Department of Health and Human Services

**DEPARTMENTAL APPEALS BOARD**

Civil Remedies Division

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| In the Case of: | ) | |
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| Holmesdale Healthcare and Rehabilitation Center (CCN: 26-5758), | ) | Date: September 24, 2009 |
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| Petitioner, | ) | |
| | ) | |
| - v. - | ) | Docket No. C-08-523 |
| | ) | Decision No. CR2010 |
| Centers for Medicare & Medicaid Services. | ) | |
| | ) | |

## DECISION

Petitioner, Holmesdale Healthcare and Rehabilitation Center, is a nursing facility located in Kansas City, Missouri, that participates in the Medicare program. Based on a survey completed April 10, 2008, by the Missouri Department of Health and Senior Services (State Agency), the Centers for Medicare & Medicaid Services (CMS) determined that the facility was not in substantial compliance with program participation requirements and imposed a per instance civil money penalty (CMP) of $10,000.

### I. Background

The Social Security Act (Act) sets forth requirements for nursing facility participation in the Medicare program, and authorizes the Secretary of Health and Human Services to promulgate regulations implementing those statutory provisions. Act § 1819. The Secretary's regulations are found at 42 C.F.R. Part 483. 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 contracts with state agencies to conduct periodic surveys to determine whether skilled nursing facilities are in substantial compliance. Act § 1864(a); 42 C.F.R. § 488.20. The regulations require that each facility be surveyed once every twelve

months, and more often, if necessary, to ensure that identified deficiencies are corrected. Act § 1819(g)(2)(A); 42 C.F.R. §§ 488.20(a), 488.308.

A facility has a right to appeal a "certification of noncompliance leading to an enforcement remedy." 42 C.F.R. § 488.408(g)(1); *see also* 42 C.F.R. §§ 488.330(e) and 498.3. However, CMS's choice of remedies or the factors CMS considered when choosing remedies are not subject to review. 42 C.F.R. § 488.408(g)(2). A facility may only challenge the scope and severity level of noncompliance found by CMS if a successful challenge would affect the range of the CMP that could be imposed by CMS or impact the facility's authority to conduct a nurse aide training and competency evaluation program. 42 C.F.R. §§ 498.3(b)(14) and (d)(10)(i). The CMS determination as to the level of noncompliance "must be upheld unless it is clearly erroneous" (42 C.F.R. § 498.60(c)(2)), including a finding of immediate jeopardy. *Woodstock Care Center*, DAB No. 1726, at 9, 38 (2000), *aff'd, Woodstock Care Ctr. v. Thompson*, 363 F.3d 583 (6th Cir. 2003). The hearing before an administrative law judge is a *de novo* proceeding. *Anesthesiologists Affiliated, et al*, DAB CR65 (1990), *aff'd*, 941 F.2d 678 (8th Cir. 1991).

Here, following a survey completed February 14, 2008, CMS determined that the facility was not in substantial compliance with dozens of Medicare participation requirements and that its conditions constituted immediate jeopardy to resident health and safety and imposed remedies. P. Ex. 1; P. Ex. 12, at 1. Based on an April 10, 2008 revisit survey CMS determined that the facility remained out of substantial compliance with Medicare participation requirements, specifically: 42 C.F.R. § 483.25(c) (Tag F314 – pressure sores); 42 C.F.R. § 483.15(h)(2) (Tag F253 – housekeeping/maintenance); 42 C.F.R. § 483.25(d) (Tag F315 – urinary incontinence); 42 C.F.R. § 483.65(a) (Tag F441– infection control); 42 C.F.R. § 483.75(m)(1) (Tag F517 – disaster and emergency preparedness); 42 C.F.R. § 483.70(a) (Tag K025 – NFPA 101 Life Safety Code Standard, smoke barriers); and 42 C.F.R. § 483.70(a) (Tag K062 – NFPA 101 Life Safety Code Standard, maintenance of automatic sprinklers). P. Ex. 2, at 1, 2, 48, 54, 65; P. Ex. 4, at 1, 4.

On April 15, 2008, CMS notified the facility that its conditions constituted immediate jeopardy to resident health and safety and that its Medicare provider agreement would be terminated on May 3, 2008, if it did not allege corrections that could be verified showing removal of immediate jeopardy. P. Ex. 13, at 1-2. CMS also notified the facility that it was imposing a $10,000 per instance civil money penalty for the facility's noncompliance with 42 C.F.R. § 483.25(c) (Tag F314 – pressure sores). *Id.* at 2. Additionally, CMS informed Petitioner that it intended to impose a CMP of $100 per day if it was not in substantial compliance at the revisit. *Id.* at 2.

On April 25, 2008, surveyors conducted a second revisit survey, and on April 29, 2008, CMS notified Petitioner that while the facility still remained out of substantial compliance, because the facility had removed the immediate jeopardy, its Medicare provider agreement would not be terminated. P. Ex. 14, at 1.

On June 11, 2008, Petitioner timely requested a hearing on several findings from the April 10 survey. Specifically, Petitioner disagreed with CMS's determinations that (1) its deficiencies amounted to immediate jeopardy; (2) it was out of compliance with 42 C.F.R. § 483.25(c) and 42 C.F.R. § 483.75(m)(1); (3) the scope and severity of the alleged deficiencies; (4) CMS's continuation of a previously imposed denial of payment for new admissions; and (5) CMS's imposition of a $10,000 CMP.

The case was assigned to me for a hearing and decision. The parties submitted a Joint Report of Readiness to Present Evidence and pre-hearing memoranda. I held a hearing from March 2 through March 3, 2009, in Kansas City, Missouri. CMS submitted 10 exhibits (CMS Exs. 1-10) and Petitioner submitted 12 Exhibits (P. Exs. 1-5, 7-10, 12-14). I accepted all of the exhibits into evidence.[1] Tr. 15, 16, 18, 311. At the hearing Petitioner narrowed the issues to its noncompliance with 42 C.F.R. § 483.25(c), the immediate jeopardy determination, and the reasonableness of the penalty. Tr. 19-20; 179-180; P. Br. at 1. The parties submitted post-hearing briefs (P. Br., CMS Br.) and reply briefs (P. Reply, CMS Reply).

## II. Issues

The issues before me are:

> (1) whether the facility was in substantial compliance with 42 C.F.R. § 483.25(c) at the time of the April 10, 2009 survey; and
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> (2) if the facility was not in substantial compliance, whether the penalty imposed, $10,000 for its noncompliance with 42 C.F.R. § 483.25(c), was reasonable.

## III. Discussion

### *A. Petitioner was not in compliance with the Medicare participation requirements at the time of the April 10, 2009 survey that it did not challenge.*

Petitioner here challenges only one of the deficiencies cited in the April 10 survey, 42 C.F.R. § 483.25(c). CMS's other deficiency determinations from that survey are final

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[1] Petitioner withdrew exhibits 6 and 11. Tr. 16, 311.

and binding. *See NHC Healthcare Athens*, DAB No. 2258, at 4 n.3 (2009); *Kenton Healthcare, LLC*, DAB No. 2186, at 4 n.1 (2008).

***B. The evidence establishes that the facility staff did not take all necessary precautions to promote healing, prevent infection, and prevent new pressure sores from developing, as required by 42 C.F.R. § 483.25(c).***

Under the statute and the "quality of care" regulation, 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 resident's comprehensive assessment and plan of care. Act § 1819(b); 42 C.F.R. § 483.25. The regulation further requires that the facility ensure, based on the resident's comprehensive assessment, that a resident who enters the facility without pressure sores does not develop them unless his or her clinical condition demonstrates that they were unavoidable. 42 C.F.R. § 483.25(c)(1).

An unavoidable pressure ulcer is one which develops "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." Guidance to Surveyors for Long Term Care Facilities, Transmittal 4, November 12, 2004, http://www.cms.hhs.gov/transmittals/Downloads/R4SOM.pdf. If a resident has pressure sores, the facility must ensure that he or she receives the treatment and services necessary to promote healing, prevent infection, and prevent new sores from developing. 42 C.F.R. § 483.25(c)(2). In assessing the facility's compliance with this requirement, the relevant question before me in this case is: did the facility "take all necessary precautions" to prevent a particular resident's new sores from developing? If the facility did so and the resident develops sores anyway, I must find no deficiency and no substantial non-compliance with the regulation. But if the evidence establishes that the facility fell short of taking all necessary precautions, then the regulation is violated. *Koester Pavilion*, DAB No. 1750, at 32 (2000).

CMS's allegations of noncompliance with section 483.25(c) center on the care provided to two residents, Resident 4 (R4) and Resident 20 (R20). CMS alleges that Petitioner did not appropriately assess the two residents who were at risk for pressure sores and that the residents developed Stage IV pressure sores. It also alleges that Petitioner did not assess resident complaints of pain during wound care, that it did not follow care plans, that it did not follow infection control measures, and that it did not ensure that physician's orders were followed (covering wound to prevent cross-contamination). CMS alleges that Petitioner did not adequately assess residents' skin or reassess a wound in a timely manner to ensure treatment was effective and to prevent the spread of infection from a wound to the bone resulting in surgery.

### 1. Resident 20

R20 was a vulnerable resident who was highly dependent on facility staff for many activities. He was assessed to require staff assistance with bed mobility, transfers, locomotion, activities of daily living, and bathing. He had limited range of motion in both legs; was incontinent of bowel and bladder; and had cognitive impairment and diabetes mellitus. CMS Ex. 8, at 20-25, 154; Tr. 30 (R20 later had a catheter). R20 was also assessed to be at risk for pressure ulcers. CMS Ex. 8, at 76, 78. As of December 10, 2007, R20 had one Stage III and two Stage II pressure ulcers. *Id.* at 29-30. His quarterly Minimum Data Set (MDS)[2], dated March 3, 2008, indicates that he had one Stage III pressure ulcer. *Id.* at 47.

The facility's documentation shows that in December 2007, R20 had two small Stage II pressure ulcers. R20 had a care plan dated December 13, 2007, for a Stage II pressure ulcer. CMS Ex. 8, at 139. Although facility documentation is unclear, at some point in January or February those pressure ulcers healed. CMS Ex 8, at 139 (Stage II on buttocks healed January 17). A facility wound report dated February 22, 2008, indicates that R20 had no pressure ulcers at that time. CMS Ex. 9, at 15. On February 26, a skin assessment shows that R20 "had a small open area on his buttocks." CMS Ex 8, at 166, 139.

On February 27, 2008, nursing notes contain an entry stating that R20 had a "Stage II", but the entry has a single line drawn through it. The note continues by stating "open area [left] ischial spine"[3] and described the wound as measuring 3 cm x 2 cm, with red-yellow inner tissue, and without drainage or odor. CMS Ex. 8, at 60. Surveyor Janet Brown-Schreiner testified that when nurses make a mistake in documentation, they are trained to draw a single line through the error and initial it. Here there are no initials. Tr. 44; CMS Ex. 8, at 60.

On February 29, 2008, the facility wound report indicated that R20 had a Stage III pressure ulcer to his left ischial area measuring 3 cm x 1 cm x 0.3 cm. CMS Ex. 9, at 16; Tr. 45. On that wound report, the space to fill in "Stage/Size Last Week" contains a zero, indicating that the wound was not present the week before. CMS Ex. 9, at 16.

CMS argues, and I agree, that it is not possible for the resident's wound to progress as quickly as Petitioner suggests. For R20 to have no pressure ulcer on February 22 and then to have a Stage III pressure ulcer on February 29 indicates that facility staff did not

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[2] The MDS is a document required by the state. It is an assessment that is to be done on admission, when there is a significant change, and quarterly thereafter. Tr. 46.

[3] The ischial area, or ischium, is the upper part of the buttocks. Tr. 47-48.

find the pressure ulcer in a timely manner. Petitioner maintains that a pressure sore may not necessarily require several days to progress from a Stage II to a Stage III and cites CMS guidance that emphasizes the importance of identifying deep tissue damage upon admission because the damage could lead to the appearance of an unavoidable Stage III or IV pressure ulcer within days of admission. Tr. at 206; P. Reply at 11. However, the CMS guidance does not state that the wound would develop from zero to a Stage III in days. The reason facilities must carefully assess a resident on admission is that the facility would not know if or when the resident may have sustained deep tissue damage before entering the facility, but the guidance does not indicate when the damage might have occurred or how long such damage would take to manifest as a pressure ulcer. Surveyor Brown-Schreiner testified that an open wound would not normally decline from a Stage II to a Stage III in two days, unless eschar has been removed or a blister opens up. Tr. 112. She later reiterated that a pressure ulcer would not develop from zero to a Stage III in a week. Tr. 141.

When the facility finally discovered R20's pressure ulcer, it did not update his care plan. Instead, it made a notation to his old care plan for a pressure ulcer that had healed on January 17. The notation does not explain the stage of the pressure ulcer, only its location. CMS Ex. 8, at 139. By March 21 the wound had progressed to a Stage IV. CMS Ex. 9, at 11. Still, the facility did not create a new care plan for the treatment of this pressure ulcer. In an interview, the facility's MDS coordinator said that the care plan for R20's wound care was vague and that she needed to address the Stage IV pressure ulcer that the resident currently had. Tr. 47; CMS Ex. 8, at 193. The facility's policy for pressure ulcers is that an acute care plan be written for each wound. P. Ex. 9, at 11. As the policy shows, the treatments for Stage II and Stage IV pressure ulcers are different. P. Ex. 9, at 4-5, 9-11. A new care plan should have been created to address the pressure ulcer when it did not heal within a reasonable time, two weeks according to the policy, and when it progressed to a new stage.

This lack of communication between staff, in part because of poor documentation, made it impossible for the facility to care properly for R20. Part of the difficulty in tracking the onset and progression of R20's pressure ulcers is that the facility's records are unclear. The record contains wound reports for R20 indicating a Stage IV pressure ulcer, left buttock, with a March 20 onset date; a Stage IV pressure ulcer, left buttock, with a March 21 onset date; and a Stage II pressure ulcer, left buttock, on the March 14 wound report. CMS Ex. 9, at 7, 10, 12. A monthly nursing summary dated March 12, 2008 indicates that R20 had no pressure ulcers. CMS Ex. 8, at 172. The Director of Nursing admitted in an interview on April 8, that the wound was at a Stage IV when it was found and was still at that stage. CMS Ex. 5, at 23.

The fact that R20's ischial wound first appears in facility documentation as a Stage III wound shows that the resident was not being assessed in a timely manner. As Surveyor Brown-Schreiner testified, pressure ulcers do not initially appear as Stage III, they

progress. Tr. 56. If staff had been performing appropriate assessments during daily care, the wound would have been identified earlier and it might not have progressed to a Stage III. Facility staff seemed to be confused as to the severity of the wound, some referring to it as Stage III, some referring to it as Stage IV. Tr. 56. Moreover, the facility did not know about three other wounds; when R20 was transferred to the wound hospital after the survey, four wounds were found. Tr. 56, 37; CMS Ex. 8, at 185.

On April 8, Surveyor Brown-Schreiner observed a pressure ulcer on R20's buttocks and excoriation to his groin area.[4] Tr. 31; CMS Ex. 8, at 195. She saw that the resident had no pressure relieving devices on his body. Tr. 42, 31. She also observed that there was no dressing on his pressure ulcer and no medication on it. Tr. 104; CMS Ex. 8, at 195. When she questioned a CNA about the situation, the CNA responded that there was no dressing on the wound when she came on duty. Tr. 104.

Surveyor Brown-Schreiner testified that R20's room had a "strong urine odor" which could indicate that his catheter was leaking or that he was wet. Tr. 32. She explained that if the catheter was leaking, then it would cause problems to R20's skin around his groin and buttocks by causing "an acidic environment that could not only add to pain but actually enhance breakdown." Tr. 33. She spoke to a nurse providing wound care to the resident about the excoriation and odor, but when she checked R20's medical records later, she saw that the staff did not contact the resident's physician to obtain an order for yeast medication to be applied. Tr. 35.

Surveyor Brown-Schreiner also observed facility staff providing incontinence and wound care to R20. A staff member providing wound care failed to follow infection control protocols. Surveyor Brown-Schreiner observed a staff member neglect to change gloves or wash her hands when they became contaminated during wound care. At one point, a staff member's gloves came into contact with feces, and instead of changing gloves, the nurse wiped them on a pad and continued giving care. CMS Ex. 8, at 195. This sort of failure could introduce bacteria into the wound, and the lack of proper hand washing and changing of gloves was not isolated to one staff member. Tr. 35; CMS Ex. 8, at 193-196.

During the wound care, the resident "hollered out very loudly" and said, "Please stop, please stop. It hurts." Tr. 49. The nurse providing care responded, "I know it hurts," and continued providing care. Tr. 49. When asked whether the resident had anything for pain, the nurse responded, "I don't know . . . I would have to check." CMS Ex. 8, at 195. The resident cried out in pain during the entire process. Tr. 49-50. Review of nurses' notes and R20's medication administration record showed that there was no documentation that the resident had experienced any pain during the care. Tr. 50.

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[4] She referred to the excoriation as a yeast infection in the statement of deficiencies. Tr. 34.

Surveyor Brown-Schreiner testified that Tylenol, which was on R20's MAR, could be used to relieve pain, but that in general it would only be effective for minor pain. Tr. 126; CMS Ex. 8, at 17. Petitioner argues that R20 was receiving three doses of pain medication a day. P. Ex. 7, at 264. However, as Surveyor Brown-Schreiner pointed out, wound care can be scheduled around medication administration or other medications can be administered before wound care to prevent pain during treatment. Tr. 129. If it was not effective in controlling the resident's pain, then the facility should have sought an order for something stronger.

The facility's own policies state that resident pain should be addressed in a care plan, and that it should be treated prior to providing any wound care.[5] Staff did not comply with that policy because they should have given the resident medication prior to providing wound care, and that was not done. *See* Tr. 50. Staff also neglected to consider that the pain could have been an indication that the wound was infected.

Petitioner argues that the resident's pressure ulcers were unavoidable due to R20's clinical conditions. P. Br. at 17-21. Petitioner cannot show that the pressure ulcers were unavoidable, though, because the facility did not define and implement interventions that are consistent with resident needs, resident goals and recognized standards of practice; monitor and evaluate the impact of the interventions; or revise the interventions as appropriate. Even if I were to accept that R20's pressure sores were clinically unavoidable that fact does not relieve the facility of its obligation, under the regulation, to provide care and services necessary to promote healing, prevent infection, and prevent other pressure sores from forming. Facility staff failed to discovery R20's pressure sore when it was at Stage I or Stage II, and thus did not provide appropriate care at that time. Once the wound was discovered, the facility did not provide care to promote healing and prevent infection. Facility staff did not address R20's complaints of pain during wound care, which could have indicated an infection. Staff did not provide him with pressure relieving devices. Staff engaged in unhygienic practices during wound care, including cleaning the wound while wearing gloves contaminated with feces and performing care without washing their hands.

Even if the staff conducted assessments, they were inadequate because they did not discover the pressure sore until it had reached Stage III. Far from "providing treatment and services necessary to promote healing, prevent infection, and prevent new sores from developing," the facility's wound care actually increased R20's risk of infection. The facility was therefore not in substantial compliance with 42 C.F.R. § 483.25(c).

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[5] Again, neither party provided the facility's policy on pain management, but Petitioner did not object to Surveyor Brown-Schreiner's articulation of the policy.

**2. Resident 4**

Like R20, R4 had significant health problems. He had limited mobility and paralysis and diabetes mellitus. CMS Ex. 7, at 165, 215. On January 2, 2008, R4 was readmitted to the facility following surgery for a fractured femur. CMS Ex. 7, at 163, 168, 197. His Resident Data Set (RDS)[6] completed on January 2, 2008, indicates that he had a surgical wound and was receiving wound care, and that he was at risk for pressure ulcers but that he did not have any pressure ulcers at that time. CMS Ex. 7, at 165, 167. The hospital discharge orders prescribed "waffle" boots, a kind of protective footwear, to be in place at all times. P. Ex. 7, at 34; Tr. 68. There is no documentation showing that the facility actually implemented the device.

From his readmission through January 16, there is no indication of pressure ulcers or skin breakdown in the nurses' notes. On January 17, facility staff discovered an "open area" on R4's right heel. P. Ex. 7, at 60. They then consulted with R4's physician and obtained an order for "waffle" boots, but from R4's readmission up until that point, the facility had done nothing to prevent breakdown or pressure on R4's heels. Tr. 68.

Facility wound reports dated January 18 show that R4 had two pressure ulcers – an unstageable pressure ulcer to his right heel that measured 4.6 cm x 4.5 cm and a Stage III pressure ulcer measuring 5.2 cm x 4.5 cm x 0.1 cm. P. Ex. 8, at 5. The size for the previous week is listed as zero. *Id.* His January 18 MDS report shows that he had one Stage IV pressure ulcer. CMS Ex. 7, at 55. On January 25, facility wound reports show that R4's pressure ulcers persisted, he had a Stage III pressure ulcer measuring 6.7 cm x 5.7 cm x 0 and an unstageable area measuring 3.6 cm x 2.3 cm. P. Ex. 8, at 7. At the hearing, Dorthine Kulp, R.N, Petitioner's regional director of quality assurance, testified that the wound report measurements actually related to one wound with two areas. Tr. 198. His February 25, 2008 MDS indicates that R20 had one Stage IV pressure ulcer. CMS Ex. 7, at 49.

Petitioner suggests that the reason it did not detect R4's pressure ulcer sooner is that it was the result of deep tissue trauma. Nurse Kulp testified that if R4 had sustained deep tissue trauma while in the hospital for surgery, it might have been difficult to detect on readmission. She said that two weeks is the usual timeframe for such a wound to manifest itself, and it was two weeks after R4 was admitted that he developed the wound to his heel. Tr. 205. Even if that were the case, the facility was not doing all that it could

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[6] Surveyor Brown-Schreiner requested that the facility send her R4's RDS. The facility sent her the document, but two pages were missing. She requested the two missing pages, but the facility provided her with the entire document. The remaining pages in the document were different than the ones the facility originally sent to her. Tr. 60-62; CMS Ex. 7, at 163-167 and 168-170. There are many discrepancies between the two assessments.

to prevent the formation of pressure sores. It did not ensure that the resident wore "waffle" boots as required by his discharge orders or try to find alternative approaches.

R4's care plan for impaired skin integrity (pressure ulcers) indicates that he had an open area on his right heel with an onset date of January 17, 2008. A notation indicates that it is a Stage II, but it is crossed out with a single line. Another notation indicates that it is a Stage IV, but that is also crossed out with a single line, and the next note reads "unstageable [right] heel." CMS Ex. 7, at 58. On January 23, treatment was changed due to healing of the Stage II pressure ulcer, and a note instructed staff to continue with treatment of the Stage IV pressure ulcer. *Id.*

As with R20, the facility did not update R4's treatment in a timely fashion. The initial treatment orders remained in place for over two months without being changed. Tr. 69. Surveyor Brown-Schreiner testified that orders are normally in place for 14 days, after which the resident is reassessed to determine whether the treatment is effective or detrimental. Tr. 69. This is consistent with the facility's own policy that states for Stage III pressure ulcers "there are several variations of treatment. The key to success is monitoring the healing process and changing the treatment if the wound does not respond with [sic] a reasonable period of time. (2 week maximum)." P. Ex. 9, at 6.

On April 8, 2008, R4 was admitted to the hospital because of the pressure ulcer on his right heel, which by then showed evidence of infection with Providencia, Staphylococcus aureus and Enterococcus faecalis. CMS Ex. 7, at 215, 219. The wound was so severe that it penetrated the bone and required a calcanectomy, an amputation of the back of the foot, in which a block of bone was removed from R4's heel. CMS Ex. 7, at 218, 220. In making his recommendations, the doctor noted that if good closure of the soft tissue was not obtained after surgery, that R4 would "certainly be faced with the possibility of a below-knee amputation." CMS Ex. 7, at 218.

As discussed above, the facility had a policy in place for the management of pressure ulcers. Facility staff did not assess R4 in a timely manner for notification of skin breakdown. Even though this was resident dependent on the staff for toileting, activities of daily living, and for mobility, no staff members found the pressure ulcer until it had reached a Stage IV level of severity. *See* CMS Ex 7, at 55.

Petitioner claims that because Surveyor Brown-Schreiner could not recall R4's medical conditions during her testimony that CMS did not know or understand R4's medical condition at the time the deficiency was discovered. However, it is clear that CMS was fully aware of R4's conditions because they are listed in the Statement of Deficiencies.

Petitioner also seems to contend that its use of Dakin's solution, which had been prescribed by a wound care doctor, was a factor for the immediate jeopardy finding. On March 28, 2008, R4 was diagnosed as having bone infection, and a wound care doctor

ordered Dankin's solution. CMS Ex. 7, at 3. The wound care doctor prescribed it, and R4's primary doctor reviewed and confirmed the order. Surveyors initially took issue with the use of the solution because it is controversial and not commonly used. Tr. 241; P. Ex. 7, at 243. Whatever "back-and-forth" the facility had with the surveyors, this is not determinative of the finding of substantial noncompliance. There were many other problems that triggered the citation.

Petitioner maintains that R4 was noncompliant in general and specifically with respect to his resistance to wearing his "waffle" boot and his resistance to being turned. Tr. 205, 211; P. Br. at 3; P. Ex. 7, at 47, 49, 50, 56. However, the examples cited by Petitioner do not show that R4 actually refused to be turned, only that when he was turned he voiced his dislike of it. On one occasion he voiced his dislike, and the nurse talked him into being turned. P. Ex. 7, at 76. None of the examples cited show that he was noncompliant with his "waffle" boot.

Still, even if he were noncompliant, that would not change the facility's obligations or excuse it from culpability in failing to meet those obligations. If the resident were noncompliant the facility would need to explore different approaches to address the pressure sore. Facility staff would also need to document the noncompliance and inform the physician that his or her orders were not being followed. While the facility informed R4's physician when he refused to use a low-air mattress, Petitioner does not contend that it informed the physician of R4's alleged noncompliance with the "waffle" boot and Petitioner has not asserted that it attempted to find alternative approaches.

As it argued with R20, Petitioner argues that R4's pressure ulcers were made unavoidable by his clinical conditions, and by his noncompliance. P. Br. at 17-21. However, the facility did not detect and treat the pressure ulcers in a timely manner. As with R20, Petitioner cannot show that R4's pressure ulcers were unavoidable because the facility did not define and implement interventions that are consistent with resident needs, resident goals and recognized standards of practice; monitor and evaluate the impact of the interventions; or revise the interventions as appropriate.

The fact that the facility did not discover the wound until it had reached a Stage III-IV shows that it was not "providing treatment and services necessary to promote healing, prevent infection, and prevent new sores from developing." If the facility staff had been properly assessing and inspecting R4, the pressure ulcer would have been detected, and treated, at the earliest point. The facility would not be able to provide the necessary services if it did not know that R4 had developed a wound. The facility's failure to follow R4's January 2 discharge orders, its failure to assess the resident for skin breakdown, and its failure to reassess the resident after the January 18 treatments were ordered resulted in a severe pressure ulcer that ultimately required amputation of part of the Resident's foot. Thus, the facility was not in substantial compliance with 42 C.F.R. § 483.25(c).

### *C. The facility's deficiencies posed immediate jeopardy to resident health and safety.*

The CMS determination as to the level of noncompliance "must be upheld unless it is clearly erroneous" (42 C.F.R. § 498.60(c)(2)), including a finding of immediate jeopardy. *Woodstock Care Center*, DAB No. 1726, at 9, 38 (2000), *aff'd, Woodstock Care Ctr. v. Thompson*, 363 F.3d 583 (6th Cir. 2003).

Although Petitioner disagrees with CMS's determination that its deficiencies posed immediate jeopardy, that determination is not subject to my review. As outlined above, a facility may only challenge the scope and severity level of noncompliance found by CMS if a successful challenge could affect the range of the CMP that CMS could impose or impair the facility's authority to conduct nurse aide training and competency evaluation programs. 42 C.F.R. §§ 498.3(b)(14) and (d)(10)(i). Per instance penalty amounts are not limited by the presence or absence of immediate jeopardy. In other words, CMS may impose the $10,000 per instance CMP regardless of whether immediate jeopardy was found. Moreover, this record, documenting as it does hospitalizations and an amputation that are directly related to the facility's noncompliance with the pressure sores regulation, fully supports CMS's finding of immediate jeopardy; it is not clearly erroneous [7]

### *D. The penalties imposed are reasonable.*

I next consider whether the CMP is reasonable by applying the factors listed in 42 C.F.R. § 488.438(f): 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 in 42 C.F.R. § 488.404 include: 1) the scope and severity of the deficiency; 2) the relationship of the deficiency to other deficiencies resulting in noncompliance; and 3) the facility's prior history of noncompliance in general and specifically with reference to the cited deficiencies.

In reaching a decision on the reasonableness of the CMP, I 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 deficiencies found, and in light of the above factors. I am not bound to defer to CMS's factual assertions or free to make a wholly independent choice of remedies without regard for CMS's discretion.

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[7] Petitioner questions the legitimacy of the immediate jeopardy finding at the April survey in part because the deficiency was not cited during the February survey even though R4 and R20 were among the sampled residents in that survey. Tr. 76-86. This is a *de novo* proceeding, so that is irrelevant.

*Barn Hill Care Center*, DAB No. 1848, at 21 (2002); *Community Nursing Home*, DAB No. 1807, at 22 *et seq.* (2002); *Emerald Oaks*, DAB No. 1800, at 9-10 (2001); *CarePlex of Silver Spring*, DAB No. 1683, at 8 (1999).

CMS has imposed a per instance CMP of $10,000 for Petitioner's noncompliance with 42 C.F.R. § 483.25(c), which is the maximum per instance CMP allowed. 42 C.F.R. § 488.438(a)(2).

With respect to the facility history, Petitioner submitted the statement of deficiencies from the February 14, 2008 survey and CMS's February 20, 2008 correspondence in which CMS determined that the facility was not in substantial compliance with *dozens* of Medicare participation requirements.[8] P. Ex. 1, at 5-196; P. Ex. 12, at 1. The findings from those surveys are final and binding.

Petitioner has not argued that its financial condition affects its ability to pay the penalty.

With respect to the remaining factors, the residents were both vulnerable and at risk for pressure sores. Facility staff did not appropriately assess the residents for pressure sores; they did not adequately assess the residents' skin; they did not assess a resident for pain during treatment even after the resident cried out in pain; and they did not follow basic infection control protocols to promote healing. Facility staff continued a treatment that worsened a pressure sore without consulting the resident's physician. Staff thus showed

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[8] Specifically: 42 C.F.R. § 483.10(c)(2)-(5) (Tag F159 – protection of resident funds); 42 C.F.R. §§ 483.10(e), 483.75(l)(4) (Tag F164 – privacy and confidentiality); 42 C.F.R. § 483.13(a) (Tag F221 – physical restraints); 42 C.F.R. § 483.13(c) (Tag F226 – staff treatment of residents); 42 C.F.R. § 483.15(g)(1) (Tag F250 – social services); 42 C.F.R. § 483.15(h)(2) (Tag F253 – housekeeping/maintenance); 42 C.F.R. § 483.20(k)(3)(i) (Tag F281 – comprehensive care plans); 42 C.F.R. § 483.20(f) (Tag F287 – automated data processing); 42 C.F.R. § 483.25 (Tag F309 – quality of care); 42 C.F.R. § 483.25(d) (Tag F315 – urinary incontinence); 42 C.F.R. § 483.25(g) (Tag F322 – naso-gastric tubes); 42 C.F.R. § 483.25(h) (Tag F323 – accidents and supervision); 42 C.F.R. § 483.25(m)(1) (Tag F332 – medication errors); 42 C.F.R. § 483.25(n) (Tag F334 – influenza and pneumococcal immunization); 42 C.F.R. § 483.35(c) (Tag F363 – menus and nutritional adequacy); 42 C.F.R. § 483.35(d)(3) (Tag F365 – food); 42 C.F.R. § 483.35(i)(2) (Tag F371 – sanitary conditions – food preparation and service); 42 C.F.R. § 483.65(a) (Tag F441 – infection control); 42 C.F.R. § 483.70(g) (Tag F464 – dining and resident activities); 42 C.F.R. § 483.70(h)(2) (Tag F467 – other environmental conditions – ventilation); 42 C.F.R. § 483.75 (Tag F490 – administration); 42 C.F.R. § 483.75(b) (Tag F492 – administration); 42 C.F.R. § 483.75(l)(1) (Tag F514 – clinical records); 42 C.F.R. § 483.75(m)(1) (Tag F517 – disaster and emergency preparedness); and 42 C.F.R. § 483.75(m)(2) (Tag F518 – disaster and emergency preparedness). P. Ex. 1, at 5-196.

disregard for the residents' care, comfort, and safety. Facility culpability justifies the penalties imposed.

In considering whether a $10,000 penalty is reasonably related to an effort to produce corrective action, I note that in a series of surveys conducted at the facility, surveyors repeatedly found the facility to be out of substantial compliance with participation requirements. Despite CMS's repeated threat of termination for the facility's substantial noncompliance with many requirements, Petitioner failed to ensure that these residents received basic wound care and assessments to prevent the development of severe Stage IV pressure ulcers.

Thus, after carefully reviewing the circumstances of this case in light of the section 488.438 factors, I do not find $10,000 an unreasonable amount.

## IV. Conclusion

For the reasons discussed above, I find that, at the time of the April 10 survey, the facility was not in substantial compliance with Medicare requirements governing quality of care, prevention of pressure sores (42 C.F.R. § 483.25(c)). I affirm as reasonable the $10,000 per instance CMP.

/s/ Richard J. Smith
Administrative Law Judge