Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Wagnon Place,
(CCN: 04-5201),

Petitioner

v.

Centers for Medicare & Medicaid Services.

Docket No. C-10-581
Decision No. CR2375

Date: May 26, 2011

DECISION

Petitioner Wagnon Place challenges the determination of the Centers for Medicare & Medicaid Services (CMS) that it was not in substantial compliance with program participation requirements. Petitioner also challenges CMS's imposition of a $4000 per instance civil money penalty (PICMP). For the reasons discussed below, I find that Petitioner was not in substantial compliance with program participation requirements at the relevant time. However, I find that the PICMP imposed is not reasonable. I find a PICMP of $1500 to be reasonable.

I. Background

Petitioner is a long-term care facility located in Warren, Arkansas. Petitioner participates in the Medicare and Medicaid programs. The Arkansas Department of Human Services (state agency) completed a complaint survey of Petitioner's facility on January 7, 2010.

The survey cited deficiencies under 42 C.F.R. § 483.10(b)(11) (Tag F157,[1] scope and severity level (ss) H[2]); 42 C.F.R. § 483.25(c) (Tag F314, ss H); and 42 C.F.R. § 483.75 (Tag F490, ss H). By letter dated January 20, 2010, CMS notified Petitioner that it was imposing PICMPs of $1500 for the deficiency at Tag F157; $1000 for the deficiency at Tag F490; and $1500 for the deficiency at Tag F314. A denial of payment for new Medicare and Medicaid admissions was to be imposed as of February 4, 2010, if Petitioner was not in substantial compliance by that date, and Petitioner's provider agreement was to be terminated if Petitioner did not achieve substantial compliance before April 7, 2010. By letter dated March 12, 2010, CMS notified Petitioner that it had achieved substantial compliance with participation requirements, rescinded the termination and denial of payment remedies, and revised the PICMPs to a $4000 PICMP for the instance of noncompliance on January 7, 2010, as described at Tag F314. Petitioner requested a hearing by letter dated March 19, 2010.

I held a hearing in this case in Little Rock, Arkansas, on November 1 and 2, 2010. A 320-page transcript (Tr.) was prepared. Testifying for CMS were state agency surveyors S. Muscovalley, R.N. (Surveyor Muscovalley) and G. Chunn, R.N. (Surveyor Chunn). Testifying for Petitioner were S. Hewitt, R.N., Petitioner's Director of Nursing (DON Hewitt) and J. Lessenberry, D.O. (Dr. Lessenberry), a consultant who provided training and monitoring services for Petitioner, including the provision of training and services for wound care. I admitted CMS Exhibits (CMS Exs.) 1 – 8[3] and Petitioner's Exhibits (P.

---

[1] The "Tag" designation is used in the State Operations Manual (SOM), Appendix PP – Guidance to Surveyors for Long Term Care Facilities. The "Tag" refers to the specific regulatory provision allegedly violated and CMS's guidance to surveyors. Although the SOM does not have the force and effect of law, the provisions of the Act and regulations interpreted clearly do have such force and effect. *State of Indiana by the Indiana Department of Public Welfare v. Sullivan*, 934 F.2d 853 (7th Cir. 1991); *Northwest Tissue Center v. Shalala*, 1 F.3d 522 (7th Cir. 1993). Thus, while the Secretary may not seek to enforce the provisions of the SOM, she may seek to enforce the provisions of the Act or regulations as interpreted by the SOM.

[2] A scope and severity level of H denotes a pattern of actual harm that does not constitute immediate jeopardy to resident health and safety. SOM, section 7400; 42 C.F.R. §§ 488.301, 488.408. In its brief, CMS inexplicably asserts that Petitioner's alleged violation of Tag F314 constituted immediate jeopardy to one of the resident examples. CMS Br. at 4. There is no evidence of record, however, that the noncompliance alleged was cited at a level of immediate jeopardy. It is regrettable that CMS chose not to file a reply brief to correct this discrepancy.

[3] In its brief, CMS asserts that it offered 10 exhibits. CMS Br. at 5. In fact, CMS proffered and I admitted only eight CMS exhibits. Tr. at 19, 300-01. It is also regrettable that CMS chose not to file a reply brief to correct this discrepancy.

Exs.) 1 – 7. Both parties filed post-hearing briefs (CMS and P. Br.) and Petitioner filed a post-hearing reply brief (P. Reply). CMS announced by e-mail that it did not choose to file a reply brief. As I note in footnotes 2 and 3, this tactical choice by CMS was manifestly unhelpful, since it had the effect of leaving certain points unclear and unaddressed.

II. Issues

The issues before me are:

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

2. Whether the remedy imposed is reasonable.

III. Controlling Law

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

Regulations define the term "substantial compliance" to mean:

> [A] level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm.

42 C.F.R. § 488.301.

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

may continue to accrue until the date the facility achieves substantial compliance, or until CMS terminates the facility's provider agreement. 42 C.F.R. § 488.440.

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

> [A] situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident.

42 C.F.R. § 488.301.

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

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

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

Petitioner vehemently contests the "H" level of scope and severity imposed by CMS. However, other than in a mistaken — and uncorrected — reference to immediate

jeopardy in its brief, CMS has not asserted that immediate jeopardy level noncompliance exists in this case. Neither party has indicated that Petitioner has lost a NATCEP. Thus, I may not address the scope and severity of CMS's noncompliance finding in my decision, and I do not do so below.

IV. Discussion

I make numbered findings of fact and conclusions of law (Findings) to support my decision. I set them forth below as separate headings, in bold and italic type, and discuss each in detail.[4]

1. Petitioner failed to comply substantially with the participation requirement at 42 C.F.R. § 483.25(c).

The regulation at 42 C.F.R. § 483.25 states 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 psychosocial well-being, in accordance with the comprehensive assessment and plan of care.

The subsection at 42 C.F.R. § 483.25(c) references pressure sores and requires that:

> (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; and
> (2) A resident having pressure sores receives necessary treatment and services to promote healing, prevent infection, and prevent new sores from developing.

The SOM notes that although the regulatory language refers to pressure sores, such sores

---

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

are also referred to as pressure ulcers.[5] A pressure sore is defined as "any lesion caused by unrelieved pressure that results in damage to the underlying tissue(s). . . . Although friction and shear are not primary causes of pressure ulcers, friction and shear are important contributing factors to the development of pressure ulcers." SOM, Appendix PP, Tag F314. The SOM defines an "unavoidable" pressure sore as,

> "Unavoidable" means that the resident developed a pressure ulcer even though the facility had evaluated the resident's clinical condition and pressure ulcer risk factors; defined and implemented interventions that are consistent with resident needs, goals, and recognized standards of practice; monitored and evaluated the impact of the interventions; and revised the approaches as appropriate.

The SOM also notes that there are other sorts of ulcers not related to pressure. These ulcers are described in the SOM, Appendix PP, at Tag F309. The SOM discusses both arterial, venous, and diabetic neuropathic ulcers. An arterial ulcer occurs "as a result of arterial occlusive disease when non-pressure related disruption or blockage of the arterial blood flow to an area causes tissue necrosis. . . . may be present in individuals with moderate to severe peripheral vascular disease . . . . usually occurs in the distal portion of the lower extremity and may be over the ankle or bony areas of the foot . . . . The wound bed is frequently dry and pale with minimal or no exudate." A venous ulcer (known previously as a stasis ulcer) "is an open lesion of the skin and subcutaneous tissue of the lower leg, often occurring in the lower leg around the medial ankle. Venous ulcers are reported to be the most common vascular ulceration and may be difficult to heal, may occur off and on for several years, and may occur after relatively minor trauma. The ulcer may have a moist, granulating wound bed, may be superficial, and may have minimal to copious serous drainage unless the wound is infected." A diabetic neuropathic ulcer "requires that the resident be diagnosed with diabetes mellitus and have peripheral neuropathy."

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

> . . . the preamble to the Notice of Final Rulemaking for section 483.25 provides that facilities "should always furnish the necessary treatment and services to prevent the development of pressure sores or, at the least, to promote the healing of sores that have developed." Clermont Nursing and Convalescent Center at 9;

---

[5] Dr. Lessenberry testified also that "sore" and "ulcer" are used interchangeably depending on what region of the country one is in. She testified that the accepted clinical standard use is pressure "ulcer." Tr. at 299. The regulations, however, reference a "pressure sore." Below, I generally use the term "pressure sore," although I may cite a pressure sore as an "ulcer," "decubitus," or "wound," depending on the context of the discussion or testimony.

> Koester Pavilion, DAB No. 1750, at 30-31 (2000), citing 56 Fed. Reg. 48,826, at 48,851 (Sept. 26, 1991); see also Woodland Village Nursing Center, DAB No. 2172, at 13 (2008) ("[the] regulatory language on pressure sore treatment and prevention applies a particularly demanding standard, i.e., that the facility must 'ensure' healing and prevention as the outcomes of that treatment and those services unless the facility can prove with clinical evidence that a negative outcome was unavoidable despite the facility having furnished all necessary care."). Thus, as the ALJ recognized, the Board has concluded that a facility cannot claim unavoidability unless it first shows that it furnished all necessary treatment and services . . . .

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

On January 7, 2010, the state agency completed a complaint investigation of Petitioner's facility. As noted above, only the noncompliance cited at Tag F314 is in contention here. Under that Tag, the state agency alleged that based on record review and interview, Petitioner failed to ensure that residents at risk of developing pressure sores, or who had pressure sores, were: (1) monitored for skin breakdown in order that skin breakdown would be quickly identified and communicated to residents' physicians; (2) assessed at least weekly to identify deterioration in order to promptly consult with a resident's physician regarding treatment; and that (3) physician's orders for treatment of pressure sores were obtained in a timely manner and implemented to prevent the potential for deterioration for two residents (Residents 6 and 8). The state agency alleged that this "failed practice" caused a pattern of actual harm for Resident 6 such that the resident developed multiple pressure sores that deteriorated because the resident did not receive prompt treatment. The state agency alleged that this failed practice also had the potential to cause more than minimal harm to 13 other residents of the facility. P. Ex. 1, at 8; CMS Ex. 2, at 8.[6]

CMS does not allege that the actual treatments and services that Petitioner provided the residents were inadequate (i.e., the way the facility changed dressings). Instead, the crux of CMS's case goes to the process by which Petitioner monitored and assessed pressure sores and notified residents' physicians in order to ensure timely treatment of pressure sores (although CMS does allege that some treatments were not documented as having been done, and thus were not done). CMS alleges generally that the process by which Petitioner assessed pressure sores and communicated that information to its staff and to residents' physicians was flawed, in that information regarding pressure sores was not timely provided to staff and, as a result, residents' physicians were not made aware of the

[6] Both parties submitted copies of the SOD, Petitioner as P. Ex. 1 and CMS as CMS Ex. 2. The parties have also submitted copies of the same documents in numerous instances. Below, I do not comb the record to indicate where each party has filed a duplicate document. In general, I try to cite to CMS's exhibits where there are duplicate exhibits.

development or change in a pressure sore in order to promptly initiate treatment or a change in treatment. Below, although I do not find that CMS has made a *prima facie* case with regard to all of the allegations in the January 7, 2010 statement of deficiencies (SOD), I do find that CMS has made a *prima facie* case of noncompliance in several respects that Petitioner has not rebutted. I discuss first the overarching failure of the process by which Petitioner communicated its assessments of pressure sores to staff and residents' physicians, and I then separately discuss Petitioner's specific failures with regard to Residents 6 and 8 and their pressure sores. I then explain why some, although not all, of CMS's allegations regarding them must be sustained, and how those sustained allegations constitute noncompliance.

The SOD relates that a registered nurse, RN-1, completed weekly body audits (body audits) of Petitioner's residents on Sunday and then filled out weekly skin/wound audit summary spreadsheets (audit summaries). The audit summaries were forwarded to the DON on the following Monday or Tuesday and treatment orders were then obtained. CMS Ex. 2, at 14-15. Surveyor Muscovalley testified that weekly audit summaries are not a regulatory requirement, and that this facility chose to do them. Tr. at 127.[7]

Surveyor Muscovalley testified that a facility needs to consult with a resident's physician early with regard to pressure sores in order to care plan for treatment of the sores and to timely start or revise treatment. She testified that a physician is integral in devising a care plan in order to either begin or change treatment of a pressure sore if an approach is not working.[8] Tr. at 31, 34.

---

[7] Apparently RN-1 was not sure how to fill out the audit summary form. Surveyor Muscovalley testified that not filling out the form correctly is an important lapse, because the facility needs to communicate accurate, detailed information to ensure that wounds are treated timely and accurately. Tr. at 61. Although there may have been discrepancies between the body audits and audit summaries, they are not material to my decision and I do not discuss them.

[8] Surveyor Muscovalley testified that she expects to see improvement in a pressure sore within a couple of weeks of initiation of a new treatment. Tr. at 31. DON Hewitt testified that a facility can watch a pressure sore for two weeks to see if a treatment is working. Tr. at 169. Petitioner takes from this that it should not be cited for a deficiency until two weeks after initiation of a new treatment. However, if a new wound develops or a wound deteriorates this rather obviously cannot mean that the facility is entitled to a "grace period" of two weeks to contact a physician to ascertain if treatment needs to be changed. That would not comport with the regulatory requirement to show that a facility furnished all necessary treatment and services or show that the development or deterioration of a pressure ulcer was unavoidable.

Surveyor Muscovalley testified that a treatment LPN at the facility told her that Petitioner has skin/wound meetings on Thursday to look over Sunday's weekly body audit summaries. The LPN also told Muscovalley that she did not understand why they were not given orders to treat the pressure sores earlier. Muscovalley testified that the LPN was "ill informed" because she got information regarding pressure sores late in the week when the body audits were done on a Sunday. Tr. at 60. Muscovalley testified that this is not a good system because it can lead to delays in treatment and tracking orders. Muscovalley testified that delaying pressure sore treatment is critical because such sores can deteriorate within 24 hours. Muscovalley testified that surveyors are told pressure sores must be acted on promptly and a physician must be contacted when a new pressure sore is identified or when deterioration occurs in an identified pressure sore. This is to get treatment started as soon as possible or change an approach for a pressure sore that is not healing. Tr. at 55-56. Here, Petitioner was tracking more than 50 sores on the weekly audit summaries and its documentation was difficult to follow and sporadic. Tr. at 57. Surveyor Chunn echoes Muscovalley's concern, noting that Petitioner's system was flawed because intervention should be done in a timely manner and that not doing so could lead to deterioration of a pressure sore. A nurse doing treatment assessments should be able to call a physician on a Sunday to ask for treatment orders. Petitioner's system, according to which it could take two or three days to get a change in treatment orders, simply takes too long. Tr. at 147-49.

DON Hewitt did not materially disagree with the surveyors' understanding of Petitioner's pressure sore assessment process. She testified that when RN-1 came in on a Sunday (or sometimes on a Monday) to assess, if she found something that needed to be addressed, such as a new wound, she would call or leave a note for staff to address the wound the next day, in order that a nurse who knew the resident could be consulted. Tr. at 167-68. Hewitt testified that RN-1 was not around during the week to explain the audit summary and the documentation at times may have been "out of whack." Tr. at 196.

As noted by the Board, the standard for determining whether a pressure sore is unavoidable is particularly demanding in requiring that a facility provide all necessary treatment and services to prevent or treat a pressure sore. The surveyors persuasively testified that a pressure sore can form or deteriorate swiftly and that time is of the essence in contacting a physician and beginning treatment. Dr. Lessenberry did not dispute that a pressure sore could develop quickly, within a few hours in a situation where a resident displays co-morbidities such as those of the residents discussed below. Tr. at 259. Petitioner's process for the assessment nurse, RN-1, to advise staff of the development or deterioration of a sore and the need for treatment alone could take more than 24 hours. Such a delay is too long. DON Hewitt's explanation that the nurse did so because she wanted to consult with a nurse who knew the patient is not a sufficient excuse or justification for the failure to inform Petitioner's staff on Sunday of her findings, and thereby to enable them immediately to contact a resident's physician to initiate or change treatment.

Resident 6: At the time of the survey Resident 6 was an 85-year-old woman. She was admitted to the facility on October 9, 2009, and a minimum data set (MDS) dated October 19, 2009, encapsulating an assessment reference date of October 15, 2009, indicates she had diagnoses of, among other things, peripheral vascular disease, hypertension, congestive heart failure, depression and anemia. CMS Ex. 6, at 35, 37, 39.[9] The October 19, 2009 MDS reflects specifically for purposes of this case that Resident 6 entered the facility with two Stage I sores and one Stage II sore.[10] CMS Ex. 6, at 40. The MDS does not note whether they were pressure sores or another type of sore. Resident 6 was hospitalized and out of the facility on October 26 through 27, and November 10 through 11, 2009. Otherwise, at all relevant times, Resident 6 was present in the facility.

The SOD reflects that Resident 6 entered the facility with or developed sores in four locations: her right lower leg, her left outer ankle, and her left and right heels. Tr. at 64-65; CMS Ex. 2, at 8-13. I discuss below as noncompliance only the examples of the pressure sores on Resident 6's heels. Surveyor Muscovalley indicated during her testimony that the wounds on Resident 6's right lower leg and left outer ankle should not have been cited under Tag F314 as they were not necessarily pressure sores but venous ulcers. She testified that the right lower leg and left outer ankle ulcers should have been cited instead under Tag F309, as a general quality of care violation.[11] Tr. at 83, 95, 122.

---

[9] Surveyor Muscovalley testified that the October 19, 2009 MDS indicated that the resident had Alzheimer's dementia. Tr. at 28. The MDS, however, does not document that Alzheimer's was one of her disease diagnoses, nor does the MDS for an assessment period ending in December 2009. CMS Ex. 6, at 39, 48. I note this, although whether or not the resident had Alzheimer's dementia is irrelevant to my decision here.

[10] Pressure ulcers are assessed in four stages. The SOM, at Appendix PP, defines a Stage I as being an observable, pressure-related alteration of intact skin, whose indicators as compared to an adjacent or opposite area on the body may include changes in skin temperature, tissue consistency, sensation, or a defined area of persistent redness in lightly pigmented skin, or with persistent red, blue, or purple hues in darker skin tones; Stage II is partial thickness loss of dermis presenting as a shallow open ulcer with a red-pink wound bed without slough or an intact or open/ruptured blister; Stage III is full thickness tissue loss where subcutaneous fat, but not bone, tendon or muscle may be exposed. Slough may be present but does not obscure the depth of tissue loss and there may be undermining or tunneling; and Stage IV is full thickness tissue loss with exposed bone, tendon or muscle. Slough or eschar may be present on some parts of the wound bed. There is often undermining and tunneling.

[11] Although Resident 6 entered the facility with a pressure ulcer on her left outer ankle, that sore healed. P. Ex. 4, at 4. A new ulcer appeared at that site which is the venous ulcer Surveyor Muscovalley agreed should have been cited under Tag F309.

CMS argues in its brief that it was not until the hearing that Petitioner raised the argument that the sores were venous ulcers and that I should thus not consider them as violations of Tag F314. CMS argues that Petitioner did not present clinical evidence to show they were venous ulcers. However, the recognition by Surveyor Muscovalley that the ulcers should have been cited under another F Tag convinces me that they were not pressure sores. CMS did not ask me to decide, and I will not decide, whether Petitioner's treatment of the right lower leg and left outer ankle ulcers constitute a violation of the participation requirement at Tag F309. Thus, I address below only Resident 6's right and left heel pressure sores in the context of Tag F314.

***Right heel pressure sore*:** Weekly body audits document the development of Resident 6's right heel pressure sore. CMS Ex. 6, at 11, 67. On October 11, 2009, this sore, with which Resident 6 was admitted to the facility, was assessed as a Stage 1, 4 cm. x 6 cm. x 0 cm. There is no documentation of the pressure sore on weekly body audits dated October 18, 25, and 31, 2009. An audit summary dated October 12, 2009, notes that the right heel pressure sore had healed. P. Ex. 4, at 4; P. Ex. 5, at 11; Tr. at 108.[12] On November 6, 2009, a Stage II fluid filled blister 4 cm. x 8 cm. x 0 cm. was identified on Resident 6's heel. CMS Ex. 2, at 11; CMS Ex. 6, at 11. Surveyor Muscovalley testified that such a sore can happen quickly. Tr. at 108-09. Muscovalley testified that Petitioner's physician was not notified of the pressure sore until four days later. Muscovalley testified that she would have expected the physician to be notified when the blister first appeared. Tr. at 109-11.

DON Hewitt testified that she was not sure why Resident 6's physician was not notified about the development of the pressure sore. Hewitt testified that it is usual to leave a Stage II blister alone and hope it will reabsorb. Hewitt testified that she is not sure if Petitioner has a policy and procedure regarding notification of a physician regarding a Stage II intact blister. Tr. at 180-82. Dr. Lessenberry testified that the pressure sore did not "necessarily" require a physician order for treatment, although it would require nursing intervention. Lessenberry did not know why the physician was notified of the pressure sore on November 11, 2009. Lessenberry posited that the facility may have decided the sore needed more than A & D ointment on it. Tr. at 260-61. Lessenberry also testified that once having had a pressure sore in an area the tissue in that area is more likely to break down again. Tr. at 288-89.

---

[12] Surveyor Muscovalley testified that the regulations do not require a facility to document on a weekly body audit that a pressure ulcer has healed. Tr. at 108. Dr. Lessenberry says there is no policy at the facility to document healed wounds on weekly body audits. Tr. at 259. However, if a facility does not somehow inform a resident's physician that a sore has healed, then the physician's treatment orders remain active, not discontinued, and the facility is obliged to follow them.

Petitioner's failure to consult Resident 6's physician for at least four days after development of the pressure sore constitutes noncompliance with the participation requirement at issue. Although Petitioner may argue that a facility needs time to see if treatment of a sore has time to work, this was a new pressure sore and the physician should have been contacted to initiate treatment. Petitioner did not submit evidence showing that leaving a new Stage II pressure sore alone in the hope that it would reabsorb is consonant with a recognized standard of care. Petitioner did not point out any facility policy in this regard. Neither Dr. Lessenberry's nor DON Hewitt's testimony convinces me that the failure to contact Resident 6's physician for treatment orders constitutes an acceptable standard of care or compliance with the regulation. The standard for compliance with the regulation is high: for development of a pressure sore to be unavoidable, a facility must be able to show that it furnished all necessary treatment and services to that sore. In this instance a healed pressure sore reappeared. Dr. Lessenberry testified that such sores are likely to reappear. It is incumbent upon a facility to properly and promptly treat such sores. If a facility is to meet that obligation, then consultation with a resident's physician, and obtaining treatment orders, or a change in orders, from the resident's physician, are imperatives.

Resident 6's physician readmitted her to the facility on November 11, 2009, and ordered treatment of the pressure sore on her right heel on that date. Specifically, Petitioner's staff was to cleanse the heel with wound cleanser, apply A & D ointment, use 4 x 4's, and wrap with Kling every day. CMS Ex. 6, at 25, 29. The treatment administration record (TAR) dated November 1 – 30, 2009, notes that Petitioner's staff initialed treatment as completed on November 11, 2009, and also on November 12 and 16, 2009. Facility staff did not initial that the treatment was done from November 13 through 15, 2009. The physician's order was changed after November 16, 2009. CMS Ex. 6, at 15. The TAR for December does not reflect treatments on December 26 or 27, 2009. CMS Ex. 6, at 16. What the TARs do document is that Petitioner's staff did not document by staff initials that right heel treatment was done on several dates, although treatment was ordered to be done every day.

DON Hewitt testified that such inconsistent documentation does not always mean that the ordered treatments were not provided. Hewitt testified that if treatments were not documented the wound report could be consulted to determine if the wound was getting better or worse. Also, dressings are signed and dated and the nurse on the next shift would have reported if a treatment had not been done. DON Hewitt testified, however, that she could not prove that the treatments were done. Tr. at 185-87. Dr. Lessenberry also testified that dressings are dated and initialed by the nurse changing the dressing. Tr. at 264. The testimony of Hewitt and Lessenberry does not plausibly suggest, much less prove, that the treatments were provided in this case. It is incumbent upon Petitioner to show that it furnished all necessary treatment and services to this right heel sore. Petitioner did not do so.

Left heel pressure sore: The same problems presented with this Resident's right heel pressure sore also present with her left heel pressure sore. Resident 6 had a pressure sore on her left heel on October 1, 2009, which the facility identified as healed on the weekly audit summary of October 12-18, 2009. P. Ex. 4, at 4. On November 11, 2009, Resident 6 was readmitted to the facility following a hospital procedure. CMS Ex. 6, at 25. On her return, a body audit identified a new pressure sore on her left heel. It was noted to be an open blister, Stage II, 4.5 cm. x 7 cm. P. Ex. 5, at 45; Tr. at 44-45, 118, 183. Resident 6's physician was not notified of the new left heel sore until November 19, 2009, when the physician ordered a change in treatment. CMS Ex. 6, at 25; Tr. at 183-84. DON Hewitt testified that she did not know why Resident 6's physician was not called until November 19, and posited that Petitioner's protocol is to leave a blister alone. Tr. at 183-84. Dr. Lessenberry testified that it was appropriate to wait until November 19, 2009, to notify Resident 6's physician because the facility was doing nursing interventions and there is no policy that a physician be notified for a blister. Tr. at 262-63. Hewitt's and Lessenberry's testimony is unpersuasive. A healed pressure sore reappeared in the same location, Resident 6's left heel. When Resident 6 returned from the hospital, the only treatment ordered was to the right heel, there was no treatment ordered for the left heel or a pre-existing order for treatment of the left heel. P. Ex. 5, at 34. It was thus incumbent upon Petitioner to get treatment orders for that sore. As discussed above regarding the right heel pressure sore, the length of time between identifying the new pressure sore and notifying the physician was too long a period to comport with participation requirements.

As noted in the SOD, the December 2009 TAR documented treatment to the left heel, but there is no documentation the treatments were administered on December 26 or 27, 2009. CMS Ex. 2, at 13; CMS Ex. 6, at 16. Dr. Lessenberry testified that missing documentation on a medication administration record (MAR) or TAR is merely a documentation error and that such an error does not affect a pressure sore. Instead, a documentation error would just be something to discuss with and re-inservice staff. Tr. at 263-64. Petitioner, however, did not show that treatment was actually done. As noted by Surveyor Muscovalley, the troubling aspect of this sore was its reappearance. Tr. at 114. Again, it is incumbent upon Petitioner to show that the pressure sore was unavoidable because all necessary treatment and services had been provided to Resident 6 to heal the left heel sore. Petitioner failed to do so.

Resident 8: Resident 8, a 95-year-old man, was readmitted to the facility on October 1, 2009. His admission orders diagnoses include "Decubitus/buttocks," a urinary tract infection, dermatitis, and a left above-the-knee amputation. CMS Ex. 7, at 21.

An admission body audit noted that he had a 5 cm. x 2 cm. Stage II pressure sore. It appears from the diagram provided to have been sited somewhere between his buttocks. CMS Ex. 7, at 5. His admission orders note that wound cleanser is to be applied once daily. The orders do not say where the cleanser is to be applied. CMS Ex. 7, at 21. On October 8, 2009, the resident's physician was contacted and he ordered that the sore was

to be cleaned with wound cleanser, Santyl was to be applied to the wound bed, the sore was to be covered with collagen to promote granulation tissue growth, and the sore was then to be covered with a foam. The dressing was to be changed daily. CMS Ex. 7, at 34. The weekly body audit done on October 11, 2009, indicates the pressure sore is a coccyx Stage III, 5 cm. x .8 cm. x .3 cm. and 100% granulation. CMS Ex. 2, at 14; Tr. at 141.

Surveyor Chunn testified that the pressure sore was deteriorating and there was no physician's order regarding the sore until October 8, 2009, seven days after the resident was admitted to the facility. Tr. at 141. Chunn testified that after the pressure sore was assessed, the resident's physician should have been notified, a treatment order obtained, and treatment interventions put in place. Tr. at 142, 146. Chunn testified that it was possible for the sore to deteriorate from a Stage II to a Stage III during this period. Tr. at 147. Dr. Lessenberry testified that it was appropriate to treat the wound for seven days with wound cleanser before notifying the resident's physician. Tr. at 278. However, as I discuss below, the physician's admission orders were unclear, and within those seven days the resident's physician should have been consulted with regard to treatment of the sore.

Surveyor Chunn testified that the physician's admission order did not specify the location of the pressure sore, and there is no documentation that the resident's physician was consulted for clarification. Tr. at 142. Chunn testified it was not enough to cite that there was a decubitus to the buttocks (CMS Ex. 7, at 21). The admission body audit indicated that the pressure sore was between the buttocks in the sacrum or coccyx area, and it documents a rash to the buttocks, not a decubitus. CMS Ex. 7, at 5; Tr. at 157-58. DON Hewitt testified that Resident 8 had a physician's order for wound cleanser when admitted and had only one sore so that the facility would know what it had to treat. Tr. at 189. Dr. Lessenberry testified that she probably would not have written the admission order in the way it was written, but that a physician can write an order "whatever [way] they want." Lessenberry testified that a more appropriate order would have been to cite the location of the pressure sore the physician wanted to be treated. Tr. at 276-77. The admission orders do not identify exactly where the pressure sore was situated and do not explain what it is that the physician wanted treated. I infer from Lessenberry's admission — that the order is not written the way she would have written it — that the substance of that order is far from clear to her. Petitioner should have contacted the resident's physician to clarify the order.

Petitioner also did not document its treatment of the pressure sore. The TAR for October 1–31, 2009, notes the physician's order of October 8, 2009 regarding treatment of the pressure sore. CMS Ex. 7, at 10. It does not, however, document that the Resident received treatment with wound cleanser through October 7, 2009. Moreover, it does not document treatment to the sore on October 24 or 25, 2009. DON Hewitt testified that it appears there was a clerical or medical record error which prevented the physician's

order from being placed on the TAR when the resident was re-admitted, although she testified that the failure did not necessarily contribute to the pressure sore going from a Stage II to a Stage III. It is not clear from her testimony, however, whether wound cleanser was ever used on the resident's pressure sore prior to October 8, 2009, or whether the error was purely documentary. Tr. at 190-94. Dr. Lessenberry was asked a question about whether, if a treatment was not documented for eight days, would that be a problem on chart review. Lessenberry testified that if she saw this on chart review she would ask "what went on here and what's happening" because, even if the treatment was not documented, that "doesn't mean that they didn't do it; that just means they didn't document it." Tr. at 281. However, whether the wound cleanser treatment was done or not, the fact remains that on numerous dates in October the TAR does not record that ordered treatment was done. As noted with Resident 6, this does not amount to a showing that the pressure sore was unavoidable and that Petitioner was doing all it could to provide all necessary treatment and services for Resident 8's pressure sore.

2. The $4000 PICMP imposed is not reasonable. A $1500 PICMP is reasonable.

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

In reaching a decision on the reasonableness of a PICMP, I must consider whether the evidence supports a finding that the amount of the PICMP is at a level reasonably related to an effort to produce corrective action by Petitioner with the kind of deficiency found, in light of the above factors. I am neither bound to defer to CMS's factual assertions, nor free to make a wholly independent choice of remedies without regard for CMS's discretion. *Barn Hill Care Center*, DAB No. 1848, at 21 (2002).

CMS initially imposed a PICMP of $1500 for the deficiency at Tag F314, $1500 for the deficiency at Tag F157, and $1000 for the deficiency at Tag F490. Without explanation other than "[t]he revision was based on an administrative review within the Regional Office of the Centers for Medicare & Medicaid Services," CMS revised the penalty to a $4000 PICMP for Tag F314, dropping the penalties for Tags F157 and 490. CMS Ex. 1, at 4.

I have no evidence with regard to Petitioner's history of noncompliance or financial condition. However, I do find that Petitioner is culpable and that its deficiencies are serious. The process by which Petitioner assessed pressure sores and then communicated that assessment to staff and to residents' physicians was flawed and could impede timely treatment of a pressure sore. The examples of Residents 6 and 8 reflect that physician notification was delayed. Moreover, Petitioner failed to document treatment of pressure sores and, without such documentation, it is not possible to know if treatments were done. CMS thus made a *prima facie* case that treatments were not done and Petitioner did not otherwise prove that the treatments were done. Thus, Petitioner did not show that the pressure sores were unavoidable, because it did not show that it actually furnished all necessary treatment and services. Accordingly, imposition of a PICMP is reasonable.

A $4000 PICMP is not, however, reasonable. On the same evidence, CMS initially imposed only a $1500 PICMP for the noncompliance at Tag F314, and CMS did not explain why it revised the PICMP to $4000. CMS simply noted in its March 12, 2010 notice letter that it was doing so. CMS has not otherwise explained the revision. It may be that there is an explanation, and it may be that had CMS not declined to file a reply brief, that explanation would be apparent and convincing. But, given CMS's deliberate waiver of a significant opportunity to plead its case, that explanation remains unvoiced. I have not sustained all of the instances of noncompliance alleged by CMS, principally those with regard to the ulcers on Resident 6's right lower leg and left outer ankle. The sustained instances of noncompliance are serious. Taking all of this into account, I find that the PICMP initially imposed for the noncompliance at Tag F314, $1500, is reasonable as a remedy for the noncompliance I have upheld.

IV. Conclusion

For the reasons discussed above, I find that Petitioner was not in substantial compliance with the Medicare participation requirement at 42 C.F.R. § 483.25(c) (Tag F314). I affirm as reasonable a $1500 PICMP for that noncompliance.

/s/
Richard J. Smith
Administrative Law Judge