Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Rae-Ann Geneva Nursing Home
(CCN: 36-6047),

Petitioner

v.

Centers for Medicare and Medicaid Services.

Docket No. C-10-75

Decision No. CR2461

Date: November 4, 2011

DECISION

Petitioner, Rae-Ann Geneva Nursing Home, violated 42 C.F.R. § 483.25(c).[1] The regulatory violation caused actual harm to a resident. Therefore, Petitioner was not in substantial compliance with program participation requirements as found by the survey of Petitioner's facility completed on July 9, 2009. There is a basis for the imposition of an enforcement remedy. The $3,200 per instance civil money penalty (PICMP) proposed by the Centers for Medicare and Medicaid Services (CMS) is a reasonable enforcement remedy.

I. Background

Petitioner is located in Geneva, Ohio, and participates in Medicare as a skilled nursing facility (SNF) and the state Medicaid program as a nursing facility (NF). On July 9,

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

2009, an annual survey of Petitioner's facility was completed by the Ohio Department of Health (state agency). Petitioner was found not in substantial compliance with program participation requirements. CMS notified Petitioner, by letter dated September 30, 2009, that it was imposing a PICMP of $3,200 for an alleged violation of 42 C.F.R. § 483.25(c). CMS also advised Petitioner that a revisit survey by the state agency determined that Petitioner returned to substantial compliance on August 24, 2009. CMS Exhibits (CMS Exs.) 1, 5; Joint Stipulation of Undisputed Fact (Jt. Stip.).

Petitioner requested a hearing before an administrative law judge (ALJ) by letter dated November 23, 2009. The case was assigned to me for hearing and decision on December 2, 2009, and an Acknowledgement and Prehearing Order was issued at my direction. On September 23 and 24, 2010, a hearing was convened in Cleveland, Ohio, and a transcript (Tr.) of the proceedings was prepared. CMS offered CMS exhibits (CMS Exs.) 1 through 8 that were admitted as evidence.[2] Tr. at 18. Petitioner offered Petitioner exhibits (P. Exs.) 1 through 5 that were admitted as evidence. Tr. at 21, 289, 356. CMS called Surveyor Kelly Sites, RN (Registered Nurse) as its sole witness. Petitioner called the following witnesses: Mindee Morrison, RN, Petitioner's Assistant Director of Nursing (ADON); Diana Randolph, RN, Petitioner's Director of Nursing (DON); Melinda Burk, LPN (Licensed Practical Nurse); and Tina L. Baum, RN, MSN (Master of Science in Nursing). The parties filed post-hearing briefs (P. Brief and CMS Brief) and post-hearing reply briefs (P. Reply and CMS Reply).

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[2] CMS attached to its post-hearing reply brief ten pages from a home care product catalog for the obvious purpose of rebutting testimony of Petitioner's witnesses at hearing. CMS Reply at 7 n.2; CMS Reply att. A. CMS did not file a motion to reopen the record or its case-in-chief, or for leave to file additional evidence. The attachment is not appropriately marked as an exhibit. Because the new evidence was not properly marked and submitted, it is not admitted as evidence or considered for any purpose. Even if the document had been properly marked and submitted, relevance has not been established as the evidence does not show the model or year of the wheelchairs used by the resident in this case or that the wheelchairs are the same as or similar to those reflected in the catalog pages offered by CMS. Evidence that is not relevant is not admissible. 42 C.F.R. § 498.60(b)(1).

II. Discussion

A. Issues

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

Whether the remedy imposed is reasonable?

B. Applicable Law

The statutory and regulatory requirements for participation of a SNF in Medicare are found at section 1819 of the Social Security Act (Act) and at 42 C.F.R. Part 483. Section 1819(h)(2) of the Act authorizes the Secretary of Health and Human Services (Secretary) to impose enforcement remedies against a SNF for failure to comply substantially with the federal participation requirements established by sections 1819(b), (c), and (d) of the Act.[3] The Act requires that the Secretary terminate the Medicare participation of any SNF that does not return to substantial compliance with participation requirements within six months of being found not to be in substantial compliance. Act § 1819(h)(2)(C). The Act also requires that the Secretary deny payment of Medicare benefits for any beneficiary admitted to a SNF, if the SNF fails to return to substantial compliance with program participation requirements within three months of being found not to be in substantial compliance – commonly referred to as the mandatory or statutory denial of payments for new admissions (DPNA). Act § 1819(h)(2)(D). The Act grants the Secretary discretionary authority to terminate a noncompliant SNF's participation in Medicare, even if there has been less than 180 days of noncompliance. The Act also grants the Secretary authority to impose other enforcement remedies, including a discretionary DPNA, civil money penalties (CMPs), appointment of temporary management, and other remedies such as a directed plan of correction. Act § 1819(h)(2)(B).

The Secretary has delegated to CMS and the states the authority to impose remedies against a long-term care facility that is not complying substantially with federal participation requirements. "*Substantial compliance* means a level of compliance with

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[3] Participation of a NF in Medicaid is governed by section 1919 of the Act. Section 1919(h)(2) of the Act gives enforcement authority to the states to ensure that NFs comply with their participation requirements established by sections 1919(b), (c), and (d) of the Act.

the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm." 42 C.F.R. § 488.301 (emphasis in original). A deficiency is a violation of a participation requirement established by sections 1819(b), (c), and (d) of the Act or the Secretary's regulations at 42 C.F.R. Part 483, subpart B. Noncompliance refers to any deficiency that causes a facility not to be in substantial compliance. 42 C.F.R. § 488.301. State survey agencies survey facilities that participate in Medicare on behalf of CMS to determine whether the facilities are complying with federal participation requirements. 42 C.F.R. §§ 488.10-.28, 488.300-.335. The regulations specify the enforcement remedies that CMS may impose if a facility is not in substantial compliance with Medicare requirements. 42 C.F.R. § 488.406. CMS is authorized to impose a PICMP from $1,000 to $10,000. 42 C.F.R. § 488.438(a)(2).

The Act and regulations make a hearing before an ALJ available to a long-term care facility against which CMS has determined to impose an enforcement remedy. Act §§ 1128A(c)(2), 1866(h); 42 C.F.R. §§ 488.408(g), 498.3(b)(13). The hearing before an ALJ is a *de novo* proceeding. *The Residence at Salem Woods*, DAB No. 2052 (2006); *Cal Turner Extended Care*, DAB No. 2030 (2006); *Beechwood Sanitarium*, DAB No. 1906 (2004); *Emerald Oaks*, DAB No. 1800, at 11 (2001); *Anesthesiologists Affiliated*, DAB CR65 (1990), *aff'd*, 941 F.2d 678 (8th Cir. 1991). A facility has a right to appeal a "certification of noncompliance leading to an enforcement remedy." 42 C.F.R. § 488.408(g)(1); 42 C.F.R. §§ 488.330(e), 498.3. However, the choice of remedies, or the factors CMS considered when choosing remedies, are not subject to review. 42 C.F.R. § 488.408(g)(2). A facility may only challenge the scope and severity level of noncompliance determined by CMS, if a successful challenge would affect the range of the CMP that may be imposed or impact the facility's authority to conduct a 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). ALJ Review of a CMP is subject to 42 C.F.R. § 488.438(e).

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

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

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

My conclusions of law are set forth in bold text followed by my findings of fact and analysis. CMS alleges, based upon the survey that ended July 9, 2009, that Petitioner was not in substantial compliance with program participation requirements due to a violation of 42 C.F.R. § 483.25(c) (Tag F314) that caused actual harm to Resident 45. Other deficiencies were alleged in Statement of Deficiencies (SOD), but no proposed enforcement remedy is based on the other deficiency citations and they are not before me. The only enforcement remedy at issue is the $3,200 PICMP based upon the noncompliance cited under Tag F314, and only that alleged noncompliance is subject to my review.

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.[4] The fact that evidence is not specifically discussed should not be considered sufficient to rebut the presumption that I considered all the evidence and assigned such weight or probative value to the credible evidence that I determined appropriate within my discretion as an ALJ. There is no requirement for me to discuss the weight given every piece of evidence considered in this case, nor would it be consistent with notions of judicial economy to do so.

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

2. Petitioner's violation of 42 C.F.R. § 483.25(c) resulted in actual harm to Resident 45.

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[4] "Credible evidence" is evidence that is worthy of belief. *Black's Law Dictionary* 596 (18th ed. 2004). The "weight of evidence" is the persuasiveness of some evidence compared to other evidence. *Id*. at 1625. It is not necessary to weigh evidence that is not credible, as it is without weight or probative value. However, credible evidence may be weighed and found to have no probative value. All credible evidence has been weighed, and its probative value has been determined.

3. Petitioner was not in substantial compliance with program participation requirements and there is a basis for the imposition of an enforcement remedy.

a. Facts

Resident 45 was 81 years old at the time of the survey. He was admitted to Petitioner's facility on April 10, 2009. CMS Ex. 6, at 21. His diagnoses included coronary artery disease, a history of cerebrovascular accident, late effects of cerebrovascular disease, including seizure activity, chronic obstructive pulmonary disease, seizure disorder, atrial fibrillation, hypertension, aphasia (impairment of the ability to use and understand words), dysphagia (difficulty swallowing), and Alzheimer's dementia. P. Ex. 2, at 19, 27; CMS Ex. 6, at 5, 14, 21. He was assessed as cognitively confused and unable to follow directions when admitted in April 2009 (P. Ex. 2, at 7), but he was assessed as able to follow simple directions on July 8, 2009 (CMS Ex. 6, at 15). Resident 45 was assessed at admission in April 2009 as being at mild risk for skin breakdown and bruising, due to his fragile skin, limited mobility, and anticoagulant therapy. CMS Ex. 6, at 11; P. Ex. 2, at 1, 3. On June 5, 2009, he was again assessed as being at mild risk. P. Ex. 2, at 3. On July 6, 2009, he was assessed as being at high risk for pressure sores. P. Ex. 2, at 3.

Resident 45's care plan addressing the risk for skin breakdown and bruising, dated April 10, 2009, included the following interventions: reporting bruising, rash, redness, irritation or open areas to the nurse; use of a pressure relieving mattress; repositioning every two hours and as necessary; providing treatment as ordered by the physician and recording treatment on the skin grid; providing good perineal care; use of pressure relieving products as ordered; monitoring skin condition; and providing a nutritional supplement as ordered. On July 7, 2009, the interventions of providing a protein supplement and multi-vitamin were added to the care plan. CMS Ex. 6, at 11; P. Ex. 2, at 1.

Resident 45's clinical records contain the following orders: an order dated April 10, 2009, for a regular mechanical soft diet with nectar thickened liquids (P. Ex. 2, at 28); an order dated April 10, 2009 for a pressure relieving mattress on a low bed (P. Ex. 2, at 28); an order dated April 13, 2009 for speech therapy to address cognitive deficits (P. Ex. 2, at 2); an order dated April 14, 2009 to use a gel cushion in the resident's wheel chair when out-of-bed and that he be prompted to void (P. Ex. 2, at 4, 28); an order dated April 17, 2009 that a Merry Walker® be used when out-of-bed for independent ambulation (P. Ex. 2, at 6); an order dated May 27, 2009 for ambulation of fifteen minutes, six days each week, without the Merry Walker® but with assistance of one to two staff (P. Ex. 2, at 8); an order dated June 5, 2009 for speech therapy treatment for dysphagia (P. Ex. 2, at 15); and an order dated June 10, 2009 for a nutritional supplement (P. Ex. 2, at 28).

Resident 45's physician, Dr. Mikhail, wrote in a progress note, dated June 6, 2009, that: the resident suffered from advanced Alzheimer's dementia; he was unable to use his Merry Walker® due to his risk for falls; and he had multiple medical problems including renal failure and congestive heart failure. Dr. Mikhail opined in his note that "skin breakdown is unavoidable due to expected decline in mental and physical condition." P. Ex. 2, at 16; Tr. at 130-31. A nursing assessment on June 20, 2009, found Resident 45's skin intact with no red areas or open areas. CMS Ex. 6, at 17.

A Wound Management Progress/Procedure Note, dated July 6, 2009, records that on July 5, 2009, new pressure ulcers were found on Resident 45's right and left trochanter, the bony protuberance of the upper thigh bone and generally the widest point of the hips.[5] The pressure ulcer on the right was assessed as a Stage II, but the notation of the stage of the ulcer on the left is unclear. P. Ex. 2, at 20. Weekly skin reports for July 6, 2009 show that both ulcers were assessed as Stage II. Diagrams on the weekly skin reports indicate that the ulcers were just to the left and right of the gluteal folds, the folds where the buttock and thigh meet, and the reports describe the sores as being on the left and right posterior trochanter. P. Ex. 2, at 22; P. Ex. 4; Tr. at 185. A July 20, 2009, weekly skin report states that the ulcer on the right trochanter had resolved. P. Ex. 2, at 22.

An occupational therapy progress note, dated July 24, 2009, indicates that an occupational therapy evaluation was completed on July 8, 2009. The note states that a new used wheelchair was located and issued on July 8, 2009. The note states that the resident had been in a wheelchair with a 16 inch by 16 inch drop seat and that the new wheelchair had a 16 inch by 18 inch sling seat. A gel seat, front anti-tippers, and a lap buddy were also placed in or on the larger wheelchair. P. Ex. 2, at 26. The occupational therapy evaluation dated July 8, 2009, indicates that the patient's current wheelchair was not accommodating and that it was necessary to switch to a different wheelchair. P. Ex. 2, at 27; CMS Ex. 6, at 14. The evaluation does not describe how the resident's old wheelchair with the 16 inch by 16 inch drop seat was not accommodating. However, an addendum to the occupational therapy evaluation indicates that Resident 45's hip width was sixteen inches and recommends that he have a wheel chair with a 16 inch by 18 inch sling seat with a gel cushion. P. Ex. 2, at 25; CMS Ex. 6, at 12. The occupational therapist's note does not indicate whether the seat on the new chair was eighteen inches wide (side to side) or eighteen inches deep (front to back). The evaluation notes that the resident had bilateral excoriated areas over his lesser trochanters. CMS Ex. 6, at 15. The

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[5] I advised the parties at hearing that I would take administrative notice of authoritative sources regarding the location and or definition of the term "trochanter." Tr. at 343-44. Both parties provided authoritative material with their post hearing briefs, which I have considered. CMS Br. att. A; P. Reply, app. D.

notes do not indicate whether or not the therapist attributed the excoriated areas to the ill-fitted old wheelchair. The therapist did not testify at hearing.

b. Analysis

The SOD alleges that Petitioner violated the regulation because Petitioner failed to ensure that adequate interventions were implemented to prevent Resident 45 from developing Stage II pressure ulcers on his hips and that Petitioner failed to ensure that appropriate interventions were implemented to promote healing. CMS Ex. 2, at 14; P. Ex. 1, at 1. I conclude that Petitioner violated 42 C.F.R. § 483.25(c) because Petitioner failed to ensure that adequate interventions were implemented to prevent the development of pressure ulcers.[6] I conclude that Resident 45 suffered actual harm due to the development of pressure ulcers on his bilateral hips or buttocks. I further conclude that Petitioner has failed to show that the development of pressure sores by Resident 45 was unavoidable.

The quality of care regulation includes the requirement that a facility ensure that a resident who enters the facility without a pressure sore not develop one unless clinically unavoidable and that a resident entering with a pressure sore receives care and services necessary for healing, to prevent infection, and to prevent other sores from developing. 42 C.F.R. § 483.25(c). CMS has adopted definitions for terms related to the regulation that are to be applied by surveyors in conducting surveys. A "pressure sore," often referred to as a "pressure ulcer," is any lesion of the skin caused by unrelieved pressure that damages the underlying tissue. "Friction" is the mechanical force exerted on skin that is dragged across any surface. "Shearing" results when layers of the skin rub against each other or the underlying tissue rubs against the skin resulting in tissue damage. Friction and shearing are not primary causes of pressure ulcers, but they are considered to be contributing factors. "Eschar" is thick, leathery, black or brown colored, necrotic or devitalized tissue that has lost its normal physical properties and biological activity, and it may be loose or firmly adhered to a wound. State Operations Manual (SOM), CMS Pub. 100-07, app. PP, Tag F314 (CMS Ex. 8).

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[6] I conclude, in the interest of judicial economy, that it is not necessary for me to analyze the alternative ground that Petitioner failed to ensure appropriate interventions were implemented to promote healing. I note however, that there is no dispute by CMS that both ulcers did heal, one within fifteen days. P. Ex. 2, at 22. Surveyor Sites opined that Petitioner could have promoted more prompt healing by arranging an occupational therapy evaluation and a change to a larger wheelchair sooner. But, she agreed that Petitioner was otherwise treating the ulcers in accordance with physician's orders. Tr. at 71-72.

The application of the regulation is well-established by decisions of various appellate panels of the Board. *Koester Pavilion*, DAB No. 1750 and *Cross Creek Health Care 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 Meadow Wood Nursing Home*, DAB No. 1841 (2002) (finding loose dressing contaminated with fecal matter constitutes violation); *Ridge Terrace*, DAB No. 1834, at 15-16 (holding a single observation by a surveyor of a nurse aide cleaning an open sore area with a stool-stained washcloth was sufficient to sustain a deficiency finding under this Tag). Once CMS establishes a *prima facie* case, the facility bears the burden of showing that the development or deterioration of a pressure sore was clinically unavoidable.

An appellate panel of the Board in *Clermont Nursing and Convalescent Ctr.*, DAB No. 1923, at 9-10 (2004), *aff'd, Clermont Nursing and Convalescent Ctr. v. Leavitt*, 142 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 <u>necessary</u> care and services" for attainment or maintenance of the highest practicable resident well-being. 42 C.F.R.
> § 483.25 (emphasis supplied). The regulation then goes on to provide that a resident with pressure sores must receive "<u>necessary</u> treatment and services" for healing, prevention of infection, and prevention of yet more pressure sores. 42 C.F.R. § 483.25(c)(2) (emphasis supplied). We therefore reject Clermont's contention that the standard is "nowhere in the regulation." That argument is belied by the plain language of the regulation.
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> Moreover, as we explained in *Koester Pavilion*, in the preamble to the final regulation, CMS expressly declined to use "less demanding" language with respect to a facility's obligation to "ensure" outcome of treatment for pressure sores. *Koester Pavilion* at 30, quoting 56 Fed. Reg. 48,826, at

> 48,850 (Sept. 26, 1991). CMS recognized that factors beyond required treatment and services, such as disease process and resident compliance, affect care outcome. *Id.* However, CMS also recognized that the regulation allows a facility to put forward "available clinical evidence" to show that "a negative resident care outcome was unavoidable." *Id.* The preamble further provides that facilities "should always furnish the necessary treatment and services" for pressure sore prevention or healing. *Id.* at 30-31(emphasis supplied). Thus, a facility may provide necessary treatment and services to ensure the prevention or healing of pressure sores, yet still be confronted with a negative outcome. In that instance, the facility may put forward clinical evidence to show that the outcome was unavoidable.

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

(1) CMS has made a *prima facie* showing of noncompliance.

The SOD charges that the bases of Petitioner's noncompliance were failure to ensure that adequate interventions were implemented to prevent Resident 45 from developing Stage II pressure ulcers on his hips and that Petitioner failed to ensure that appropriate interventions were implemented to promote healing when the ulcers were discovered. CMS Ex. 2, at 14; P. Ex. 1, at 1. CMS argues that Petitioner was noncompliant because Petitioner failed to provide Resident 45 a properly fitted wheelchair leading to the development of the two pressure ulcers and that, when the ulcers were discovered, Petitioner failed to immediately provide a properly fitted wheelchair. CMS Br. at 1. CMS also argues that, in addition to failing to provide a properly fitted wheelchair, Petitioner failed to comply with the resident's care plan and failed to increase its monitoring and to implement additional skin interventions when it was determined that the resident's condition was deteriorating. CMS Br. at 16.

The evidence presented by CMS establishes a *prima facie* case of noncompliance. When Resident 45 was admitted in April 2009, he was assessed as at risk for developing skin breakdown and bruising due to his fragile skin, limited mobility, and anticoagulant therapy. CMS Ex. 6, at 11. Petitioner developed a care plan to address the resident's risk for developing pressure sores that included many interventions typically used for addressing such problems, including: use of pressure relieving devices; a turning schedule; ensuring good nutrition; ensuring good perineal care; and monitoring and reporting skin condition. CMS Ex. 6, at 11. Nursing assessments from June and July 2009 show that Resident 45 was on intravenous antibiotics, and he was having problems with edema or swelling due to fluid retention. On June 20, 2009, he was found to have

no open areas of skin. CMS Ex. 6, at 16-17. An assessment dated July 6, 2009, states that Resident 6 had been suffering a physical decline over the last couple weeks. He was unable to ambulate and was having difficulty standing. CMS Ex. 6, at 18. The limited clinical data collected by the surveyor and presented by CMS shows that Resident 45 was assessed at risk for pressure ulcers in April 2009, and then had a physical decline in June 2009. However, his care plan for skin breakdown was not updated with new interventions to address the change in his ambulation or his problems with edema. Surveyor Sites also testified that she repeatedly observed Resident 45 in a wheelchair during the survey. Tr. 57-60. The evidence shows, and there is no dispute, that during the night shift of July 5 to July 6, 2009, a nurse discovered that the resident had a pressure sore on each buttock or posterior hip, which Petitioner's staff and contractor wound nurse described as the trochanter region. CMS Ex. 6, at 5, 8-9, 15, 21. Although the parties argued extensively regarding whether the ulcers were on the buttocks or hips to support their respective theories for the cause of the ulcers, the proper characterization of the location of the ulcers or identification of their cause is not critical for the CMS *prima facie* showing in this case. The undisputed fact that ulcers developed in the general area of the hips and buttocks is sufficient.

The evidence that the resident was assessed by Petitioner as at risk for pressure sores, the evidence of a decline in his physical condition, the absence of new interventions on the care plan to address the increased risk, and the evidence that the resident did develop two pressure sores while in Petitioner's care are a *prima facie* showing that Petitioner violated 42 C.F.R. § 483.25(c). Further, the CMS evidence shows that both ulcers were open, with a scant amount of thin, clear exudate, with necrotic tissue at one wound, and pain associated with one wound. CMS Ex. 6, at 9. The open wounds and associated pain amounts to actual harm. Accordingly, CMS has made a *prima facie* showing of noncompliance under Tag F314.

(2) Petitioner has failed to establish that the development of the ulcers was unavoidable.

The regulation requires that a resident who enters a facility without pressure sores not develop them unless his or her clinical situation is such that the development of sores is unavoidable. 42 C.F.R. § 483.25(c)(1). Thus, the regulation establishes a defense of unavoidability. Petitioner's argument in this case is that, if CMS made a *prima facie* showing of noncompliance, then Petitioner has met its burden to show that the ulcers were unavoidable. The gist of Petitioner's argument is that it did all it was supposed to with respect to delivering care and services to prevent pressure sores, but they developed anyway, and, therefore, they were unavoidable. P. Br. at 19-22; P. Reply at 6-10. I conclude based on my review of all the evidence that Petitioner has not shown the ulcers were unavoidable.

Petitioner's ADON Mindee Morrison testified that the ulcers were discovered on the night shift of July 5 and 6, 2009, and she was applying dressings to Resident 45's sores when the surveyors arrived the morning of July 6, 2009. Tr. at 127-28. She testified that, when the wheelchair was changed on about July 8, 2009, it was a change in the depth of the seat not its width. ADON Morrison failed to mention that there was also a change in the type of seat from drop seat to a sling seat. She testified that the length of the resident's femurs was the problem. She testified that there was no friction or pressure between the sides of the wheelchair and the resident's hips. Tr. at 133-34, 136, 142, 171-72. ADON Morrison did not testify as to how she recalled the occupational therapist's thinking, as it is not documented. She also did not explain how she recalled that it was the depth of the seat, and not its width, that changed. She testified that the sores were on the "posterior buttocks trochanter region" not on the hip area. Tr. at 138, 140. ADON Morrison opined that the pressure sores were unavoidable, but she did not identify the possible source of the pressure that caused the sores or why they could not be avoided. Tr. at 142, 146-47, 166. She testified that the care planning team also did not determine the cause of the sores. Tr. at 147, 167-68.

Petitioner's DON, Diana Randolph, testified that Resident 45 had a significant decline prior to developing the pressure ulcers, and he had been in the hospital the month before and was released on June 4, 2009. She testified that the resident suffered renal failure, severe heart problems, sepsis, dehydration, pneumonia, and changes in his mental status in June 2009. Tr. at 179, 198-99. About 6:15 a.m. on July 6, 2009, the night nurse advised her of Resident 45's ulcers, and she wanted the wound nurse, who was scheduled to be in that day, to view the ulcers with her. Tr. at 181. DON Randolph testified that she assessed the ulcers and documented the assessment, including their location, which she testified was the posterior buttock region, just below the mid-line of the buttock. She opined that, based on the location of the ulcers, it was not possible that the ulcers were caused by rubbing against the metal part of the wheelchair. Tr. at 185-87, 189. She testified that there were no sores prior to July 5, 2009. Tr. at 187. DON Randolph testified that she observed Resident 45 in his old wheelchair, and there was no problem with his hips contacting the sides of the wheelchair. She admitted however that she did not actually look at the chair or determine its characteristics. Tr. at 189, 190, 223. DON Randolph testified that the occupational therapist ordered a different wheelchair with the 16 inch by 18 inch seat because the therapist wanted more depth in the seat because the resident had long legs. She testified that the width of the seat in the new chair was the same as the old chair. DON Randolph did not testify as to how she recalled the occupational therapist's thinking, as it is not documented. She also did not explain how she recalled that it was the depth of the seat, and not its width, that changed. Tr. at 190. She opined that the pressure sores were unavoidable, and the resident received all necessary services and treatment to prevent the development of sores and to promote the healing of the sores when they did develop. Tr. at 192, 197-98. Both pressure ulcers did heal. Tr. at 192. DON Randolph opined that the wheelchair did not cause the pressure sores but did not state a basis for that opinion. Tr. at 198. She testified, in response to

my questioning, that she was a member of the care planning team, and the team concluded that the ulcers were a result of his co-morbidities and significant physical and mental decline. Tr. at 201. She could not identify the cause of the sores, and she could identify no new interventions except the change in the wheelchair and the addition of nutritional supplements. DON Randolph testified that the change in the depth of the seat of the wheelchair helped with the resident's ability to self-propel and helped with circulation in his legs. Tr. at 201-07.

Petitioner's Minimum Data Set coordinator, Melinda Burk, LPN, testified that she observed Resident 45 in his wheelchair and did not see his hips rubbing against the sides of the chair, and he appeared comfortable in the old chair. Tr. at 237. She testified that Resident 45 had a physical change, and he went from using a Merry Walker® to the wheelchair. The occupational therapist evaluated the wheelchair and all equipment Resident 45 was using and ordered a wheelchair with the deeper seat due to the length of his legs and the need for more support of his legs. Tr. at 238. LPN Burk did not testify as to how she recalled the occupational therapist's thinking, as it is not documented. She also did not explain how she recalled that it was the depth of the seat, and not its width, that changed. She opined that the pressure sores were on the lower buttocks not the hips. Tr. at 242-43. But, on cross-examination, LPN Burk admitted that she did not herself observe or assess Resident 45's pressure sores or participate in the treatment of them and that she only looked at the paperwork on the sores. Tr. at 244. She also opined that the old wheelchair did not cause the pressure sores, but she did not state a basis for that opinion. Tr. at 243.

Tina Baum, RN, was qualified as an expert with expertise in wounds and ulcer care. Tr. at 301-02. She reviewed records of Resident 45 provided by Petitioner. She opined that, in the time between Resident 45's return from the hospital in June 2009 and the discovery of his ulcers, Petitioner was doing all it could do. Tr. at 304-05. On cross-examination, she admitted that she never saw Resident 45 or his wheelchair. Tr. at 328. RN Baum testified that the records showed that the ulcers were on the posterior buttocks not the sides of the hips. Tr. at 306. She testified that the occupational therapy evaluation showed that the resident required a wheelchair with a deeper seat not a wider seat, though she did not explain the source of this information, and it is not reflected on the face of the therapist's evaluation. Tr. at 307-08. She opined that the pressure sores were unavoidable because Petitioner identified Resident 45 as being at risk and Petitioner developed and implemented a plan to address the risk. Tr. at 312. RN Baum testified that immediate treatment was initiated to resolve the ulcers and prevent their recurrence. Tr. at 312-13. She agreed that a Stage II ulcer amounts to harm but subsequently testified that, given the facts related to the ulcers Resident 45 suffered, they did not amount to real harm. Tr. at 316-18. I do not find the opinion weighty. RN Baum did not explain what she meant by "real harm" or address the clinical records that showed the ulcers were open and that there was pain associated with at least one ulcer. In response to my questions, she opined that the ulcers were probably related to the bed, perhaps the use of an

incontinence pad, rather than the wheelchair given the time that the sores were discovered. Tr. at 325-27.

Petitioner's evidence shows that, when he was admitted in April 2009, Resident 45 was assessed as at mild risk for developing pressure sores. On June 5, 2009, he was again assessed as being at mild risk. P. Ex. 2, at 3. However, one day later, Resident 45's physician advised Petitioner, by a progress note dated June 6, 2009, that he expected that Resident 45 would decline in mental and physical condition and that skin breakdown would be unavoidable due to his multiple medical problems, including renal failure and congestive heart failure. The physician's note clearly advised Petitioner that the resident's risk for pressure sores had increased. The physician's note also states that Resident 45 failed in his use of the Merry Walker®, which confirms that Petitioner knew then that the resident would be spending more time in his bed or his wheelchair, also increasing his risk for pressure sores from use of those devices. P. Ex. 2, at 16. Petitioner presented no evidence that it reassessed the resident's risk for skin breakdown following the June 6, 2009, physician's progress note. In fact, Petitioner's evidence shows that there was no assessment using the "Braden Scale" tool that had previously been used for assessing Resident 45, until July 6, 2009, after the two ulcers on his buttocks or hips were discovered. P. Ex. 2, at 3. Petitioner has also presented no evidence that the bed and mattress Resident 45 was using or the wheelchair he was using were evaluated on or after June 6, 2009, in light of his increased risk for pressure sores. In fact, the occupational therapy assessment completed on July 8, 2009 (P. Ex. 2, at 25-27), establishes that the resident was in a wheelchair of incorrect size and seat type for a month after the physician alerted Petitioner of the increased risk for pressure ulcers.

Petitioner relies upon the physician's June 6, 2009 progress note and the testimony of its expert witness and staff witness as evidence that the pressure ulcers were unavoidable. However, Petitioner's argument fails for several reasons. First, there is no dispute that both ulcers healed. The fact that the ulcers healed is inconsistent with the ulcers being unavoidable. If, when the cause of the ulcers is removed the body has sufficient resources to heal, then it is not credible that the ulcers were unavoidable. Second, while Petitioner's expert and staff witnesses assert that the ulcers were unavoidable, the evidence Petitioner presented shows that the care planning team never determined the actual cause of the wounds. Tr. at 147, 167-68, 201-07. The surveyor concluded that the wounds were probably caused by a poorly fitted wheelchair and friction between the resident's hips and the sides of the wheelchair. Petitioner argues that the chair was wide enough. But, Petitioner argues that the occupational therapy evaluation and the testimony of Petitioner's witnesses show the seat of the wheelchair was not deep enough for the resident's long legs and his propelling of the wheelchair with his feet. If I accept Petitioner's version of the facts, the evidence that the seat was not deep enough suggests that the sores could have been caused by friction and shearing or impairment of circulation due to the movement of the resident's hips and buttocks on the drop seat of the wheelchair, while the resident was self-propelling his wheelchair with his feet.

Petitioner's expert witness offered a third possible explanation for the development of the ulcers. She opined, based on her understanding of the location of the ulcers and her belief they occurred late at night while the resident was in bed rather than during the evening while he was in his wheelchair, that the resident may have had an incontinence pad bunched under his buttocks and hips, which caused the ulcers to form. Tr. at 325-27. Each of the potential causes of the ulcers was clearly avoidable by ensuring a proper fit of the wheelchair, or by ensuring the incontinence pad was not bunched in the bed. However, there is no evidence that the care planning team determined the cause, or devised and implemented an intervention to address the cause (Tr. at 147, 167-68, 201-07), other than to evaluate the old wheelchair and issue a new wheelchair and add a nutritional supplement. Third, because Petitioner failed to reassess the resident's needs following the June 6, 2009 physician's note and Petitioner failed to present any evidence that the fit of the old wheelchair was properly evaluated prior to July 8, 2009, Petitioner simply cannot show it delivered all necessary care and services to prevent the development of Resident 45's pressure sores. Fourth, the physician's opinion that the development of pressure sores was unavoidable was rendered on June 6, 2009, and without consideration of evidence related to the development of the two specific sores more than thirty days later, and his opinion is thus not considered weighty. Finally, the opinion of the Petitioner's expert was admittedly developed without knowledge of the actual cause of the sores, as were the opinions of Petitioner's nurses, and those opinions are not considered weighty.

I conclude that Petitioner has not shown that the ulcers discovered during the night shift of July 5 and 6, 2009, were unavoidable. Petitioner has also not shown that Resident 45 suffered no harm or that there was not a risk for more than minimal harm due to the regulatory violation.

4. A PICMP of $3,200 is a reasonable enforcement remedy.

I have concluded that Petitioner violated 42 C.F.R. § 483.25(c) and that the violation caused actual harm to Resident 45. 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 per day CMP for the number of days that the facility is not in compliance, or a PICMP for each instance that a facility is not in substantial compliance, whether or not the deficiencies pose immediate jeopardy. 42 C.F.R. § 488.430(a). The minimum amount for a PICMP is $1,000, and the maximum is $10,000. 42 C.F.R. § 488.438(a)(2). I conclude that there is a basis for the imposition of a $3,200 PICMP in this case. Petitioner states that the reasonableness of the PICMP is not at issue in this case. P. Reply at 11; P. Reply, app. B, Conclusion of Law 4. Nevertheless, I review the reasonableness of the enforcement remedy.

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

There is no evidence of a history of noncompliance or repeated deficiencies. Petitioner has specifically stated that there is no issue regarding its ability to pay. Tr. at 33. The noncompliance was serious as the resident suffered actual harm while in a seriously compromised state, but the noncompliance was an isolated incident. The facility was culpable in that it failed to properly assess the resident after the physician identified him as being at increased risk, and Petitioner failed to ensure the care planning team properly assessed the cause of the ulcers to permit the team to identify possible effective interventions. I also note that the $3,200 PICMP is in the lower half of the authorized range.

Accordingly, I conclude that the $3,200 PICMP is a reasonable enforcement remedy in this case.

III. Conclusion

For the foregoing reasons, I conclude that Petitioner was not in substantial compliance with program participation requirements due to a violation of 42 C.F.R. § 483.25(c) that caused actual harm to Resident 45. A $3,200 PICMP is a reasonable enforcement remedy.

/s/
Keith W. Sickendick
Administrative Law Judge