Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Heritage House of Marshall Health & Rehabilitation Center
Docket No. A-14-10
Decision No. 2566
March 25, 2014

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Heritage House of Marshall Health & Rehabilitation Center (Heritage) appeals the August 22, 2013 decision of an Administrative Law Judge (ALJ), *Heritage House of Marshall Health & Rehabilitation Center*, DAB CR2902 (2013) (ALJ Decision). The ALJ determined that Heritage was not in substantial compliance with the Medicare participation requirements and sustained a civil money penalty (CMP) of $700 per day for the period April 12 through June 15, 2011. For the reasons stated below, we affirm the ALJ Decision.

Legal Background

To participate in Medicare, a long-term care facility like Heritage must at all times be in "substantial compliance" with the requirements in 42 C.F.R. Part 483. The Secretary of Health and Human Services (Secretary) contracts with state survey agencies to conduct periodic onsite surveys to assess compliance with those requirements. Social Security Act (Act) §§ 1819(g), 1864(a); 42 C.F.R. Part 488, subpart E. Survey findings are reported in a Statement of Deficiencies (SOD). A "deficiency" is a "failure to meet a participation requirement specified in the Act or [42 C.F.R. Part 483]." 42 C.F.R. § 488.301. "Substantial compliance" is "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." *Id.* "Noncompliance" is "any deficiency that causes a facility to not be in substantial compliance." *Id.*

CMS may impose various remedies on a facility that is found not to comply substantially with the participation requirements, including a per-day CMP for the number of days that the facility is not in substantial compliance. 42 C.F.R. § 488.408(d), (e). In choosing a remedy, CMS considers the "seriousness" of the facility's noncompliance and may consider other factors specified in the regulations. *Id.* § 488.404(a), (c). "Seriousness" is a function of two factors: (1) "severity" – that is, whether the noncompliance has created a "potential" for "more than minimal" harm to residents, resulted in "actual harm," or placed residents in "immediate jeopardy" (the latter circumstance being the highest

degree of severity); and (2) "scope" – whether the noncompliance is "isolated," constitutes a "pattern," or is "widespread." *Id.* § 488.404(b); *see also* State Operations Manual (SOM), CMS Pub. 100-07, Appendix P - Survey Protocol for Long Term Care Facilities, Part 1, sec. IV ("Deficiency Categorization"); SOM, Chapter 7 – Survey & Enforcement Process for Skilled Nursing Facilities & Nursing Facilities, Rev. 97, § 7400.5.1 (matrix of scope and severity levels). For deficiencies that do not constitute immediate jeopardy but either caused actual harm or caused no actual harm but had the potential for more than minimal harm, CMS may impose per-day CMPs in amounts ranging from $50 to $3,000 per day. 42 C.F.R. § 488.438(a)(1)(ii). For deficiencies that constitute immediate jeopardy and any repeated deficiencies for which a lower level penalty amount was previously imposed, CMS may impose per-day CMPs of $3,050-$10,000. *Id.* § 488.438(a)(1)(i), (d)(2).

Factual Background[1]

Surveyors from the Texas Department of Aging and Disability Services (state survey agency) conducted a recertification and complaint survey of Heritage from May 23 to 26, 2011. Based on the results of that survey, CMS determined that Heritage was not in substantial compliance with the Medicare participation requirements at 42 C.F.R. §§ 483.10(b)(11), 483.25(c), 483.25(g)(2), 483.65, 483.75(f), and 483.75(j)(2)(ii). CMS imposed CMPs of $700 per day from April 12 through June 15, 2011, for a total penalty of $45,500.

Heritage requested a hearing on CMS's determination. Based on the parties' written submissions and the evidence and testimony presented at a three-day, in-person hearing, the ALJ sustained all six of CMS's noncompliance findings and concluded that the amount of the CMP imposed was reasonable. Heritage timely appealed the ALJ Decision to the Board. After the parties submitted written briefs, the Board held oral argument in the case on February 14, 2014.

Standard of Review

We review a disputed finding of fact to determine whether the finding is supported by substantial evidence in the record as a whole, and a disputed conclusion of law to determine whether it is erroneous. *Departmental Appeals Board, Guidelines -- Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's Participation in the Medicare and Medicaid Programs* (Guidelines), available at http://www.hhs.gov/dab/divisions/appellate/guidelines/prov.html.

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[1] Background information is drawn from the ALJ Decision and the record before the ALJ and is not intended to substitute for his findings.

Analysis

On appeal to the Board, Heritage challenges the ALJ's conclusions that the facility was not in substantial compliance with the Medicare participation requirements at sections 483.10(b)(11), 483.25(c), 483.65, 483.75(f), and 483.75(j)(2)(ii).[2] Heritage also contests the reasonableness of the penalty imposed. As we explain below, we conclude that substantial evidence supports the ALJ's conclusions that Heritage did not comply substantially with the regulations, although for some deficiencies our determination is based on slightly different or narrower grounds than those articulated by the ALJ. We also agree with the ALJ that the amount of the CMP imposed is reasonable.

1. The ALJ's conclusion that Heritage did not comply substantially with section 483.10(b)(11) is supported by substantial evidence and free of legal error.

Section 483.10(b)(11) provides in relevant part that a facility must "immediately . . . consult with the resident's physician" when there is a "significant change in the resident's physical, mental, or psychosocial status (i.e., a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications)." The ALJ based his conclusion that Heritage was not in substantial compliance with section 483.10(b)(11) on his findings that a pressure sore on Resident 2's right hip showed significant changes in April and May 2011, and that nothing in the clinical records indicated that Heritage had consulted with Resident 2's treating physician during that time. ALJ Decision at 12-13.

The facts in the following two paragraphs are undisputed except as noted. Resident 2 was readmitted to Heritage from the hospital in June 2010. P. Ex. 11, at 1; CMS Ex. 5, at 134. Her diagnoses included debility, diabetes, dysphagia, dementia, spinal stenosis, hypertension, and cachexia (generalized wasting caused by an inability to absorb nutrients). P. Ex. 4, at 1, 4; P. Ex. 5, at 6; Hr'g Tr. at 340-41. Resident 2's condition was certified to be terminal, so she qualified for and elected to receive hospice care. Heritage contracted with another entity to provide Resident 2 with hospice care at Heritage's facility, but Heritage staff remained responsible for her daily care, and Heritage's Medical Director acted as her treating physician. P. Ex. 12; Hr'g Tr. at 656.

[2] Heritage does not challenge the ALJ's conclusion that the facility was not in substantial compliance with section 483.25(g)(2).

On February 25, 2011, the hospice nurse providing care for Resident 2 noted that the resident had a new pressure sore on her right hip.[3] CMS Ex. 5, at 1. At that time, the sore was unstageable and covered by an eschar approximately 1.5 centimeters long. *Id.* at 1, 23; Hr'g Tr. at 678. On March 22, 2011, the hospice nurse noted that the sore was unmeasurable, still covered by an eschar, the surrounding skin was healthy and intact, and there was no exudate or odor. CMS Ex. 5, at 119. On April 12, 2011, Heritage Nurse V.S. noted that the sore was 2.5 centimeters long, 4 centimeters wide, and 2.4 centimeters deep, and that there was now green necrotic tissue in the wound bed. *Id.* at 41. According to one of the surveyors, Nurse V.S. told her that the green necrotic tissue was new and that the wound also had an odor on that date. Hr'g Tr. at 58, 165; CMS Ex. 19, at 12.

The ALJ concluded that "the fact that Resident 2's wound to her right hip increased in size as well as developed undermining, greenish discharge and odor was sufficient to constitute a 'significant change' that should trigger the physician's consultation requirement" under section 483.10(b)(11). ALJ Decision at 13. Heritage argues that, to the contrary, no significant changes occurred in the condition of the sore.

As noted above, section 483.10(b)(11) identifies the deterioration in health status in "clinical complications" as a significant change in a resident's condition that triggers a facility's duty to immediately consult with the resident's physician. Heritage maintains that the interpretive guidelines for section 483.10(b)(11) in the SOM "define 'clinical complication' as the development of a Stage II pressure ulcer, onset or recurrent delirium, recurrent urinary tract infections, and the onset of depression." P. Br. at 3. According to Heritage, because none of these specified complications was identified as a basis for its alleged noncompliance with the regulation, the deficiency finding should not stand. *Id.* Heritage's argument ignores that the interpretive guidelines explain that "[c]linical complications are <u>such things as</u>" the developments Heritage cites. SOM, Appendix PP – Guidance to Surveyors for Long Term Care Facilities, Rev. 70, F157, "Interpretive Guidelines §483.10(b)(11)" (emphasis added). Because the guidelines provide only an illustrative – rather than exhaustive – list of the sorts of developments that constitute "clinical complications," the fact that the list does not include the basis for the deficiency finding here (changes in the condition of a pressure sore) is not determinative.

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[3] Heritage contends that the pressure sore did not develop at the facility. P. Br. at 4. The record does not support Heritage's assertion. Heritage witnesses testified that at the time of her admission Resident 2 had a scar on her right hip from a prior pressure sore. Hr'g Tr. at 352-55, 658. However, although the record contains many notes regarding an existing pressure sore on Resident 2's coccyx prior to February 25, 2011, nothing in the record refers to the existence of a pressure sore on her right hip until that date. In fact, a weekly pressure ulcer record completed by Heritage's Assistant Director of Nursing (ADON) shows that the date of onset for the hip pressure sore was February 25, 2011. P. Ex. 6, at 1. In addition, a Minimum Data Set completed for Resident 2 by Heritage staff on May 23, 2011 indicates that she had one unhealed Stage II pressure ulcer that developed after admission and one unhealed Stage IV ulcer that was present on admission (presumably the coccyx sore). CMS Ex. 5, at 131, 156-57. In any event, even if the pressure sore on Resident 2's right hip developed before admission, there was still a significant change in the condition of the sore between March 22 and April 12, 2011, as we discuss below.

In finding that Resident 2's hip pressure sore had deteriorated by April 12, 2011, the ALJ relied on Nurse V.S.'s notes from that date and the surveyor's testimony that the notes showed deterioration. ALJ Decision at 5, citing CMS Ex. 5 at 41; Hr'g Tr. at 58. Heritage argues that, to the contrary, the changes to Resident 2's sore observed on April 12, 2011 were not evidence that the sore was deteriorating. Heritage asserts that the ALJ gave inadequate weight to the testimony of Resident 2's treating physician on this point. P. Br. at 9-10, 13; Oral Arg. Tr. at 6. The treating physician testified that the sloughing off of the eschar covering the sore was expected given how it was being treated and that development of "greenish-yellow" necrotic tissue in the base of a wound is normal. Hr'g Tr. at 680, 686. As Heritage concedes, however, the treating physician's testimony about the lack of clinical deterioration in the sore goes to the alleged changes in the period from April 28 to May 24, 2011, not to the period between March 22 and April 12. Oral Arg. Tr. at 38; Hr'g Tr. at 705-706. Heritage also relies on testimony from the two experts who appeared on its behalf at the hearing who suggested that an increase in the surface area and amount of drainage from a wound can be evidence of healing rather than infection. P. Br. at 10-11; Oral Arg. Tr. at 50; *see* Hr'g Tr. at 381-82, 595-96.

Regardless of whether the sore had actually deteriorated as of April 12, 2011 or was in the process of healing, it is undisputed that green tissue and drainage and foul odor can be indications of infection. Both Heritage's Director of Nursing (DON) (when interviewed by the surveyor) and one of Heritage's experts (at the hearing) admitted that green or yellow discharge is a potential sign of infection in a wound. CMS Ex. 19, at 6; Hr'g Tr. at 68, 596, 603. Resident 2's treating physician implicitly acknowledged that green tissue or drainage could be a sign of infection when she told Heritage's ADON that such symptoms do "not always signify infection." P. Ex. 1, at 1; *see also* P. Ex. 33 (physician's statement that, "if a wound showed signs of infection[,] cultures should be obtained and then antibiotic started"). The treating physician's physician assistant (PA) also told the surveyor that wounds should not have foul odor, and when Heritage conducted an in-service training of staff on identifying signs and symptoms of infection, foul odor was one of the signs or symptoms mentioned. CMS Ex. 18, at 15; CMS Ex. 21, at 6.

Resident 2's treating physician testified that she would not want a hospice patient to have an infection because it could be painful. Hr'g Tr. at 732. In addition, the surveyor testified that an infection in Resident 2's hip pressure sore could lead to sepsis, a life-threatening condition, and that a pressure sore on the hip was particularly vulnerable to infection, especially for a resident, like Resident 2, who was incontinent of bowel. *Id.* at 71-74.

In the preamble to the final rule implementing section 438.10(b)(11), the Secretary "recognize[d] that judgment must be used in determining whether a change in the resident's condition is significant enough to warrant notification" and "accept[ed] the comment that only those injuries which have the potential for needing physician

intervention must be reported to the physician." 56 Fed. Reg. 48,826, 48,833 (Sept. 26, 1991). Because the green tissue and odor Nurse V.S. first noted in Resident 2's hip pressure sore on April 12, 2011 could have been signs of infection, the change in the resident's health status had the potential for needing physician intervention and was significant. Thus, Heritage staff was required to immediately consult with Resident 2's physician.

The ALJ found "no instance in Resident 2's medical records indicating that at any time the facility did notify, but, most importantly, did consult with Resident 2's physician regarding the status of the right hip wound." ALJ Decision at 13. Heritage disputes this finding. Heritage relies on the testimony of Resident 2's treating physician that Nurse V.S. "communicated" with her on April 14, 2011 about the status of Resident 2's hip pressure sore, which was why the physician ordered a test to evaluate Resident 2's albumin level on that date. Oral Arg. Tr. at 14-15; *see* Hr'g Tr. at 680-82, 733; CMS Ex. 5, at 23 (physician telephone order). The ALJ found, however, that "the after-the-fact claims by Resident 2's physician (that she was aware of Resident 2's condition . . .) made after the survey and in response to the surveyors' findings" were not "as credible as documentation made contemporaneously with the events." ALJ Decision at 13. Heritage contends that the ALJ erred in giving so little weight to the physician's testimony. P. Br. at 13-14; Oral Arg. Tr. at 6, 10, 15.

We note at the outset that Heritage presented no testimony from any Heritage nurse about any consultation with any physician about Resident 2's hip pressure sore between February 2011 and the survey (and, as the ALJ noted, facility records did not document any such consultation). Even accepting the physician's testimony that Heritage staff consulted with her on April 14, 2011 about the changes to Resident 2's hip pressure sore, any such consultation occurred too late to meet the requirements of section 483.10(b)(11). As initially drafted, the regulation granted a facility up to 24 hours in which to notify the resident's physician of a significant change in the resident's status. In response to critical comments, the phrase was modified to require that the physician be notified immediately of any significant change. 56 Fed. Reg. at 48,833. Thus, as the ALJ observed, the "use of the term 'immediately' in the regulatory requirement indicates that consultation is expected to be done as soon as the change is detected, without any intervening interval of time." ALJ Decision at 12. Here, Nurse V.S. observed changes in Resident 2's hip pressure sore on April 12, 2011 that might have signified infection, but the testimony by Resident 2's physician on which Heritage relies at most shows that V.S. communicated with her about those changes on April 14, two days later. Notification after a two-day delay does not constitute the immediate consultation required by section 483.10(b)(11).

Heritage appears to argue that it complied substantially with section 483.10(b)(11) because the treating physician's PA saw Resident 2 on April 13, 2011. P. Br. at 8. However, as Heritage acknowledges, the PA visited Resident 2 on that date to conduct a

routine annual exam, not in response to information that he received from Heritage about the changes to Resident 2's hip pressure sore immediately after the changes were detected. *See* P. Ex. 5 at 2 (PA's progress notes), 3 (annual exam form). Thus, even if the PA checked on the pressure sore on April 13 (which is unclear), this was merely fortuitous rather than the result of immediate notification by Heritage, and so did not meet the requirements of section 483.10(b)(11).

The ALJ also based his determination that Heritage was not in substantial compliance with section 483.10(b)(11) on his finding that Resident 2's physician was not consulted about additional signs that the pressure sore might be infected during mid-April to late May 2011. ALJ Decision at 9-10, 13. Heritage challenges this finding, pointing to the physician's testimony that she "examined Resident 2's wounds" on April 28, 2011 and that the hip pressure sore was not infected or deteriorating, and to the report of a wound-care specialist who examined the sore in late May 2011 and found that there was no evidence of infection. P. Br. at 6, 10-13, citing Hr'g Tr. at 690-96; P. Exs. 2, 3, 33. We need not address the conflicting evidence regarding Resident 2's symptoms during this later period nor decide that the pressure sore was, in fact, infected in order to affirm the ALJ's conclusion that Heritage did not comply substantially with section 483.10(b)(11). Staff's failure to immediately consult with Resident 2's physician about the significant change to the resident's health status observed on April 12, 2011 is sufficient to uphold the ALJ's conclusion since that failure had the potential for more than minimal harm.

Heritage also contends, as it did before the ALJ, that even if there is sufficient evidence to conclude that it did not comply substantially with section 483.10(b)(11), its cited level of noncompliance with the regulation – Level H under CMS's scope-and-severity grid, pattern of actual harm – should be reduced. P. Br. at 15-16; P. Req. for Hr'g at 14. The ALJ did not expressly address Heritage's argument.

Under 42 C.F.R. Part 498, a facility may appeal the level of noncompliance found by CMS for a particular deficiency only if a successful challenge would affect: (1) the range of CMP amounts that CMS could collect, or (2) a finding of substandard quality of care that results in the loss of approval for a facility's nurse aide training program. 42 C.F.R. § 498.3(b)(14). Heritage's challenge meets neither of these criteria. CMS imposed the lower possible range of per-day CMPs ($50-$3,000), so Heritage's challenge would not impact the CMP range. *See id.* § 488.438(a)(1). In addition, although Heritage asserts that a Level H deficiency under section 483.10(b)(11) constitutes a finding of substandard quality of care, the regulations define "substandard quality of care" as one or more deficiencies related to the participation requirements only at sections 483.13, 483.15, and 483.25. *Id.* § 488.301. Deficiencies related to section 483.10 are not included. As discussed below, moreover, Heritage did not show that it lost approval for a nurse aide training program as a result of a finding of substandard quality of care. Thus, Heritage did not have a right to an ALJ hearing on the scope and severity of the deficiency, and it was not prejudiced by the ALJ's failure to address the argument.

Accordingly, we conclude that the ALJ's determination that Heritage was not in substantial compliance with section 483.10(b)(11) is supported by substantial evidence and free of legal error.

2. The ALJ's conclusion that Heritage did not comply substantially with section 483.25(c) is supported by substantial evidence and free of legal error.

The introductory language to section 483.25 ("Quality of Care") provides: "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." Section 483.25(c) requires a facility to ensure that 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." 42 C.F.R. § 483.25(c)(1). The regulation also provides that a facility must ensure that a "resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing." *Id.* § 483.25(c)(2). The ALJ concluded that Heritage did not comply substantially with section 483.25(c) because it failed to follow both physician orders and interventions in Resident 2's care plan related to the pressure sore on her right hip. ALJ Decision at 8-10.

The following facts are undisputed. On February 25, 2011, the hospice nurse who discovered the pressure sore on Resident 2's right hip obtained a physician order to apply wound gel to the sore, to cover it with Mepilex dressing, and to change that dressing every three days and as needed. CMS Ex. 5, at 10, 23. Resident 2's care plan also was updated to require that she receive weekly documented skin assessments (also called body audits) by a licensed nurse and weekly skin grids documenting the location, stage, size, exudates, and wound bed for each pressure sore.[4] *Id.* at 94, 95, 97.

Despite the physician's order to change the dressing on Resident 2's hip sore every three days, skin treatment records for the months of April and May 2011 show that Heritage did not change the dressing on April 20 or 26.[5] CMS Ex. 5, at 38; P. Ex. 6, at 6. In addition, despite the requirement in Resident 2's care plan to conduct and document weekly body audits, weekly body audit charts covering April and May 2011 show that Heritage performed only one body audit on Resident 2 in April and two in May. CMS Ex. 5, at 41, 42. Furthermore, despite the care plan requirement to complete weekly skin grids for each of Resident 2's pressure sores, the record contains only two weekly

[4] Resident 2's care plan was also updated to require that her physician be notified of any signs or symptoms of skin breakdown. CMS Ex. 5, at 95.

[5] These records also show no dressing change on April 29 or May 19, 2011, but Resident 2's treating physician testified that she witnessed nurses providing wound care to the resident on April 28 (Hr'g Tr. at 689-90, 717) and hospice records indicate that a hospice nurse changed the dressing on the sore on May 19 (P. Ex. 7, at 10).

pressure sore records, dated May 2 and 9, 2011. P. Ex. 6, at 1-2, 7-8. Heritage presented no testimony from any member of its staff averring that Resident 2's dressings were changed or body audits and skin grids were performed more frequently than shown in the resident's clinical record.

The Board "has repeatedly stated that a facility's failure to follow its care plan or a doctor's order may be grounds for concluding that the facility is not in substantial compliance with section 483.25 quality of care standards." *Venetian Gardens*, DAB No. 2286, at 5 (2009). Thus, Heritage's documented failure to follow the physician's order and Resident 2's care plan amply supports the ALJ's conclusion that Heritage was not in substantial compliance with section 483.25(c).

Heritage nevertheless argues that the ALJ's conclusion should be overturned because the surveyors did not cite Heritage's failure to implement the steps in Resident 2's (or any other resident's) care plan related to pressure sores as the basis for their conclusion that the facility was not in substantial compliance with section 483.25(c). According to Heritage, the ALJ violated the facility's due process rights by "going outside the parameters of the survey report to make findings to support his ruling." P. Br. at 24.

Heritage's argument lacks merit. As noted above, the lead-in language to section 483.25 specifically references the need for a facility to provide services in accordance with a resident's plan of care, so any deficiency finding under the quality of care regulation potentially puts at issue a facility's compliance with the plan of care. The only care plan intervention the SOD specifically mentioned with respect to Resident 2 was the plan to notify the physician of any changes, but the SOD found generally that Heritage "failed to provide necessary care and services to prevent the worsening of existing pressure sores . . ." for Resident 2. CMS Ex. 2, at 21. Heritage's hearing request indicates Heritage knew that whether it had provided the interventions in Resident 2's plan of care (which was based on an assessment of her needs) was relevant in determining whether it was providing the necessary treatment and services required by section 483.25(c) because Heritage addressed that issue in the hearing request. P. Req. for Hr'g at 24-28.

Moreover, the Board has consistently held that "the SOD does not rigidly frame the scope of evidence to be admitted concerning any allegation relating to a cited deficiency," because "after an administrative appeal has commenced, a federal agency may assert and rely on new or alternative grounds for the challenged action or determination as long as the non-federal party has notice of and a reasonable opportunity to respond to the asserted new grounds during the administrative proceeding." *NHC Healthcare Athens*, DAB No. 2258, at 17 (2009); *Green Hills Enterprises, LLC*, DAB No. 2199, at 8 (2008) (internal quotations and citations omitted). Here, Heritage received specific notice that CMS had taken the position that the facility's lack of compliance with Resident 2's care plan and physician orders constituted noncompliance with section 483.25(c). At the hearing, counsel for CMS repeatedly asked one of Heritage's experts about facility records

suggesting that Resident 2's care plan and the physician's order had not been followed. Hr'g Tr. at 597-600, 608. In addition, in the section of its post-hearing brief addressing section 483.25(c), CMS argued at length that the evidence established that Heritage failed to follow the care plan and the order, and that on this basis Heritage was not in substantial compliance with the regulation. CMS Post-Hr'g Br. at 12, 15, 18-20. Heritage had the opportunity to respond to CMS's contentions on this point and to request further proceedings on this issue in its post-hearing reply brief, but chose not to do so. *See* P. Closing Reply Br.

Heritage also maintains that the evidence establishes that Resident 2's hip sore improved rather than deteriorated during April and May 2011, which shows that the facility "properly discharged its responsibility" under section 483.25(c). P. Br. at 22-23; *see also* Oral Arg. Tr. at 15-17. Heritage relies on nursing notes from May 23 and 24, 2011 that noted granulating tissue in the sore (an indication of healing) and on the wound-care specialist's assessment on May 24 that the sore was not infected and in fact was one of the "best-looking" pressure sores that he had seen from a nursing home in some time. P. Br. at 22, citing P. Exs. 2, 3, 6, 33. Heritage also emphasizes that Resident 2's physician testified that she was aware of the sore's condition, that the sore was not infected, and that it was never going to heal completely. *Id.* at 23; Oral Arg. Tr. at 17.

The record contains mixed evidence about the condition of Resident 2's hip sore between late April and late May 2011. Progress notes and other records covering the period April 28 to May 17, 2011 rated the sore as either Stage III or Stage IV at various points in time, noted that it had grown in width but was less deep, and alternately noted the presence or the absence of odor, slough, and exudate. *See* P. Ex. 5, at 2; P. Ex. 6, at 1; P. Ex. 7, at 2, 10; CMS Ex. 5, at 42. We also note that the nurses' and the wound-care specialist's assessments of the sore on May 23 and 24, 2011 are contradicted by the testimony of one of the surveyors about the condition of the sore on May 23. According to the surveyor, when she entered Resident 2's room on that date, there was a noticeable odor in the room that a Heritage nurse informed her was coming from the resident's hip sore, and when the nurse removed the dressing on the sore, there was a "copious amount of foul-smelling yellow and green drainage" covering the dressing. Hr'g Tr. at 62. In addition, when the surveyor interviewed Heritage and hospice staff about Resident 2's sore, they reported that the sore had drainage and a foul odor (although some said these signs were recent and others indicated the resident consistently had these signs). CMS Ex. 19, at 5, 13, 15. However, we need not determine whether the sore was improving by late May 2011. Even if that was the case, it is insufficient to establish that the treatments and care plan interventions that Heritage staff failed to perform during April and May were not necessary to promote healing and prevent infection of Resident 2's hip sore.

Heritage further argues that the development and any deterioration of Resident 2's right hip pressure sore were "clinically unavoidable" within the meaning of section 483.25(c)(1). P. Br. at 17-18; Oral Arg. Tr. at 7-8. The ALJ correctly rejected this

argument, noting that a facility "cannot claim unavoidability as an affirmative defense unless it first demonstrates it furnished all necessary treatment and services." ALJ Decision at 10, citing *Woodland Village Nursing Ctr.*, DAB No. 2172, at 13 (2008). As the ALJ concluded, because Heritage "failed to follow the specified care plan directives and interventions prescribed as well as the physician's orders," it clearly did not furnish all necessary treatment and services. *Id.*

Heritage also argues that it was in substantial compliance with section 483.25(c)(1) or (2) because "hospice bears equal if not more responsibility for managing a hospice resident's medical conditions." P. Br. at 22. However, Heritage's contract with the hospice organization specifically provided that Heritage "shall provide care to each Resident Hospice Patient to keep him/her comfortable, clean, and protected from accident, injury or infection." P. Ex. 12, at 4. In addition, the section devoted to skin integrity and vascular access in the hospice care plan for Resident 2, which Heritage staff signed, provided that both Heritage and hospice would "[a]ssess, measure and describe pressure ulcers," but delegated responsibility for "[d]ressing changes as ordered" solely to Heritage. P. Ex. 11, at 2, 3. Thus, Heritage's failure to change the dressing on Resident 2's pressure sore in accordance with the physician's order is sufficient to establish its noncompliance with section 483.25(c)(2), even if hospice was jointly responsible for monitoring the sore.

Heritage also challenges, as it did below, its cited level of noncompliance with section 483.25(c) – Level H, pattern of actual harm. P. Br. at 23-24; P. Req. for Hr'g at 30. The ALJ failed to address Heritage's argument, but the ALJ's error is harmless because Heritage did not have a right to an ALJ hearing on its level of noncompliance with the regulation.

Unlike the finding of noncompliance with section 483.10(b)(11), a deficiency finding related to section 483.25(c) at Level H is a finding of substandard quality of care, so CMS's determination of the level of noncompliance here would be appealable if that determination resulted in the loss of approval for Heritage's nurse aide training program. *Id.* § 498.3(b)(14). Heritage did not specifically assert, much less show, that it lost approval for a nurse aide training program as a result of this substandard quality of care finding. *See, e.g.,* P. Pre-Hr'g Br. at 1 (describing the recommended enforcement actions), 32 (scope and severity argument); CMS Pre-Hr'g Br. at 1 (no remedies other than the CMP were imposed). In any event, the imposition of a CMP of $5,000 or more automatically results in the loss of approval of a facility's nurse aide training program. *See* Act § 1819(f)(2)(B); 42 C.F.R. § 483.151 (b)(2)(iv), (f)(1). Thus, even if any loss was initially triggered by CMS's determination of Heritage's level of noncompliance with section 483.25(c), reversing that determination would not provide a basis for us to reinstate the approval, given that we are upholding a total CMP amount of more than $5,000. *See Buena Vista Care Ctr.*, DAB No. 2498 (2013); *Cedar Lake Nursing Home*, DAB No. 2390 (2011).

For the foregoing reasons, the ALJ's conclusion that Heritage was not in substantial compliance with section 483.25(c) is supported by substantial evidence and free of legal error.

3. The ALJ's conclusion that Heritage did not comply substantially with section 483.65 is supported by substantial evidence and free of legal error.

Under section 483.65, a facility must "establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of disease and infection." Among other things, a facility must establish an infection control program under which it "[i]nvestigates, controls, and prevents infections in the facility." 42 C.F.R. § 483.65(a)(1). The ALJ determined that Heritage failed to maintain an effective infection control program because it did not ensure that staff wore appropriate personal protective equipment when caring for Resident 1, who had Clostridium difficile (C. Diff.), a contagious, multi-drug-resistant bacteria. ALJ Decision at 3, 16-17. In addition, the ALJ determined that the care plan for Resident 6, who also was infected with C. Diff., failed to address the disease and that Heritage did not post a sign on Resident 6's door indicating that special precautions were necessary when caring for her, in contravention of its own infection control policy. *Id.* at 17.

Heritage contends that it had the required infection control policies in place and that appropriate personal protective equipment was available for staff. P. Br. at 33. It points out that the witnesses who testified at the hearing disagreed about whether it is necessary to wear a protective gown when caring for a resident with C. Diff. *Compare* Hr'g Tr. at 195-96 *with id.* at 620-23. It also argues that no residents developed an infection or experienced a more severe infection as a result of its staff's failures to wear gowns when caring for Resident 1 and to post a sign on Resident 6's door. P. Br. at 33-34.

Substantial evidence supports the ALJ's conclusion that Heritage did not comply substantially with section 483.65. As an initial matter, a facility is not in substantial compliance with the regulation just because it has infection control policies in place. Section 483.65 provides that a facility must both "establish and <u>maintain</u> an infection control program" and that the program must be "designed" to achieve a "safe, sanitary, and comfortable environment" and the prevention of disease and infection. 42 C.F.R. § 483.65 (emphasis added). The regulation can only reasonably be interpreted as requiring not just that an infection control policy exist, but also that the policy be followed. As the Board has explained, given section 483.65's use of the word "maintain" and its "focus on health outcomes," the regulation can "reasonably be read as requiring the facility to implement an effective infection control program in their daily interaction with residents." *Park Manor Nursing Home*, DAB No. 2005, at 60 (2005). The Board noted that CMS's position that the regulation requires that a facility actually follow aseptic and isolation techniques was consistent with the regulatory history. *Id.* at 60-61.

Heritage did not deny that its staff failed to wear protective gowns when caring for Resident 1. Although Heritage's nursing expert testified that a gown is not normally required when caring for a resident with C. Diff., the standard precautions under the facility's own infection control policy provide that gowns should be worn "during procedures and resident care activities that are likely to generate splashes or sprays of blood, body fluids, secretions, or excretions." CMS Ex. 20, at 13. Resident 1's care plan indicated that she had a tendency to smear her feces, and one of the surveyors testified that a potential symptom of C. Diff. is watery, loose diarrhea. CMS Ex. 4, at 7; Hr'g Tr. at 196. Thus, the ALJ reasonably concluded that, by failing to wear protective gowns while caring for Resident 1, staff ran the risk that the resident's contaminated fecal matter "could be transferred unknowingly" to their clothing. ALJ Decision a 16-17. In this way, staff could then inadvertently spread C. Diff. to other residents. In addition, although one of the surveyors noted that cloth gowns were available for use, multiple nurses admitted to the surveyor that they had been wearing only gloves when providing care. CMS Ex. 16, at 12, 27, 29. Accordingly, the ALJ could reasonably determine on this basis that Heritage failed to implement its own infection control policy and that Heritage was therefore not in substantial compliance with section 483.65.

In any event, the ALJ also based his conclusion that Heritage was not in substantial compliance with section 483.65 on Heritage's failure to follow its infection control procedures with regard to Resident 6. Heritage's infection control policy provides that, when isolation control precautions are implemented, a sign should be placed at the entrance to the affected resident's room instructing visitors to report to the nurses' station before entering. CMS Ex. 20, at 15. Heritage does not dispute that it should have implemented isolation control precautions for Resident 6 after she tested positive for C. Diff. – including placing a sign on her door – but did not do so. Heritage's failure to implement procedures to prevent the spread of Resident 6's C. Diff. infection was also a sufficient basis for concluding that Heritage did not comply substantially with section 483.65.

Accordingly, we conclude that the ALJ's determination that Heritage was not in substantial compliance with section 483.65 is supported by substantial evidence and free of legal error.

4. **The ALJ's conclusion that Heritage did not comply substantially with section 483.75(f) is supported by substantial evidence and free of legal error.**

Under section 483.75(f), a facility must "ensure that nurse aides are able to demonstrate competency in skills and techniques necessary to care for residents' needs, as identified through resident assessments, and described in the plan of care." The ALJ concluded that Heritage was not in substantial compliance with section 483.75(f) based on undisputed evidence that one of the surveyors saw nurse aides provide improper incontinence care to two residents. ALJ Decision at 17-18. Specifically, when providing incontinence care to

Resident 8, a nurse aide failed to change her gloves before touching a clean item and did not clean Resident 8's labia. CMS Ex. 16, at 7; Hr'g Tr. at 199, 202. In addition, when providing incontinence care to Resident 13, a nurse aide did not use soap or wipe Resident 13's labial area and did not wash her hands before or after leaving the room to get a clean pad. When she returned, the aide rolled Resident 13 over and another aide wiped Resident 13 from back to front with a dry cloth and did not separate the resident's buttocks to clean her anal area. CMS Ex. 16, at 15; Hr'g Tr. at 208-9. The nurse aides' actions were inconsistent with Heritage's written policy concerning incontinence care as well as an evaluation form used by the facility to assess its nurse aides' competency in providing incontinence care. CMS Ex. 20, at 1, 3. In addition, when the surveyor who had observed the nurse aides spoke with Heritage's ADON, the ADON acknowledged that staff providing incontinence care should change their gloves before touching clean items, separate the labia of female residents, and clean from front to back. CMS Ex. 16, at 8; Hr'g Tr. at 209.

As it did before the ALJ, Heritage argues that just because the three nurse aides failed to properly perform incontinence care during the survey does not mean they are not competent. P. Br. at 34. Heritage contends that the aides' failures were isolated incidents triggered by their nervousness about being observed. It emphasizes that the aides in question are all certified by the State of Texas, including in the area of incontinence care, and that their skills are checked on a routine basis. *Id.* at 34-35. Heritage also notes that when the surveyors questioned the aides about how to properly provide incontinence care, the aides answered correctly. *Id.* at 35.

The ALJ properly rejected Heritage's arguments. The regulation requires nurse aides to be able to "demonstrate" their competency to provide necessary care. Demonstrating competency in a skill set requires correctly carrying those skills out. The aides in question failed to do so.

Heritage also argues that the deficiency finding is inappropriate because the nurse aides' actions did not cause any resident harm. P. Br. at 35. Heritage acknowledges that CMS did not find actual harm and instead determined that the facility's noncompliance with section 483.75(f) was at Level E, pattern of no actual harm with potential for more than minimal harm that is not immediate jeopardy. *Id.*; *see* CMS Ex. 2, at 49 (SOD). However, according to Heritage, under *Mabee Health Care Center*, DAB CR2525 (2012), a finding of noncompliance with section 483.75(f) at Level E is inappropriate where the nurse aides in question are certified by the state, their skills are verified on a routine basis, and their actions did not result in harm to any resident. Oral Arg. Tr. at 21-22.

ALJ decisions like *Mabee* are not binding precedent on the Board or other ALJs. *See, e.g., Michael D. Dinkel*, DAB No. 2445 (2012); *Mark B. Kabins, M.D.*, DAB No. 2410 (2011). In any event, we agree with the ALJ here that *Mabee* is distinguishable from this

case. In *Mabee*, the ALJ accepted as credible testimony that the nurse aides possessed competent transfer skills, as demonstrated by their passage of a competency exam that tested those skills, and noted that CMS had not alleged that any residents suffered pain or injury during the transfers at issue. But the ALJ in *Mabee* also determined that any mishandling by the aides did not pose a risk for more than minimal harm. Here, the ALJ concluded that the nurse aides' actions in this case, unlike in *Mabee*, created a "very real likelihood of harm" because staff's failure to follow appropriate protocols for incontinence care "can easily result" in residents developing urinary tract infections. ALJ Decision at 18. As the ALJ noted, Resident 8 was "known to be prone to urinary tract infections," so providing her with proper incontinent care was "critical." *Id.* While Resident 13 was not known to have the same tendency, the ALJ observed that "it is a basic of incontinent care to never wipe a female patient from back to front; to do so is to risk contamination." *Id.* Heritage does not dispute that the nurse aides' actions here did not constitute proper incontinence care and created the potential for more than minimal harm to two residents.[6] Thus, the ALJ's conclusion that Heritage failed to comply substantially with section 483.25(f) is supported by substantial evidence and free of legal error.

5. The ALJ's conclusion that Heritage did not comply substantially with section 483.75(j)(2)(ii) is supported by substantial evidence and free of legal error.

Section 483.75(j)(2)(ii) requires a facility to "[p]romptly notify the attending physician of [laboratory] findings." The ALJ determined that Heritage did not comply substantially with this requirement because its staff failed to promptly fax to Resident 8's attending physician laboratory (lab) results dated May 14, 2011 indicating that the resident's urinary tract infection was resistant to Cipro, the antibiotic that had been prescribed to treat it. ALJ Decision at 18. The ALJ also concluded that, even if staff did fax the lab results, when the attending physician did not order a change in treatment, staff had a responsibility to follow up to make sure the physician received the results and to learn what course of treatment should be pursued. *Id.* at 19.

Heritage argues that the record shows staff faxed the lab results immediately after receiving them and that the ALJ's contrary conclusion is improperly "based on surmise." P. Br. at 37. In addition, Heritage maintains that the ALJ's conclusion about staff's supposed failure to follow up with the physician is misplaced because that failure was not the basis for the deficiency finding. *Id.*

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[6] Heritage argues that the ALJ erroneously concluded that the nurse aides' failures caused actual harm. P. Br. at 36; Oral Arg. Tr. at 21-22. The ALJ stated that he "disagree[d]" with Heritage's argument that the nurse aides' actions did not cause harm to any resident. ALJ Decision at 18. However, as we have explained, the ALJ's determination that Heritage was not in substantial compliance with section 483.25(f) was appropriately based on his conclusion that the nurse aides' failures had the potential for more than minimal harm, so any error by the ALJ is harmless.

Substantial evidence supports the ALJ's finding that staff did not promptly notify Resident 8's attending physician of the lab results. As the ALJ noted, Resident 8 received Cipro from May 13 to May 19, 2011, five days after the lab results came in, and was not prescribed a new antibiotic between that date and May 24, 2011, when a surveyor discovered the lab results and discussed them with staff. ALJ Decision at 18; *see* Hr'g Tr. at 205-7; CMS Ex. 10, at 11. The ALJ reasonably concluded that the physician's failure to change Resident 8's prescription suggested that the physician did not receive the lab results indicating that the prescription was ineffective. ALJ Decision at 18 n.8. The surveyor also testified that when she spoke to a nurse at Heritage about the lab results, the nurse admitted that she had not looked at them. Hr'g Tr. at 206; CMS Ex. 16, at 24 (surveyor notes). According to the surveyor, the nurse stated that "had she looked back" at the results and seen that the resident's infection was resistant to Cipro, she "would have faxed the doctor so he would have changed" the prescribed medication. Hr'g Tr. at 206. The nurse also told the surveyor that when faxing things to doctors, the protocol was to initial the fax and to chart in the nursing notes that the fax was sent. *Id.* As the ALJ noted, the record does not contain a fax transmission record documenting that the lab report was faxed to the physician. ALJ Decision at 18 n.8. Instead, the lab report in question is stamped "Faxed," but the box below this phrase where there is space to write the date of transmission or other notes, such as the initials of the person who sent the fax, is not completed. P. Ex. 32, at 3. In addition, the record does not contain any nurse's notes related to Resident 8 indicating that staff faxed the lab results. Thus, the discrepancy between the nurse's description of the paper trail that generally exists when something is faxed to a doctor and the (lack of) paper trail here also suggests that the attending physician did not receive Resident 8's lab results.

This evidence is sufficient to uphold the ALJ's determination that Heritage was not in substantial compliance with section 483.75(j)(2)(ii). Accordingly, we need not address the ALJ's additional conclusion that, even if staff did fax the lab results to Resident 8's attending physician, staff was responsible for following up to make sure the physician received the results and to check whether additional treatment was required.

6. The amount of the CMP is reasonable.

An ALJ (or the Board) determines de novo whether a CMP is reasonable based on the evidence in the record concerning the factors specified in section 488.438. *See* 42 C.F.R. § 488.438(e), (f). Those factors are: (1) the facility's history of noncompliance; (2) its financial condition, that is, its ability to pay a CMP; (3) the severity and scope of the noncompliance, and "the relationship of the one deficiency to other deficiencies resulting in noncompliance"; and (4) the facility's degree of culpability, which includes neglect, indifference, or disregard for resident care, comfort or safety. *Id.* §§ 488.438(f), 488.404(b), (c)(l).

Here, CMS imposed a CMP of $700 per day from April 12 through June 15, 2011. Heritage argues that the ALJ erred in sustaining this penalty because CMS "did not present any evidence" that the penalty amount is "justified" or that it "followed the factors set forth in section 488.438 and 488.404" when determining the penalty. P. Br. at 38. According to Heritage, a CMP of $700 per day for over two months is not justified, "especially when [the] treating physician for the two most significant deficiencies at issue here confirmed that the facility's actions did not cause any resident harm." *Id.*

The Board has explained that "[i]n effect, there is a presumption that CMS has considered the regulatory factors in setting the amount of the CMP and that those factors support the CMP amount imposed by CMS." *Coquina Ctr.*, DAB No. 1860, at 32 (2002). Thus, "[u]nless a facility contends that a particular regulatory factor does not support that CMP amount," CMS does not have "a responsibility to produce evidence as to that factor" and the ALJ must sustain the CMP amount. *Id.* If the application of a particular regulatory factor is disputed, the ALJ must make an independent determination of whether the CMP amount imposed is reasonable based on the evidence in the record. *Id.*

In sustaining the penalty amount, the ALJ determined that the facility's "failures did result in actual harm to residents or posed a strong likelihood of actual harm." ALJ Decision at 19. As noted above, CMS may impose per-day CMPs of $50-$3,000 for deficiencies that do not constitute immediate jeopardy but either caused actual harm or caused no actual harm but had the potential for more than minimal harm. 42 C.F.R. § 488.438(a)(1)(ii). We agree with the ALJ that Heritage's deficiencies fall in this category. By failing to immediately consult with Resident 2's physician when the resident's hip pressure sore exhibited potential signs of infection and by failing to follow the physician's order for dressing changes and to carry out all of the interventions in her care plan related to the sore, Heritage placed the resident at risk of infection and further health complications. Staff's failure to wear protective gowns when caring for Resident 1 and to post a sign on Resident 6's door warning visitors of her infection created a risk that the residents' C. Diff. could spread to other residents in the facility. By failing to provide proper incontinence care to Residents 8 and 13, nurse aides risked giving the residents urinary tract infections. Because staff failed to timely notify Resident 8's treating physician that her urinary tract infection was resistant to the prescribed antibiotic, Resident 8 received ineffective treatment.[7]

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[7] The seriousness of Heritage's failure to comply substantially with section 48.325(g)(2), which Heritage does not dispute on appeal, is also relevant. The ALJ found that Heritage was out of substantial compliance with section 483.25(g)(2) because on two occasions nurse aides lowered to a flat position the bed of a resident who was being tube fed. ALJ Decision at 14. As the ALJ concluded, this created a risk that the resident would aspirate. *Id.*

In addition, Heritage does not argue that its financial condition is such that it is unable to pay the penalty. Since Heritage has not alleged that it is unable to pay, this regulatory factor does not apply regardless of the CMP amount.

Heritage also contests the duration of the CMP upheld by the ALJ, contending that CMS "did not affirmatively show that the facility was out of compliance on any particular day between April 12 and June 15, 2011" and "certainly did not present evidence that the facility was out of compliance for nearly one month after the survey ended." P. Br. at 38. We need not consider Heritage's argument because Heritage did not raise it before the ALJ. *See* ALJ Decision at 19 (noting that Heritage did "not contest the length of time during which CMS imposed the CMP"); Guidelines (the "Board need not consider . . . issues which could have been presented to the ALJ but were not").

In any event, under the applicable regulations, a per-day CMP "may start accruing as early as the date that the facility was first out of compliance, as determined by CMS or the State," and accrues until the date CMS finds the facility in compliance. 42 C.F.R. § 488.440(a), (b). Generally, the latter finding requires either a revisit survey to determine that a facility has achieved substantial compliance, or the submission of "written credible evidence" through "documentation acceptable to CMS or the State agency" that substantial compliance was achieved on a particular date. *Id.* § 488.440(h). Substantial evidence establishes that Heritage was not in substantial compliance with section 483.10(b)(11) on April 12, 2011 when it failed to immediately notify Resident 2's treating physician of the changes to the pressure sore on the resident's right hip. Thus, CMS reasonably determined that Heritage was out of compliance with the regulations beginning on that date. Substantial evidence also establishes Heritage's failure to comply with regulations on various subsequent dates in April and May 2011 when the facility did not follow Resident 2's care plan, when staff did not follow the facility's infection control policies, when nurse aides failed to demonstrate proper incontinence care, and when staff did not timely notify Resident 8's physician of lab results. The exact rationale behind CMS's determination to end the accrual of a per-day CMP on June 15, 2011 is unclear from the record, but Heritage appears to have submitted to CMS a Plan of Correction dated June 13, 2011 that describes in-service trainings and other corrective actions in which the facility "will" engage. CMS Ex. 2, at 57, 58, 60. Thus, CMS could reasonably rely on the Plan of Correction to conclude that Heritage did not return to substantial compliance prior to June 15, 2011, and Heritage has not pointed to any written credible evidence establishing that it came back into substantial compliance on an earlier date.

Accordingly, we conclude that a CMP of $700 per day from April 12 to June 15, 2011 is reasonable.

Conclusion

For the reasons discussed above, we affirm the ALJ's conclusions that Heritage was not in substantial compliance with the Medicare participation requirements at sections 483.10(b)(11), 483.25(c), 483.65, 483.75(f), and 483.75(j)(2)(ii), and we uphold the CMP imposed based on that noncompliance as well as Heritage's admitted noncompliance with section 483.25(g)(2).

/s/
Stephen M. Godek

/s/
Leslie A. Sussan

/s/
Judith A. Ballard
Presiding Board Member