Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Golden Living Center – Trussville,
(CCN: 01-5131),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-11-477

Decision No. CR2634

Date: September 28, 2012

DECISION

Petitioner, Golden Living – Trussville, challenges the determination of the Centers for Medicare and Medicaid Services (CMS) that it was not in substantial compliance with program requirements. Petitioner also challenges CMS's imposition of a civil money penalty (CMP) of $4050 per day for the period December 26, 2010, through March 4, 2011. For the reasons discussed below, I sustain CMS's imposition of the CMP.

I. Background

Petitioner is a long term care facility located in Trussville, Alabama. Petitioner participates in the Medicare and Medicaid programs. The State of Alabama Department of Public Health (state agency) completed a complaint and revisit survey of Petitioner's facility on March 4, 2011.[1] The state agency determined that Petitioner was not in

[1] Petitioner does not appeal the surveys or associated remedies that either preceded or followed the March 4, 2011 revisit survey. At issue here is only related to the findings of the March 4, 2011 survey. *See* P. Readiness Report at 2-4. Petitioner also does not specifically contest the associated two-year prohibition on Petitioner's ability to offer a

substantial compliance with participation standards beginning December 26, 2010. Petitioner was cited for six deficiencies, one of which was substandard quality of care at the level of immediate jeopardy regarding pressure sores. Petitioner appeals only the immediate jeopardy violation at 42 C.F.R. § 483.25(c) (F-314) related to the care provided to Resident 4 (R4) who developed pressure sores while a resident at Petitioner's facility. Based on these findings, CMS imposed a $4050 per-day CMP from December 26, 2010, through March 4, 2011.[2]

Petitioner requested a hearing by letter dated May 20, 2011.[3]

I held a hearing in this case in Birmingham, Alabama on February 21 and 22, 2012. A 376-page transcript (Tr.) was prepared. Testifying on behalf of CMS was Jackie Wray, R.N., (Surveyor Wray), a surveyor with the state agency. Testifying on behalf of Petitioner were Cynthia Burleson, R.N., Petitioner's Clinical Nurse Consultant (Nurse Burleson), Verwanda Unna Evans, L.P.N., Petitioner's Treatment Nurse (Nurse Evans), and Brenda Barton, R.N., Petitioner's Clinical Nurse Consultant (Nurse Barton). I admitted CMS Exhibits (CMS Exs.) 1 – 8 and Petitioner's Exhibits (P. Exs.) 1 – 35. Both parties filed post-hearing briefs (CMS Br. and P. Br.) and post-hearing reply briefs (CMS Reply and P. Reply).[4]

II. Issues

1. Whether Petitioner was in substantial compliance with participation requirements in the Medicare and Medicaid programs;

2. Whether CMS's determination of immediate jeopardy was clearly erroneous; and,

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nurse aide training and competency evaluation program (NATCEP). *See* P. Br. at 7. Accordingly, I sustain the two-year prohibition on Petitioner's ability to offer an NATCEP.

[2] The immediate jeopardy was relieved on March 5, 2011, when the scope and severity was lowered to a "D" level, to allow the facility time to monitor and revise its corrective actions as needed to establish substantial compliance. CMS Ex. 1, at 1

[3] In its hearing request, Petitioner makes a due process argument I am without authority to hear. P. Hearing Request at 7. The argument is preserved for appeal.

[4] At the close of the CMS case-in-chief, Petitioner moved for summary disposition arguing that CMS failed to establish a *prima facie* case that Petitioner was not in substantial compliance. Tr. at 128-129. I denied Petitioner's motion. Tr. at 132-133.

3. Whether the remedies imposed are reasonable.

III. Controlling Law

Sections 1819 and 1919 of the Social Security Act (Act) and the regulations at 42 C.F.R. Part 483 govern Petitioner's participation in Medicare and Medicaid. Sections 1819 and 1919 of the Act provide the Secretary of Health and Human Services (Secretary) with authority to impose remedies, including CMPs, against long-term care facilities for failure to comply with participation requirements.

Regulations define the term "substantial compliance" as:

> [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.

The Secretary has delegated to CMS and the states the authority to impose remedies against long-term care facilities not complying substantially with federal participation requirements. The applicable regulations at 42 C.F.R. Part 488 provide that state survey agencies, on behalf of CMS, may survey facilities participating in Medicare and Medicaid to ascertain whether the facilities are complying with participation requirements. 42 C.F.R. §§ 488.10-488.28. The regulations contain special survey conditions for long-term care facilities. 42 C.F.R. §§ 488.300-488.335. Under Part 488, a state or CMS may impose a CMP against a long-term care facility if a state survey agency ascertains that the facility is not complying substantially with participation requirements. 42 C.F.R. §§ 488.406, 488.408, and 488.430. The CMP may begin to accrue as early as the date that the facility was first substantially out of compliance or may continue to accrue until the date the facility achieves substantial compliance, or until CMS terminates the facility's provider agreement. 42 C.F.R. § 488.440.

The regulations specify that if a CMP is imposed against a facility based on an instance of non-compliance, the CMP will be in the range of $1000 to $10,000 per instance. 42 C.F.R. § 488.438(a)(2). When a CMP is imposed against a facility on a per-day basis, it must fall into one of two broad ranges of penalties. 42 C.F.R. §§ 488.408, 488.438. The upper range of CMP, from $3050 per day to $10,000 per day, is reserved for deficiencies that constitute immediate jeopardy to a facility's residents and, in some circumstances, for repeated deficiencies. 42 C.F.R. § 488.438(a)(1)(i), (d)(2). The lower range of CMP, from $50 per day to $3000 per day, is reserved for deficiencies that do not constitute immediate jeopardy, but either cause actual harm to residents or cause no

actual harm, but have the potential for causing more than minimal harm. 42 C.F.R. § 488.438(a)(1)(ii). "Immediate jeopardy" is defined as:

> [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.

Sections 1819(f)(2)(B) and 1919(f)(2)(B) of the Act prohibit approval of a NATCEP if within the last two years the facility has been subject to, among other things, an extended or partial extended survey; imposition of a CMP of not less than $5,000; or imposition of a denial of payment for new admissions.

A facility may challenge the scope and severity that CMS cites only if a successful challenge would affect the range of CMP amounts that CMS imposed or would affect the facility's NATCEP. 42 C.F.R. § 498.3(b)(14), (d)(10)(i). CMS's determination as to the scope and severity of noncompliance "must be upheld unless it is clearly erroneous." 42 C.F.R. § 498.60(c)(2). This includes CMS's finding of immediate jeopardy. *Woodstock Care Center*, DAB No. 1726, at 9 (2000), *aff'd*, *Woodstock Care Center v. U.S. Department of Health and Human Services*, 363 F.3d 583 (6th Cir. 2003).

The Departmental Appeals Board (Board) has long held that the net effect of these regulations is that a provider has no right to challenge the scope and severity assigned to a noncompliance finding except in the situation where that finding is the basis for an immediate jeopardy determination. *See, e.g., Ridge Terrace*, DAB No. 1834 (2002); *Koester Pavilion*, DAB No. 1750 (2000).

A facility must prove by the preponderance of the evidence that it is in substantial compliance. *Batavia Nursing and Convalescent Center*, DAB No. 1904 (2004), *aff'd*, *Batavia Nursing and Convalescent Center v. Thompson*, 129 F. App'x 181 (6th Cir. 2005). To put the facility to its proof, CMS must initially present a *prima facie* case of noncompliance with Medicare participation requirements, providing evidence on any factual issue that the facility disputes that is "[s]ufficient to establish a fact or raise a presumption unless disproved or rebutted." *Alden Town Manor Rehabilitation and Health Care Center*, DAB No. 2054, at 4 (2006). Once CMS has made such a showing as to any disputed facts, the burden of proof shifts to the facility to show at the hearing that it is more likely than not that the facility was in substantial compliance. *Alden Town Manor*, DAB No. 2054, at 4-5; *see generally Evergreene Nursing Care Center*, DAB No. 2069 at 7-8 (2007)(discussing the "well-established framework for allocating the burden of proof on the issue of whether [a] SNF was out of substantial compliance"); *Golden Living Center – Riverchase*, DAB No. 2314, at 8 (2010).

IV. Discussion

I make numbered findings of fact and conclusions of law (Findings) to support my decision. I set them forth below as separate headings, in bold and italic type, and discuss each in detail.[5]

1. Petitioner failed substantially to comply with the pressure sore prevention requirement at 42 C.F.R. § 483.25(c) (Tag F-314).

The noncompliance at issue here involves the pressure sore prevention requirement at 42 C.F.R. § 483. 25(c), one of the quality of care requirements set forth in 42 C.F.R. § 483.25. The quality of care requirement specific to pressure sore prevention and treatment provides as follows:

> Based on the comprehensive assessment of a resident, the facility must ensure that—
>
> (1) A resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable; and
>
> (2) A resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing.

42 C.F.R. § 483.25(c).

A pressure sore is defined as "any lesion caused by unrelieved pressure that results in damage to the underlying tissue(s) . . . . Although friction and shear are not primary causes of pressure ulcers, friction and shear are important contributing factors to the

[5] I have reviewed the entire record, including all the exhibits and testimony. Because the Federal Rules of Evidence do not control the admission of evidence in proceedings of this kind (*see* 42 C.F.R. § 498.61), I may admit evidence and determine later, upon a review of the record as a whole, what weight, if any, I should accord that evidence or testimony. To the extent that any contention, evidence, or testimony is not explicitly addressed or mentioned, it is not because I have not considered the contentions. Rather, it is because I find that the contentions are not supported by the weight of the evidence or by credible evidence or testimony.

development of pressure ulcers."[6] Medicare State Operations Manual (SOM), Appendix PP, Tag F314. The SOM defines an "unavoidable" pressure sore as follows:

> "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.

In assessing a facility's compliance with this participation requirement, the Board has stated:

> [T]he preamble to the Notice of Final Rulemaking for section 483.25 provides that facilities "should always furnish the necessary treatment and services to prevent the development of pressure sores or, at the least, to promote the healing of sores that have developed." *Clermont Nursing and Convalescent Center* at 9; *Koester Pavilion*, DAB No. 1750, at 30-31 (2000), citing 56 Fed. Reg. 48,826, at 48,851 (Sept. 26, 1991); *see also Woodland Village Nursing Center*, DAB No. 2172, at 13 (2008) ("[the] regulatory language on pressure sore treatment and prevention applies a particularly demanding standard, i.e., that the facility must 'ensure' healing and prevention as the outcomes of that treatment and those services unless the facility can prove with clinical evidence that a negative outcome was unavoidable despite the facility having furnished all necessary care."). Thus, as the ALJ recognized, the Board has concluded that a facility cannot claim unavoidability unless it first shows that it furnished all necessary treatment and services . . . .

Gooding Rehabilitation & Living Center, DAB No. 2239, at 14-15 (2009).

The application of the regulation is well-established by decisions of various appellate panels of the Board. In *Koester Pavilion* and *Clermont*, the Board also held that a *prima facie* case of noncompliance exists when the evidence establishes that a nursing home resident having no pressure sores on admission develops a pressure sore in the facility, and the burden then shifts to the facility to establish that the pressure sore was clinically unavoidable. *Koester Pavilion* DAB No. 1750, at 34; *Clermont* DAB No. 1923, at 9; *see also Woodland Village Nursing Center*, DAB No. 2172, at 13 (2008)(evidence that resident developed a pressure sore while under a facility's care is enough to show a

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[6] The SOM notes that although the regulatory language refers to pressure sores, such sores are also referred to as pressure ulcers. Below, I generally use the term "pressure sore," although I may cite a pressure sore as an "ulcer," "decubitus," or "wound," depending on the context of the discussion or testimony.

deficiency in the absence of clinical evidence from the facility proving such negative outcomes to have been clinically unavoidable), *aff'd, Woodland Village Nursing Center v. U.S. Department of Health and Human Services*, 239 F. App'x 80 (5th Cir. 2007).

Moreover, if a resident is admitted with a pressure sore, a facility must do more than simply maintain the status quo; it must promote healing. If the resident's wound deteriorates, it is "sufficient to find noncompliance with section 483.25(c) unless the facility proved that it had timely taken all necessary measures, consistent with professional standards of care, to promote the healing . . ., prevent infection, and prevent even more pressure sores from developing." *Stone County Nursing and Rehabilitation Center*, DAB No. 2276, at 11 (2009). As discussed below, Petitioner did not make this showing.

R4 was an 86-year old woman with diabetes, deep venous thrombosis, status-post hip replacement, dementia, hypertension, and hypothyroidism. R4 was particularly susceptible to pressure sores given her diagnoses and that she was bed-bound, was incontinent of bowel and bladder, was on anti-coagulant therapy, and had nutritional issues. She was admitted to Petitioner's facility in March 2010 with a stage II pressure ulcer on her coccyx. CMS Ex. 2, at 9, 133, 163-168; P. Ex. 11, at 2; P. Ex. 12, at 2. By October 2010, Petitioner was able to heal R4's pressure sore. CMS Ex. 2, at 45, 132, 175.

Neither party disputes that by December 17, 2010, R4 developed another pressure sore in the same area. CMS Br. at 8; P. Br. at 19. The fact that R4 developed a new pressure sore while at Petitioner's facility establishes a *prima facie* case of noncompliance. CMS Br. at 8; P. Br. at 19; *see* Tr. at 132 (denying Petitioner's motion and finding that CMS established its *prima facie* case). As stated, a nursing home can overcome a *prima facie* case of noncompliance with section 483. 25(c) based on development of pressure sores by showing that it provided all the care and services needed to prevent pressure sores but that the lesions developed in spite of those measures because the lesions were clinically unavoidable. *E.g.*, *Koester Pavilion*, DAB No. 1750, at 34; *Clermont*, DAB No. 1923, at 9. "Clinically unavoidable" in this context "means not just unsurprising given the clinical condition of the resident, but incapable of prevention despite appropriate measures taken in light of the clinical risks." *Harmony Court*, DAB No. 1968, at 11 (2005), *aff'd, Harmony Court v. Leavitt*, 188 F. App'x 438 (6th Cir. 2006). A facility "cannot meet its burden of proof on the issue of whether a pressure sore is unavoidable merely by establishing that the resident's clinical condition heightens the risk that pressure sores will develop." *Id.* (quoting *Ivy Woods Health Care and Rehab. Ctr.*, DAB No. 1933, at 9 (2004), *aff'd, Ivy Woods Health Care and Rehab. Ctr. v. Thompson*, 156 F. App'x 775 (6th Cir. 2005)).

As Petitioner points out, much of this record consists of "detailed, even tedious, reference and cross-reference to excerpts of documentation from Resident#4's chart. . . ." P. Br. at

5. CMS asserts that Petitioner failed to conduct necessary skin assessments and physician-ordered treatments. On the other hand, Petitioner contends that the assessments and treatments were conducted, but were simply not documented accordingly or consistently. Petitioner argues that although its documentation of R4's care was defective, its care of R4's wound care was sufficient. P. Br. at 4-5. Petitioner asserts that this documentary evaluation "illustrates that Petitioner's nurses were performing ordered skin assessments, wound measurements, treatments, and the like." P. Br. at 5. As discussed below, I find that CMS prevails on the basis of the facility's records as corroborated by statements attributed to the facility staff and clinical providers.

In March 2010, R4 was readmitted to Petitioner's facility with a stage II pressure sore. Many physician orders were issued during her stay at the facility, including one on August 25, 2010, when R4's physician ordered weekly skin assessments. CMS Ex. 2, at 126. By October 25, 2010, R4's pressure ulcer had healed. CMS Ex. 2, at 45, 132, 175. On October 29, 2010, R4's doctor ordered a preventative treatment to be applied to R4's coccyx twice a day. CMS Ex. 2, at 175. Specifically, the doctor ordered the nursing staff to "[a]pply skin protectant with zinc for protection of previous skin concern to coccyx [every day] and [as needed]." P. Ex. 2, at 175.

By December 17, 2010, R4 developed another pressure sore on her coccyx that was larger than her initial pressure sore. CMS Ex. 2, at 131. On that date, R4's physician ordered the nursing staff to clean R4's wound with cleanser, apply a Duoderm dressing, and change the wound dressing every three days and to do so more frequently as needed. CMS Ex. 2, at 97. The wound did not heal but continued to grow. CMS Ex. 2, at 39.

On February 3, 2011, R4's physician discontinued the Duoderm change every three days, and replaced it with orders to clean the wound with cleanser, apply Santyl ointment, and to cover the wound with dressing every other day and as needed. CMS Ex. 2, at 39-40, 67. Still the wound continued to grow. Between February 3 and 9, it had doubled in size and depth and had developed a noticeable odor. CMS Ex. 2, at 39.

On August 25, 2010, R4's physician ordered weekly skin assessments. CMS Ex. 2, at 126. Skin assessments, or body audits, are a "head-to-toe" assessment of a resident with an emphasis on contact-pressure points on the resident's body, such as behind the ears, on the knees, elbows, buttocks, heels, and between the fingers and toes. The nurse looks for skin conditions, including but not limited to pressure sores. Tr. at 58-59, 330-331, 356. The medication administration records (MARs), where R4's weekly skin assessments were recorded, reflect that the assessments were not conducted as ordered on November 1, 2010, November 15, and November 29. CMS Ex. 2, at 126. It is entirely reasonable to believe that if these assessments had been conducted as ordered, they would have been likely to reveal R4's pressure at a very early stage in its development, and would have alerted the facility and R4's physician to the need for active management of the developing lesion. However, these assessments were not conducted, and by December

17, R4 had developed the new pressure ulcer, larger than the previous healed ulcer. Despite this new development, Petitioner again failed to conduct skin assessments on December 27, 2010, (CMS Ex. 2, at 96), January 17, 2011, January 24, January 31 (CMS Ex.2, at 83), February 21, and again during the survey on February 28, 2011 (CMS Ex. 2, at 65).

Petitioner argues that any error lies with the documentation of the care, not with the substance of the care actually provided to R4. Petitioner contends that simply because a particular form is not completed, that lapse does not mean that the assessment was not conducted. Surveyor Wray testified, however, that the facility informed her that Nurse Gray was responsible for conducting the seemingly-missed assessments. Surveyor Wray testified that when interviewed, Nurse Gray flatly stated that if she did not initial that the skin assessment was done, she did not perform one. Tr. at 63, CMS Ex. 2, at 46-7. Nurse Gray stated that she was too busy to perform all of the body audits for which she was responsible. CMS Ex. 2, at 47-48. Furthermore, Nurse Gray worked the 11 P.M. to 7 A.M. shift and added that it was often difficult to perform the body audits because she had to wake up the residents in order to conduct the assessment. *Id*.; Tr. at 63.

Petitioner argues that the assessment was provided either by another nurse and not documented or documented in another location in the Resident's chart. P. Br. at 16-17. Petitioner, however, did not provide evidence that the weekly body audits were performed but not documented; there is nothing in this record to support that position other than Petitioner's unsupported assertion. Petitioner produced no witness to testify that he or she conducted the ordered assessments. Petitioner has pointed out no evidence that the required full body assessments were conducted in accordance with the doctor's order. Petitioner states that: "Nurse Barton reviewed the documentary evidence in detail, and matched 'missing' weekly skin assessments to documentation of interventions that of necessity would require observation" of R4's wound. P. Br. at 22; Tr. at 234-240. Petitioner appears to argue that while performing other treatments or services on R4, the staff essentially performed the skin assessments implicitly. Petitioner fails to recognize that the focus of the assessment is relevant to the quality of that assessment performed. Furthermore, even if Petitioner's nursing staff observed R4's coccyx while applying the skin protectant with zinc,[7] there is no evidence that R4's coccyx was actually evaluated for pressure ulcer potential, or that the remainder of her body was assessed to assure that R4 suffered no further decomposition in other areas of her body. Petitioner simply has not provided any reliable evidence that the skin assessments were conducted as ordered by R4's physician.

As previously noted, by December 17, 2010 R4 developed another pressure sore on her coccyx. On that date, R4's physician ordered the nursing staff to clan R4's wound with

[7] The November 2010 MAR reflects that the skin protectant was not applied each day, let alone additionally as needed on November 1 and November 20. CMS Ex. 2, at 124.

cleanser, apply a Duoderm dressing, and change the wound dressing every three days and more frequently as needed. CMS Ex. 2, at 97. Petitioner's staff followed the order on December 17, 20, and 23, but failed to carry out the order on December 26 and 29. CMS Ex. 2, at 97; *see* CMS Ex. 2, at 38. In January 2011, Petitioner's staff failed *five times* to change the Duoderm every three days. CMS Ex. 2, at 85; P. Ex. 26, at 26. Still the wound continued to grow. CMS Ex. 2, at 39. The order was discontinued on February 3, 2011. CMS Ex. 2, at 68.

The surveyors interviewed the facility's wound care nurse, Ms. Collier, about the missed treatments. She stated that she did not know why they were missed but suspected that they were missed while someone else was responsible, or that the dressings were changed by another nurse who did not document the care. CMS Ex. 2, at 53. The surveyor's review of the facility's work schedule indicated that Ms. Collier was responsible and on duty during the missed treatment on December 31, 2010, and all five of the missed treatments in January 2011. CMS Ex. 2, at 55.

Petitioner argues that the staff may not have changed the dressings exactly every third day but, in essence, they were close enough: "there are in fact about a dozen occasions over several months where a treatment ordered for a certain day was not documented as done *on that day*, but in most cases the treatment was documented a day or two earlier or later." P. Br. at 22. Whatever this may suggest about Petitioner's diligence in complying with R4's physician's orders, this is not a situation of a single mistake Petitioner's staff made in which they were off by one day in providing or documenting care. Rather, the record shows a serious lack of consistency in providing care for R4. For example, in January, rather than changing R4's dressing every three days and as needed[8] in accordance with the doctor's order, her bandage was changed after four days; then after five days;[9] then two days; two days again; then R4's bandage was not changed again for six days; [10] then after one day; and again her bandage was not changed for over a week. CMS Ex. 2, at 85; P. Ex. 26, at 26; CMS Ex. 2, at 39. Moreover, there is no evidence that

[8] I note that Petitioner misinterprets the doctor's order as stating "every three days **or** as needed." P. Br. at 22 (emphasis added). The order, however, is for "every three days **and** as needed." *See, e.g.,* CMS Ex. 2, at 85 (emphasis added).

[9] I note that nursing notes dated January 10 indicate that the nurse cleaned R4's wound and changed the Duoderm dressing on that date. CMS Ex. 2, at 169. Even presuming that the care was done that date and not indicated as such in the MAR, it still leaves the dressing unchanged on R4 for four days. CMS Ex. 2, at 85.

[10] I note that it is conceivable that Nurse Collier changed the Duoderm dressing on January 17, 2011 without documenting it in the MAR, however that still leaves R4's dressing unchanged for a five-day period, rather than a six-day period. CMS Ex. 2, at 39; compare CMS Ex. 2, at 85.

R4's dressing was changed at any time in February before it was discontinued on February 3, leaving her dressing unchanged for a ten-day period.

On February 3, 2011, R4's physician discontinued the Duoderm change every three days, and replaced it with orders to clean the wound with cleanser, apply Santyl, ointment, and to cover the wound with dressing every other day and as needed. This new order was also not followed. CMS Ex. 2, at 39-40, 67.

Finally, on February 14, R4 was seen by a wound care physician, Dr. Chaicharncheep ("Dr. Chai"). Dr. Chai changed the wound care orders to daily dressing changes using both Santyl and Dakins. CMS Ex. 2, at 66. Dr. Chai found the wound "with a lot of dead tissue," debrided the wound, and changed the wound care orders to daily dressing changes using both Santyl and Dakins. CMS Ex. 2, at 30, 32-33, 66. Dr. Chai spent a great deal of her visit consulting with staff. CMS Ex. 2, at 30-31, 33. The following day Petitioner's staff recorded that R4's pressure ulcer had grown to a stage III with a foul smell and heavy yellowish exudate, and that the lesion was painful to the touch. CMS Ex. 2, at 40; P. Ex. 17, at 5. Dr. Chai even communicated with the facility's administrator, also a RN, and became concerned when the administrator reported that they did not like to do daily dressing changes due to "increased risk of contamination." CMS Ex. 2, at 26, 31. Petitioner's staff still appeared not to have performed the wound care specialist's order as directed on February 16 and 21. CMS Ex. 2, at 64-66. Dr. Chai returned on February 22 to follow up and found that the wound had once again deteriorated. R4's wound progressed to a stage IV pressure ulcer and Dr. Chai again found the wound in need of debriding. CMS Ex. 2, at 34. Dr. Chai changed to daily dressing changes, ordered a topical antibiotic, and an oral antibiotic. CMS Ex. 2, at 30, 34, 40, 71. The survey began the following day. P. Ex. 1, at 1. During surveyor observation rounds, the wound care nurse found R4's wound to be "unstageable." CMS Ex. 2, at 36. Dr. Chai returned again on March 3, this time finding that the wound showed increased granulation, an indication that the condition of the wound had improved. CMS Ex. 2, at 35. Dr. Chai also noted that she discussed R4's care with nursing staff and state surveyors. *Id*.

Petitioner argues that "handful of occasions" when the facility missed assessments or treatments "would be unlikely to cause any adverse effect on this particular longstanding wound." P. Br. at 23; (citing Tr. at 196, 224, 316-317). It is Petitioner's stated position here that "delaying a dressing change for a day or two is not likely to have any practical impact, as modern dressings are designed to be effective for several days." P. Br. at 23; citing, Tr. at 338. Finally, Petitioner argues that there is no evidence that R4's "wound persisted, or worsened at any time, because of, or even corresponding to, any delayed or missed treatment." P. Br. at 23; see P. Br. at 27-28. The overall implication of these statements of Petitioner's position is simply not sustainable on this record of explicit and detailed orders, given by a physician well aware of the R4's condition and needs, which orders were neglected or ignored by facility staff.

The standard for compliance with the regulation is high: for development of a pressure sore to be unavoidable, a facility must show that it furnished all necessary treatment and services to that sore. In this instance a healed pressure sore reappeared. It is incumbent upon a facility to properly and promptly treat such sores. If a facility is to meet that obligation, then consulting with a resident's physician, obtaining treatment orders or a change in orders, and then following those orders are obvious and indispensible imperatives. Under the circumstances, documenting the following of the physician's orders for R4's wound treatment would have provided the most basic evidence of having providing a necessary treatment, which evidence as a practical matter was required to establish that the wound was unavoidable. *See Gooding Rehabilitation & Living Center*, DAB No. 2239, at 15 (2009). Petitioner has not made such a showing. And in failing to make that showing, Petitioner has failed to demonstrate that it provided the necessary care and treatment to prevent the addition or progression of R4's pressure sore, or that it was otherwise unavoidable.

The evidence shows that during the time in issue, the facility simply neglected to take the measures for wound care and skin checks that R4's physician ordered. Although Petitioner's briefing — and its efforts at trial — suggests that the lacunae in the records are nothing more than mistakes in record-keeping, clerical errors unrelated to good nursing practice and reasonable medical care, there are simply too many for that to be a viable position. If there were that many "mistakes," then none of the facility's records would be reliable or trustworthy as bases for resident care across the board. The far-more-convincing evidence *contra* is in the CMS interviews with staffers T. Gray and T. Collier, and the wound-care physician Dr. "Chai." These interviews support the assertion that the skin checks and treatments were not conducted as ordered, and that the absence of documentation accurately reflects the absence of actual care provided to a resident known to be at high risk of pressure ulcers. While in Petitioner's care R4 developed a pressure sore on her coccyx or sacrum that progressed to a stage IV then eventually became unstageable. I conclude this is actual harm.[11] Accordingly, I conclude that Petitioner violated 42 C.F.R. § 483.25(c) based upon the care provided to the Resident, and that she suffered actual harm as a result.

2. Petitioner's noncompliance at a level of immediate jeopardy extended from December 26, 2010 through March 3, 2011.

Once the period of noncompliance is shown to have opened, it becomes Petitioner's obligation, under most circumstances, to show when it closed.

[11] The evidence shows open ulcers and they amount to actual harm because any open wound has associated pain, risk for infection, and other complications.

The Board in *Cary Health*, DAB No. 1771 (2001) explained that noncompliance is presumed to continue until the facility demonstrates that it has achieved substantial compliance. In *Taos Living Center*, DAB No. 2293, (2009), however, the Board clarified that it has never held that the presumption of continued noncompliance is unrebuttable (or that findings of continuing noncompliance are an exception to the regulatory provision of hearing rights on findings of noncompliance resulting in enforcement actions). In *Brian Center,* DAB No. 2336, (2010), the Board explained that the facility's burden extends to overcoming CMS's determination as to when the immediate jeopardy was removed. CMS's judgment that corrective measures were insufficient to abate the immediate jeopardy prior to the date CMS determined "is, in essence, a determination that the level of noncompliance continued to present immediate jeopardy" to residents. Thus, a "determination by CMS that a SNF's ongoing compliance remains at the level of immediate jeopardy during a given period constitutes a determination about the 'level of noncompliance' and, therefore, is subject to the clearly erroneous standard . . . ." *Id*. at 7-8.

Petitioner argues that its failure to provide wound care had no effect on R4's wound deterioration and that no actual harm was sustained by her. I find Petitioner's failure to provide adequate wound care to have caused her wound to reappear and rapidly deteriorate, much less simply fail to heal. That is actual harm. Petitioner's failure to provide physician-ordered needed care had, at the very least, the likelihood of causing serious injury to R4, particularly given her compromised health. Tr. at 34, 53-54. December 26, 2010 corresponds with the date of the first missed wound care treatment after R4 re-developed her pressure sore. The state surveyors found the facility's allegation of credible compliance acceptable based on a number of interventions instituted by the facility including nursing staff received retraining on clinical guideline related skin integrity, a contract with a wound care physician group to provide oversight and consultation to the licensed nurses (attained February 11), the new hire of a full-time RN treatment nurse, quality assurance, consultant and supervisor monitoring of wound care and documentation audits. I find this an acceptable period of time based on the evidence and arguments presented. Petitioner has not offered a compelling argument to the contrary.

3. The CMP imposed for the period of immediate jeopardy of $4050 per day from December 26, 2010, through March 3, 2011, is reasonable.

To determine whether the CMP imposed is reasonable, I apply the factors listed in 42 C.F.R. § 488.438(f), which are: (1) the facility's history of noncompliance; (2) the facility's financial condition; (3) factors specified in 42 C.F.R. § 488.404; and (4) the facility's degree of culpability, which includes neglect, indifference, or disregard for resident care, comfort, or safety. The absence of culpability is not a mitigating circumstance in reducing the amount of the penalty. The factors listed in 42 C.F.R. § 488.404 include: (1) the scope and severity of the deficiency; (2) the relationship of the

deficiency to other deficiencies resulting in noncompliance; and (3) the facility's prior history of noncompliance in general and specifically with reference to the cited deficiencies.

In reaching a decision on the reasonableness of the CMP, I must 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 Petitioner with the kind of deficiency found, in light of the above factors. I am neither bound to defer to CMS's factual assertions, nor free to make a wholly independent choice of remedies without regard for CMS's discretion. *Barn Hill Care Center*, DAB No. 1848, at 21 (2002).

In evaluating the regulatory factors, I find that Petitioner has not submitted evidence regarding its financial condition. These deficiencies are serious and Petitioner is culpable in that Petitioner's actions had a serious negative effect on R1's care and comfort. The facility is highly culpable in that its staff repeatedly failed to provide necessary wound care to R4. The immediate jeopardy deficiency revealed a systematic problem related to pressure sore care and treatment: the nursing and wound care staff neglected or disregarded explicit orders for the care of R4. The penalty falls in the low range of permissible penalties. I find the $4050 per-day CMP from December 26, 2010 through March 3, 2011, is reasonable.

V. Conclusion

For the reasons discussed above, I find that Petitioner's facility was not in substantial compliance with Medicare participation requirements and that its noncompliance posed immediate jeopardy to resident health and safety. I find that a $4050 per-day CMP, from December 26, 2010, through March 3, 2011, is reasonable.

/s/
Richard J. Smith
Administrative Law Judge