Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Life Care Center of Paradise Valley (CCN: 03-5146),	)	Date: October 19, 2007
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-04-451
	)	Decision No. CR1673
Centers for Medicare & Medicaid Services.	)	
	)	

DECISION

I sustain the determination of the Centers for Medicare & Medicaid Services (CMS) to impose civil money penalties (CMPs) against Petitioner, Life Care Center of Paradise Valley (Life Care or facility), in the amount of $500 per day, for a period that began on April 15, 2004 and which ended on June 1, 2004.

I. Background

Life Care is a skilled nursing facility doing business in Phoenix, Arizona. It participates in the Medicare program. Life Care was surveyed for compliance with Medicare participation requirements on April 12-15, 2004 (April survey) by surveyors employed by the Arizona Department of Health Services Survey Agency (Survey agency). The surveyors found that Life Care was not complying substantially with several Medicare participation requirements. On June 2, 2004, the Survey agency conducted a revisit survey and found that Life Care had resumed substantial compliance as of that date.

CMS concurred with the surveyors' findings of noncompliance and proposed to impose sanctions against Life Care consisting of a CMP of $500 per day for the period of April 15 through to June 1, 2004, totaling $24,000, and disqualifying Life Care from operating a nurse aide training program for a period of two years. Notices dated May 20, 2004 and July 7, 2004.[1]

On July 9, 2004, Life Care requested a hearing. The case was assigned to me for a hearing and a decision. In its request for hearing, Life Care stated that it was not contesting all of the deficiencies cited during the April survey.[2] Consequently, I will only consider those deficiencies which Petitioner has chosen to challenge and upon which it has presented evidence.

A schedule was established for the parties to file written submissions including proposed exhibits and briefs. CMS filed a *Motion for Full or Partial Summary Judgement* on March 4, 2005. During a telephone conference on March 22, 2005, I informed the parties' of my ruling denying the motion. *See* Summary of Prehearing Conference; Ruling Denying CMS's Motion for Full or Partial Summary Judgment; and Order, dated March 23, 2005.

An in-person hearing was held in this matter from May 10, 2005 through May 12, 2005, in Phoenix, Arizona. During the course of the hearing, there being no objections, the following exhibits were admitted: CMS exhibits (Exs.) 1-49, and Life Care's exhibits (P. Exs.) 1-49.[3] Transcript (Tr.) at 10, 13.

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[1] The May 20, 2004 notice informed Life Care that a denial of payment for new admissions (DPNA) was to go into effect on June 4, 2004; however, as Life Care achieved substantial compliance prior to that date, the DPNA remedy was never effectuated. Notice dated July 7, 2004.

[2] Life Care has chosen to challenge eight of the deficiencies listed in the April Statement of Deficiencies (SOD) which include seven deficiencies cited at the D-level, constituting a potential for more than minimal harm, and one deficiency at the G-level, constituting actual harm (F-tags: 226, 241, 281, 309, 314, 332, 371, 514). Request for Hearing at 5. Life Care chose not to appeal seven B-level deficiencies identified in the April SOD (F-tags: 252, 253, 272, 274, 286, 363, 368). *Id.*

[3] During the direct testimony of Nurse Myrna Deagnon, Life Care moved to include additional exhibits into evidence. CMS objected. I denied Life Care's motion as the parties had ample opportunity for full and open exchange of all documents prior to the hearing. *See* Tr. 779-87.

At the hearing, seven surveyors testified for CMS: Katrina Jean Huff, Registered Nurse (R.N.), Susan Parry, R.N., Debra K. Mayo, R.N., JoLee Kennedy, R.N., Elizabeth Stewart, R.N., Patricia Ross, R.N., and Deborah Romero, R.N. Also testifying for CMS was expert witness Courtney H. Lyder, R.N., N.D., G.N.P., F.A.A.N. Life Care presented the testimony of four witnesses: David M. Franey, M.D., Denise Wald, R.N., Mary Anne Stanford, Administrator, and Myrna Deagnon, R.N., Clinical Services Coordinator. The parties were provided with a copy of the certified transcript of the hearing and opportunity to note any prejudicial errors. On July 11, 2005, CMS filed a list of transcript errors which are duly noted; however, I did not find any error noted by CMS to be prejudicial to either party. CMS's post-hearing brief (CMS PHB) was received on August 29, 2005. Life Care's post-hearing (P. PHB) was received on October 20, 2005, and Life Care's findings of fact and conclusions of law were received on December 16, 2005. CMS's reply brief (CMS Reply) and proposed findings of facts and conclusions of law were received on December 23, 2005.

This decision is based on the complete record which includes the parties' arguments, written submissions, all exhibits admitted into the record, and the witness testimony adduced during the hearing.

II. Issues

The issues in this case are whether a sufficient basis existed for CMS to impose its remedies for the April survey and, if so, are they reasonable.

III. Applicable Law

Long-term care providers, such as Life Care, participate in the Medicare program by entering into provider agreements with the Department of Health and Human Services (HHS). Requirements of participation are imposed by statute and regulation. Social Security Act (Act) §§ 1819, 1919; 42 C.F.R. Parts 483, 488, and 489. In order to continue participation in the Medicare program, providers must remain in substantial compliance with program requirements. To be in substantial compliance, a facility's deficiencies may pose no greater risk to resident health and safety than "the potential for causing minimal harm." 42 C.F.R. § 488.301.

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, which includes imposing a CMP. Act, § 1819(h). CMS may impose a CMP for the number of days that the facility is not in substantial compliance with one or more program requirements, or for each instance that a facility is not in substantial compliance. 42 C.F.R. §§ 488.430(a); 488.440. The presence of a single deficiency cited at the D-

level or above is sufficient to establish a facility's noncompliance with applicable regulations and authorize the imposition of remedies. *Beechwood Sanitarium,* DAB No. 1824 (2002).

The regulations specify that a CMP imposed against a provider will fall into one of two broad ranges of penalties. 42 C.F.R. §§ 488.408; 488.438. The lower range of CMPs, from $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).

IV. Burden of Proof

When a penalty is imposed and appealed, CMS must established a prima facie case that the facility was not in substantial compliance with federal participation requirements. To prevail, the facility must overcome CMS's showing by a preponderance of evidence. *Emerald Oaks*, DAB No. 1800, at 4 (2001); *Cross Creek Health Care Center*, DAB No. 1665 (1998), applying *Hillman Rehabilitation Center*, DAB No. 1611 (1997), *aff'd Hillman Rehabilitation Center v. HHS*, No. 98-3789 (GEB), slip op. at 25 (D.N.J. May 13, 1999). I adopt the burden as set forth in the Board's decision in the *Hillman* case, and as stated and discussed in detail in the *Batavia Nursing and Convalescent Center* and *Batavia Nursing and Convalescent Inn* cases. *See Batavia Nursing and Convalescent Center*, DAB No. 1904 (2004); and *Batavia Nursing and Convalescent Inn*, DAB No. 1911 (2004).

V. Findings of fact, conclusions of law and discussion.

I make findings of fact and conclusions of law (Findings) to support my decision in this case. However, I do not make a Finding on every deficiency in controversy during these proceedings. The Departmental Appeals Board (Board) has previously approved an administrative law judge's (ALJ's) discretion to exercise judicial economy and not discuss every alleged deficiency. *Beechwood Sanitarium*, DAB No. 1824 (2002), at 22; *Beechwood Sanitarium*, DAB No. 1906 (2004). Specifically, I discuss only those deficiency citations that have been assessed to support the noncompliance alleged and the remedies imposed.

A. I do not have authority to hear and decide Life Care's constitutional arguments or its assertions that CMS's processes violate federal law.

In its prehearing brief, Life Care raises various challenges to the constitutionality of CMS's Medicare regulations and the regulatory enforcement process, asserting that aspects of the process violate various statutes. P. PHB at 9-10. Life Care asserts that this

failure is a violation of the Medicare Act and its due process protections. I do not have authority to hear and decide these arguments. My authority to hear and decide cases involving CMS is defined by regulations and by the delegations of the Secretary of the Department of Health and Human Services (Secretary). The regulations do not confer any authority on an ALJ to hear and decide constitutional questions, or to decide whether CMS's processes are unlawful. *See* 42 C.F.R. §§ 498.3; 498.5. However, I note that Life Care's constitutional arguments are preserved for appeal in a forum that can hear them.

Second, Life Care challenges the Board's policy to impose the burden to demonstrate "substantial compliance," claiming that it is inconsistent with the requirements of the Administrative Procedure Act and thus deprives Life Care of its property without due process of law. P. PHB at 9. Life Care alleges that it was unconstitutionally forced to bear the burden of proving compliance, rather than the agency being required to prove the violation. *Id*. I note that the question of which party bears the ultimate burden of proving its case by the preponderance of the evidence is one that affects the outcome only where conflicting evidence rests near equipoise and the decision-maker must determine which party prevails. *Fairfax Nursing Home*, DAB No. 1794, *aff'd sub nom*., *Fairfax Nursing Home v. Dep't of Health & Human Srvcs.*, 300 F.3d 835, 840, n.4 (7th Cir. 2002), *cert. denied*, 537 U.S. 111 (2003); *Meadow Wood Nursing Home*, DAB No. 1841 (2002), *Milpitas Care Center*, DAB No. 1864 (2003).

Lastly, Life Care challenges the Board's policy which permits CMS to impose CMPs without first being required to offer evidence that CMS considered the regulatory criteria set forth at 42 C.F.R. §§ 488.404 and 488.438(f). Life Care asserts that this failure is a violation of the Medicare Act and its due process protections. Life Care was provided with a de novo hearing and review by this forum as to the reasonableness of CMS's proposed sanctions. Life Care has had opportunity to present its arguments through these proceedings and, at hearing, an opportunity to testify, to present witnesses and evidence, and to rebut CMS's evidence and witnesses. Thus, Life Care has been afforded ample opportunity to exercise its due process rights.

B. Life Care failed to comply substantially with Medicare participation requirements during the April 15, 2004 - June 1, 2004 period.

CMS alleges that Life Care was not providing residents with services or treatment as required. Specifically: (1) that residents at high risk for pressure ulcer development were not adequately cared for to prevent ulcers; (2) potentially harmful practices were allowed to continue without facility correction; (3) clean sanitary habits were not enforced in daily practice; and (4) facility documentation was incomplete or inaccurate. CMS Ex. 1.

The April SOD sets forth one G-level deficiency in which "actual harm" is alleged (F-tag 314), and seven deficiencies cited at the D-level, constituting a "potential for more than minimal harm" (F-tags: 226, 241, 281, 309, 314, 332, 371, 514).

I first address the G-level deficiency F-tag 314 where CMS alleges that Petitioner caused "actual harm" to a resident due to alleged inadequate care of the resident's skin which either worsened existing, or caused the development of, pressure sores.

1. The evidence establishes that, as of the April survey, Life Care failed to comply substantially with the requirements of 42 C.F.R. § 483.25(c) - F-tag 314(G) - Quality of Care.

The regulation that is at issue here governs the prevention and treatment of pressure sores.[4] The regulation provides that a resident who enters a facility does not develop pressure sores unless his or her clinical condition makes the development unavoidable. 42 C.F.R. § 483.25(c)(1). Therefore, a facility has a duty to take all reasonable measures to ensure that a resident does not develop a pressure sore. Although not a strict liability regulation, it does presume that pressure sores are avoidable. Where a resident develops a pressure sore, the burden thus falls on the facility to provide an explanation as to why the sore was unavoidable.

Life Care was cited for failing to comply with this requirement because it failed to provide care and services necessary to prevent pressure sores from developing and subsequently worsening on R6's right heel and right lower calf. CMS Ex. 1, at 23. Life Care was cited at a G-level deficiency constituting "actual harm." *Id*.

CMS contends that the record clearly demonstrates that R6's pressure sores were avoidable. CMS PHB at 59. CMS contends further that staff failed to timely and adequately assess R6 for risk of pressure sores and provide appropriate treatment. *Id.*

Life Care admits that much of its documentation of the assessments and care of R6's skin condition was not very good, but argues that its care was not deficient and its actions did not cause any actual harm to R6. P. PHB at 2, 8. Life Care claims that R6's skin issues were an unavoidable consequence of appropriate treatment for R6's fractured leg which, according to Life Care, was R6's most serious and pressing medical issue. *Id*. at 8. Life Care insists that the care provided to R6's pressure sores was appropriate and that the

[4] In this decision the terms pressure sores, pressure ulcers, sores, ulcers, and wounds are used interchangeably.

treatment actually resulted in improvement or resolution of the wounds prior to R6's discharge several months after admission, and within several weeks after the April survey. *Id.* at 2, 8.

The key issue for my review is whether R6s pressure sores were unavoidable. Since Life Care was only cited for pressure sores that developed on R6's right knee and right calf, I will limit my discussion to those specific wounds.

a. R6's Clinical Condition Upon Admission to Life Care.

Upon admission to Life Care on February 26, 2004, R6, an 80-year-old female, had a diagnoses of right distal femur fracture, emphysema, diabetes mellitus, and hypertension. P. Ex. 4, 6. R6 had lived with her daughter prior to admission, and was admitted following a fall in the home which resulted in a severe fracture to her right femur. P. Ex. 5, at 3. Her orthopedic surgeon noted that she had "multiple fractures up and down the leg." P. Ex 30, at 4. Previous to this fracture, R6 had surgery for a right hip prosthesis in 2001, and again in February 2004. P. Ex. 5, at 3.

Upon admission, R6 required a full-length brace on her right leg which extended from hip to ankle to support the fracture, and also a soft brace on her left leg and abductor pillow.[5] P. Ex. 19, at 1; Tr. at 793. R6's attending physician, Dr. David Franey, testified that the fracture, which contained several fragments, could not be treated surgically, and required that R6 be immobilized with the brace. Tr. at 450-51; *see also* P. Ex. 30, at 4. Dr. Franey stated that in spite of R6's other medical conditions, the primary focus of treatment for R6 was her fractured leg. Tr. at 449, 468.

Life Care avers that R6's leg injury was serious and posed a significant risk of death by either exacerbation of her underlying cardiac, circulatory and pulmonary conditions, or by complications of the fracture itself - i.e., blood clot or pneumonia resulting from immobility. P. PHB at 14-15; P. Ex. 19, at 1. The clinical record notes that the day following her admission to Life Care, R6 was rushed back to the hospital after exhibiting symptoms of a possible blood clot in her lungs. P. Ex. 9, at 1.

[5] Although the clinical record does not state specifically, inference can be made that the soft brace on her left leg was removed at the hospital after her readmission on February 27, 2004. *See* testimony of Myria Deagnon, Tr. at 796.

Dr. Franey testified that R6 was wearing the full-length leg brace pursuant to the orthopedic surgeon's order. Tr. at 451. He testified that the treatment for a fracture similar to R6's would be to immobilize the area with either a casting or a brace. Tr. at 451. Dr. Franey testified further that the decision as to the best treatment modality to use, casting verses use of a brace, is a decision the orthopedic surgeon would make and, in the case of R6, Dr. Franey stated that the surgeon was managing the fracture. Tr. at 451. Dr. Franey further testified that in his practice it was not an uncommon order for a brace being required to be worn 24 hours per day. Tr. at 454.

There is no dispute between the parties that R6's most pressing problem was her severely fractured leg, and that R6's skin condition was compromised from the use of a full-length leg brace 24-hours per day to treat the fracture. Surveyor Katrina Huff agreed that R6's use of the leg brace further impacted the risk of her developing pressure ulcers. Tr. 361-62. Therefore, as noted above, the crux of the issue here is whether the pressure sores which developed subsequent to R6's admission were unavoidable. To determine this, I must review whether facility staff provided timely and adequate assessment of R6's wounds, and once assessed, whether staff provided appropriate treatment.

b. Life Care's Skin Care Policy.

Life Care's skin care policy at the time of the survey stated:

> Each resident is to be evaluated for special needs related to skin care at the time of admission . . . all residents are to receive weekly skin assessments by licensed personnel. A certain number of checks should be done each day to accomplish this objective by the end of each week.
>
> Lesions which are present, or which develop subsequently to admission, are treated according to medical direction and are conscientiously followed. On a weekly basis, an in-depth assessment is performed and recorded on the Weekly Pressure Ulcer Program Report in the resident's medical record.

CMS Ex. 21, at 33.

The policy further requires that the resident's pressure sore description be listed on the Weekly Wound Care Tracking Report and a weekly assessment be made addressing the site, stage, size, diameter, depth, presence or absence of drainage, odor, color of drainage and surrounding tissue, the resident's response to treatment or progress, and indication as to whether dietary and the physician were notified. CMS Ex. 21, at 34, 35.

c. Assessment of R6's Skin Condition Subsequent to Admission.

CMS alleges that inconsistent documentation was found in R6's clinical record and Life Care's staff failed to conduct weekly assessments of R6's pressure sores as required by the facility's policy governing skin care. As previously noted, Life Care was specifically cited for its failure to prevent pressure sores on R6's right heel and her right lower calf from developing and subsequently worsening. CMS Ex. 1, at 23. Therefore, my review of R6's clinical record focused on the assessment and treatment of pressure ulcers that developed on R6's right heel and right calf during her stay at Life Care.

It is clear from R6's clinical record that she was at high risk for the development of pressure sores. As previously noted, R6 had a full-length brace on her right leg which extended from hip to ankle. R6 did exhibit evidence of several pressure sores upon admission to Life Care, however, none are noted on her right heel and right lower calf.[6]

(1) Assessment of R6's Right Lower Calf Wound.

CMS argues that R6's right lower calf wound was first noted by a CNA on March 9, 2004, but staff did not begin assessing and tracking this wound until April 8, 2004, almost a month after the wound was first identified. Life Care disagrees, and asserts that the right lower calf wound was first identified and assessed on April 8, 2004.

A review of R6's clinical record shows that on March 8, 2004, a nursing notes entry reveals that red areas were noted on R6's right leg due to the leg brace. P. Ex. 19, at 3. The entry is insufficient to determine the exact location being referenced, it is not clear as to whether the red areas are on the back or the front of R6's leg. The entry further notes that the orthopedic surgeon's office was contacted and that R6's brace would be checked during an afternoon appointment to the surgeon's office that day. *Id.*

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[6] For example, upon admission on February 26, 2004, nursing notes indicate R6 had a "reddened" area on the left buttock, and a "soft area" on the left heel. P. Ex. 19, at 1. Skin care forms dated February 26, 2004 identify problem areas on the left buttock and left heel. P. Ex. 20, at 1, 2. An Initial Data Collection Tool/Nursing Service form completed on the day of admission, depicts an anatomical diagram documenting that R6 had problem skin areas that "shows signs of redness" on her left upper buttock and her left heel. P. Ex. 5, at 2. The form further states that her left heel was "soft/mushy." *Id.* I note that Life Care was not cited for failure to assess or treat these wounds. They are mentioned in this decision to note that R6 did have pressure sores when she was admitted to Life Care.

A Shower Body Check Program form completed by a certified nurse assistant (CNA) , dated March 9, 2004, depicts an anatomical diagram which identifies the dorsal aspect of the R6's right calf as a problem area. CMS Ex. 21, at 8.[7] Nurse Deagnon testified that the Shower Body Check form is a communication tool used by CNAs at Life Care to identify areas that they would like the licensed nurse to look at, and further assess. Tr. at 836, 837. Later that day, on March 9 at 1542 hours, a licensed nurse wrote that R6 had two open areas on her leg caused by the leg brace and that the brace company would be coming to re-fit the brace. P. Ex. 19, at 4. A subsequent entry that same day at 2000 hours reveals R6's right leg brace was off and that she remained in bed. *Id*.

A March 10 entry in the nursing notes, recorded at 0100 hours, reveals that R6's brace remained off. P. Ex. 19, at 4. That same day, an entry recorded at 1430 hours states that R6 was in bed all day, although there is no reference as to whether the brace is on or off. *Id*.

A nursing note entry dated March 11 states that R6's skin was assessed. P. Ex. 19, at 5. The notation provides a listing of the locations on R6's legs where wounds were noted which included the right and left heels, the left shin, and the back of R6's right knee and right upper thigh. *Id*. There is no mention of a wound on R6's right lower calf. *Id*.

On April 8, a Care of the Skin assessment reveals a right lower calf wound which was assessed as a stage III pressure ulcer. CMS Ex. 21, at 12. A second assessment of the area, dated April 13, describes the wound as a stage III pressure ulcer. *Id*. On April 15, Surveyor Huff observed Life Care's Director of Nursing (DON) Denise Wald perform a wound measurement of R6's right calf. CMS Ex. 1, at 27. The right calf was assessed as a stage IV pressure ulcer, according to Surveyor Huff, 40% of the wound bed contained eschar (necrotic dead tissue). *Id*.; *see also* Tr. at 375, 377. During the survey, Surveyor Huff found staff was unable to explain the discrepancies in the assessments of R6's right lower calf completed on April 13 and April 15, 2004. *Id*.

Nurse Deagnon testified that it was not surprising to her that R6's wound on the right lower calf opened on or about April 8, and, when identified, was then assessed as a stage III or IV wound. Tr. at 843. She stated that the pressure of a brace could have been the cause. Tr. at 843-44. She further testified that the nurse obtained a treatment order the same day and, based on the record, the wound was consistently assessed during the next few weeks. P. Exs. 9, at 9; 20, at 8; 19, at 9; Tr. at 845-46.

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[7] The Shower Body Check Program notes several other suspicious area, however, as previously addressed, Life Care was not cited for these wounds and I do not consider them in making my decision.

Dr. Franey, R6's attending physician, testified that it is difficult to evaluate the skin that is under a brace, stating: "anytime you have a fixed object on the body, like a brace, it's going to have impact on the skin. . . . the skin can break down. More commonly, it's at the upper portion or lower portion of the cast or brace. . . . [a]nything more internal, you can't really see, but it's still at risk." Tr. at 452.

Based on my record review and the testimony adduced at hearing from both Nurse Deagnon and Dr. Franey, I find it very credible that due to the right full-length leg brace, it was not until April 8 that R6's right lower calf wound was first noted. There had been a problem area noted on March 9 by a CNA during a shower check. The problem was examined later that day by a licenced nurse and ruled out as a problem. I also find that once identified, in-depth assessments were taken by staff of R6's right lower calf on April 13 and April 15, as required by Life Care's skin care policy. P. Exs. 19, at 4; 20, at 8; CMS Ex. 21, at 8, 33.

I conclude that the evidence established that R6's right leg calf wound was first identified on April 8, 2004, and, once identified, Life Care staff provided proper weekly assessment of R6's right leg calf wound pursuant to its skin care policy.

(2) Assessment of R6's Right Heel Wound.

It is clear from the evidence presented that Life Care failed to initiate weekly risk assessments on R6's right heel once the pressure sore was identified. R6's right heel wound was identified on March 9 as a stage II ulcer, yet no further in-depth assessment occurred until April 7 - almost a full month later. P. Exs. 19, at 5; 20, at 6,[8] 8; CMS Ex. 21, at 10, 33; Tr. at 284, 375. Life Care's exhibit 19, on page 5, contains a nursing entry which states that a skin assessment was performed on R6's right heel on March 11. The notation references a black blister on R6's right heel. P. Ex. 19, at 5. However, there is no corroborating documentation of this assessment in R6's Care of the Skin assessment and I find that the March 11 nursing entry is insufficient to constitute an in-depth assessment of R6's right heel. For example, the notation fails to reference the size, stage, diameter, and color of the wound as required by Life Care's skin care policy. CMS Ex. 21, at 34, 35.

[8] I note for the record that P. Ex. 20, at 6 contains treatment documentation which was entered subsequent to the survey which occurred April 12-15, 2004. Specifically, Life Care's exhibit contains entries of treatment provided to R6 on April 15 and May 2, 2004; however, CMS's copy of the same document does not. *Compare* P. Ex. 20, at 6 *with* CMS Ex. 21, at 10.

CMS's expert witness Dr. Lyder, a pressure ulcer expert and wound specialist, testified at hearing that some individuals with multiple comorbid conditions are more vulnerable to pressure and, in spite of aggressive interventions, they develop ulcers. Tr. at 47. Therefore, as Dr. Lyder testified, risk assessment and skin care represent a critical step in a facility's ability to prevent the development of pressure sores. CMS Ex. 42; Tr. at 47-48.

R6's clinical record evinces a pattern of inconsistencies in Life Care's assessments of R6's pressure sores once identified. Surveyor Katrina Jean Huff, testified that she characterized the written assessments she reviewed during the survey as inconsistent. Tr. at 372-78, 380, 383-87, 389-95. For example, a March 11, 2004 Minimum Data Set (MDS) notes R6 had three stage II and two stage IV skin ulcers - the locations of the wounds are not specified. P. Ex. 25, at 5. However, a review of each of the Care of the Skin assessment sheets does not indicate any stage IV pressure sores for R6. CMS Ex. 21, at 9-12; P. Ex. 20, at 1-7, 9. Additionally, R6's plan of care, dated March 17, 2004, notes her potential for impaired skin integrity, and describes her skin condition and, among other wound references, specifically mentions a stage IV ulcer on her right heel. P. Ex. 26, at 1. A review of R6's Care of the Skin assessment does not reveal any notations of a stage IV ulcer on her right heel. Other discrepancies noted involve Life Care's exhibit 20, at page 8, which is a Care of the Skin assessment of R6's lower calf. The exhibit lists stage IV pressure ulcers, but the information appears to have been altered since the survey. *Compare* P. Ex. 20, at 8 *with* CMS Ex. 21, at 10.

Life Care argues that R6's pressure sores were unavoidable due to her presenting medical conditions, particularly her leg brace. P. PHB at 4. However, I note that there were times where R6 did have her full-length leg brace off and her skin condition could have been observed. For example, a March 10 entry at 0100 notes R6's brace remained off. P. Ex. 19, at 4. That same day, a 1430 note states that R6 was in bed all day, although there is no reference as to whether the brace is on or off. *Id.* Also, on March 8, R6 did visit with her orthopedic surgeon who noted: "The family states they take the brace off and on. . . .The foot and leg reveal a superficial abrasion over the superior anterior tibial area. . . .The posterior thigh shows a superficial abrasion of the skin from rubbing." P. Ex. 30, at 1. The orthopedic surgeon recommended R6 to "return to Hanger Orthotics to have her brace padded." P. Ex. 30, at 1.

Life Care claims that even after R6's skin breakdowns were called to her orthopedic surgeon's attention, he twice reiterated his order that the brace should be worn at all times. P. Ex. 9, at 6, 7. Life Care avers that after the March 9 exam, R6's orthopedic surgeon did recommend padding, and the Hanger Orthotics representative supplied fracture socks to reduce friction. P. Exs. 14, at 1; 30, at 1.

Although I take Life Care's assertions into consideration, the record also shows an April 19 note from a visit with R6's orthopedic surgeon which reveals that he examined R6, noted that she was developing pressure ulcers, but wrote: "This is a nursing issue and needs to be addressed by her attending physician." P. Ex. 30, at 2. Clearly, the responsibility for the assessment and treatment of R6's skin was the responsibility of Life Care and its staff.

Although the use of the full-length leg brace did impede Life Care's ability to examine R6's skin while it was on, and R6's physicians (attending and orthopedic surgeon) made a professional choice to address her more serious and pressing medical problem which was her fractured femur, this does not negate Life Care's responsibility to monitor and accurately assess R6's skin condition status once a pressure sore was identified, and to aggressively treat the pressure sore, given R6's compromised medical status. Life Care's deference to the orthopedic surgeon's treatment decisions regarding R6's fractured leg is not at question. Rather, I look to Life Care's responsibility, as was the case with R6's care, to inform the physician once a pressure ulcer is identified so that proper clinical intervention can be started, to continue to closely monitor and assess the identified pressure ulcer, and to apply the proper treatment as identified by the resident's attending physician. It was not the presence of R6's full-leg-brace that impeded Life Care's to do so, it was the failure of Life Care's staff to follow the prescribed treatment and to continue to assess the status of R6's right heel pressure sore once it was identified.

The parties do not dispute that R6 was compromised upon admission and that it was difficult to evaluate her skin under a brace. Nor do the parties question the orthopedic surgeon's initial order for R6 to use the brace 24 hours per day. But I find that given R6's recognized heightened risk for the development of pressure ulcers, Petitioner has not satisfactorily explained why it failed to properly conduct timely assessments of R6's right heel pressure sore.

d. Life Care's Treatment of R6's Pressure Sores.

Life Care was also cited for failure to provide proper treatment to R6's right lower calf and right heel wounds. CMS Ex. 1, at 23. Life Care claims that "[e]xcept for critiques of Petitioner's documentation, and some relatively minor lapses in care, CMS points to no clinical evidence that supports its argument that any of Petitioner's supposedly improper acts or omissions made the Resident's wounds worse, or even hindered their healing." P. PHB at 30.

During the relevant period of review, Life Care did have a skin care policy for treatment of pressure sores which required that staff, after observation and evaluation of the affected skin area, notify the physician for the treatment order as follows:

1. Name of cleanser
2. Name of medicated ointment, debridement or other ointment
3. Type of dressing
4. Number of times to perform treatment
5. Duration of treatment
6. Dietary Intervention.

CMS Ex. 21, at 35. The policy further required that for residents with multiples pressure sores, a separate treatment order must be written for each, and numbered to assist in tracking improvements. *Id*. The policy required that "[a]fter completion of each treatment, staff are to date and initial each dressing and then document on the Treatment Administration Record." *Id.*

(1) Treatment to R6's Right Lower Calf.

On April 8, 2004, R6's right lower calf pressure sore was identified to be a stage III ulcer, and vaseline dressing was noted as at the treatment intervention. P. Ex. 20, at 8. A physician treatment order for the right lower calf wound was obtained on April 8, 2004 which required the area to be cleaned with baby shampoo, and staff to apply zero forty to the center of the wound, and then cover with gauze wrap with Kerlex. P. Ex. 9, at 22. The order required that treatment be provided two times per day for 10 days, and then reevaluated. *Id.* The recommended treatment was noted in the nurses notes. P. Ex. 19, at 9.

However, the record reveals that staff did not consistently follow the treatment as ordered. R6's April Treatment Record shows that the order was applied during the 6-2 shift, but not the 2-10 shift. CMS Ex. 21, at 17. A separate notation on April 8 indicates that during the 2-10 shift the treatment was not provided, with a further notation "waiting for clarification from MD." CMS Ex. 21, at 16. The Treatment Record reveals staff initialed that the order was followed twice daily from April 9 -14, except for April 9 and 12, on the 2-10 shift. CMS Ex. 21, at 17. There is no notation in the nurses notes as to why the treatments were not applied on April 8, 9, and 12. P. Ex. 19, at 9. Outside of a nurses note on April 14 which states that dressings were changed on all wounds, there is

no explanation as to why the order had not been continued for 10 days as required by the April 8 physician's order. P. Ex. 9, at 22. Life Care admits that documentation of treatment for R6's lower calf wound was inconsistent. P. PHB at 6.

(2) Treatment to R6's Right Heel.

On March 9, 2004, R6's right heel wound was assessed and described as a stage II pressure ulcer. P. Ex. 20, at 6. The assessment notes Duoderm under the treatment section. *Id.* However, in reviewing the nurses notes for March 8, 9, and 10, there is no documentation that the attending physician was notified of R6's right heel problem as required by Life Care's skin care policy. P. Ex, 19, at 3-4; CMS Ex. 21, at 35.

The record shows that a physician's order for treatment to the right heel was obtained on March 31, a total of 22 days after the assessment of the pressure ulcer. P. Ex. 9, at 10. The order stated that staff were to apply normal saline to the right heel, pat dry, apply Accuzyme, and changed daily or as needed, for 10 days, after which the order would be reevaluated. *Id.*

However, the physician's order for treatment to R6's right heel was transcribed incorrectly on the April 2004 Treatment Sheet as the left heel, not the right - and it was not until April 5, that staff noticed the error and began the more aggressive treatment ordered. CMS Ex. 21, at 13, 15.[9]

An April 7, 2004 assessment of R6's right heel sore revealed the wound was now a stage III pressure ulcer. P. Ex. 20, at 6. On April 7, 2004 the physician's order indicates Duoderm is to be discontinued, and reiterates the March 31 physician's order for R6's right heel. P. Ex. 9, at 8. Until then, R6's right heel had not been treated in accordance with the March 31 physician's order. Rather, R6's right heel sore was treated with Duoderm which was initiated without a physician's order. Once notified, the attending physician specifically discontinued the use of Duoderm for R6's right heel. P. Ex. 9, at 8.

Life Care agrees that there was no physician's order to begin Duoderm, but states that actions taken by staff for treatment of R6's pressure sore was consistent with its skin treatment protocol. P. PHB at 22, n.11. However, I note that at the hearing, Dr. Franey, R6's attending physician, testified that if a resident had a pressure ulcer at stage III or IV, he would want to know. Tr. at 469. Dr. Franey testified further that if the facility's skin care policy directed staff to notify the attending physician regarding presence of pressure sores he would have expected to be notified. Tr. at 470.

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[9] I note for the record that Petitioner's exhibit of R6's Treatment Record for March 2004 shows initials were entered on March 31, 2004; however, the copy provided to the surveyor during the April 12-15, 2004 survey does not have initials indicating the March 31, 2004 physician's order for treatment to R6's right heel was initiated by staff. *Compare* P. Ex. 11, at 1 *with* CMS Ex. 21, at 13.

Life Care agrees that the March 31 physician's order to treat the right heel was transcribed incorrectly to the April Treatment Sheet as "left" heel. P. PHB at 23, n.12; CMS Ex. 21, at 15. According to Life Care, there was no act or omission by staff which caused R6's right heel to breakdown, or which delayed its healing.

I find Life Care's assertions unpersuasive. R6 was considered high risk for developing pressure sores. As noted above, R6 wore a full-length leg brace which impeded her self-mobilization, and her diabetic diagnosis placed her at high risk for complications from pressure ulcers. Life Care's skin treatment policy, at the time of survey, required that the attending physician be notified of the existence of a pressure ulcer. CMS Ex. 21, at 35. Dr. Franey should have been notified of the pressure ulcer. Tr. at 290, 369.

a. Interim Orders for Duoderm.

Life Care claims facility nurses did start treatments of R6's various stage I and stage II sores with Duoderm as soon as they were identified which was appropriate treatment for such wounds. Life Care points to the R6's physician order summary sheet which contains an entry providing for use of "interim facility/county orders." P. Ex. 10, at 1. Life Care states that under the wound care protocol in use at the time, a nurse could have initiated the Duoderm treatment for a stage I or II pressure sore without first obtaining a specific physician order. Life Care claims that initiation of treatment pursuant to a protocol is appropriate.

In support of this assertion, Nurse Deagon testified that the use of Duoderm with R6 was consistent with the facility's protocol for wound care treatment for stage I and stage II pressure ulcers. Tr. at 799. However, according to Surveyor Huff's interview with nursing administration, Life Care did not have its own interim orders or a wound protocol for Duoderm without a physician's order. Tr. at 365. Surveyor Huff testified as to her interview with DON Wald:

> I asked her if they had a protocol which would enable the nurses to put on a duoderm. She says, there is no protocol. The facility does not have a protocol. The nurse should have called the physician and notified them to obtain an order, and that is what their policy and procedure states.

Tr. at 365-66.

At the hearing, DON Wald testified that she did not recall the discussion with Surveyor Huff. Tr. at 735. She acknowledged that R6's April 2004 Physician's Order, initiated February 25, 2004, did state "May use interim orders county/facility," and explained that the county did have interim orders for county patients who are Medicaid recipients. Tr. at 734. She testified that the interim orders "guide the nursing staff in applying certain

interventions and then when to call the physician." Tr. at 734. She testified further that the interim orders are available "[s]o nursing staff would not have to call the physician, for example, in the middle of the night when a resident maybe had an elevated temp or had some complaints of minor pain. Tr. at 734-35. However, DON Wald subsequently agreed that R6 was not a county patient. Tr. at 735.

I find Life Care's assertion that the typed notation "May use interim orders county/facility" actually provided nurses with physician orders to initiate the use of Duoderm with R6, without first calling R6's attending physician, unavailing. First, R6 was not a county patient and therefore the interim orders did not apply to her care. Even if they did, her compromised medical condition and her risk for the development of pressure ulcers do not equate to a resident with an "elevated temp" or "minor pain." Moreover, Life Care's skin care policy specifically states that the nurses are to contact the physician for guidance as to the proper treatment. CMS Ex. 21, at 35.

b. Interventions Implemented by Life Care.

Nurse Deagnon testified that staff implemented numerous interventions to address R6's condition, including periodic turning and positioning. Tr. at 789-90. However, the evidence before me does not support Nurse Deagnon's assertions. There is inconsistent documentation regarding R6 being repositioned. At times there is no documentation of repositioning over several days, and there is no documentation that R6 was repositioned while in her Gerry chair. Tr. at 389-92.

Additionally, R6's clinical record reveals a March 12, 2004 entry from the Hanger Orthotics indicating that R6's brace was being evaluated, that R6 was not wearing a fracture sock[10] underneath the brace and should, and that the brace was donned, internally rotated (incorrectly turned inward). CMS Ex. 21, at 40. At the hearing, Surveyor Huff testified that applying any brace improperly can create a possible problem for development of pressure ulcers. Tr. at 371. She further testified that the fracture stockings were to help prevent sheer friction from the brace against the resident's skin. Tr. at 371.

Life Care argues that the problems with the leg brace were beyond its control, i.e. R6's family caused the brace to be improperly donned. Tr. at 192. However, I find that the leg brace should have been adjusted sooner than a week after admission - and clarification sought regarding the use of the brace, how long it should be worn, as well as the need for

[10] A fracture sock is a preventive device that can be worn by a resident under a leg brace in order to assist with the possible forces the leg brace could cause. *See* testimony of Dr. Lyder, Tr. at 132.

fracture socks. Even though Life Care avers that staff were concerned about the orthopedic surgeon's order for the brace to be worn 24 hours per day, that does not address or justify the lack of documentation to support this.

Life Care is correct in its assertion that the regulation at 42 C.F.R. § 483.25(c) does not make the development of a pressure sore a *per se* regulatory violation. Life Care claims that R6 developed skin breakdowns following her admission to Life Care which were caused by use of the full-length leg brace which complicated assessment and treatment. However, as noted above, this did not relieve Life Care of the responsibility to be diligent in its monitoring, assessment and treatment. I find the record supports a deficiency in this area as the evidence is clear that once identified, Life Care failed to provide required monitoring and assessment of R6's right heel, failed to notify her attending physician of the pressure ulcers as required by its own skin care policy, failed to accurately and consistently document the status of R6's pressure sores, and failed to follow the physician's order for treatment to the right heel for several days. Life Care concedes that the documentation of its assessments and care of R6's skin was not very good. *See* P. PHB at 2; Tr. at 843.

Without proper assessment a facility is unable to identify critical interventions to guard against pressure ulcers. I find that Life Care's evaluation of R6's clinical condition upon admission was inconsistent with subsequent assessments, and that staff inconsistently implemented interventions that were prescribed by her attending physician. Staff were aware that R6 was at risk for skin breakdowns, they knew that the leg brace was contributing to the breakdowns, therefore they should have been consistent and accurate in their treatments of the wounds once identified. The record as a whole reveals gaps in both the documentation and the actual course of R6's treatment itself.

Life Care fails to provide a reasonable justification for the gaps in documentation and the inconsistency of the actual course of treatment for R6. Life Care claims that R6's pressure sores healed uneventfully within one month of admission, characterizes the gaps in documentation and treatment as "relatively minor errors," but agrees that "perhaps the recommendation for a fracture sock could have come earlier. . . ." P. PHB at 39. I am not persuaded by Life Care's assertions that its omissions did not cause harm to R6, and that R6 eventually recovered from her pressure ulcers does negate a violation under the regulation as suggested by Life Care.

CMS has the burden of coming forward with sufficient evidence to establish a prima facie case, and if it does not do so, then CMS would lose even if the provider presents no evidence. Here, CMS successfully demonstrated a causative link between the alleged noncompliance and the asserted harm as an element of its prima facie case. The lack of accurate and timely assessments and facility staff's delay in contacting the attending physician for appropriate treatment and applying the physician's orders did cause actual

harm to R6. R6's right heel deteriorated and became a stage III pressure ulcer due to the lack of proper assessment of her wound, and staff failure to follow the attending physician's treatment orders appropriately. Specifically, the orders were carried out for six days to the wrong heel. Nurse Surveyor Huff testified that a wound on any lower extremity of an individual who is diabetic, as was R6, is serious as these individuals are more prone to infections, they heal very slowly and, if not monitored, they can lose a limb. Tr. at 369. At hearing**,** Life Care's DON clearly stated that "some of R6's pressure ulcers caused her pain." Tr. at 748. The April 8, 13, and 15 assessments of R6's right lower calf pressure ulcers are reported as "painful" to R6. P. Ex. 20, at 8.

I find that R6 did not receive the necessary treatment and services to address her right lower calf and right heel pressure ulcers. I conclude that CMS has established a prima facie case that as of the April survey, Life Care failed to comply substantially with the requirements of 42 C.F.R. § 483.25(c). I further conclude that Life Care has failed to successfully overcome CMS's showing by a preponderance of the evidence.

As previously noted, for reasons of judicial economy, I do not discuss every deficiency in controversy during these proceedings. *See Beechwood Sanitarium*, DAB No. 1824 (2002), at 22; *Beechwood Sanitarium*, DAB No. 1906 (2004). During the April survey, Life Care was cited for seven deficiencies at the D-level, constituting a potential for more than minimal harm. Although I have reviewed the complete record in this matter, including all testimony of witnesses, pleadings by the parties, and evidence admitted for all eight deficiencies for which Life Care was cited, I elect not to discuss in this decision the following alleged deficiencies.

> (1) Whether Life Care failed to comply substantially with the requirements of 42 C.F.R. § 483.15(a) - F241(E) - Quality of Life. Section 483.15 of the regulation provides that "a facility must promote care for residents in a manner and in an environment that maintains or enhances each resident's dignity and respect in full recognition of his or her individuality." Life Care was found to violate this regulation due to the practice of having 10-15 minute delays in meal services to residents seated at the same table thus depriving them of a dignified dining experience.
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> (2) Whether Life Care failed to comply substantially with the requirements of 42 C.F.R. § 483.25 - F309(D) - Quality of Care. The regulation at 42 C.F.R. § 483.25 requires that each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psycho social well-being, in accordance with the comprehensive assessment and

plan of care. Life Care was found not to be in compliance with this regulation when based on the surveyor's observations two residents who were supposed to be wearing TED hose as ordered by their attending physicians were not " on in the A.M. and off at bedtime." CMS Ex. 18, at 2.

(3) Whether Life Care failed to comply substantially with the requirements of 42 C.F.R. § 483.25(m)(1) - F332(D) - Quality of Care. CMS purports that during the med pass. three medication errors were observed out of 45 opportunities, resulting in a medication error rate of 6.6%. CMS Ex 1, at 28. The regulation requires that a facility's medication error rate must be less then 5%. 42 C.F.R. § 483.25(m)(1).

(4) Whether Life Care failed to comply substantially with the requirements of 42 C.F.R. § 483.75(1) - F514 (E) - Administration. The regulation at 42 C.F.R. § 483.75(l) requires a facility maintain clinical records on each resident in accordance with accepted professional standards and practices that are complete, accurately documented, readily accessible, and systematically organized.

2. The evidence establishes that, as of the April survey, Life Care failed to comply substantially with the requirements of 42 C.F.R. § 483.13(c) - F-tag 226(D)- Staff Treatment of Residents.

The regulation that is at issue requires that each facility develop and implement written policies and procedures that prohibit mistreatment, neglect, and abuse of residents. 42 C.F.R. § 483.13(c).

Life Care was found to be in violation of this regulation. Specifically, staff did not implement the facility's written policy regarding abuse of residents when they failed to report to the administration recurring episodes of bruising to R5. Moreover, this failure to report resulted in Life Care not intervening and preventing additional bruising incidents to R5. CMS PHB at 3; CMS Ex. 1, at 1. I find that although Life Care did have policies and procedures aimed at protecting residents from harm, on three occasions facility staff failed to implement those policies with respect to R5.

Life Care's policy regarding abuse prohibition states that "[a]ll personnel will promptly report any incident or suspected incident of resident abuse and/or neglect, including injuries of unknown origin." CMS Ex. 29, at 11. The policy further states that "[a]ll alleged or suspected violations involving . . . injuries of unknown origin (e.g. bruising and skin tears) will be promptly reported to the administrator and/or director of nursing. *Id.* Additionally, the policy requires that staff be trained in "[i]dentification procedures to identify events, such as suspicious bruising, occurrences and patterns that may constitute abuse. . . . in order to "correct and intervene in situations in which abuse (including injuries of unknown origin) . . . are more likely to occur." CMS Ex. 29, at 3.

R5, an 83-year-old female, was admitted to Life Care on September 6, 2000. Her diagnoses included arthritis, joint disorder with pain, dementia and depression. P. Ex. 36, at 1; CMS Ex. 20, at 6, 8. Based on surveyor notations recorded during the survey, R5's quarterly MDS assessment, dated February 27, 2004, reveals that R5 required total assistance of one staff member with transfers, dressing, incontinent care, bathing and personal hygiene activities. CMS Ex. 20, at 3. A resident assessment notes R5 had short and long-term memory deficits, severely impaired decision making ability, and communication impairment due to a language barrier. CMS Ex. 20, at 6.

Incidents of R5's unreported bruising include:

1. Weekly Body Check form for R5, dated December 8, 2003, notes "fading discolorations to leg" and "skin fragile." CMS Ex. 20, at 9. The size, color, or cause of the bruise was not noted. There was no documentation of a bruise noted on the December 1, 2003 Weekly Body Check assessment form. CMS Ex. 20, at 9.; Tr. at 606-07. There was no evidence in the record that the bruise had been reported to facility administration or the DON for further investigation as outlined in Life Care's policy. CMS Ex. 29, at 11.

2. The Weekly Body Check form, dated January 12, 2004, reveals that R5 was assessed to have a "Bruise on R[right] outer thigh, bruise on L[left] hand . . .. " No notation of a bruise was noted on the January 5, 2004 body check.[11] CMS Ex. 20, at 5.[12]

3. There is no documentation in the nurses notes from October 24 through January 13, 2004 of R5's bruises. CMS Ex. 20, at 7. A nurses note dated January 14, 2004, at 4:30 a.m., states: "Bruise noted to L hand," with no reference as to causative factors. *Id*.

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[11] I take judicial note that on R5's Weekly Body Check form, the facility nurse appeared to erroneously record having assessed R5 on "1/5/03," rather than January 5, 2004. I consider January 5, 2004 the date she intended to enter. *See* CMS Ex. 20, at 5.

[12] I also take judicial note that on the April SOD, page 2, the state surveyors incorrectly transcribed the date of R5's weekly body check - January 8, 2004 was recorded instead of the correct date of January 12, 2004. I find this to be harmless error and I place reliance on the actual assessment form and consider the date of January 12, 2004 as the accurate assessment date for R5's weekly body check. *Compare* CMS Ex. 20, at 5 *with* CMS Ex. 1, at 2.

> 4. During an April 14, 2004 interview conducted by the state surveyor, a family member reported a large purple bruise on R5's left leg. According to the surveyor's notes, when this was reported to nursing staff at 10:15 a.m., the bruised area measured 7.5 cm x 3.5 cm. CMS Ex. 44, at 1. Based on the surveyor's notes, the facility nurse was unaware of the bruising prior to the examination. CMS Ex. 1, at 2. The surveyor also noted that the nurse stated that an incident report would need to be completed, although she suspected the bruises were sustained during R5's transfers. *Id.* at 2-3. There was no previous documentation regarding the injury in R5's clinical record. During the interview the family member suggested that the recurring incidents of bruising of R5 were the result of one-person transfers by facility staff.

On April 14, 2004, DON Wald was interviewed by the surveyor. Wald stated that she was not aware of the three instances of bruising to R5 in the previous four months as staff had not reported the incidents to the facility's administration. CMS Ex. 1, at 3; Tr. at 650-51.

According to Life Care, if the bruises were not of unknown origin, then it was not necessary to notify the DON of the need to conduct an investigation. P. PHB n.23. Life Care claims the record shows that the cause of the R5's bruising was not abuse, neglect or mistreatment, but rather was accidental bumps during transfers. At hearing, DON Wald testified that R5 required assistance of staff to conduct transfers, and staff may have used a mechanical life which could have caused the bruising. Tr. at 705. Life Care argues that the regulation requires investigation of bruising only of unknown origin. P. PHB at 40.

Life Care further claims that R5's bruises were not reported to administration as staff knew all along that R5's bruising stemmed from a prescribed medication taken by R5 - Salsalate. P. Ex. 36; Tr. at 768-69. At hearing, Nurse Deagnon stated that R5 received Salsalate which could increase her risk of bruising from even relatively minor normal and routine touching and movement. Tr. at 769. CMS argues that the surveyor was aware that R5 was being administered Salsalate and that based on her consultation of drug reference books, she concluded that Salsalate would not predispose R5 to bruising unless it was combined with other medications like thinners. Tr. at 636.

I find staff's failure to report resulted in the failure by facility administration to investigate episodes of bruising. If the episodes of bruising had been timely reported, then an investigation and review would have determine the origin of the bruises and an evaluation of the resident's need for two-person transfers. As a result of staff's failure to properly identifying, investigating and report R5's bruises, there was no proper review of the bruising incidents by R5's clinical team and Life Care administration. This failure left R5 vulnerable to possible further bruising.

The evidence before me does not support Life Care's assertions as to the cause of R5's bruises. Life Care has advanced two possible causative factors, the mechanical lift and R5's administration of Salsalate. Life Care itself is unsure of the origin. I find that R5's bruises were of "unknown origin" and facility staff failed to follow the reporting requirements outlined in its own policy. CMS Ex. 28, at 11. I also find that this failure subjected R5 and other residents in the facility to the potential for more than minimal harm.

3. The evidence establishes that, as of the April survey, Life Care failed to comply substantially with the requirements of 42 C.F.R. § 483.20(k)(3)(i) - F-tag 281(E) - Resident Assessment.

The regulation at 42 C.F.R. § 483.20(k)(3)(i) requires that a facility provide services in accordance with professional standards of quality. Life Care was found to be in violation of this regulation when it failed to follow physician's orders in administering medications to three residents (R5, R10, R30), and when it failed to comply with its own policy in providing percutaneous endoscopic gastrostomy (PEG) tube care to R19.

I shall discuss the deficiency findings relative to R5 and R19, as they, standing alone, support the citation in this case.

I shall not discuss the following alleged deficiency citations for R10 and R30 as follows:

(1) Life Care was cited when, contrary to physician's orders, staff failed to document whether R10's blood pressure and heart rate were taken before each administration of Clonidine. CMS Exs. 1, at 16; 22, at 5-6.

(2) Although R30 was discharged on March 27, 2004, almost sixteen hours after she was admitted on March 26, 2004, neither R30's Medication Administration Record (MAR) nor her nurses notes contain documentation that R30 received any of her prescribed medications. CMS Exs. 47, at 3-4; 49, at 1-2.

a. R5's Medication.

R5's diagnoses included dementia, depression, and communication impairment stemming from a language barrier. CMS. Exs. 1, at 16; 20, at 4, 6; 46, at 4. A progress note dated March 8, 2004 reveals that R5's tongue was coated with a white substance, and exhibited some redness. P. Ex. 35, at 1. R5's physician's order, dated March 8, 2004, states Nystatin oral suspension, 5 cubic centimeters, three times daily for ten days for a diagnosis of candidiasis of the oral mucosa and pharynx. P. Ex. 37, at 1.

According to a March 8 nurses note, the physician's order was "received and carried through." P. Ex. 35, at 1. The nurses note also indicates "faxed 3-12 " and "faxed 3-17." *Id*.; Tr. at 621. However, based on the March 2004 MAR, Nystatin was not administered to R5 until March 19, 11 days after the physician's order. CMS Ex. 20, at 8; Tr. at 621-22.

Surveyor Patricia Ross interviewed a facility nurse on April 14, 2004. Surveyor Ross testified that the nurse stated that upon returning to work on March 12, 2004 after a vacation, she found that Nystatin for R5 had not yet been delivered by the pharmacy to the facility. CMS Ex. 1, at 17; Tr. at 622. Life Care blames the pharmacy. Tr. at 644-46. However, it was not until March 12, a delay of four days, before Life care staff actually faxed the prescription to the pharmacy. CMS Ex. 20, at 4; Tr. at 621. Life Care staff then waited an additional five days, until March 17, before sending a second fax to the pharmacy. *Id.* Additionally, staff failed to properly report the failure to administer R5's Nystatin to the appropriate nursing supervisor.

Life Care admits to the allegation that it failed for several days to administer certain medication to R5 to treat her oral infection (thrush). Life Care also concedes that it did not follow up appropriately after the two inquiries with the pharmacy failed to produce the medication. P. PHB at 47; P. Ex. 1, at 16. However, Life Care argues that R5 did not appear to suffer discomfort or pain during that time and when the medication was obtained, the infection cleared uneventfully. P. PHB at 47; P. Ex 37.

I find Life Care's assertions unavailing and conclude that facility staff's failure to obtain and administer R5's medication as ordered by her physician on a timely basis placed R5 at risk for more than minimal harm.

b. R19's PEG Care.

R19 was admitted to Life Care on March 17, 2004. CMS Ex. 1, at 19. R19's diagnoses included chronic airway obstruction, post cerebrovascular accident with right sided hemiplegia (paralysis), diabetes and hypothyroidism. *Id.* She had a PEG tube upon admission for feeding and medication administration. R19 was receiving daily doses of Glucerna, a nutritional supplement taken by diabetics, through her PEG tube. *Id.*

CMS contends that Life Care failed to meet standards of practice by failing to provide and document PEG tube care to R19 since her admission on March 17, 2004. Life Care's staff did not maintain or provide safe and effective nursing care, in that PEG tube care was not provided, per R19's physician's orders or in accordance with Life Care's policy and procedure for tube care. This failure left R19 at risk of not receiving all of the nutrients from her tube feedings as well as exposing R19 to the risk of infection. CMS Br. at 25.

During the medication pass on April 13, Surveyor Ross observed R19's tube site and noted an accumulation of grime at the PEG tube site and that there was no dressing present. CMS Ex. 16, at 1. Surveyor Ross also observed that during the medication pass the PEG site was scabbed over. *Id*. A second observation by Surveyor Susan Parry, on April 15, revealed that the "PEG tube site has crusted gunk over the plastic," and the PEG site "did not have a drsg [dressing]." CMS Ex. 26, at 4.

Life Care was required to provide safe and effective tube care to the PEG tube site for R19. However, there was no documentation that tube care had been provided for almost an entire month, from March 22 until April 14, 2004.[13] In addition, the surveyor noted that there was no dressing on the PEG site on April 13 and 15, 2004. CMS Exs. 16, at 1; 26, at 4.

Life Care's policy for PEG tube care provides that the purpose of tube care is "to prevent irritation and skin breakdown around feeding tube; to prevent odor, and to prevent discomfort." CMS Ex. 29, at 19. Surveyor Parry credibly testified that it is standard nursing practice to administer tube care and that "a PEG tube requires cleaning every shift and then dressing applied to the tube while there is still drainage coming from it. Tr. at 489, 499.

Additionally, Life Care's policy and procedure provided staff with guidelines for assessing residents with PEG tubes. Specifically, assessment should include evaluation of the "condition around site of tube insertion; vital signs; condition of [resident's] mouth and gums; nutritional status; hydration and fluid balance; abdominal distention; draining [including] amount, color and odor; and allergies." CMS Ex. 29, at 20.

R19's care plan did not include physician orders for PEG tube care, and there was no documentation in the clinical record that PEG tube care had even been provided for R19 during her stay at Life Care from March 17 through to April 15, 2004. CMS Exs. 1, at 19; Tr. at 493.

Life Care claims that at the time of the survey, R19's condition had improved and she was in the process of being weaned from the PEG tube. According to Life Care, R19's attending physician had ordered the tube-feeding stopped the very day of the survey. Life Care further claims that "even if the Peg tube was 'grimy' on the occasion of the Surveyor's single observation - there is no corroboration of that allegation - and there plainly was no potential for harm." P. PHB at 49-50; P. Ex. 40.

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[13] According to R19, this was the first time tube care had been provided by facility staff. CMS Ex. 29, at 21.

I disagree. Life Care's assertion is unsupported by documentation in R19's clinical records. Additionally, Life Care has failed to provide documentation of the provision of tube care to R19 pursuant to its own policy and procedures. I find that Life Care's failure to administer medications in accordance with physician orders, and to provide PEG tube care to R19 consistent with its own facility policy leaves residents in its facility at risk for more than minimal harm.

4. The evidence establishes that, as of the April survey, Life Care failed to comply substantially with the requirements of 42 C.F.R. § 483.35(h)(2) - F-tag 371(E) - Dietary Services.

The regulation under 42 C.F.R. § 483.35(h)(2) requires that a facility store, prepare, distribute, and serve food under sanitary conditions. Life Care failed to be in compliance with this regulation when, on several occasions, it failed to provide sanitary storage, preparation, distribution and service of food to facility residents.

(1) On April 13, 2004,[14] during lunch service in the main dining room, staff were observed handling food with their bare hands while in the process of serving food. CMS Ex. 17, at 2; Tr. at 554-55. Surveyor JoLee Kennedy observed a nurse who was not wearing gloves at the time "gently push the cake back on the plate, lick her fingers, and then continue to serve." *Id.* The nurse was not wearing gloves at the time she handled the resident's cake. After licking her fingers, the nurse was noted as never leaving the room and continuing to serve other residents. Tr. at 555. Life Care failed to provide a sanitary environment and reduce the risk of infection through hand washing or using gloves to prevent transmission of noxious organisms.

(2) On April 13, 2004, a nursing assistant was observed distributing ice to residents in an unsanitary manner. CMS Ex. 1, at 33. The surveyor observed the nursing assistant handling an ice scoop without wearing gloves in the course of distributing ice into residents' water pitchers. CMS Ex. 28, at 7, Tr. at 599. The same staff member was also observed touching various residents' equipment and/or room furnishings, then touch the ice scoop, and then place the ice scoop directly on the ice in its container. CMS Ex. 1, at 33; Tr. at 599. The nursing assistant repeatedly handled and stored the ice scoop directly on the ice in the same unsanitary manner. CMS Ex 28, at 7; Tr. at 599. The nursing assistant's conduct exposed residents to germs from the handle of the ice scoop. Tr. at 589-99.

[14] CMS points out that a typographical error on the April SOD incorrectly notes this observation on April 12, rather the correct date of April 13, 2004.

> (3) On April 14, 2004, Surveyor Kennedy observed that the air vents in the ceiling were heavily soiled, and coated with a thick layer of gray materia. There were also black markings on the ceiling adjacent to the vents. Tr. at 552; CMS Ex. 17, at 4. The dirty vents were located over the tray line directly above the food preparation area. CMS Ex. 17, at 4; Tr. at 553. Surveyor Kennedy also noted that the plate warmer appliance in the food line had crusted particles of food on it, and that the coffee urn had a heavy coating of dust on its top. CMS Ex. 17, at 3; Tr. at 552.

Life Care claims that there had not been any prior incidence of food borne illness at the facility and past inspections by the county health department had not resulted in citations. As for grime on the vents in the food preparation area, Life Care's claim that it followed a cleaning schedule does not explain the observations of the surveyor of black grime dust and grease clinging to two kitchen ceiling vents over the tray line and food preparation area. Nor does Life Care's claim address the unsanitary distribution of dessert and ice by two of its employees.

Life Care also claims that "the cited examples are trivial." P. PHB at 53. Life Care asserts that it had in place effective sanitation policies and procedures, including cleaning schedules, and lines of responsibility for supervising cleaning. Life Care maintains that the facility consistently earned very high scores in periodic inspections by the Maricopa Country Health Department. According to Ms. Stanford, there never has been an outbreak of food-born illness at the facility. P. PHB at 53-54; Tr. at 759-60. Life Care further claims that dusty or stained ceiling vents seems unlikely to be related to food preparation, a dusty coffee maker is unlikely to compromise food safety, and that none of the cited observations posed any risk of causing food-borne illness. P. PHB n.33.

I find Life Care's arguments unpersuasive and outweighed by the convincing evidence before me. CMS has established, and Life Care has not successfully rebutted, that Life Care failed to comply substantially with the requirements of 42 C.F.R. § 483.35(h)(2).

Life Care also defends its behavior by repeatedly stating that there was a lack of any actual harm and therefore a deficiency can not be sustained. The fact that no negative consequences resulted does not establish the absence of a violation. It is a long settled principle that CMS is not required to demonstrate that residents have suffered actual harm in order to establish a prima facie case of a violation. *See Beechwood Sanitarium*, DAB No. 1906 (2004). An appellate panel has also noted that "implicit in Congress' requirement that a facility [substantially comply with each regulation] is a finding that a failure to do so poses a threat of more than minimal harm. *Beverly Health & Rehabilitation - Springhill*, DAB CR 553 (1998), *aff'd* DAB No 1696 (1999).

C. A CMP of $500 per day for each day of the April 14, 2005 - June 1, 2004 period is reasonable.

Life Care failed to prove by a preponderance of the evidence that it was in substantial compliance with the applicable Medicare requirements during the April survey period. A facility is not in substantial compliance when at least one of the deficiencies cited in the survey poses a risk to resident health and safety greater than the potential for causing more than minimal harm. For the reasons previously outlined, I find Life Care was not in substantial compliance with more than one of the participation requirements which posed the potential for causing minimal harm.

It is well-settled that, in reaching a decision on the reasonableness of the CMP, I may not look into CMS's internal decision-making processes. Instead, I consider whether the evidence presented on the record concerning the relevant regulatory factors 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 other factors involved (financial condition, facility history, and culpability). 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); *Community Nursing Home* DAB No. 1807, at 22 (2002), *et seq*.; *Emerald Oaks*, DAB No. 1800, at 9 (2001); *CarePlex of Silver Spring*, DAB No. 1683, at 8 (1999).

Having found a basis for imposing a CMP, I now consider whether the $500 per day CMP is reasonable. I apply the four factors listed at 42 C.F.R. § 488.438(f), which include: (1) the facility's history of noncompliance, including repeated deficiencies; (2) the facility's financial condition; (3) the seriousness of the deficiencies as set forth at 42 C.F.R. § 488.404; and (4) the facility's degree of culpability.

First, in regards to Life Care's history of noncompliance, CMS presented evidence that Life Care was cited for many of these same deficiencies at the D-level or above in surveys prior to the April survey. CMS Ex. 6, at 1; CMS PHB at 88. Life Care did not present any evidence as to the facility's prior compliance, nor did it rebut CMS's assertions.

Second, as to Life Care's financial condition, Life Care did not submit evidence that the financial viability of the facility was at risk by paying the CMP. While an ALJ may consider a facility's financial condition in determining whether the amount of a CMP is within a reasonable range, the facility must initially raise that issue as a basis for disputing the reasonableness of the amount of the CMP; otherwise, the ALJ can properly exercise his discretion in excluding it. *Community Nursing Home,* DAB No. 1807*,* at 21, 26 (2002). Where either party fails to take advantage of its opportunity to submit evidence of a facility's financial condition, that opportunity is waived. *Id.* at 15-16;

Emerald Oaks, DAB No. 1800 (2001). In this case, the record is silent as to Life Care's financial solvency, and Life Care has not claimed that its financial condition makes the amount of the CMP unreasonable.

Third, the seriousness of Life Care's failure to provide care and services necessary to prevent pressure sores from developing and subsequently worsening on R6's right heel and right lower calf provides strong support in and of itself for the $500 per day that CMS determined to impose.

Fourth, the Life Care's degree of culpability in regards to the deficiencies cited was high. Although Life Care has advanced arguments regarding interventions that it made on behalf of its residents, particularly R6, these do not counterbalance Life Care's failures to provide necessary services and treatments to its residents.

Where there is no immediate jeopardy alleged, a CMP may be imposed within a range from $50 - $3,000 per day for each day of continued noncompliance. 42 C.F.R. § 488.438(a)(1)(ii). Based on the testimony offered at the hearing, the documentary evidence, the arguments of the parties, and the applicable law and regulations, I concluded that from April 15, 2004 through June 1, 2004, Life Care was out of substantial compliance with federal regulatory requirements. Life Care has offered no evidence that would rebut or detract from the foregoing. The CMP which CMS determined to impose here - $500 per day - is at the lower end of the non-immediate jeopardy range. I find that the CMP imposed by CMS in this case is reasonable.

VI. Conclusion

Based on my review of all of the evidence and testimony advanced in this case, I sustain the determination of CMS to impose a CMP against Life Care in amount of $500 per day, for a period that began on April 15, 2004 and which ended on June 1, 2004.

/s/
Alfonso J. Montano
Administrative Law Judge