDS with an assessment reference date of September 18, 2008, shows that she was assessed as severely impaired for daily decision-making; she rarely understood others but could sometimes be understood; she was totally dependent upon staff for activities of daily living including bed mobility; and she was incontinent of bowel and bladder; she had two Stage 2 pressure ulcers; she was noted to have a pressure relieving device for both bed and chair, to be on a turning/repositioning program, to have nutrition or hydration interventions, to be receiving ulcer care and surgical wound care, to receive the application of dressings and ointments and medication, and other preventive or protective skin care. P. Ex. 11, at 260-64. A "Global RAP Narrative" dated September 18, 2008, indicates that the significant change MDS was done because Resident 6 developed an excoriation to the left lower buttock. The Narrative also indicates that Resident 6 continued to receive treatment for her coccyx wound, with a weekly wound consult; and that she was at risk for further skin breakdown due to her deficits and diagnoses. The Narrative lists the following interventions: treatment of the ulcers as ordered, daily monitoring of the skin during activities of daily living, nutritional supplement, turning and repositioning every two hours, and perineal care after each episode of incontinence. P. Ex. 11, at 279-80.

Resident 6's care plan dated June 18, 2008, with updated interventions in June and July 2008, show that she was assessed as at risk for further skin breakdown due to decreased mobility and self-care deficits, with an open area on her coccyx on admission and MRSA in her craniotomy wound. The goal was to have no further skin breakdown. The care planned interventions were to: monitor skin everyday during activities of daily living; assist with turning and repositioning; provide perineal care with every incontinence episode; she was to wear mittens to prevent her from picking her head wound; she was to be given a supplement with every meal; she was to have treatment to the coccyx as ordered. P. Ex. 11, at 245. A continuation sheet for the care plan contains additional interventions dated July 23, 2008, related to cleaning the coccyx wound and the use of Tegasorb dressings to be changed every three days for three weeks. The intervention of applying a skin preparation wipe to the coccyx as a protective measure was added on July 31, 2008. Use of a low air loss mattress was not added as an intervention until September 24, 2008. Carol Wagner RN, a special project person for Petitioner testified that a pressure relief mattress was added as an intervention on June 9, 2008, according to a "late entry" added to the care plan on October 4, 2008. Tr. at 819, 853. P. Ex. 11, at 247. Another continuation sheet includes an intervention, dated August 5, 2008, to continue treatment to the coccyx including keeping off pressure and report any changes to the physician. An intervention dated September 18, 2008, requires turning and repositioning, perineal care, a supplement with every meal, and treatment to the left buttock. P. Ex. 11, at 249.

b. Analysis

The gist of the CMS case and the basis for the deficiency citation is that Petitioner did not do all that was necessary for Resident 6 to prevent the development of new pressure ulcers.[8] The fact that Resident 6 developed multiple pressure ulcers while under Petitioner's care is undisputed.

The evidence shows that Resident 6 had a care plan from June 2007 that required: skin checks daily during care; turning and repositioning every two hours; cleaning after each episode of incontinence; maintaining her skin clean and dry; that she be up in her geriatric chair for some time each day; and that she have a pressure relief mattress. P. Ex. 11, at 256. Despite her care plan, Resident 6 developed an open pressure ulcer on her sacrum on December 26, 2007 that was reported to be closed on about February 29, 2008.[9] P. Ex. 11, at 283-85, 298, 307-08. Petitioner has presented no evidence that the care planning team evaluated the effectiveness of the interventions from the June 2007 care plan or that any new interventions were proposed and implemented based upon the development of the new ulcer on about December 26, 2007. The development of the new ulcer should have alerted the care planning team that existing interventions were inadequate or that new interventions were required. The development of the new ulcer triggers the inference that Petitioner was not doing all that was necessary.

Either the sacral ulcer reopened or a new ulcer developed over Resident 6's coccyx on about March 13, 2008. P. Ex. 11, at 309. The evidence shows that Resident 6's care plan was revised on March 18, 2008 to address her sliding down in her bed and noncompliance with turning and repositioning. The interventions added on March 18, 2008, were to assist the resident with positioning in bed, monitoring her for turning and repositioning, and assessing her skin during activities of daily living. P. Ex. 11, at 258. The coccyx or sacral ulcer was reported to have closed as of March 20, 2008. P. Ex. 11, at 309. Petitioner presented no evidence to explain why issues related to position in the bed and noncompliance were not addressed by the care planning team prior to the development of an ulcer on March 13, 2008. The evidence indicates that the resident's

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[8] CMS refers to the reopening of a pressure ulcer on the coccyx. Based upon my review of the evidence, it is not possible or necessary to distinguish between the reopening of a mostly healed pressure ulcer and the development of a new ulcer in proximity to the prior pressure ulcer.

[9] Petitioner's records do not indicate the "stage" for the various ulcers reported. However, the descriptions in the cited clinical records support an inference that the ulcers were all Stage 2 as described by the SOM, app. PP, Tag F314.

noncompliance and sliding in bed existed prior to the development of the ulcer. Because the resident was known to be at risk for skin breakdown, Petitioner's failure to care plan to address sliding in bed and noncompliance with turning and repositioning triggers the inference that Petitioner was not doing all that was necessary.

On about May 23, 2008, Resident 6 developed another pressure ulcer over her coccyx. P. Ex. 11, at 301. The ulcer continued to be reported on May 30, 2008. P. Ex. 11, at 301-302. The evidence does not show that the care planning team evaluated the effectiveness of the interventions from the June 2007 care plan as updated through March 18, 2008, or that any new interventions were proposed and implemented based on the development of the new ulcer on about May 23, 2008. The development of the new ulcer should have alerted the care planning team that existing interventions were inadequate or that new interventions were required. The development of the new ulcer triggers the inference that Petitioner was not doing all that was necessary.

The evidence shows that Resident 6 went to an acute care hospital sometime between May 30 and June 5, 2008. On June 5, 2008, she was readmitted to Petitioner's facility. On June 5, 2008, she was reported to have an ulcer over her coccyx, whether or not this was the same ulcer reported on May 30, 2008 is not clear, but I infer it is. Petitioner's records show that the ulcer was closed as of June 18, 2008. P. Ex. 11, at 288-89. The evidence does not show that the care plan was updated prior to June 18, 2008, while the ulcer was opened. However, a new care plan was developed following completion of the admission MDS with the reference date of June 18, 2008.

The June 18, 2008 care plan required that Resident 6's: skin be monitored everyday; that she be turned and repositioned, but the frequency is not indicated; that she be cleaned after every episode of incontinence; that she receive a supplement with every meal; and that she have treatment of her coccyx as ordered. P. Ex. 11, at 245. A pressure relief mattress was added as an intervention on June 9, 2008, although it was not documented until October 4, 2008, after the survey. P. Ex. 11, at 247; Tr. at 853. Petitioner argues that a pressure relief mattress was a standard intervention for residents subject to skin breakdown. P. Br. at 19. Petitioner does not specify in its brief when Resident 6 was placed on a pressure relief mattress. However, if Petitioner's position is that Resident 6 was on a pressure relief mattress prior to June 9, 2008, surely staff who updated the care plan with the late entry on October 4, 2008, would have indicated a date earlier than June 9, 2008. Nurse Wagner testified only that a pressure relieving mattress was in use at the time of the survey. Tr. at 819. Petitioner does not present credible evidence as to why the pressure relief mattress was not actually listed on Resident 6's care plan until October 2008, after the survey and long after June 2007, the first evidence in the clinical record of a care plan for skin breakdown. Petitioner also does not explain why a nutritional supplement was not added as an intervention until June 2008.

The evidence shows that on or about July 23 or 24, 2008, Resident 6 developed a new pressure ulcer over her lower sacrum that was evaluated by the physician on July 31, 2008. P. Ex. 11, at 230-31. Interventions added on July 23, 2008, related to cleaning the coccyx wound and the use of Tegasorb dressings to be changed every three days for three weeks. The intervention of applying a skin preparation wipe to the coccyx as a protective measure was added on July 31, 2008. An intervention was added, dated August 5, 2008, to continue treatment to the coccyx, including keeping off pressure, and report any changes to the physician. P. Ex. 11, at 249. Wound assessments were done on August 7 and 14, 2008, and orders included the continued use of a "low air loss mattress." P. Ex. 11, at 232-35. Resident 6's care plan at the time did not list either a "low air loss mattress" or a "pressure relief mattress." Petitioner presented evidence that it used a Panacea® Ultimate 3000 mattress for Resident 6, which according to manufacture's literature is not an air mattress. P. Ex. 42; Tr. at 819. According to the care plan and the testimony of Petitioner's witness, RN Wagner, the low air loss mattress, first ordered August 7, 2008, was not actually implemented by Petitioner until September 24, 2008. Tr. at 853; P. Ex. 11, at 247. The wound was reported to be resolved on August 21, 2008. P. Ex. 11, at 236-37. Resident 6's new ulcer on her left buttock triggered the addition of interventions to the care plan on September 18, 2008, including turning and repositioning, perineal care, a supplement with every meal, and treatment to the left buttock. P. Ex. 11, at 249. An intervention added to the care plan dated September 24, 2008, specified the use of the low air loss mattress (Tr. at 853; P. Ex. 11, at 247) that had been ordered on August 7, 2008 and again on August 14, 2008. P. Ex. 11, at 232-35. The next entry on the care plan is the October 4, 2008 entry that indicates it is a late entry and that a pressure relief mattress was to be implemented on June 9, 2008.

I conclude that there is a *prima facie* showing of a violation of 42 C.F.R. § 483.25(c) because Petitioner did not do all that was necessary to prevent Resident 6 from developing new pressure sores. The evidence does not show that the effectiveness of interventions was assessed or that new interventions were implemented when Resident 6 develop new or reopened ulcers in December 2007, May 2008, or late June 2008. Furthermore, the evidence shows that Petitioner failed to implement the low air loss mattress in August 2008, when it was ordered. I conclude that there is no merit to Petitioner's argument that Resident 6's pressure ulcers were unavoidable. P. Br. at 18-20; P. Reply at 15-16. The evidence shows that Resident 6 had multiple pressure sores that healed, which is good evidence that the development of new pressure sores was avoidable. RN Wagner agreed with counsel for CMS that the fact a resident has ulcers that heal is an indication the resident has the physiological resources necessary to heal and, thus, prevent ulcers. Tr. at 853-54. Furthermore, Petitioner added new interventions over time that led to the resolution of each ulcer, which shows that the addition of proper interventions that are properly implement, would be effective for the healing and prevention of ulcers. RN Wagner characterized the interventions implemented by Petitioner to address skin breakdowns to be "aggressive interventions." Tr. at 822. However, RN Wagner did not similarly characterize Petitioner's interventions to prevent

the development of new ulcers or the reopening of old ulcers. Petitioner offers no explanation for why the evidence does not show it implemented the pressure relief mattress, nutritional supplement, and other interventions that ultimately proved effective, when Resident 6 was first assessed as at risk for pressure ulcers in June 2007.

Petitioner argues that Resident 6 was not a risk for any harm due to Petitioner's treatment of her. To the contrary, Resident 6 developed open sores on her coccyx or sacrum which I conclude is actual harm with or without specific indication that the resident suffered pain or discomfort to any particular degree.[10]

Accordingly, I conclude that Petitioner violated 42 C.F.R. § 483.25(c) based upon the example of Resident 6, and that the resident suffered actual harm as a result.

2. Petitioner violated 42 C.F.R. § 483.25(d)(2) (Tag F315) as alleged by the survey completed on September 24, 2008, and that violation resulted in actual harm.

3. Petitioner violated 42 C.F.R. § 483.25(d)(2) (Tag F315) as alleged by the survey completed on December 4, 2008, and that violation posed the risk for more than minimal harm.

The quality of care regulation requires that, based up the comprehensive assessment of a resident, a facility must deliver necessary care and services to ensure that:

> (1) A resident who enters the facility without an indwelling catheter is not catheterized unless the resident's clinical condition demonstrates that catheterization was necessary; and
> (2) A resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract

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[10] The surveyors cited this deficiency at a scope and severity of D (CMS Ex. 1, at 49), which means no actual harm with potential for more than minimal harm but not immediate jeopardy. I need only find a potential for more than minimal harm to conclude that there is a deficiency that provides a basis for imposition of an enforcement remedy. However, for purposes of assessing the reasonableness of the remedy it is necessary to consider the seriousness of the deficiency. A deficiency that causes actual harm is generally considered to be more serious than one that does not. In this case, the surveyor's conclusion that there was no actual harm is clearly and plainly in error as a matter of fact. The evidence shows open ulcers and they amount to actual harm because any open wound has associated pain, risk for infection, and other complications.

> infections and to restore as much normal bladder function as possible.

42 C.F.R. § 483.25(d).

The surveyors allege in the SOD for the September 24, 2008 survey, that Petitioner violated the regulation for the following reasons:

> Petitioner failed to ensure that Residents 5, 6, and 27, who were incontinent, received treatment and services necessary to prevent urinary tract infections (UTIs); and
>
> Petitioner failed to ensure that Resident 10 did not continue to have a urinary catheter after the condition that required the catheter resolved.

The surveyors also alleged that nurse aides were unable to demonstrate competency in skills and techniques related to catheter and perineal care. The surveyors allege that all four residents suffered actual harm in the form of UTIs. CMS Ex. 1, at 55-56. I conclude that the example cited by the surveyors related to Resident 5 establishes a violation of 42 C.F.R. § 483.25(d)(2). Thus, it is not necessary to discuss the examples cited by the September 2008 survey related to Residents 6, 10, and 27.

The surveyors allege in the SOD for the survey completed on December 4, 2008, that Petitioner violated the regulation because Petitioner failed to ensure that Resident 5's catheter tubing was maintained in the proper position. The surveyors allege that the violation posed a risk for more than minimal harm. I agree that there was a deficiency that posed a risk for more than minimal harm.

a. Resident 5 Facts

Resident 5 was 79 at the time of the survey. P. Ex. 12, at 8. She had an indwelling Foley catheter. CMS Ex. 13, at 25, 30, 44; P. Ex. 12, at 10. The following diagnoses or history were considered during her July 30, 2008, care plan conference: gastroesophageal reflux disease (GERD), diabetes mellitus (DM), hypertension, history of urosepsis, history of calculus of the kidney, spinal stenosis, muscle spasms, congestive heart failure, hyperlipidemia, hypothyroidism, Parkinson's Disease, depression, osteoarthritis, peripheral neuropathy, urinary retention, seasonal allergies, anemia, insomnia, and complications of the eye due to the DM. P. Ex. 12, at 13. The clinical record shows that Resident 5 had laboratory testing to detect UTIs and that antibiotics were ordered as treatment on December 6 and 21, 2007; March 4 and 21, 2008; June 17 and 20, 2008; July 3, 2008; and August 28, 2008. CMS Ex. 13, at 33, 35-37, 39, 41, 46-47, 49-53, 55-56, 59-60, 62-66, 69-71, 73; P. Ex. 12, at 32, 34-37, 47-49, 53-55, 63-65, 70-71, 87-92, 94, 96, 99-109. Petitioner's clinical records include short-term care plans for each UTI.

Each short-term care plan includes the following interventions: administer the particular antibiotic prescribed, encourage increased fluids, monitor for adverse signs and symptoms (some specify to notify the physician if any observed), and provide good perineal care and/or keep the resident clean and dry. P. Ex. 12, at 101-09. Petitioner also offered evidence of two long-term care plans, one related to a problem of a staghorn calculus and the other a risk for infection due to Foley catheter use and a history of urine retention. P. Ex. 12, at 2, 5. An Operative Report shows that on January 16, 2007, Resident 5 had two renal stones or staghorn calculi removed, with no residual stones observed. P. Ex. 12, at 20-22. Petitioner's care plan dated January 20, 2007, identified Resident 5 as at risk for increased pain due to the staghorn calculi and their removal as well as urosepsis, among other things. The care planned interventions dated January 20, 2007, required the administration of various medications as ordered; comfort measures; repositioning in bed, monitoring pain level, and notifying the physician if the interventions were not effective. On October 10, 2007, a new intervention to administer Actonel as ordered was added. On September 5, 2008, the intervention of giving Tylenol as ordered was added. P. Ex. 12, at 2. The care plan for the infection risk due to the Foley catheter and history of retention of urine is dated January 2007, and includes the following interventions: monitor for signs and symptoms of infection and report any noted; Foley catheter care daily with changes as necessary; good perineal care; good hydration; and laboratory testing as ordered. The care plan includes an entry dated October 18, 2007, that lists a particular size Foley catheter that was to be changed as necessary. A subsequent entry on an uncertain date requires that antibiotics be administered as ordered. The final entry appears to be dated June 2008, and specifies that an antibiotic is to be administered for ten days followed by laboratory testing. P. Ex. 12, at 5. Resident 5's MDS with an assessment reference date of April 25, 2008, shows that she had a UTI within the preceding thirty days. CMS Ex. 13, at 24-25. Resident 5's MDS with an assessment reference date of July 25, 2008, shows that she also had a UTI within the thirty days preceding that assessment. CMS Ex. 13, at 29-30.

b. Resident 5 Analysis

I conclude that there is merit to the allegation that Petitioner failed to deliver necessary care and services to prevent UTIs for Resident 5, who required a Foley catheter to maintain continence. The regulation requires that Petitioner deliver treatment and services necessary to ensure that an "incontinent" resident not develop UTIs. 42 C.F.R. § 483.25(d)(2). Resident 5 was assessed on both MDSs in the record as being continent of bladder. However, the MDS form specifies that a resident should be assessed as "continent" if the resident's urine is controlled by use of a catheter, as it was in the case of Resident 5. CMS Ex. 13, at 25, 30. I construe the requirement of 42 C.F.R. § 483.25(d)(2) broadly to oblige Petitioner to deliver necessary treatment and services to ensure that a resident does not develop UTIs even though the resident is assessed as continent, when that assessment is based on the use of a urinary catheter. A broad construction is appropriate as it is undisputed that use of a urinary catheter poses an

increased risk for development of UTIs, just as incontinence poses an increased risk for infection. Petitioner specifically recognized the increased risk for UTIs associated with Foley catheter use by care planning for the risk in January 2007. P. Ex. 12, at 5. In this case, Resident 5 was at increased risk for UTIs due to the continued use of the Foley catheter. Petitioner recognized the risk and prepared the January 2007 care plan. P. Ex. 12, at 5.

The evidence shows that Resident 5 had multiple UTIs between December 6, 2007 and August 28, 2008. However, the long-term care plan reflects no additional interventions during the period except the administration of antibiotics and follow-up laboratory work. P. Ex. 12, at 5. Similarly, the short-term care plans for each of the UTIs between December 2007 and August 2008, include the nearly identical interventions. P. Ex. 12, at 101-09. Petitioner has provided me no evidence that the care planning team assessed the effectiveness of chosen interventions to prevent UTIs or considered alternative interventions to prevent UTIs. Thus, I conclude that Petitioner has failed to rebut the CMS *prima facie* showing of a violation of 42 C.F.R. § 483.25(d)(2).

Petitioner argues that Resident 5 had a staghorn calculus that predisposed her to colonization of bacteria that is generally asymptomatic and that the standard of care is not to treat. P. Br. at 22-23. This argument verges on being frivolous. The evidence Petitioner has produced shows that Resident 5 had two renal stones or staghorn calculus removed in January 2007. The operative report for the procedure shows that no residual stone or calculus remained after the operation. P. Ex. 12, at 20-22. Petitioner has presented no credible objective evidence that shows that any physician examined Resident 5 and diagnosed her with a staghorn after January 2007. Furthermore, Petitioner's clinical records cited above, including laboratory reports, show that Resident 5 was diagnosed with UTIs and treated with antibiotics. Thus, Petitioner's argument that Resident 5 did not have recurring UTIs but suffered from urinary tract bacterial colonization due to staghorn calculus is not supported by the evidence of record. Petitioner cites to the testimony of Thomas Woodbury, DO, Petitioner's Medical Director at page 746 of the transcript in support of the assertion that "Resident 5 never had recurrent UTIs because the colonization of bacteria was due to her staghorn horn calculus. I note that Dr. Woodbury is neither an urologist nor a nephrologist. P. Ex. 36, at 9-12. I further note that Petitioner misrepresents Dr. Woodbury's testimony. Dr. Woodbury testified generally about staghorn calculus and bacteria, but he never testified that Resident 5 redeveloped or had residual staghorn calculus following her surgery in January 2007. Dr. Woodbury also never opined that the diagnoses of the multiple UTIs between December 2007 and August 2008 were wrong or that the prescription of antibiotics was in error. Tr. at 745-54. Dr. Woodbury testified that he was not Resident 5's treating physician. Tr. at 772.

Petitioner also elicited testimony from John Randolph, MD. P. Ex. 36, at 13-15. Dr. Randolph testified as to the standard of care for treatment of UTIs in elderly nursing

home residents. He testified regarding conducting an appropriate history and physical, and the need for confirmation by laboratory testing. He also testified that, although 100,000 colonies of bacteria is a UTI per se, a UTI is not diagnosed based only upon a laboratory report but also upon signs and symptoms. He testified that asymptomatic bacteriuria is common in the elderly and does not require treatment as a UTI. Tr. at 859-76. Dr. Randolph testified that he never treated a patient at Petitioner's facility. He agreed that if a physician for a resident at Petitioner's facility diagnosed a UTI and prescribed antibiotics, he was not in a position to challenge that diagnosis. Tr. at 876. Dr. Randolph did not testify specifically about Resident 5 or any other resident at Petitioner's facility.

Accordingly, I conclude that Petitioner was not in substantial compliance with program participation requirements based on a violation of 42 C.F.R. § 483.25(d)(2) (Tag F315) that caused Resident 5 actual harm in the form of multiple UTIs.

c. Facts Related to Resident 5 and the Survey of December 4, 2008.

The surveyors allege in the SOD for the survey that ended on December 4, 2008, that there were four regulatory violations. However, only the alleged violation of 42 C.F.R. § 483.25(d) posed a risk for more than minimal harm to a resident. The surveyors allege that Petitioner violated this regulation, because Petitioner failed to ensure that Resident 5's urinary catheter tubing and collection bag were positioned so that the catheter drained to the collection bag and not back to the bladder. CMS Ex. 68, at 3-4. According to the SOD, a surveyor observed Resident 5 asleep in bed on December 1, 2008, with her catheter tubing and urine collection bag hanging on the bed side-rail, which was above the level of the resident's bladder. The surveyor cited positioning of the catheter tube and the collection bag as a deficiency because the position of the bag and tubing could allow urine to flow back to the bladder and pose a risk for infection. Surveyor Nichols testified at hearing that even with an anti-reflux valve, urine in the tubing between the bladder and the valve could flow back to the bladder if the bag and tubing is placed above the level of the bladder. Surveyor Nichols also pointed out that with the bag and tubing positioned above the level of the bladder, the bladder could not empty properly. CMS Ex. 68, at 4; Tr. at 86-88, 90.

Petitioner does not dispute that Surveyor Nichols observed that Resident 5's urinary catheter tubing and catheter bag were hung at a level above Resident 5's bladder. P. Br. at 29-30.

d. Analysis Related to Resident 5 and the Survey of December 4, 2008

Petitioner does not deny that urinary catheter tubing and the catheter bag should be hung below the level of the resident's bladder. P. Br. at 29-30. Petitioner argues that the error

was not its fault as the catheter bag was improperly positioned by a hospice aide, not a facility staff member. P. Br. at 30. Petitioner cites no authority that recognizes a defense that Petitioner is not responsible for care delivered in its facility by hospice aides who are not employees. Petitioner argues that the facts reflect an isolated incident and no other catheter bags or tubing were observed to be improperly positioned. P. Br. at 30. Petitioner cites no authority for the proposition that a single violation must be excused. Petitioner also cites no authority for the proposition that a single violation is not an adequate basis for imposing an enforcement remedy, if the single violation has the potential for causing more than minimal harm. Petitioner argues that Surveyor Nichols did not realize that the catheter tubing and bag had an anti-reflux valve and that there was no potential for harm. P. Br. at 30. Surveyor Nichols admitted at hearing that she did not determine whether or not Resident 5's catheter had an anti-reflux valve. However, contrary to Petitioner's assertion, Surveyor Nichols was familiar with anti-reflux valves, their purpose, and that they were used at Petitioner's facility. She opined that even with an anti-reflux valve it was not safe to hang a catheter bag or tubing above the level of the resident's bladder. Tr. at 87-88. As a trained nurse, Surveyor Nichols was qualified to render the opinion and Petitioner presented no evidence to rebut the opinion. I conclude that the weight of the credible evidence shows that there is a risk for more than minimal harm secondary to hanging a catheter bag or tubing above the level of the bladder. I also conclude that Petitioner has neither rebutted the CMS *prima facie* showing nor established an affirmative defense.

Accordingly, I conclude that Petitioner was not in substantial compliance with program participation requirements due to a violation of 42 C.F.R. § 483.25(d)(2) (Tag F315) that posed a risk for more than minimal harm to Resident 5. I further conclude that Petitioner returned to substantial compliance on December 16, 2008, the date alleged by CMS, as Petitioner has presented no evidence or argument to support a conclusion that it returned to substantial compliance at an earlier date.

4. There is a basis for the imposition of enforcement remedies from September 24 through December 15, 2008.

5. A CMP of $500 per day from September 24 through December 3, 2008 and $100 per day from December 4 through 15, 2008, a total CMP of $36,700; and a DPNA from November 22, 2008 through December 15, 2008, are reasonable enforcement remedies.

I have concluded that Petitioner was not in substantial compliance with program participation requirements due to violations 42 C.F.R. § 483.25(c) and (d) and that the violations posed a risk for more than minimal harm. Accordingly, there is a basis for imposing enforcement remedies in this case. If a facility is not in substantial compliance with program requirements, CMS has the authority to impose one or more of the enforcement remedies listed in 42 C.F.R. § 488.406, including a CMP. CMS may impose

a daily CMP for the number of days that the facility is not in compliance or a per instance CMP for each instance that a facility is not in substantial compliance. 42 C.F.R. § 488.430(a). The regulations establish two ranges for a daily CMP. 42 C.F.R. §§ 488.408, 488.438. The lower range for a CMP – $50 per day to $3,000 per day – is applicable when there is no immediate jeopardy, but there is either actual harm or a risk for more than minimal harm. 42 C.F.R. § 488.438(a)(1)(ii).

If I conclude, as I have in this case, that there is a basis for the imposition of an enforcement remedy and the remedy proposed is a CMP, my authority to review the reasonableness of the CMP is limited by 42 C.F.R. § 488.438(e). The limitations are: (1) I may not set the CMP at zero or reduce it to zero; (2) I may not review the exercise of discretion by CMS in selecting to impose a CMP (or the CMS selection of any other authorized remedy); and (3) I may only consider the factors specified by 42 C.F.R. § 488.438(f) when determining the reasonableness of the CMP amount. In determining whether the amount of a CMP is reasonable, the following factors specified at 42 C.F.R. § 488.438(f) must be considered: (1) the facility's history of noncompliance, including repeated deficiencies; (2) the facility's financial condition; (3) the seriousness of the deficiencies as set forth at 42 C.F.R. § 488.404(b), the same factors CMS and/or the state were to consider when setting the CMP amount; and (4) the facility's degree of culpability, including, but not limited to, the facility's neglect, indifference, or disregard for resident care, comfort, and safety and the absence of culpability is not a mitigating factor. The factors that CMS and the state were required to consider when setting the CMP amount and that I am required to consider when assessing the reasonableness of the amount are set forth in 42 C.F.R. § 488.404(b): (1) whether the deficiencies caused (i) no actual harm but had the potential for minimal harm, (ii) no actual harm but had the potential for more than minimal harm, but not immediate jeopardy, (iii) actual harm that is not immediate jeopardy, or (iv) immediate jeopardy to resident health and safety; and (2) whether the deficiencies are isolated, constitute a pattern, or are widespread. My review of the reasonableness of the CMP is *de novo* and based upon the evidence in the record before me. In reaching a decision on the reasonableness of the CMP, I consider whether the evidence supports a finding that the amount of the CMP is at a level reasonably related to an effort to produce corrective action by a provider with the kind of deficiencies found, and in light of the above factors. I am not bound to defer to the CMS determination of the reasonable amount of the CMP to impose but my authority is limited by regulation as already explained. I am to determine whether the amount of any CMP proposed is within reasonable bounds considering the purpose of the Act and regulations. *Emerald Oaks*, DAB No. 1800, at 10 (2001); *CarePlex of Silver Spring*, DAB No. 1683, at 14–16 (1999); *Capitol Hill Cmty. Rehab. & Specialty Care Ctr.*, DAB No. 1629 (1997).

The evidence does not show a history of noncompliance by Petitioner that required the imposition of enforcement remedies. The evidence of noncompliance introduced by CMS shows prior instances that were apparently quickly corrected and required no

enforcement remedies to encourage Petitioner to return to substantial compliance. CMS Ex. 62-64. CMS does not urge me to consider any history of noncompliance in determining whether the proposed remedies are reasonable. CMS Br. at 30; CMS Reply at 25. Petitioner has presented no evidence regarding its financial condition or an inability to pay the CMP proposed. Therefore, I conclude that the amount of the CMP would not cause a substantial financial burden to Petitioner. *Crestview Parke Care Ctr. v. Thompson*, 373 F.3d 743, 756 (6th Cir. 2004). I conclude that Petitioner's noncompliance was serious and caused actual harm to residents. I also conclude that Petitioner was culpable within the meaning of the regulations.

CMS proposes a $500 per day CMP from September 24 through December 3, 2008 and a $100 per day CMP from December 4 through 15, 2008. Both amounts proposed are at the low end of the range of authorized CMPs. I conclude the proposed CMPs are reasonable in duration and amount. I also conclude that CMS was authorized to impose a discretionary DPNA beginning November 22, 2008 and continuing until substantial compliance was achieved on December 15, 2008, and that the DPNA was a reasonable enforcement remedy. 42 C.F.R. §§ 488.402, 488.404, 488.406(a), 488.408.

III. Conclusion

For the foregoing reasons, I conclude that Petitioner was not in substantial compliance with program requirements from September 24, 2008 through December 15, 2008. A basis exists to impose the following enforcement remedies, which are reasonable: a CMP of $500 per day from September 24 through December 3, 2008 and $100 per day from December 4 through 15, 2008, a total CMP of $36,700; and a DPNA from November 22, 2008 through December 15, 2008.

/s/
Keith W. Sickendick
Administrative Law Judge