Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

In the Case of:	DATE: September 30, 2009
Columbus Nursing & Rehabilitation Center,	
Petitioner,	Civil Remedies CR1905 App. Div. Docket No. A-09-83
- v. -	Decision No. 2273
Centers for Medicare & Medicaid Services.	

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Columbus Nursing & Rehabilitation Center (Columbus), a nursing facility in Wisconsin that participates in the Medicare and Medicaid programs, appeals the February 23, 2009 decision of Administrative Law Judge (ALJ) José A. Anglada. Columbus Nursing & Rehabilitation Center, DAB CR1905 (2009) (ALJ Decision). The ALJ concluded that Columbus was not in substantial compliance with a federal requirement for the prevention and care of pressure sores with respect to five residents and that the noncompliance was at the immediate jeopardy level for the period April 23, 2006 through April 26, 2006. The ALJ sustained the imposition of a civil money penalty (CMP) of $6,200 per day for that period.

For the reasons discussed below, we sustain the ALJ Decision in full.

Applicable law

Federal law and regulations provide for imposing remedies on nursing facilities that do not comply substantially with requirements for participation in the Medicare and Medicaid programs. Sections 1819 and 1919 of the Social Security Act (Act) (42 U.S.C. §§ 1395i–3, 1396r); 42 C.F.R. Parts 483, 488, and 498.[1] "Substantial compliance" is defined as "a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health and safety than the potential for causing minimal harm." 42 C.F.R. § 488.301. The Centers for Medicare & Medicaid Services (CMS) may impose a CMP for the days on which the facility is not in substantial compliance. 42 C.F.R. §§ 488.406, 488.408, 488.430. Per-day CMPs range from $3,050-$10,000 for noncompliance that poses immediate jeopardy, which 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. §§ 488.408(e)(2)(ii), 488.301.

The applicable program requirement at issue here, at 42 C.F.R. § 483.25(c), provides as follows:

> (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.

[1] The current version of the Act can be found at www.ssa.gov/OP_Home/ssact/comp-ssa.htm. Each section of the Act on that website contains a reference to the corresponding United States Code chapter and section. Also, a cross-reference table for the Act and the United States Code can be found at 42 U.S.C.A. Ch. 7, Disp Table, and the U.S.C.A. Popular Name Table for Acts of Congress.

Standard of review

Our standard of review on a disputed finding of fact is whether the ALJ decision is supported by substantial evidence on the record as a whole. Our standard of review on a disputed conclusion of law is whether the ALJ decision is erroneous. Guidelines -- Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's Participation in the Medicare and Medicaid Programs, www.hhs.gov/dab/guidelines/prov.html.

Factual Background[2]

The Wisconsin Department of Health and Family Services surveyed Columbus's facility beginning in late April 2006 and concluding May 10, 2006. A 164-page Statement of Deficiencies (SOD) cites noncompliance with 22 individual requirements, with the deficiency under the pressure sore regulation deemed to pose immediate jeopardy. CMS Exhibit (Ex.) 1. CMS adopted those findings and, on May 31, 2006, informed Columbus that it was imposing remedies including a per-day CMP of $6,200 for four days beginning April 23, 2006 and continuing through April 26, 2006. CMS Ex. 2, at 8-13. Columbus requested an ALJ hearing to challenge CMS's determinations; in February 2007, CMS filed a motion for summary judgment which the ALJ denied after briefing by the parties. The ALJ convened an in-person hearing on March 19 and 20, 2008. Prior to the hearing, however, the parties resolved all but one of the noncompliance findings, the alleged violation of the pressure sore regulation, which concerns five residents of Columbus's facility. The ALJ found in favor of CMS on that issue.

Columbus challenges the ALJ Decision as to each resident. In our analysis below, we address each resident in the order that the ALJ addressed them.[3]

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[2] The information presented in the background section and analysis is from the ALJ Decision and the record and is undisputed except where noted. This information should not be treated as new findings.

[3] In addition, Columbus contends that it did not have adequate notice prior to the hearing that some of the facts on which the ALJ made findings would be grounds for his decision because they were not alleged in the SOD and/or CMS's motion for summary judgment. That is not correct for any findings that are

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Analysis

I. We sustain the ALJ's conclusions on noncompliance as to each resident.

Resident 12

Resident 12 was an 83-year old woman who was at high risk for developing pressure sores but had none when she was admitted to Columbus on February 15, 2006, following surgical correction of a recent left hip fracture. ALJ Decision at 5. She was dependent for bed mobility, required a two-person assist for repositioning, and had joint pain in her pelvis and additional diagnoses including dementia and diabetes. Id. and at 11. Edema had developed in her left leg by February 19, 2006 and was treated with "TED" anti-embolism compression hose beginning on March 1, 2006. It is not disputed that nurse's notes show that on March 3, 2006, she was observed to have on her left heel a 4 centimeter (cm) Stage IV pressure sore that had a black center surrounded by red soft tissue. CMS Ex. 26, at 66. The pressure sore was seen to have opened on March 7 and changed from a blister to bleeding and then to dry and black. ALJ Decision at 8; P. Ex. 9, at 37-38. The sore was described as Stage IV with black eschar and was 2.3 x 2 cms on May 2, 2006, when the resident was discharged to another facility. P. Ex. 9, at 50.

Columbus disputes the ALJ's determinations that the pressure sore was avoidable and that the facility failed in its obligation to prevent development of the avoidable sore. The ALJ also determined, however, that once the sore appeared, Columbus failed to ensure that Resident 12 received necessary treatment and services to promote healing, prevent infection and prevent new sores from developing, which alone is a basis for the deficiency. Because we sustain that determination, Columbus's arguments that the sore was unavoidable and that the resident received appropriate care to prevent the sore, even if accepted, would not provide a basis to reverse the ALJ's findings with respect to this resident. For the sake of brevity, we thus address only the ALJ's determination that

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essential to our decision or the ALJ Decision, as we discuss below.

Columbus failed to properly care for the resident's pressure sore after it developed.

The ALJ found that, once the sore developed on the resident's heel, the facility failed to consistently implement interventions ordered by Resident 12's physician, Bruce Kraus, M.D., such as keeping her heel elevated off the bed, and committed a series of lapses and oversights in her care. These included not covering the sore after it burst open, in violation of facility wound care protocols, neglecting to timely change the dressing as the physician prescribed, and using interventions not prescribed by the physician that were less effective than, and potentially impeded, the heel elevation he did prescribe. ALJ Decision at 13-14. Furthermore, the ALJ found, the alternative interventions, including use of a heel boot, a heel protector and an air mattress, were used only intermittently and not properly documented. Id. at 8, 13. He also found that the facility failed to adequately communicate with Dr. Kraus about the resident's condition, both before but particularly after she developed the pressure sore.

Substantial evidence in the record supports the ALJ's findings that Columbus failed to take all reasonable measures in caring for the sore and failed to consistently follow the physician's orders. Columbus for the most part does not dispute the ALJ's findings as to the sequence of events and the steps that Columbus took in its treatment of the resident. Rather, it disputes the significance of those findings. Columbus argues, essentially, that at least one of the interventions the physician ordered was unnecessary, and that Columbus's failure to follow his order or assure consistent application of the best treatment modalities was thus harmless. That hindsight argument is speculative at best, especially given that Columbus's treatment left the resident with a Stage IV pressure sore. We address below three of the facility's lapses in its treatment of the pressure sore that the ALJ discussed and that provide substantial evidence of noncompliance.

First, when facility staff noticed the pressure sore on the resident's left heel on March 3, 2006, the physician was contacted by telephone and ordered that both of the resident's heels be elevated "off bed;" and the facility that day amended her care plan to include that intervention ("heels off of bed, prop up with pillow"). CMS Ex. 26, at 14, 53. Yet, one week later, the facility discontinued elevating the resident's heels, pursuant to a nursing order issued without consulting the

physician. CMS Ex. 26, at 68-69; P. Ex. 9, at 38, 87; Transcript of Hearing (Tr.) at 215 (Kraus). Columbus characterizes this action as a decision to substitute a pressure-relieving air mattress in place of "floating" the heels. Columbus argues that elevating the heels may not have been the best treatment for her edema and that placing an object such as the pillow on the mattress to elevate the heel would impede or diminish the mattress's pressure-relieving qualities. However, there is no indication that facility staff engaged in any such analysis contemporaneously and concluded that elevating the heels was not advisable for this resident. The facility did not document consulting the physician to question his decision to elevate the resident's heels, despite the facility's including "air mattress" in the resident's care plan. CMS Ex. 26, at 53. Furthermore, the physician testified that elevation was a preferable intervention to an air mattress, since it prevented any contact by the heels with any surface.[4] Tr. at 256.

[4] The ALJ also found a conflict between the comprehensive care plan, which called for an "air mattress," and the nursing care plan, which referred to a "special mattress." ALJ Decision at 13. CMS maintains they are not equivalent, which Columbus disputes. Compare CMS Br. at 12, n.11 with P. Reply at 4. Although Columbus claims lack of notice of this issue, CMS's motion for summary judgment specifically states that the "special mattress" provided for in the nursing care plan is not the same as the air mattress in the March 3, 2006 skin integrity care plan (part of the comprehensive care plan). MSJ at 41, 73. The larger point regarding the mattress, in any case, is that Columbus elected to use it in place of the preferred intervention of elevating the resident's heels that had been ordered by the resident's physician. A finding that the two mattresses were identical would thus not undermine the ALJ's determination. Similarly unsupported is Columbus's claim that it lacked notice that "occasional" use of the heel protectors or soft boots was at issue. P. Reply at 4. CMS's motion for summary judgment states that soft boots and the heel protector were not identified in the care plan or Dr. Kraus's order as a permissible intervention, and, if used instead of elevating, would have been inconsistent with the plan. MSJ at 73-74. A finding regarding heel protectors and boots again is not necessary to our decision.

The next two failures were distinct instances of the facility failing to follow its wound care protocols or the physician's orders for dressing the pressure sore wound. On March 8, 2006, facility nursing staff, without consulting Resident 12's physician, discontinued covering her pressure sore and left it "open to air." CMS Exs. 26, at 68-69; 44, at 3, 7, 8, 13. Columbus does not dispute this finding but argues that leaving a pressure sore open to air is an accepted treatment and that its staff had discretion to order it without consulting the physician. Even if leaving the sore open to air is an accepted treatment in some circumstances, and even if a nurse may initiate it in some circumstances, Columbus failed to show that it could be appropriate in these circumstances or that a nurse has discretion to use it in the face of a contrary physician's order. Leaving the sore uncovered, moreover, violated the facility's wound care protocols, which require that wounds of Stage II or greater severity be protected with a skin sealant/barrier and that a "black heel" be covered with a dry protective dressing. CMS Ex. 44, at 27. CMS's State Operations Manual (SOM) also indicates that Stage III and IV ulcers should be covered. SOM, App. PP, Tag F314. The facility again presented no evidence of any contemporaneous and reasoned determinations to ignore the requirements of its own policy.

The evidence also supports a finding that the facility did not adhere in late April 2006 to the schedule the physician ordered for applying, to the open pressure sore wound, a enzymatic debriding ointment, Santyl, that helps soften dead tissue. Tr. at 152 (surveyor), 243-44 (Kraus). On April 9 and again on April 19, the physician ordered that Santyl be applied twice a day to the resident's pressure sore wound, which had opened on March 7 and was still observed to have black dried tissue on April 9. P. Ex. 9, at 22. Columbus does not dispute that during the period April 24 through April 26 the Santyl dressing was not changed on three consecutive nights. CMS Ex. 59, at 13. Columbus asserts instead that this failure was not harmful because the manufacturer recommends application once daily. Again, however, there is no evidence that the facility engaged in any analysis based on the manufacturer's recommendation or documented any other reason for concluding that it need not follow the physician's orders. We agree with the ALJ that Columbus did not show that its failure to follow the physician's instructions was harmless for this resident, who needed attentive care to ensure proper healing of her pressure sore, which at that point had persisted for almost two months.

We further conclude that substantial evidence supports the ALJ's finding that the facility failed generally to properly apprise the resident's physician of her condition. Dr. Kraus testified that the resident was free of pressure sores before he prescribed compression hose to combat the edema in her left leg (Tr. at 213), but she had a history of a coccyx pressure sore at a prior facility (Tr. at 229), and was at high risk for pressure sores. The report of Dr. Kraus's visit of February 25, 2006 makes no mention of the edema affecting her left leg, even though staff had noted edema that day. P. Ex. 9, at 26; CMS Ex. 26, at 63. The ALJ could reasonably infer that the staff failed to alert the physician to the signs of edema. The physician's report of March 15, 2006 does not mention the sore on the resident's left heel even though it had burst open on March 7 and shortly became black (i.e., necrotic). CMS Ex. 26, at 19. The ALJ could reasonably infer that the staff failed to inform the physician of the changes to the condition of the pressure sore over the preceding week. Dr. Kraus indicated that he relied on the nursing staff to apprise him of changes in a resident's condition, including changes in a resident's skin condition. Tr. at 207-08, 247. He did not order debridement of the heel wound until April 9, 2006, indicating that he was previously unaware that it had become necrotic. CMS Ex. 26, at 17. The facility also did not inform Dr. Kraus when they decided to overrule his order that the heels be elevated; he testified that he would expect to be notified when the facility staff discontinued a treatment he had ordered. Tr. at 242-43. The facility's failure to accurately and promptly inform Dr. Kraus of Resident 12's condition is emblematic of its haphazard approach to caring for this resident's pressure sore. This evidence amply supports the ALJ's conclusion that the facility was not in substantial compliance with the regulation.[5]

[5] Columbus argues that it had no notice of the allegation of deficient communication with Dr. Kraus, but the SOD stated that there was no documentation that Columbus notified the physician when the resident's pressure sore opened and was later observed to be necrotic. CMS Ex. 1, at 80-81. CMS's motion for summary judgment cited the facility's failure to ask the physician about treating the necrosis, its failure to apply treatment as frequently as ordered, and its failure to inform him that the resident was at high risk for pressure sores upon admission. MSJ at 74-75, 77-79, 81, 83-84. Thus, Columbus was aware that the adequacy of its communication with Dr. Kraus about this resident was at issue. Columbus also argues that the

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Finally, we reject Columbus's argument that the pressure sore on Resident 12's heel was only at Stage II. Columbus argues that the sore could not be accurately assessed because it was covered by eschar. The facility's own records consistently describe the sore as being at Stage IV, including its wound care log which lists it as "Visualized Stage" IV, for the weeks of March 6, 13, 20, and 27, 2006. CMS Ex. 44, at 3, 7, 8, 13; see also P. Ex. 9, at 50 (pressure ulcer progress report showing wound at Stage IV on April 25, 2006 and on May 2, 2006, when the resident was discharged to another facility). In any event, the facility's witness conceded that a wound elusive of staging due to being masked by eschar should be treated as if it is Stage IV. Tr. at 370-71. Furthermore, Columbus's wound care protocols require covering Stage II wounds as well as Stage IV wounds. Even finding that the wound was unstageable, therefore, would not lessen the facility's obligations regarding treatment of the wound.

For these reasons we sustain the ALJ's determination that Columbus failed to give Resident 12 the necessary treatment and services to promote healing of pressure sores, prevent infection, and prevent new sores from developing.

Resident 2

Resident 2 was 85 years old and suffered from dementia and end-stage Alzheimer's disease, needed assistance repositioning, and required total care for his needs. It is not disputed that the resident was admitted without pressure sores, but had a history of a heel pressure sore, was at high risk for pressure sores, and did develop a Stage II sore on his gluteus that was noted on April 11, 2006. ALJ Decision at 15. The ALJ determined that Columbus's care was deficient because on three occasions on April 24 and 25, 2006, the surveyor observed the resident lying

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ALJ "suggested" that the facility was deficient because Dr. Kraus did not see Resident 12 until 10 days after her admission and that this suggestion was improper because it was not alleged as a deficiency in the SOD, and because the ALJ cites no evidence or regulation that this was deficient practice. P. Request for Review (RR) at 10-11. The ALJ did not make any such deficiency finding. While he noted CMS's allegation to this effect, he did not address or adopt it in his analysis.

in bed with his heels not elevated or suspended, contrary to the order of his physician. Id., citing P. Ex. 3, at 7; CMS Ex. 17, at 4-5; CMS Ex. 61, at 3.

Columbus argues that there was no noncompliance because the resident did not have a pressure sore on his heel. He did, however, have a pressure sore on his gluteus and was thus a resident with pressure sores to whom the facility was obliged to provide necessary treatment and services to prevent new sores from developing. He had a history of a pressure sore on his right heel, and his physician determined that the treatment and services needed to prevent new sores from developing included elevation of the heels. CMS Ex. 17, at 21; P. Ex. 3, at 7. Failure to follow the physician's order was thus deficient.

Columbus also questions the significance of the resident's heels not having been elevated, characterizing the surveyor's observations as momentary. Columbus cites testimony from the physician and its two nurses to the effect that a physician would normally order heels be elevated "at all times" to treat existing pressure sores, but that for prevention of sores, heels need be elevated only when a resident is to be in bed for at least two hours, and need not be elevated when the resident is receiving care. RR at 17-18, citing Tr. at 472-73, 496; P. Ex. 48, at 9; Ex. 49, at 9. The surveyor testified, however, that on only one occasion was the resident receiving care, from a nurse who applied a barrier ointment to one of his heels, after which she did not elevate his heels, but placed them onto the mattress. Tr. at 144-46. We conclude that the ALJ could rely on the testimony of a number of observations over a short period of time to conclude that the facility was not consistently providing the services deemed necessary by Resident 2's physician.

Columbus argues that the SOD did not identify failure to elevate the resident's heels as a basis for this deficiency, citing only a sore on or near the resident's ear caused by an oxygen tube, an allegation that the ALJ did not address. Columbus argues that its ability to produce witnesses with personal knowledge that the resident was receiving care when observed without elevated heels was thus hindered. These arguments are unfounded, however. The SOD did cite the surveyor's reports that Resident 2's heels were not elevated under another deficiency (Tag F282) that was settled by the parties "shortly before" the hearing began on March 19, 2008. CMS Ex. 1, at 61; CMS Post-Hg. Br. at 2. CMS also, however, cited the surveyor's

reports as a basis for the instant deficiency under Tag F314 in its motion for summary judgment filed in February 2007, at which point Tag F282 was still at issue. Thus, Columbus had notice from the time of its receipt of the SOD that the failure to elevate this resident's heels was a basis for CMS's imposition of sanctions against it, and had notice from the motion for summary judgment that CMS was relying on this failure as a basis for finding noncompliance with section 483.25(c).

We thus sustain the ALJ's determination that Columbus failed to give Resident 2 the necessary treatment and services to promote healing of pressure sores, prevent infection, and prevent new sores from developing.

Resident 8

Resident 8 was paraplegic with congestive heart failure, hypertension, and diabetes mellitus who had no pressure sores upon admission in February 2005. Columbus does not dispute that she had a Stage I pressure sore on February 1, 2006, and four Stage IV pressure sores as of March 12, 2006. ALJ Decision at 15.

Columbus does, however, challenge the ALJ's determination that the facility was deficient because it failed to document its care of her wounds for two weeks in April 2006 after it fired its "wound nurse." Id. at 15-16, citing P. Ex. 6, at 32, 36 (notes of interim Director of Nursing). Columbus also challenges the ALJ's finding that the nurse changing the resident's wound dressings during the survey did not wash her hands or cleanse the wound, used a gloved finger instead of an applicator to spread ointment on the wound, and applied too much pressure to the wound with her finger. Id. at 16, citing CMS Ex. 61, at 7, 8, 9; Tr. at 154-55, 293.

Regarding wound documentation, the facility does not dispute that there were no "wound tracking logs" for Resident 8 subsequent to April 5, 2006 as the ALJ found, but argues that the ALJ cited nothing in the record or any legal authority for his finding that "proper documentation of a resident's wounds" (which Columbus calls "detailed documentation") is "one of the necessary components of treatment and services to promote healing and prevent new sores from developing." RR at 19; ALJ Decision at 15-16. The SOM advises that it "is important that the facility have a system in place to assure that the protocols for daily monitoring and for periodic documentation of

measurements, terminology, frequency of assessment, and documentation are implemented consistently throughout the facility" and advises "daily monitoring (with accompanying documentation, when a complication or change is identified)." SOM, App. PP, Tag F314. The facility's wound care protocols for Stage II - IV wounds require that they be formally measured and assessed weekly and their progress charted. CMS Ex. 44, at 27. The ALJ's inference that the proper care of pressure sores as severe as those afflicting this resident entailed *some* periodic documentation was reasonable in the absence of any showing of an effective alternative approach.

Columbus did not deny the lacunae in its usual documentation of this resident's four Stage IV pressure sores during the two-week period referenced by the ALJ, and nurse's notes for that period do not reflect episodic recording of the state of the wounds. P. Ex. 6, at 30-33, 36-37. Absent such information, it is difficult to see how the facility would be able to ascertain the effectiveness of its interventions or apprise staff from shift to shift of the treatment and progress of a pressure sore. The ALJ Decision does not require that effective documentation take the form of the wound tracking log that the facility elected to use but failed to maintain in the case of Resident 8. Indeed, the ALJ did not impose any specific documentation standards. He observed that ensuring that a wound receives optimal care perforce requires a capacity to track what treatment is provided and what effects follow. Columbus has not argued that it had some means other than clinical documentation to achieve that goal. We conclude that the ALJ finding of inadequate wound documentation is supported by substantial evidence.

Columbus further disputes that the nurse was required to have washed her hands during the process of changing Resident 8's pressure sore dressings, citing a guide to the treatment of pressure ulcers that CMS submitted that advises that gloves be changed and hands washed "between patients." RR at 19, citing CMS Ex. 50, at 8 (Columbus's emphasis). Even if we ignored the surveyor's testimony, credited by the ALJ, that the nurse should also wash when moving from "dirty" to "clean" stages in wound dressing, we would conclude that substantial evidence supports the ALJ's finding of noncompliance with section 483.25(c). This is because the ALJ based his deficiency finding, in addition, on the surveyor's further testimony that the nurse failed to cleanse the wound during the dressing change and used excess pressure. Columbus questions the credibility of the surveyor's observations by alleging an inconsistency between her

declaration and hearing testimony over whether the nurse failed to cleanse both wounds or only one wound. The testimony and the declaration both report failure to cleanse both wounds, so we see no inconsistency. Tr. at 153-54; CMS Ex. 61, at 7 (failure to clean "either wound"). Columbus also cites Dr. Kraus's testimony to the effect that using a gloved finger to apply an ointment to the resident's wound would not have been inappropriate as long as "undue pressure" was not applied. Tr. at 198-99. However, the surveyor did testify that the nurse's finger moved and disrupted the exposed tissue of the resident's ischial wound, which the ALJ could reasonably conclude indicated undue pressure. Tr. at 154. Columbus concedes that the nurse was hurried in her treatment of this resident because of her history of resisting care. RR at 21. Having taken the testimony of both the surveyor and the nurse, the ALJ decided to credit the surveyor's account, and we see no basis to disturb his finding that the nurse "was taking short cuts and not compliant with acceptable nursing standards" in treating this resident's pressure sores. ALJ Decision at 16.

Columbus also asserts that the SOD did not allege failure to document the resident's wound care. This is correct, but CMS' motion for summary judgment did note the gap in the wound tracking log's documentation of the resident's pressure sores during April 2006. MSJ at 18-19, 94. Thus, Columbus had notice of this basis for the deficiency. Columbus also argues that the SOD did not allege that the nurse had failed to wash her hands; however, we sustain above the ALJ's deficiency determination on his other findings, which are sufficient to support his determination. We therefore need not address the claim of lack of notice on hand-washing standards.

For these reasons, we sustain the ALJ's determination that Columbus failed to give Resident 8 the necessary treatment and services to promote healing of pressure sores, prevent infection, and prevent new sores.

Resident 9

Failure to follow a physician's orders to elevate a resident's heels was also at the heart of the ALJ's determination that Columbus was deficient in its care of Resident 9. This resident was a 90-year-old woman who had urinary incontinence, an indwelling catheter, and a history of circulatory disorders, anemia, edema, diabetes mellitus and cerebrovascular accident. ALJ Decision at 16. It is undisputed that she developed a left

heel blister from wearing an improperly fitting shoe at the end of December 2005, and that the heel blister was described as a Stage IV pressure area as of March 21 and April 9, 2006. CMS Ex. 23, at 48, 54 (care plan).

In support of his conclusion that the facility failed to give the resident the necessary treatment and services to promote healing of her pressure sore, prevent infection, and prevent new sores from developing, the ALJ cited the surveyor's eight observations of the resident in bed without her heels elevated during April 23 through April 25, 2006. ALJ Decision at 17-18, citing CMS Ex. 61, at 11-13. These included instances of the resident wearing slippers while on the bed without her heels elevated, and facility staff failing to elevate her heels upon the conclusion of treatment. Tr. at 156-57. The ALJ also cited the surveyor's testimony that she never saw any evidence that Columbus was following the physician's orders to elevate the resident's heels with a foam wedge. Tr. at 157-58.

On appeal, Columbus posits that the surveyor may have seen the resident shortly before or after treatments or activities such as meals, and cites the surveyor's note that on April 23 she observed the foam wedge on a chair in the resident's room as evidence that the wedge was accessible. Columbus's theories regarding the reason the resident was seen without her heels elevated are speculative and do not address why the foam wedge was not in use when she was observed neither receiving treatment nor in the process of being taken to or from a meal. During the hearing the surveyor clarified that, while she did see the foam wedge in the resident's room on the first day of the survey, she never actually saw it in use. Tr. at 157-58. As with Resident 2, the high number of observations over a short period of time is substantial evidence supporting the ALJ's decision that the facility was not providing the services deemed necessary by her physician.[6] Thus, we sustain the ALJ's determination that Columbus failed to give Resident 9 the necessary treatment and services to promote healing of pressure sores, prevent infection, and prevent new sores from developing.

[6] Columbus also argues that the SOD indicates only six observations of the resident without her heels elevated. Whether there were only six such observations or more as indicated in the surveyor's declaration (CMS Ex. 61, at 11-13) is immaterial to the conclusion that the facility was not providing the services ordered by the resident's physician.

Resident 13

Resident 13 was admitted to the facility without any pressure sores on March 16, 2006, but, by April 9, 2006, had developed a Stage II pressure sore on her right buttock, about 3 inches away from the crease of the buttock and 2 inches below the belt. At that time, the pressure sore was open and measured 0.3 cm x 0.2 cm in size. ALJ Decision at 18-19, citing CMS Exs. 27, at 62 (nurse's notes) and 44, at 17 (wound tracking log); Tr. at 326, 332. The ALJ rejected Columbus's argument that the wound was not actually a pressure sore and found Columbus deficient because it failed to follow the April 10, 2006 order of the resident's physician to dress the wound every three days, with a type of absorbent foam dressing that has a protective backing and is intended to absorb excess fluid. ALJ Decision at 19. Instead, the facility decided to leave the wound open to air. CMS Ex. 27, at 62.

Columbus argues that the physician's order that the dressing be changed "Q3day/PrN till healed," CMS Ex. 27, at 18, meant that facility was to apply the dressing only as needed ("PrN"), in which case it would be changed every three days. Columbus cites the two declarations of its nurses that the physician's order was "prn in nature" and thus supported not applying the dressing. P. Exs. 48, at 44; 49, at 45. The nurses testified that, based on their understanding of how the resident's physician wrote orders, the dressing was to be used only if needed, in which case it was to be changed three times per day. P. Exs. 48, at 44; 49, at 45; Tr. at 382-83, 407. One of the nurses, however, offered conflicting testimony on what the order meant, saying that as recorded by the facility, the order was to change the dressing every three days and more often if needed, such as if the dressing became dirty; that the slash mark preceding "PrN" in the order as transcribed meant "and p.r.n." and that applying the dressing was thus not optional; and, thus, that the order meant that the dressing was to be changed at least as often as ordered, and more frequently if needed. Tr. at 375-77, 383-85. The other nurse's testimony was less than clear but she, too, agreed that the order meant to change the dressing at least every three days, unless the wound had healed. Tr. at 415-17, 460-66.

The resident's physician did not testify, but Dr. Kraus testified that he would interpret such an order as meaning that the dressing was to be changed at least as often as the number of days specified in the order, or more often in the presence of

circumstances such as drainage. Tr. at 217-18. We note that a treatment record sheet that the facility created to record its implementation of the physician's order contains designated spaces to verify treatments every three days and PRN, supporting an inference that the facility at the time did not view the very use of the dressing as optional. P. Ex. 10, at 25. We agree with the ALJ that Columbus's arguments on this point are unpersuasive and that the notation in the order "seems fairly clear and self explanatory." ALJ Decision at 19.

Columbus also argues that leaving a wound open to air is a recognized therapy for a wound of this size that is not draining. RR at 27. The nurse's notes indicate that on April 10, 2006 the Director of Nursing determined that the wound could be left open to air. P. Ex. 10, at 82. As in the case of the orders for Residents 2 and 9 that the facility did not implement, Columbus has not shown that it consulted with the resident's physician and persuaded him to change his order to dress the wound. Columbus contends that its failure to follow the physician's order was essentially harmless, due to the size of the wound. RR at 26-28. We note, however, that the sore became larger over time and was 0.5 cm and still open on April 25, 2006, at which time the facility decided to begin dressing the wound, as the physician had ordered. CMS Ex. 27, at 67. The ALJ moreover was justified in finding, based on the surveyor's testimony, that the risk of fecal contamination of this open wound, due to its location, was a factor that militated in favor of following the doctor's order to cover the wound. Tr. at 115.

Finally, Columbus questions whether the wound on this resident's right buttock was even a pressure sore, and refers to it instead as simply an open area or a pinpoint abrasion. P. Reply at 17; ALJ Decision at 19. Columbus relies on the two nurse declarations citing "some question" as to whether the wound when first observed "was even pressure related," and one nurse's testimony that it was not. P. Exs. 48, at 44; 49, at 45; Tr. at 373. The facility's wound treatment log, however, states that the Stage II wound was caused by pressure, and both the physician's order for dressing and the corresponding treatment record created to implement that order describe a "stage two decubi" on the resident's right buttock. P. Ex. 10, at 25, 72. The two surveyors who saw the wound testified that it was a pressure sore. Tr. at 31, 106-07. The ALJ's finding that this wound was most likely a pressure sore is thus supported by substantial evidence. ALJ Decision at 19.

We thus sustain the ALJ's determination that Columbus failed to give Resident 13 the necessary treatment and services to promote healing of pressure sores, prevent infection, and prevent new sores from developing.

II. The ALJ did not err in concluding that Columbus did not show that CMS's determination that the noncompliance posed immediate jeopardy was clearly erroneous.

CMS's determination as to the level of noncompliance must be upheld unless it is clearly erroneous. 42 C.F.R. § 498.60(c). This requirement places a "heavy burden" on Columbus to overturn CMS's determination that the noncompliance was at the immediate jeopardy level. Liberty Commons Nursing & Rehab Center - Johnston, DAB No. 2031, at 18 (2006), and cases cited therein, aff'd, Liberty Commons Nursing & Rehab Ctr. - Johnston v. Leavitt, 241 F. App'x 76 (4th Cir. 2007). We agree with the ALJ that Columbus did not meet that burden here.

The ALJ sustained CMS's determination primarily based on the fragile conditions of Residents 12 and 9 and the persistence of their pressure sores over periods of months. He observed that pressure sores on such elderly residents, especially those who are immobile, cognitively impaired, and have weakened immune systems, can cause life threatening infections, gangrene and eventual amputation. The ALJ also determined that Columbus's "systemic flaw" of inattentiveness to the needs of the five residents at issue was likely to cause them serious injury, harm, impairment, or death and "equally exposed other residents similarly situated to the likelihood of suffering serious injury, harm, impairment, or death." ALJ Decision at 20-21.

Columbus argues that CMS's evidence at most established only a theoretical risk of serious injury or harm to the residents from their pressure sores that falls short of the definition of immediate jeopardy, noncompliance that "has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301. Columbus cites the testimony of its physician and its two nurse declarants to the effect that they were unaware of a pressure sore ever becoming seriously infected, resulting in sepsis, or causing serious harm, injury, impairment or death. RR at 31.

The testimony of the three surveyors, and, indeed, Columbus's own witnesses, amply supports the ALJ's findings as to the risks that pressure sores pose to residents, particular those with

diabetes who have sores on their extremities, including increased pain, infection, gangrene, and death. Tr. at 27, 147-48, 160-61. One surveyor testified that she had seen residents with Stage IV pressure sores develop such complications. Tr. at 27. Similarly, Columbus's two nurses who submitted declarations acknowledged that serious complications can arise from pressure sores that are not properly treated, and one in fact testified that she had seen instances of pressure sores becoming infected and had encountered other "harmful" and "serious conditions" such as osteomyelitis develop from complications of Stage IV pressure sores. Tr. at 394-96, 456-57. The nurse who was seen changing the dressing on Resident 8 also reported having seen pressure sore wounds become infected. Tr. at 312. Dr. Kraus acknowledged the possibility of infection, sepsis, osteomyelitis, amputation or death from pressure sores that are untreated or improperly treated, and had warned Resident 8 of those consequences when she was resistant to care. Tr. 250-51.

This testimony as to the consequences of failing to properly treat pressure sores is particularly compelling here, where a common feature of Columbus's noncompliance for all five residents was its failure to provide adequate care of existing pressure sores, including failure to follow orders of residents' physicians. Those failure had serious results. The Stage IV sore on Resident 12's heel persisted for months and was still present when she was discharged to another facility on May 2, 2006. The sore on Resident 13's heel actually worsened during the time that the facility failed to follow the physician's order to cover it with a dressing. Resident 8 developed four Stage IV sores at the facility, one of which was described by one of Columbus's nurse declarants as the worst she had seen in a long time. Tr. at 392-93. That these and the other two residents did not develop infections is fortuitous but does not demonstrate clear error in CMS's immediate jeopardy determination. See, e.g., Barbourville Nursing Home, DAB No. 1962, at 11 (2005) (although improperly treated pressure sore did not become infected, facility "failed to establish that the undisputed facts regarding treatment . . . cannot reasonably be viewed as supporting an immediate jeopardy determination"), aff'd, Barbourville Nursing Home v. U.S. Dep't of Health & Human Servs., 174 F. App'x 932, 942 (6th Cir. 2006) ("expert observations and professional opinion testimony of the surveyors" justified an immediate jeopardy determination). Thus, substantial evidence supports the ALJ's finding that

Columbus did not establish that CMS's immediate jeopardy determination was clearly erroneous.

III. The ALJ did not err in finding that the amount of the CMP was reasonable.

In finding that that the $6,200 CMP that was imposed for each day of noncompliance at the immediate jeopardy level from April 23 through April 26, 2006 was reasonable, the ALJ considered the four factors specified in 42 C.F.R. § 488.438(f): (1) the facility's history of noncompliance, including repeated deficiencies; (2) the facility's financial condition; (3) the factors specified in 42 C.F.R. § 488.404 (the scope and severity of the deficiencies, the relationship of one deficiency to other deficiencies resulting in noncompliance, a facility's prior history of noncompliance in general and specifically with reference to the deficiency at issue); and (4) the facility's degree of culpability.

Columbus argues that any immediate jeopardy that existed was not serious enough to justify a CMP more than twice the minimum per-day amount ($3,050) for immediate jeopardy. Columbus asserts that the most serious harm alleged was the development of "a blister on [Resident 12's] heel which was unstageable" and disputes that there was any "neglect, indifference, or disregard for resident safety" warranting a CMP above the minimum amount. RR at 31. Columbus's attempt to minimize the extent of its noncompliance is unpersuasive. As discussed above, Resident 8 developed four Stage IV sores while at the facility, and she and another resident had sores that persisted for months. Additionally, Columbus's failure to care properly for the five residents was typified by failure to follow physician orders for the treatment and prevention of pressure sores and inconsistent application of interventions; failures that resulted both from neglect and from deliberate decision. We have also rejected Columbus's denial that Resident 12 had a Stage IV pressure sore. We find no error in the ALJ's conclusion that, based on "the indifference of the facility to proper nursing standards" and its disregard for physician orders, Columbus "was extremely culpable." ALJ Decision at 22.

Columbus argues that it has never before been cited for an immediate jeopardy deficiency. It does not dispute that it was cited for noncompliance in June, July and August 2004 and in June 2005; as well as for noncompliance specifically relating to pressure sores in August 2002, July 2003, and August 2004. Id.

at 21. We agree with the ALJ that this history of noncompliance is extensive. Finally, Columbus does not dispute the ALJ's determination that CMS had adequately accounted for the facility's financial condition, and that Columbus had not questioned the duration of the deficiencies (and thus the CMP), which was only for four days. Id.

We thus sustain the ALJ's determination that the CMP imposed, in the middle of the range authorized, was reasonable.

Conclusion

For the reasons explained above, we affirm the ALJ's findings of fact and conclusions of law and uphold the ALJ Decision in full.

_____/s/_____
Judith A. Ballard

_____/s/_____
Constance B. Tobias

_____/s/_____
Leslie A. Sussan
Presiding Board Member