Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Four Seasons Nursing Center of Westland,
(CCN: 235578),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-10-763

Decision No. CR2544
Date: May 15, 2012

DECISION

I sustain the determination of the Centers for Medicare & Medicaid Services (CMS) to impose civil money penalties (CMPs) against Petitioner, Four Seasons Nursing Center of Westland, of $7,250 per day for four days of immediate jeopardy, and $650 per day for 35 days, for a total CMP of $51,750.

I. Background

Petitioner is a skilled nursing facility located in Westland, Michigan. It participates in the Medicare program, and its participation is subject to the requirements of sections 1819 and 1866 of the Social Security Act (Act), as well as implementing regulations at 42 C.F.R. Parts 483 and 488. Petitioner's hearing rights are governed by regulations at 42 C.F.R. Part 498. To participate in the Medicare program, a nursing facility must maintain 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.

The Secretary of Health and Human Services contracts with state survey agencies to conduct surveys to determine whether skilled nursing facilities are in substantial compliance. Act § 1864(a); 42 C.F.R. § 488.20.

This appeal involves an incident on January 26, 2010 when an 85-year old resident, R101, sustained a blister on his left inner knee. This blister was discovered immediately after he received moist heat pack therapy on that knee by a physical therapist at Petitioner's facility. R101 was moderately cognitively impaired and had diagnoses and health conditions which included arteriosclerotic vascular disease, congestive heart failure, anemia, and a history of lower left extremity deep vein thrombosis and edema, among others. CMS Ex. 6 at 10-11, 14, 20 and 91. The Michigan Department of Community Health, the state survey agency, initially sent a surveyor to Petitioner's facility on February 5, 2010 for investigation of an anonymous complaint it received. Transcript (Tr.) at 29. That anonymous complaint alleged that a Resident had been burned in physical therapy. Tr. at 29. The surveyor then performed a partial extended complaint survey that ended on February 17, 2010. Following the survey, CMS determined that Petitioner was not in substantial compliance with the following requirements: Tag F323 (42 C.F.R. § 483.25(h)), Accidents and Supervision; Tag F225 (42 C.F.R. § 483.13(c)(1)(ii)-(iii), (c)(2)), Staff Treatment of Residents; and Tag F490 (42 C.F.R. § 483.75), Administration.[1] By letter dated April 27, 2010, CMS notified Petitioner that it imposed a CMP of $7,250 per day for four days of immediate jeopardy beginning February 12, 2010 and continuing through February 15, 2010 for a total of $29,000 and a CMP of $650 per day beginning February 16, 2010 and continuing through March 22, 2010 for 35 days for a total of $22,750.

Petitioner timely requested a hearing of the deficiencies found and remedies imposed. I conducted a hearing in this matter on May 16 through May 19, 2011 in Detroit, Michigan and a transcript of the proceedings was prepared. CMS offered CMS Exhibits (Exs.) 1 through 27, which were admitted. Petitioner offered P. Exs. 1 through 42. I treated the deposition of Petitioner's witness, Riley Rees, M.D., as P. Ex. 43. I admitted P. Exs. 1-22, 24-28, 30-40, and 42-43. Petitioner withdrew its proposed P. Exs. 23, 29, and 41.

CMS called Surveyor David Bolden, R.N., as a witness. Petitioner called Patricia D. Lyden, R.N., MS, LNHA, Petitioner's Administrator; David J. Fertel, DO, a vascular surgeon and the wound care physician providing services to Petitioner's residents; Jeff Barry, R.N., the wound care nurse employed by Petitioner; Tiju James, PT, the physical therapist who provided the moist heat pack therapy to R101; and Manoj Kummanathil-

[1] In its report of readiness, its prehearing memoranda and its post-hearing brief, CMS states that the testimony and evidence show that Petitioner also was noncompliant with Tag F314 (42 C.F.R. § 483.25(c)), Pressure Sores, and relies on that tag as an additional and/or alternative basis for finding Petitioner in substantial noncompliance at the immediate jeopardy level.

Santhakumari, PT, the Manager of Physical Therapy at Four Seasons. The testimony of Riley Rees, MD, whom Petitioner offered as an expert witness, was taken by deposition; the transcript of that deposition appears as P. Ex. 43. The parties filed post-hearing briefs (CMS Br. and P. Br.) and post-hearing reply briefs (CMS Reply and P. Reply).

II. Issues, Findings of Fact, and Conclusions of Law

A. Issues

The issues before me are:

- From February 12, 2010 through March 21, 2010, was the facility in substantial compliance with Medicare requirements?
- Was CMS's determination of immediate jeopardy level noncompliance clearly erroneous? and
- Is the penalty imposed, $7,250 per day for the period February 12 through February 15, 2010 and $650 per day for the period of February 16, 2010 through March 22, 2010, reasonable?

B. Findings of Fact and Conclusions of Law

I make the following findings of fact and conclusions of law (Findings) in bold below together with my analysis.[2]

Petitioner's dispute here centers largely on discrediting the findings by Surveyor David Bolden. The physical therapist, Tiju James, denies the statements Surveyor Bolden attributes to her and contends that her words were taken out of context or misquoted entirely. Similarly, Petitioner's other key actors contend they too were misquoted or that the statements attributed to them in the Statement of Deficiencies were untrue. *See* P. Exs. 6, 7, 8, 9, 11, 13, 14, and 27, 28, 29, and 30. However, I have reviewed the statements, declarations and testimony of Petitioner's personnel. What I am struck with is the ever-shifting and changing content of their statements regarding the incident involving R101 on January 26, 2010 stemming from the moist heat pack therapy (and the likelihood of harm to any other residents who might receive this type of treatment) in an

[2] I have reviewed the entire record, including all the exhibits and testimony. As I am not bound by the strict terms of the Federal Rules of Evidence, I may admit evidence or testimony 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 were not material to my determinations or were not supported by the weight of the evidence or by credible evidence or testimony.

effort to try to convince me that Petitioner was in substantial compliance with participation requirements. What troubles me even more, however, is the possibility that one of Petitioner's key witnesses fabricated documentation in order to bolster Petitioner's claims that it followed the requisite policy and procedures. CMS Ex. 16 at 57. I find Petitioner's indirect assertions of surveyor bias unfounded and a misperception of the role of surveyors in the survey process. *See Community Northview Care Center*, DAB No. 2295 at 26-32 (2009) (indicating that surveyor interviews with facility staff, residents, and family are a usual and important part of the survey process). Also, allegations of surveyor bias "are largely irrelevant where noncompliance is demonstrated by objective evidence independent of surveyor reports or testimony." *Canal Medical Laboratory*, DAB No. 2041 at 5-6 (2006). I found that to be evident here. In any event, I found Surveyor Bolden's testimony to be credible and consistent; he did his job as he was trained to do it and there is no demonstrated indication he had any motivation to do otherwise.

1. Petitioner failed to comply substantially with the Medicare participation requirements.

CMS contends that Petitioner failed to comply substantially with certain Medicare participation requirements. Specifically, Petitioner failed to report immediately an injury of unknown origin to the Administrator of the facility and to other officials in accordance with state law (Tag F225); to supervise R101 adequately in accordance with Petitioner's own established protocol during the administration of moist heat pack therapy on January 26, 2010, thereby causing R101 to sustain a "blister" on his left knee (Tag F323); and to administer the facility so that it used its resources effectively and efficiently to attain or maintain the highest practicable physical, mental and psychosocial well-being of its residents.

a. Tag F323 – Adequate supervision to prevent accidents

Petitioner makes several arguments contending it adequately supervised its residents, specifically R101: it argues that Tiju James, the physical therapist providing the treatment, followed the requisite protocol; that the "blister" was not caused by the moist heat therapy; that the "blister" was not a burn; and that the "blister" was either a "stasis ulcer," a "pressure ulcer," an "abrasion" of "unknown etiology," or a "friction and shear injury." P. Pre-Hearing Memorandum at 13, 18-19, 20; P. Supplemental Brief in Opposition to CMS's Motion for Summary Affirmance at 18. Petitioner therefore essentially contends that whatever the wound was in terms of a clinical definition, it was not the result of any lack of supervision by Petitioner or any failure on the part of Petitioner to administer the moist heat pack therapy pursuant to applicable protocol. Rather, Petitioner contends that the "fact that the area filled with fluid during the

treatment cannot be classified as a "wound" that occurred as a result of the treatment itself . . . [i]t simply manifested itself at that time." P. Supplemental Brief in Opposition to CMS's Motion for Summary Judgment at 17; *see also* P. Pre-Hearing Memorandum at 19.

I find that the evidence as a whole amply supports CMS's finding that Petitioner was not in substantial compliance with section 483.25(h). Petitioner failed to follow its own procedure and policy for moist heat pack therapy. As a result, this failure resulted in a lack of adequate supervision and assistance to R101 to mitigate a foreseeable risk of harm, and had the potential for injury to other residents who also received such treatment.[3] A major factor in my determination here was the credibility of Petitioner's evidence and witness testimony. My credibility determination appropriately involves more than simply evaluating witness "demeanor" or other behavior apparent from in-person observation. *Lifecare Center of Tullahoma*, DAB No. 2304, at 24 (2010). Where documents or objective evidence may contradict a witness' testimony or the testimony is internally inconsistent or implausible, I may appropriately find that evidence lacks credibility. *See Ginsu Products, Inc. v. Dart Industries, Inc.*, 786 F. 2d 260, 263 (7th Cir. 1986). When the credibility of evidence is in issue, it calls into question the reliability and credibility of all the evidence presented by that party. Such a situation exists here. I agree with CMS that the account of Ms. James was inconsistent and, in many instances, incomprehensible. But what troubles me most is the sudden appearance of a document presented by Petitioner to the State for its Informal Deficiency Review (IDR) of a seemingly contemporaneous progress note which now purports to show that Ms. James made five minute checks on R101 on January 26, 2010 and the total treatment time was 10 minutes. CMS Ex. 16 at 57. First, this document is inconsistent with Ms. James' testimony that she did not write progress notes every time she completed a treatment because it was done weekly. Tr. 266. Ms. James testified that she did not write a progress note about each therapy session and that it is the policy to do a weekly note. Tr. 342; CMS Ex. 6 at 95 showing *weekly* status updates for the weeks of 1/21/2010 and

[3] Petitioner argues in its reply brief that CMS abandoned any arguments with respect to R102 and R103 as a basis for a deficiency under Tag F323. P. Reply at 10. Petitioner however misapprehends the stated deficiency. The surveyor found with respect to R101 that Petitioner failed to follow its established policy and protocol for moist heat pack therapy. As stated in the Statement of Deficiency for Tag F323, since R102 and R103 also received moist heat pack therapy, they too were at risk for serious injury due to Petitioner's failure to follow its policy and procedure for administration of this therapy. Thus, if I find that Petitioner did not follow its policy and procedure for this therapy with respect to R101, I can reasonably infer that there is a great likelihood that Petitioner also placed at risk any other resident who was receiving this therapy. This did not require that CMS do anything more than establish that R102 and R103 had orders for this therapy. CMS presented this evidence. CMS Ex. 8 at 13, 14; CMS Ex. 9 at 37, 44, and 45. Consequently, CMS did not abandon its argument.

1/28/2010 with no mention of the incident on 1/26/2010. Next, she originally testified that this document was her soft copy (Xerox) of the progress note she wrote on January 14, 2010 to which she added her note for January 26, 2010. CMS Ex. 27, Vol. 1 at 74 *referring* to P. Ex. 3 at 35 and *comparing* it to CMS Ex. 6 at 101. However, in pointed questioning by the Assistant State Attorney General during the state proceeding, it became immediately apparent that this new document was not merely the copy of the January 14 progress note with a new entry for January 26 but rather the January 14 note on the two documents were different. CMS Ex. 27, Vol. 1 at 73-75. When caught in this discrepancy at the state proceeding, Ms. James could offer no explanation for the two different January 14, 2010 notes. The explanation she offered at the hearing before me was for the most part incomprehensible and inconsistent. Tr. 350; 352-53. And, her explanation simply cannot be reconciled with her earlier testimony before me. *See* Tr. 346, 356-357. In fact, after CMS questioned Ms. James about the apparent discrepancies in the two documents, Petitioner's counsel stipulated that the notes were indeed different. Tr. 348. I find — as CMS argues — that it is highly suspect that the only "contemporaneous" documentation supporting the assertion that Ms. James performed the required five-minute checks on R101 exists only in this lately-produced progress note of dubious origin. CMS Br. at 15. Here, Petitioner tried to discredit Surveyor Bolden by casting this dispute into the proverbial "he said – she said" situation. What Petitioner overlooks is that my review of the facts involved is *de novo* and I must determine whether CMS has made a *prima facie* case of a deficiency. I look to the entire body of evidence in doing so, and am interested in determining whether the entire record, and not simply one witness's statements, support that *prima facie* case. If I find that it has, then I must determine whether Petitioner, by a preponderance of the evidence, rebutted that prima facie case.

I do not find that Petitioner has rebutted CMS's *prima facie* case that showed Petitioner was not in substantial compliance with its policy and procedure for administering moist heat pack therapy. In doing so, I also find that P. Ex. 3 at 35 lacks credibility as does the entire testimony of Ms. James, the physical therapist who administered the heat pack therapy. Her testimony was replete with inconsistencies on critical aspects of the administration of the heat pack therapy, encompassing not only the duration of the therapy but other key aspects, such as whether she measured the temperature of the heat pack after it was removed from the hydrocollator and whether she left R101's side or was treating only R101 at the time of the incident. *Compare* P. ex. 40 with P. Ex. 28; Tr. 259; P. Ex. 43 at 59.

It is undisputed that on January 26, 2010, R101 had no blister or mark on his left knee prior to receiving moist heat pack therapy. Yet a fluid-filled blister did appear on his knee when Ms. James removed the heat pack from his knee. P. Ex. 3 at 22, 5, 11. Whether R101's "wound" or "blister" can be more precisely characterized as a pressure ulcer, a stasis ulcer, a pressure sore, or a burn is not necessarily relevant to my determination of whether Petitioner provided adequate supervision to R101 and to

similarly situated residents to prevent accidents. The occurrence of the wound is the important fact; the specific kind of wound is relevant only to shed light on the nature of the supervision being provided and its adequacy for the resident's condition. *Briarwood Nursing Ctr*., DAB No. 2115 at 11 (2007); *St. Catherine's Care Ctr of Findlay, Inc.*, DAB No. 1964 at 11 (2005). The fact that a "wound" appeared on R101's knee after he received moist heat pack therapy necessarily requires Petitioner as well as the state surveyor to look closely at whether this wound could have been or would have been prevented had Petitioner taken all measures that are within its power to prevent accidents or injuries that are reasonably foreseeable. Contrary to Petitioner's contentions, this is not and never has been a strict liability standard; rather it is the duty of the facility to provide its residents with adequate supervision pursuant to the regulatory requirements for Medicare participation at 42 C.F.R. § 483.25(h).

Surveyor Bolden explained that he examined the facility's policy for moist heat pack treatment, and that the facility's policy and procedures called for the physical therapist conducting the treatment to check the area being treated at least every five minutes during the course of the moist heat pack therapy — given R101's cognitive function and his history of certain illnesses — in order to protect him from burns or adverse reaction to the heat. CMS Ex. 7; CMS Ex. 27, Vol 2 at 56, 59; CMS Ex. 26 at 5 (elderly individuals are at greater risk of thermal injury).

At no time did the surveyor indicate that R101 should not have received moist heat therapy. Rather, the surveyor explained that he simply was reviewing whether Petitioner's implementation of the heat pack therapy to R101 was consistent and in accordance with the facility's own policies and procedures for such therapy. CMS Ex.7 at 3; CMS Ex. 13 at 5, 6. The policies and procedures specifically state that once the heat pack is applied, the physical therapist should inspect the area of treatment every five minutes and the treatment should be discontinued if there are any signs of redness. In order to determine this, Surveyor Bolden made his request — at the time he entered the facility for the survey — for all of the documents that Petitioner used to document its treatment of R101. Tr. 31, 33-40; 43-44; 262, 264. The documents he was given at the time of the survey are contained in CMS Exhibit 6, pages 93-105 and 107. The only document that Surveyor Bolden received that contained any mention of duration of the therapy was the Rehab Services Screen form (CMS Ex. 6 at 107) from the Rehabilitation M.A.S.T.E.R.S., the physical therapy contractors for whom Ms. James worked. On that form dated January 26, 2010, Ms. James had hand-written on the bottom corner of the page:

> Resident was getting moist heat pack 5-15 minutes with [8 layers of towel] + heat pad, Resident didn't complain about any pain or overheat after treatment done noted blister and informed.

CMS Ex. 6 at 107; Tr. 43; Tr. 290.

Because of the ambiguity of this note, Surveyor Bolden testified that he asked Ms. James three times how long the hot pack was on R101, and each time he asked her to show him a record which would confirm this. He testified that she told him:

> that she inspected the area prior to the treatment, that there were no injuries present . . . She put the treatment—the hot pack therapy on, that it was on for a timeframe that she couldn't define. I offered her the record to review. There was the one note [CMS Ex. 6 at 107] that said it was on from five to 15 minutes. I asked her to clarify how long that meant it was really on for. Several different times and different ways, I tried to word the question. She said she didn't know. It could have been for 15 minutes, it could have been up to 20 minutes. She doesn't know how long it was really on for. . . .

Tr. at 41-42; *see also* Tr. at 44.[4] He further stated:

> I asked her about the - - what she was doing during the course of the treatment itself, did she go back and look at the leg, did she examine it for signs of redness, for early signs of injury . . . She said she did not.

Tr. at 42. Given what Ms. James told Surveyor Bolden she did during the therapy session, he determined that the facility's policies and procedures were not followed and that this failure resulted in lack of adequate supervision of R101 during his heat pack therapy. This lack of supervision in these circumstances also resulted in actual injury to this resident. Specifically, the surveyor was told by Ms. James that she did not remove the pack every five minutes to check the area receiving treatment.

There is nothing in the contemporaneous medical records given Surveyor Bolden indicating that assessments to the area were made every five minutes from the time the heat pack was applied to the time the heat pack was removed. CMS Ex. 6 at 4. Also, the policy and procedures state that the temperature of the heat pack before application should be 103° F to 113° F. CMS Ex. 6 at 4; CMS Ex. 13 at 6; CMS Ex. 27, Vol. 1 at 96-97. While there was a temperature log for the water in the hydrocollator, there was no contemporaneous documentation showing that the temperature of the heat pack had been checked prior to its application to R101. P. Ex. 17. Moreover, no one told or showed

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[4] Surveyor Bolden testified that he specifically asked Ms. James about her note (CMS Ex. 6 at 107) indicating the resident was getting heat pack therapy "5-15 minutes" and asked again how long she applied the heat pack for and she responded that she didn't know exactly how long it was on for. He also testified that he asked her directly whether she removed the heat pack and towels to look at the knee any time during the therapy and she told him that the only time she looked at the knee was when she removed the heat pack at the end of the therapy and she found the blister. Tr. at 44; CMS Ex. 27, Vol. 1 at 96-97.

Surveyor Bolden how the temperature of the heat pack was determined after it had been removed from the Hydrocollator.[5] CMS Ex. 3 at 21; CMS Ex. 13 at 6. Ms. James testified that it generally took about 10 minutes for the packs to cool down after removal from the hydrocollator. Tr. 316. She claimed that she took the temperature of the hot pack with a digital thermometer prior to placing it on the resident but she admits there is no contemporaneous documentation that was done.[6] She also states that she never told Surveyor Bolden about this nor did she show him the thermometer. Tr. 317 ("I didn't [show him] -- he never asked me for the entire procedure, so I didn't show him the entire procedure."); Tr. 421. 422. While she claims now that she checked the temperature of the heat pack prior to applying it on R101, her testimony and her prior statements are internally inconsistent. *See also* P. Ex. 43 at 56, and 79 (Dr. Rees testified that when Ms. James demonstrated the heat pack procedure for him she did not measure the temperature of the pack after it was removed; she merely waited a period of time before she placed it). The Physical Therapy Manager testified that while he was present in the room when the therapy was administered to R101, his back was to the therapist and resident and he did not actually see Ms. James as she prepared and administered the therapy to the resident.[7]

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[5] A hydrocollator is a professional heating unit with thermostat controls which contains water that is heated by the unit. P. Ex. 15. The heat packs, which are filled with silica gel, are soaked in the water heated by the hydrocollator. The temperature of the water in the hydrocollator should be between 165°-175° F. CMS Ex. 13 at 6; P. Ex. 16 at 4.

[6] Rehabilitation Masters, Ms. James' employer, requires all therapists to demonstrate Hot Pack Employee Competency. To this end, each employee performs the steps of the required procedure which is documented on a form by Rehabilitation Masters. I note that the form presented to demonstrate Ms. James' competency at Step 3 does not specify or require the therapist, once the heat pack is removed from the hydrocollator, to ascertain the temperature of the heat pack before applying it to the patient. *See* P. Ex. 16 at 4. Also, not once in three of her statements made after the incident does she even mention measuring the temperature of the hot pack after it is removed from the hydrocollator; the first mention of this was during the state proceeding and in a supplemental declaration some months after that. *See* P. Exs. 9, 10, 28 and *compare with* CMS Ex. 27, Vol.1 at 43 and P. Ex. 40 at 4.

[7] This witness's initial testimony was misleading and confusing, leading one to initially believe that he actually saw what Ms. James did. Tr. 380 (when asked if he knew if Ms. James waited long enough for the hot pack to cool down, he responded, "She did.") He indicated however that his testimony was based on the supposition that she followed the procedures as he did not actually see what she did. Also, there is no indication from his testimony that it was customary to take the temperature of the pack when it was removed. Rather it appears that the usual practice was to wait some time after the removal of the pack to allow the excess water to evaporate and for the pack to cool down. Tr. 381. I was left with the distinct impression that measuring the temperature of the heat pack after

Tr. 596-597 ("Tiju James called me. She asked me, 'Manoj, can you turn around and look at his knee?' . . . So then I asked Tiju to tell me what happened.") He therefore had no first- hand knowledge of whether she followed the policies and procedures; he did not actually see her prepare the heat pack or administer the therapy. He merely asked her to describe to him what she did after the fluid-filled blister was found on R101's knee.

Thus, Petitioner has provided no reliable contemporaneous documentation or evidence to rebut CMS's *prima facie* case that Petitioner was not in substantial compliance with 42 C.F.R. § 483.25(h) and followed its own policy and procedures for administration of the moist heat pack therapy.

b. Tag F314 – Pressure Sores

In an effort to rebut CMS's determination that it failed adequately to supervise the administration of the moist heat pack therapy to R101, Petitioner turns its focus to the nature of the "wound" and argues that the lesion (the fluid-filled blister) was not a thermal injury caused by the moist heat pack therapy but was the result of a shear or friction-type pressure ulcer or stasis ulcer. Petitioner defends itself against the citation based on the lack of adequate supervision by arguing that the wound was not the result of the heat therapy but was caused by friction or pressure (because R101 'was known to prefer lying on his side with his knees together or while on his back he would consistently cross his legs, causing pressure to the inner surfaces of his knees"). P. Ex. 8; *see also* P. Exs. 6, 7, 22, 25, 26, 42. CMS, however, argues that if I should find the wound to be caused from shear, friction, or pressure, then I should find that R101's wound was an avoidable facility-acquired pressure sore stemming from Petitioner's failure to comply with 42 C.F.R. § 483.25(c) (F314 – Pressure Sores).

I am baffled that Petitioner would expect that its argument that the wound on R101's knee was the result of friction or a shear injury brought on or aggravated by the moist heat pack therapy would somehow amount to a defense against a finding that Petitioner did not substantially comply with Medicare requirements.[8] The applicable regulation

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its removal from the hydrocollator and prior to application on a patient was something that routinely became part of the procedure after the survey ended and this deficiency was found.

[8] Petitioner contends that a wound resulting from friction or shear is not a pressure sore, yet one of its witnesses did testify that injuries resulting from known friction or shear could be avoided if appropriate interventions were in place. P. Ex. 23 at 42, 59. In this instance, whether it is labeled a shear or friction wound, a statis ulcer, or a pressure sore, a facility is under an obligation, once it knows that its resident is at risk for such an injury to do whatever is reasonably possible to prevent such an injury. I also note that Petitioner's administrator testified that the fact that R101's wound was included on the

requires that each resident receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care. 42 C.F.R. § 483.25. That regulation further provides—

> (c) *Pressure Sores*. 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 . . . .

There is no dispute that when R101was admitted to the facility, he had no "wound" and was not considered at risk for developing a pressure ulcer or pressure sore. CMS Ex. 6 at 16. The first time documentation in his records suggested that R101 might be at risk for developing a pressure ulcer was his Resident Assessment Protocol Summary (RAP) dated January 27, 2010. This RAP was clearly developed after the wound to his knee appeared on January 26, 2010. CMS Ex. 6 at 25 and 28; *compare with* CMS Ex. 6 at 21 (the Minimum Data Set Assessment which accompanies R101's RAP dated January 27, 2010 and does not indicate under "Section M. Skin Condition" any ulcer or wound experienced by R101 within the last 90 days). Similarly, R101's MDS dated February 2, 2010 at Section M does not reflect any skin problem or ulcer within the time from the last MDS or within the last 90 days. CMS Ex. 6 at 32. The Daily Skilled Nurses Notes given to the surveyor when he arrived at the facility on February 5, 2010 had only one indication of a wound to R101's knee. CMS Ex. 6 at 49-92. The entry on January 26, 2010, the date of the incident, had the following entry by the Assistant Director of Nursing—

> Called to therapy dept. to visualize a fluid filled area to L knee. Res. Denied pain. Knee to be wrapped [with] Kerlix for protection if res allows.

CMS Ex. 6 at 70. There is no mention anywhere in the Skilled Nurses Notes for the period of January 26 through February 5, 2010, that R101 had any wound or problem to his knee.

Furthermore, if R101 was at risk for the formation of a pressure ulcer, or if facility staff knew that R101 "was known to prefer lying on his side with his knees together or while on his back he would consistently cross his legs, causing pressure to the inner surfaces of his knees," the facility should have provided specific interventions for this risk in his

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Weekly Pressure Sore Report does not mean the wound was in fact a pressure sore. P. Ex. 3 at 14. However, this document as well as the Weekly Wound Measurement Report show that the facility treated the "wound" as a pressure sore as it was "staged" and labeled by the facility as a pressure sore, *even though the form allowed for other labels for the wound as appropriate*. P. Ex. 3 at 14-16; CMS Ex. 10 at 99.

individualized care plan. P. Ex. 8. The documents given Surveyor Bolden contain no care plan interventions related to a potential risk for pressure ulcer formation (CMS Ex. 6). Petitioner presented a care plan intervention related to R101's apparent risk for pressure ulcer formation with the documents presented to the State for the IDR review. CMS Ex. 10 at 94. That care plan is dated as initiated on February 2, 2010, after the incident on January 26, 2010 and well after R101's initial admission assessments. The care plan specifies the following interventions: report to licensed nurse any areas of redness, sign or symptoms of skin breakdown observed during daily care; weekly skin assessment by licensed nurse; float heels while in bed; protect edematous skin from injury; provide incontinence care as needed; pressure reduction mattress on bed; cushion to wheelchair daily when up in wheelchair; labs as order; monitor wheelchair and furnishings in environment for sharp edges that could cause injury; encourage intake of 75-100% of diet and fluids daily; consult wound care team as needed. CMS Ex. 10 at 94. However, none of these "interventions" address the observations of the wound nurse (I have observed [that R101] habitually keeps his legs together, so that his knees are touching") or of the Physician Assistant ("[R101] was known to prefer lying on his side with his knees together, or while on his back would consistently cross his legs, causing pressure to the inner surfaces of his knees, resulting in knee-to-knee contact"). P. Ex. 27; P. Ex. 26. If these two staff members observed that this was occurring, they rather plainly had an obligation to make sure that R101's behavior was addressed through specific interventions in his individualized care plan. One need only look at R101's care plan to see that this was not done; not one of the interventions on his care plan addresses the claims by these two facility staff members that R101 allegedly kept his knees together. CMS Ex. 10 at 94. Indeed, if this was a concern then one would expect some intervention that would direct some sort of pillow or foam protectors to be used between R101's knees to protect against this obvious source of potentially-dangerous pressure or friction. And, as a result, if R101's wound could be considered a pressure sore, there is nothing in the record — nor has Petitioner provided any argument or evidence — to indicate that development of pressure sores would be unavoidable due to R101's clinical condition.

Therefore, I conclude that even if Petitioner's wound was due to friction or shear as Petitioner argues, at best that only establishes that Petitioner was not in substantial compliance with Tag F314.

c. Tag F225 – Investigate/Report allegation of mistreatment, neglect, or abuse, including injuries of unknown source

Petitioner initially did not address this deficiency finding; it only addressed the deficiencies for which immediate jeopardy was cited. Petitioner's Pre-Hearing Memorandum of Law. It was only after CMS moved for summary judgment with respect to this deficiency that Petitioner stated that CMS was not entitled to summary judgment with respect to this deficiency. P. Supplemental Brief in Opposition to CMS' Motion for

Summary Affirmance at 21. Then in its posthearing brief and posthearing reply brief, it did not address this deficiency finding.

The regulation requires that the facility must ensure that all alleged violations involving mistreatment, neglect, or abuse, including injuries of unknown source, are reported immediately to the administrator of the facility and to other officials in accordance with State law, that the facility must have evidence that all alleged violations are thoroughly investigated, and that the results of all investigations must be reported to the administrator and to other officials in accordance with State law within five working days of the incident. 42 C.F.R. § 483.13(c).

The facility's own policy requires that any alleged case of mistreatment, neglect, or injuries of unknown source must be reported to the Administrator immediately and then the facility Administrator or his or her designee must, within 24 hours of the incident, notify the State licensing/certification agency as well as the resident's representative and attending physician. CMS Ex. 11. There is no dispute that this particular incident was not reported to the State at the time of its occurrence or shortly thereafter. In fact, the only way the State became aware of the incident was through an anonymous complaint which led to the survey in question. CMS Ex. 27, Vol. 2 at 7. Moreover, while the Administrator may dispute some aspects of her conversation with Surveyor Bolden, she never directly disputes that she was not specifically and immediately told about this incident or injury as required by facility policy. P. Ex. 14.

Nor is there any mention in the Nurse's Notes that R101's doctor was informed of this wound or that his family was notified at the time of the incident or shortly after. I find it puzzling that although the Incident/Accident Report indicates that Dr. Hammoud was notified on January 26, 2010 at 12:30 p.m., there is no mention anywhere else in R101's medical records, physician orders, or Nurses Notes for that date that the doctor was notified or, if he was, that he called the facility with respect to this accident. CMS Ex. 6 at 108. I would expect the Nurses Notes to reflect not only the incident but that Dr. Hammoud was informed of the incident and the doctor's response to the reported incident. Nothing of that nature appears in the medical records for this Resident. The Incident Report also requires the reporter to specify what person, agency, legal guardian, designated rep, or next of kin was notified of this incident yet the Incident Report states only that "Res spoke to family." CMS Ex. 6 at 108. While R101's initial Minimum Data Set Assessment indicates that he is responsible for himself, the record also suggests that it was apparent on admission that he was cognitively impaired. CMS Ex. 6 at 18. The record also indicates that R101's family — his wife and daughters — were actively involved with his care and visited on a regular basis. CMS Ex. 10 at 70. I find it then troubling that Petitioner did not notify R101's family of the incident but left it to the Resident to do so himself.

The first mention in R101's medical records of any information from the doctor appears on February 4, 2010 and then on February 6, 2010, the day before and the day after the surveyor arrived for the complaint survey. CMS. Ex. 10 at 92-93. Actually, the physician order dated February 4, 2010 is the only contemporaneous record in the medical record indicating that the physician was even aware of the wound to R101's knee. *See* also P. Ex. 4 at 4 and P Ex. 5. This telephone order though is dated February 4, 2010 and comes some nine days after the incident on January 26, 2010. The first physician note dated February 4, 2010 calls for cleaning the wound to R101's left knee with normal saline and wound cleanser and applying triple antibiotic cream with a dry dressing every day. CMS Ex. 10 at 92. The only indication that that R101's doctor may have been apprised of the situation is from the February 6, 2010 Daily Skilled Nurses Notes, which was the day after the surveyor arrived for the complaint survey. CMS Ex. 10 at 53. The note indicates that "Dr. Clark Hammoud in today, new order . . . wound care consult."

Both the terms of 42 C.F.R. § 483.13(c) and the facility's own policy require a prompt and thorough investigation culminating in a report setting out the results of the investigation. CMS Ex. 11 at 6. The only documented review of the incident appears in a four-sentence note from a February 2, 2010 Safety Meeting. CMS Ex. 6 at 110. I find nothing about this note amounts to the kind of Investigation Report contemplated by the facility's own policy, much less the requirements of the regulation. Thus, I conclude that Petitioner was not in substantial compliance with 42 C.F.R. § 483.13(c) - tag F225.

d. Tag F490 – Administration

A facility must be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident. 42 C.F.R. § 483.75. As I pointed out above, while the facility had policies and procedures for reporting and investigating injuries of unknown origin as well as policies and procedures for providing moist heat pack therapy, they failed to follow their own established policies and procedures. Also, the Board has held that a finding of noncompliance with respect to 42 C.F.R. §483.75 may be derived from findings of noncompliance with other participation requirements. *Life Care Center of Tullahoma*, DAB No. 2304 at 45 (2010), *citing Stone County Nursing and Rehab. Ctr.*, DAB No. 2276 at 15-16 (2009). There is no dispute that the Administrator was not informed of the incident in question, there is no dispute that Petitioner failed to report the injury to the State as required, and there is no dispute that Petitioner failed to investigate the incident thoroughly and properly as required. Thus, I find that the evidence supports the finding that Petitioner was not in substantial compliance with this requirement.

2. CMS's finding of immediate jeopardy was not clearly erroneous.

Immediate jeopardy exists if a facility's noncompliance has caused, or is likely to cause, "serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301. A finding of actual harm is not a prerequisite for a finding of immediate jeopardy. *Stone County Nursing & Rehab* Center, DAB No. 2276 at 19 (2009). CMS's determination as to the level of a facility's noncompliance (which would include an immediate jeopardy finding) must be upheld unless it is "clearly erroneous." 42 C.F.R. § 498.60(c). The Board has observed repeatedly that the "clearly erroneous" standard imposes on facilities a heavy burden to show no immediate jeopardy and has sustained determinations of immediate jeopardy where CMS presented evidence "from which '[o]ne could reasonably conclude' that immediate jeopardy exists." *Barbourville Nursing Home*, DAB No. 1962, at 11; *Florence Park Care Center*, DAB No. 1931, at 27-28 (2004).

I find that CMS's assertion that the facility's noncompliance created a situation of immediate jeopardy was not clearly erroneous. Here, Petitioner failed to provide adequate assistance and supervision to R101 to protect him from accidents because it failed to follow its own policies and procedures for the application of moist heat pack therapy. This failure caused not only R101 serious injury, but had the likelihood of causing serious harm or serious injury to the other two residents, R102 and R103, who were receiving the same therapy. Petitioner argues that the "harm" or wound was not serious and therefore no immediate jeopardy existed. I disagree. Here, the failure to follow its procedures resulted in actual harm to this resident. Any wound resulting from the failure to properly administer a therapy is serious. Given R101's conditions and his age, it is merely fortuitious that his injury was not more serious, or attended by more dangerous *sequelae*. It should be beyond debate that any wound in an elderly patient has the potential for serious negative outcomes including dangerous infection and pain. I also find that Petitioner was culpable in this situation where its staff failed to follow its own policies and procedures for administering and supervising a resident receiving moist heat pack therapy.

3. The penalty imposed is reasonable.

CMS imposed a civil money penalty (CMP) in the amount of $7,250 per day for four days beginning February 12, 2010 and continuing through February 15, 2010 and a CMP of $650 per day for 35 days beginning February 16, 2010 and continuing through March 22, 2010.

In order to determine whether the CMPs are 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 factor. The factors listed in 42 C.F.R. § 488.404 include: (1) the scope and severity of the deficiency; (2) the relationship of 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 a provider with the kind of deficiency found, and 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).

Petitioner did not contest the reasonableness of the CMP and presented no argument or evidence to dispute CMS's determination. I note that the CMP of $7,250 per day is at the higher penalty range for situations of immediate jeopardy ($3,050-$10,000). However, CMS indicates that Petitioner has a recent history of noncompliance with Tag F323 at the scope and severity level of G in two past surveys (March 2009 and February 2008). CMS Ex. 18. I agree with CMS that this recent history of actual harm under Tag F323 combined with Petitioner's failures here with respect to R101 shows Petitioner's continuing inability to recognize situations that could result in an accident and Petitioner's continuing failure to investigate thoroughly and report incidents to the Administrator. I further find that the facility here is culpable for the deficiency because it did not properly supervise its staff to determine whether its own policies and procedures were being implemented as required. These factors taken together are more than sufficient to sustain the CMP of $7,250 for four days. I further conclude that the CMP of $650 for 35 days until substantial compliance was achieved on March 23, 2010 is reasonable as verified by revisit surveys on March 23, 2010 and April 12, 2010.

I therefore find the penalties imposed reasonable.

III. Conclusion

For the reasons discussed above, I find that Petitioner was not in substantial compliance with Medicare requirements and that some of its noncompliance posed immediate jeopardy to resident health and safety. I affirm as reasonable the penalties imposed.

/s/
Richard J. Smith
Administrative Law Judge