Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

In the Case of:	DATE: April 30, 2009
Alexandria Place,	
Petitioner,	Civil Remedies CR1827 App. Div. Docket No. A-09-2
	Decision No. 2245
- v. -	
Centers for Medicare & Medicaid Services.	

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Alexandria Place (Alexandria), a North Carolina skilled nursing facility, appeals the August 5, 2008 decision of Administrative Law Judge (ALJ) Steven T. Kessel, Alexandria Place, DAB CR1827 (2008) (ALJ Decision). At issue before the ALJ was a determination by the Centers for Medicare & Medicaid Services (CMS) that Alexandria was not in substantial compliance with numerous Medicare and Medicaid participation requirements – including the requirements at 42 C.F.R. §§ 483.25, 483.25(n), and 483.75(o) – as determined during surveys of the facility in February and April 2007. The ALJ determined that Alexandria failed to substantially comply with the foregoing regulations and upheld CMS's determination to impose civil money penalties (CMPs) against Alexandria of $3,050 per day for the period October 15, 2006 through February 21, 2007, and $150 per day for the period February 22, 2007 through March 25, 2007.

For the reasons discussed below, we affirm the ALJ Decision.

Legal Background

The participation requirements for long-term care facilities that participate in Medicare as skilled nursing facilities and Medicaid as nursing facilities are set forth at 42 C.F.R. Part 483, subpart B. A facility's compliance with the participation requirements is assessed through surveys performed by state agencies. 42 C.F.R. Parts 483, 488, and 498. Survey findings are reported in a Statement of Deficiencies (SOD), which identifies each alleged failure to comply with a participation requirement.

CMS may impose enforcement remedies, including CMPs, when it finds that a facility is not in "substantial compliance" with one or more of the participation requirements. See 42 C.F.R. §§ 488.400 et seq. "Substantial compliance" means a level of compliance "such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm." 42 C.F.R. § 488.301. Under the regulations, the term "noncompliance" means "any deficiency that causes a facility to not be in substantial compliance." Id.

CMS determines the amount of a CMP based in part on the "seriousness" of the noncompliance, i.e., its scope and severity. See 42 C.F.R. §§ 488.438(f)(3), 488.404. The most severe deficiencies are those that pose "immediate jeopardy" to resident health or safety. 42 C.F.R. § 488.404(b). "Immediate jeopardy" is defined as "a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301. For noncompliance at the immediate jeopardy level, CMS may impose a per-day CMP in the range of $3,050 to $10,000 per day. 42 C.F.R. § 488.438(a)(1). For noncompliance that does not pose immediate jeopardy, CMS may impose a per-day CMP of between $50 and $3,000 for each day the facility is not in substantial compliance. Id. In determining the amount of a CMP, CMS takes into account factors specified at 42 C.F.R. §§ 488.438(f), 488.404.

In an ALJ proceeding, a facility may challenge any finding of noncompliance that results in the imposition of a CMP or other enforcement remedy. 42 C.F.R. §§ 488.408(g)(1), 498.3(b)(13). The seriousness of noncompliance is subject to review only if a successful challenge would affect the applicable range of CMP

amounts or a finding of substandard quality of care that led to loss of approval for a facility's nurse aide training and competency evaluation program (NATCEP). 42 C.F.R. § 498.3(b)(14). CMS's determination concerning the seriousness of a facility's noncompliance must be upheld unless it is "clearly erroneous." 42 C.F.R. § 498.60(c)(2).

Procedural Background

Based on a February 2007 survey, the North Carolina Department of Health and Human Services (State agency) found that Alexandria failed to comply with 11 program participation requirements. CMS Ex. 1. The State agency found that four of the deficiencies posed immediate jeopardy to the health and safety of facility residents. CMS Ex. 1; CMS Pre-Hearing Br. at 6-7; CMS Final Br. at 1. The alleged immediate jeopardy level deficiencies involved the quality of care requirements at 42 C.F.R. § 483.25, the pneumococcal immunization requirements at 42 C.F.R. § 483.25(n)(2), the quality assessment and assurance requirements at 42 C.F.R. § 483.75(o), and the medical director requirements at 42 C.F.R. § 483.75(i). Id. The State agency found that the immediate jeopardy began October 15, 2006 and continued through February 21, 2007, and that Alexandria's noncompliance continued at a less serious level beginning February 22, 2007. CMS Ex. 1; CMS Ex. 28, at 1, 5.

In April 2007, the State agency performed a revisit survey. CMS Ex. 28, at 8. The revisit survey found that Alexandria had achieved substantial compliance with the program participation requirements as of March 26, 2007. Id. CMS concurred with the State agency's survey findings. Based on those findings, CMS imposed a $3,050 per-day CMP on Alexandria for the period from October 15, 2006 through February 21, 2007, and a $150 per-day CMP for the period from February 22, 2007 through March 25, 2007. See CMS Ex. 28, at 5, 8.

Alexandria filed a request for an ALJ hearing, contending that it was in substantial compliance with all participation requirements during the period at issue, that the immediate jeopardy findings were unwarranted, and that the remedies imposed were "improper and disproportionate" and "unduly burdensome." CMS Ex. 2, at 5. The parties later agreed to have the ALJ decide the case based on their documentary evidence and written legal arguments.

The ALJ Decision

The ALJ made findings of fact and conclusions of law regarding three of the deficiency citations in the SOD. The ALJ determined that:

- Alexandria was not in substantial compliance with 42 C.F.R. §§ 483.25, 483.25(n) and 483.75(o);

- CMS's determination that Alexandria's noncompliance posed immediate jeopardy to resident health and safety during the period October 15, 2006 through February 21, 2007 was not clearly erroneous;

- Alexandria remained noncompliant at less than the immediate jeopardy level of severity from February 22, 2007 through March 25, 2007; and

- The CMPs imposed by CMS for Alexandria's noncompliance – a $3,050 per-day CMP for the period October 15, 2006 through February 21, 2007 (the period of immediate jeopardy), and a $150 per-day CMP for the period February 22 through March 25, 2007 – were reasonable in amount and otherwise legally justified.

ALJ Decision at 3-14. The ALJ also sustained the suspension of approval for Alexandria's NATCEP. Id. at 1, n.1.

Standard of Review

We review a disputed finding of fact to determine whether the finding is supported by substantial evidence, and a disputed conclusion of law to determine whether it is erroneous. Guidelines -- Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's Participation in the Medicare and Medicaid Programs, http://www.hhs.gov/dab/guidelines/prov.html.

Discussion

In its request for review of the ALJ Decision, Alexandria states that it disagrees with each of the ALJ's factual findings and legal conclusions. Alexandria Request for Review (P. Br.) at 2,

¶ 6. Below, we discuss Alexandria's major arguments.[1] We explain the bases for our determination that the ALJ's findings and conclusions are supported by substantial evidence on the whole record and free of legal error. We address, in turn, each of the ALJ's findings and conclusions.

> *1. The ALJ's conclusion that Alexandria failed to substantially comply with 42 C.F.R. § 483.25 is supported by substantial evidence on the record and free of legal error.*

The opening paragraph of section 483.25 sets forth the overarching standard of the quality of care regulation. It 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.

The Board has held that this standard requires facilities to monitor and adequately document each resident's condition, to coordinate orders and ensure the sufficiency of resident care plans. See, e.g., The Laurels at Forest Glenn, DAB No. 2182, at 6 (2008); Spring Meadows Health Care Center, DAB No. 1966, at 16-20 (2005). The Board also has held that the quality of care regulation imposes on facilities a duty to provide care and services that, at a minimum, meet accepted professional standards of quality care. Spring Meadows at 17, and authorities cited therein.

In this case, the ALJ upheld CMS's determination that Alexandria was not in substantial compliance with section 483.25, as evidenced by the facility's failure to ensure that a resident who had a peripherally inserted central catheter (PICC) line received dressing changes. The resident, identified as Resident 19 for purposes of the survey, was an 81-year old woman who had resided at Alexandria since April 2005. In December 2006,

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[1] Although some specific points made by Alexandria may not be discussed in detail in this decision, we considered all of the arguments in the parties' briefs in reaching the conclusions set forth below.

Resident 19 was hospitalized for a variety of conditions, including fecal impaction, pneumonia, and septic shock (the latter condition a complication of an E. coli infection). P. Ex. 13, at 121. When Resident 19 was discharged from the hospital and readmitted to Alexandria on December 29, 2006, she had a PICC line in place that was inserted in her upper left arm. Id. at 142; P. Ex. 28. The PICC line insertion site dressing consisted of a 4-inch by 4-inch white gauze bandage, which was covered by a transparent bandage. P. Exs. 24; 34, at 1; 35, at 1. The hospital discharge instructions for the PICC line stated that the dressing "should be changed weekly and as needed." P. Ex. 13, at 159; see also P. Ex. 13, at 158 (hospital's "physician's order" for "Protocol for PICC/Midline Management," stating: "Send Picc Discharge Instructions with patient if going home with Picc line.").

The ALJ found, and Alexandria does not dispute, that Resident 19's PICC line dressing was not changed at any time between December 29, 2006 and January 22, 2007, when Resident 19 was sent back to the hospital for evaluation of abdominal pain and diarrhea. ALJ Decision at 3. According to the hospital records, when the hospital physician removed the PICC line dressing on January 22, he noted a "foul smell" and determined that the resident likely had developed "PICC line sepsis." P. Ex. 13, at 153-54. This diagnosis was later reflected in both the hospital's discharge records and Alexandria's records. P. Ex. 13, at 99, 145, 148; CMS Ex. 17, at 64.

The ALJ determined that Alexandria violated section 483.25 by failing to ensure that Resident 19's PICC line dressing was changed in accordance with the hospital's discharge instructions and with professional standards of quality care. ALJ Decision at 4-5. The ALJ also concluded that the facility was noncompliant with the quality of care regulation because it "failed to plan for, or to implement, any plans for caring for the PICC line." Id. at 5. Noncompliance was further demonstrated, the ALJ determined, by Alexandria's failure to have a facility policy addressing how to care for PICC lines. Id.

Alexandria contends that the ALJ erred in finding that the facility was required to change Resident 19's PICC line dressing and that its failure to do so violated the quality of care standard. P. Br. at 2-8. Specifically, Alexandria argues:

- Alexandria "appropriately planned for, monitored and assessed the PICC line site on a daily basis and in accordance with physician orders." Id. at 3-6.

- The ALJ did not sufficiently consider or assign proper weight to evidence that Resident 19's attending physician and physician assistant observed and assessed the resident multiple times between December 29, 2006, and January 22, 2007 and that neither ordered the PICC line dressing to be changed or identified evidence of infection or pain at the site. Id. at 6-7.

- The ALJ erred in finding the PICC line was infected. Id. at 7-8.

- The ALJ failed to consider and assign greater weight to expert testimony that the facility properly cared for Resident 19, consistent with her attending physician's orders. Id. at 8.

We reject these arguments. Under the quality of care standard, a facility must carry out *every* applicable order and ensure the sufficiency of resident care plans so that each resident receives all of "the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being." 42 C.F.R. § 483.25. Here, Resident 19's December 2006 hospital records include the December 29, 2006 document expressly identified as a "physician order" and labeled "Protocol for PICC/Midline Management," which states, among other things: "Send Picc Discharge Instructions with patient if going home with Picc line." P. Ex. 13, at 158. The "Discharge Instructions for PICC Line" in turn instruct that the PICC line dressing "should be changed weekly and as needed." Id. at 159.

In spite of this unambiguous instruction, Alexandria employees reported, and the facility and hospital records establish, that at no time during the 25-day period between Resident 19's December 2006 and January 2007 hospitalizations was the PICC line dressing changed. CMS Ex. 1, at 2-4, 6-7; CMS Ex. 17, at 128. Nor did Alexandria update Resident 19's care plans to reflect the hospital discharge instruction to change the PICC line dressing. CMS Ex. 1, at 2, 4; CMS Ex. 17. Thus, while it may have been appropriate for the facility to regularly flush the PICC line and routinely assess the area around the PICC line

dressing consistent with other relevant orders, this care alone was not *sufficient* to meet the regulatory standard, which requires facilities to coordinate, plan for, and implement all applicable orders. As the ALJ found, the PICC line care that Alexandria provided was "no substitute" for the required dressing changes. ALJ Decision at 5.

Substantial evidence on the record also supports the ALJ's determination that Alexandria's failure to sufficiently plan for and change Resident 19's PICC line dressing between December 29, 2006 and January 22, 2007 contravened professional standards of quality nursing care. According to the Centers for Disease Control and Prevention's "Guidelines for the Prevention of Intravascular Catheter-Related Infections," gauze dressings used for PICC lines in adults should be changed every two days, while transparent dressings must be changed at least every seven days. CMS Att. A, at 17. Resident 1 had both types of dressings applied at the PICC line insertion site. P. Ex. 34, at 1; P. Ex. 35, at 1. In addition, a record copy of guidelines issued by a PICC line manufacturer provides that gauze tape dressings should be changed every 24 hours and transparent (without gauze) dressings should be changed every seven days. P. Ex. 13, at 197. According to University of Wisconsin Health System guidelines, "Preparing and Caring for Your Midline or PICC Catheter," also included in the record, the dressing should be changed, at a minimum, every seven days. P. Ex. 13, at 204, 208.[2] A nursing facility policy addressing PICC care, which the record indicates Alexandria obtained from a "sister facility" after Resident 19's death, states that a "dressing change should be done on a 72 hours basis unless ordered otherwise by the attending physician." CMS Ex. 1, at 4-5; CMS Ex. 17, at 72. Thus, substantial evidence supports the ALJ's determination that, at a minimum, professional standards of quality care require PICC line dressings to be changed every seven days, and Alexandria's failure to change Resident 19's PICC line dressing

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[2] The copy of the guidelines in the record, printed from the website, http://www.uwhealth.org/healthfacts/B_EXTRANET_HEALTH_INFORMATION-FlexMember-Show_Public_HFFY_1104449359467.html, inadvertently cuts off the text at the right margin of the document. The full instructions can be viewed at the referenced website.

for more than three weeks plainly violated this professional standard.[3]

We also find no merit in Alexandria's contention that the ALJ should have found the facility's assessments of Resident 19's PICC line insertion site sufficient since the assessments would have put the facility on "notice of any developing infection." P. Br. at 5. According to Alexandria, staff caring for the resident made daily observations of "the site directly around the PICC line that was not covered by the bandage and there was no evidence of infection [discharge, discoloration or odor coming from the area] around the site." Id. Though staff may have been able to observe the area around the PICC line that was "not covered by the bandage," as Alexandria submits, we see no error in the ALJ's conclusion that the assessments were inadequate since facility employees could not have observed "the area *underneath the dressing because they never removed the dressing.*" ALJ Decision at 5 (emphasis in original). Indeed, the evidence shows that the PICC line infection was detected at the hospital (by a "foul smell") only after the dressing was removed. P. Ex. 13, at 153.

We additionally reject Alexandria's argument that the ALJ "erred in determining physician orders regarding Resident #19's PICC line were not followed." P. Br. at 6. Alexandria submits that Resident 19's attending physician never ordered the PICC line dressing to be changed, even though the physician and physician assistant observed and assessed the resident on four occasions between the resident's December 2006 and January 2007 hospitalizations. In addition, Alexandria argues, the "formal discharge summary from the hospital" and "discharge instructions signed by the nurse" do not reference changing the PICC line dressing. P. Br. at 6, citing P. Ex. 13, at 164-168. Further, Alexandria submits, the hospital discharge instructions "referenced and relied on by the ALJ were not in fact signed by any physician and failure to follow those instructions is thus not a violation of a physician's order." P. Br. at 6, citing P. Ex. 13, at 158-59.

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[3] As we discuss later, the expert witness statements submitted by Alexandria do not assert that this was not the applicable professional standard. P. Exs. 31, 32.

The absence of an order by Resident 19's attending physician to change the PICC line dressing does not excuse Alexandria's failure to follow the hospital discharge instruction to change the dressing weekly and as needed or to seek further guidance. Nor does the absence of a signature on the hospital physician order to send the PICC line instructions home with the resident justify ignoring the instructions. The quality of care standard requires facilities not only to implement the signed orders of attending physicians, but also to plan for, and ensure that each resident receives, *all* of the care and services necessary for the resident to attain or maintain the highest practicable physical, mental, and psychosocial well-being. Commensurate with this requirement is the responsibility to coordinate orders with care givers and "communicate effectively with the attending physician" so that staff has sufficient guidance to provide each resident all the required care and services. See The Laurels at Forrest Glenn at 16. Here, facility employees failed to communicate effectively with the attending physician, as well as the hospital, to ensure that Resident 19 was provided all of the care and services necessary for her to attain or maintain the highest practicable physical well being. There is no evidence that any of the facility employees communicated with the attending physician about proper care of the PICC line dressing. Indeed, Alexandria does not deny that the attending physician indicated to the surveyor that he assumed there were orders for dressing changes and stated that "he would have expected nurses to alert him" if there were none. CMS Ex. 1, at 6; CMS Ex. 19, at 28. Nor is there evidence that Alexandria made any effort to contact the hospital physician to verify, to the extent it was unclear, that the discharge instructions for dressing changes should be followed.

We further reject Alexandria's argument that the ALJ erred in concluding that Resident 19's PICC line was infected. Alexandria submits that the PICC line was not infected since the resident was being treated with antibiotics; facility staff who cared for Resident 19 "saw absolutely no signs of infection" such as redness, swelling, drainage or odor; and the resident "never complained of soreness or pain around the PICC site." P. Br. at 7-8. Alexandria further contends that the attending physician and physician assistant did not identify any evidence of infection or pain. Id. at 6-7.

Substantial -- indeed overwhelming -- evidence on the record supports the finding that Resident 19 had developed a PICC line

infection. As noted above, the hospital records show that the emergency room physician found on January 22, 2007 that Resident 1 had sepsis, which he "suspect[ed]" was "related to her infected PICC line." P. Ex. 13, at 153. The emergency room physician's report also stated that the "[t]otal time coordinating" Resident 19's Emergency Department care included "identifying her clearly infected PICC line . . . ." Id. at 154. The hospital records further confirm that Resident 19 had developed a form of sepsis that was not present during her prior, December 2006, hospitalization, indicating it was caused by a different source.[4] P. Ex. 13, at 120-122, 144, 155. The January 24, 2007 hospital discharge records list "sepsis" and "PICC line infection" as the resident's first and second discharge diagnoses. Id. at 145. A hospital discharge report states that the "patient probably did have line sepsis as she had an old PICC line in since her last admission." Id. at 144, 148. Alexandria's own records themselves show that, upon readmission to Alexandria on January 24, and at the time of her death, on January 30, 2007, Resident 1 had a PICC line infection and sepsis. Id. at 10-11; CMS Ex. 17, at 64.

In light of this evidence, we concur with the ALJ that the administration of antibiotics to the resident in the period between her December 2006 and January 2007 hospitalizations is irrelevant -- the antibiotics plainly did not prevent the PICC line infection, nor did the administration of the medications excuse the facility from discharging its responsibility to prevent a PICC line infection from developing. Likewise, the facility's failure to detect the infection through staff assessments does not prove that the line was not infected, as Alexandria argues. Rather, it points to the inadequacy of those assessments and the critical importance of following the discharge instructions to change the dressing weekly in that the PICC line infection was detected only when the dressing was removed at the hospital. P. Ex. 13, at 153-54. Further, that Resident 19 did not complain of pain at the PICC line entry site does not establish that the PICC line was not infected since Alexandria pointed to no evidence that an infection would have necessarily caused Resident 19 pain at the site.

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[4] During the December hospitalization, Resident 19 was diagnosed with E-coli sepsis, a gram-negative bacteria. The sepsis diagnosed in January 2007 was of a gram-positive bacteria. Alexandria Ex. 13, at 120, 144, 155.

Finally, we reject Alexandria's argument that the ALJ failed to give appropriate weight and consideration to the written testimony of two experts (Linda Howard, R.N., and Michele Ann Haber, M.D.) that Alexandria "appropriately cared for Resident 19." P. Br. at 8. According to these experts, the facility's care for Resident 19 was consistent with physician orders for the resident. P. Exs. 31-32. In addition, Dr. Haber testified that it could not be determined that any PICC line infection caused the resident's death. P. Ex. 32.

In addressing this testimony, the ALJ rejected the claim that the care given the resident was consistent with physician orders. He noted that there were no physician orders *not* to change the dressing, and "the only orders governing [the dressing] were issued by the hospital and they definitely told Petitioner to change the dressing." ALJ Decision at 7. It is true that the hospital physician discharge order which incorporated the protocol for dressing changes which Alexandria provided from its records was not signed. P. Ex. 13, at 158-59.

What Alexandria characterizes as the "formal discharge summary" is actually an "addendum" to the discharge order dictated by the physician and transcribed on December 29, 2006 but also not signed. P. Ex. 13, at 164. The document identified as "physician orders - protocol for PICC/midline management," which is what the ALJ referred to as the only orders governing the dressing, states that PICC discharge instructions should be sent with the patient if she leaves with the PICC. P. Ex. 13, at 158. The addendum states that, indeed, the "patient is discharged to Alexandria Place with a PICC line in place." P. Ex. 13, at 164. This document thus simply confirms that the PICC discharge instructions were to be sent with the patient (which they were). The addendum cannot reasonably be viewed as a different order superseding the instructions in the physicians orders already issued, as Alexandria claims. In no way does the addendum support Alexandria's position that failing to change the dressing for more than three weeks was somehow consistent with the physician orders.

In any case, Alexandria's nurses were not free to ignore the physician's order and discharge instructions simply because they were not again referred to in the addendum. If they were at all uncertain about whether to follow the protocol in the PICC discharge instructions sent with the patient from the hospital, they should either have contacted the discharging physician to

determine whether the written order should be followed and/or the attending physician for further instructions on caring for the PICC line. Their failure to do either demonstrates the facility's failure to coordinate and plan care for the resident consistent with federal requirements for quality of care.

Furthermore, the ALJ correctly concluded that it was unnecessary that he decide whether a PICC line infection caused Resident 19's death or even that the resident's PICC line was infected. "An adverse outcome of Petitioner's noncompliance," the ALJ wrote, "while certainly not irrelevant, is not necessary in order for me to find noncompliance." ALJ Decision at 7. Noncompliance exists where a facility's deficiencies pose a "potential for more than minimal harm," and "immediate jeopardy" exists where a facility's noncompliance has caused, *or is likely* to cause "serious injury, harm, impairment or death to a resident." 42 C.F.R. § 488.301 (emphasis added). Resident 19's medical records, the survey interviews, and the medical literature discussed above amply support the conclusion that the facility's failure to change the resident's PICC line dressing, at a minimum, "created a high probability that the resident would become infected." ALJ Decision at 12. As discussed in greater detail below, Alexandria did not present evidence sufficient to show that CMS's determination as to the immediate jeopardy level of the noncompliance was clearly erroneous.

Accordingly, we uphold the ALJ's determination that Alexandria failed to comply substantially with section 483.25.

> *2. The ALJ's conclusion that Alexandria was not in substantial compliance with 42 C.F.R. § 483.25(n) is supported by substantial evidence on the record and is free of legal error.*

On October 7, 2005, CMS published a final rule "to increase immunization rates in Medicare and Medicaid participating long-term care facilities," and thereby prevent the spread of certain infectious diseases. 70 Fed. Reg. 58,834, 58,840. The rule set forth, among other things, facility standards to promote immunization against invasive pneumococcal disease. Pneumococcus is a bacterial pathogen that can cause invasive infections (including bacteremia and meningitis), pneumonia and other lower respiratory tract infections, and upper respiratory infections. P. Ex. 29, at 7-9; 70 Fed. Reg. at 58,836. Pneumococcal disease is particularly prevalent in the elderly

populations and in individuals with certain underlying medical conditions, such as chronic cardiovascular or pulmonary disease and diabetes. P. Ex. 29, at 7-9. At least 500,000 cases of pneumococcal pneumonia are estimated to occur annually in the United States, and 40,000 of those cases result in death. P. Ex. 29, at 8-9. Immunization is performed by administering a pneumococcal polysaccharide vaccine (PPV). P. Ex. 29, at 10-11; 70 Fed. Reg. at 58,837.

The final rule, codified at 42 C.F.R. § 483.25(n), provides:

> (2) *Pneumococcal disease.* The facility must develop policies and procedures that ensure that--
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> (i) Before offering the pneumococcal immunization, each resident or the resident's legal representative receives education regarding the benefits and potential side effects of the immunization;
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> (ii) Each resident is offered a pneumococcal immunization, unless the immunization is medically contraindicated or the resident has already been immunized;
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> (iii) The resident or the resident's legal representative has the opportunity to refuse immunization; and
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> (iv) The resident's medical record includes documentation that indicates, at a minimum, the following:
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> (A) That the resident or resident's legal representative was provided education regarding the benefits and potential side effects of pneumococcal immunization; and
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> (B) That the resident either received the pneumococcal immunization or did not receive the pneumococcal immunization due to medical contraindication or refusal.
>
> (v) *Exception.* As an alternative, based on an assessment and practitioner recommendation, a second pneumococcal immunization may be given after 5 years following the first pneumococcal immunization, unless medically contraindicated or the resident or the resident's legal representative refuses the second immunization.

The effective date of the final rule was October 7, 2005. CMS issued detailed guidance in its State Operations Manual[5] (SOM)

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[5] The relevant SOM appendix is online at www.cms.hhs.gov/

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concerning this provision "effective October 15, 2006." CMS S&C-06-24, September 14, 2006; see also CMS Pub. 100-07 State Operations Provider Certification Transmittal 21, October 20, 2006. Noting that pneumococcal pneumonia "is a common cause of hospitalization and death in older people," the SOM states that due to "the clinically complex conditions of most nursing home residents, it is especially important for the facility to have a program in place for the prevention of disease." SOM App. PP, F334. The immunization regulation "complements [the] existing infection control regulation [42 C.F.R. § 483.65] in the areas of prevention of the development and transmission of disease." Id. Thus, the administration of the PPV "is essential to the health and well-being of long term care residents." SOM App. PP, F334.

The SOM further states that an "effective immunization program involves collaborating with the medical director to develop resident care policies for immunization(s) that reflect current standards of practice . . . ." Id. Those standards include physician-approved policies for immunization orders, identification of each resident's immunization status, and mechanisms for recording and monitoring the administration of the vaccines. Id. If the PPV is not provided, the manual states, records must include "documentation as to why the vaccine was not provided, such as medical contraindications, refusal, or vaccine was already given prior to admission." Id.

The ALJ upheld CMS's determination that Alexandria failed to substantially comply with section 483.25(n) because the evidence established that the facility had no "systematic and comprehensive" policies and procedures in place to ensure that *all* of the regulatory criteria were met between October 15, 2006 and February 22, 2007. ALJ Decision at 8. The ALJ rejected Alexandria's reliance on certain residents' PPV consent forms as evidence that the facility was in compliance with the regulation. The ALJ concluded that this evidence showed only that some residents had signed consent forms, not that Alexandria had the requisite plans and procedures in place to meet *all* of the regulatory requirements. He found "no dispute" that Alexandria had "no set policy or procedures in place for

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(Continued. . .)
manuals/downloads/som107_Appendicestoc.pdf.

PPV." ALJ Decision at 8. Obtaining consents at admission addresses "only one small part" of the requirements. Id.

The ALJ also found that, as a consequence of the facility's noncompliance, nine residents (Residents 3, 6, 7, 10, 11, 12, 13, 17, and 20) were not offered the PPV during the period between October 15, 2006 and the time of the survey, February 22, 2007. Alexandria, the ALJ found, therefore "had no system in place to assess whether any of these residents needed to be vaccinated." Id. at 8.

The ALJ rejected Alexandria's arguments that the facility's resident records evidence compliance by showing that five of the nine residents who had not been offered the PPV did not require vaccination because they had previously received it; that two of the residents were not required to be vaccinated since they were at the facility for less than 30 days; that one resident would not consent to receiving the PPV; and that two residents would not have benefited from the vaccine because they had aspiration pneumonia. "Saying that some of the residents did not really need to be vaccinated," the ALJ wrote, "begs the question of whether [Alexandria] had the required systems in place." ALJ Decision at 10. The ALJ concluded that the facility's contentions were "irrelevant" because during the period at issue, Alexandria "was in no position to make rational determinations about these residents' needs, nor was it able to meet their needs without a system in place in compliance with [the] regulatory requirements . . . ." Id. at 9, 10. We agree.

We conclude that substantial evidence supports the ALJ's finding that Alexandria had not developed or implemented the required policies and procedures. According to surveyor notes and summaries of surveyor interviews in the SOD, Alexandria's Director of Nursing (DON) and Administrator told the surveyor on February 22, 2007 that "there was no policy or procedure in place" implementing the pneumococcal vaccine requirements and that "no pneumococcal vaccines had been given in the facility." CMS Ex. 1, at 22-36; CMS Ex. 19, at 31-32. Further, the DON "acknowledged that consent forms had been sent out to residents' responsible parties and that while some had been returned, others had not." Id. Surveyor interview notes and the SOD also show that the facility's Medical Director "acknowledged he had not participated in the development of policies at the facility specific to the pneumococcal vaccine nor had he written specific orders to offer/administer the vaccine to individual residents."

CMS Ex. 1, at 22-36; CMS Ex. 19, at 28. Moreover, at no time in the course of this appeal has Alexandria produced evidence that prior to the February 2007 survey it had a comprehensive policy and procedures that fully satisfied the criteria of section 483.25(n), nor has it disputed that the DON, Administrator or Medical Director made the statements attributed to them.

Alexandria argues that its efforts at obtaining consents and providing education "*ultimately* would have resulted in administration of the PPV vaccine if the Resident's medical history [revealed] such vaccination was appropriate." P. Br. at 10-11 (emphasis added). The evidence on which Alexandria relies consists of the signed consent forms of eight residents. P. Br. at 10, citing P. Ex. 8, at 3; P. Ex. 12, at 15; CMS Ex. 7, at 9; CMS Ex. 9, at 7; CMS Ex. 10, at 8; CMS Ex. 12, at 8; CMS Ex. 13 at 7; CMS Ex. 14 at 6. The language on the forms indicates that the consent was obtained pursuant to a 2001 North Carolina law requiring immunization of employees and residents in "adult care homes and nursing homes." P. Ex. 8, at 3; P. Ex. 12, at 15; CMS Ex. 7, at 9; CMS Ex. 9, at 7; CMS Ex. 10, at 8. We agree with the ALJ that these forms do not demonstrate that Alexandria had developed and established any comprehensive policies and procedures to ensure that every facility resident was fully educated about the benefits and potential side effects of the PPV or that every resident or legal representative was provided opportunity to consent to, or refuse, the PPV, or that the PPV was actually offered to those residents who consented. Rather, they show only that some facility residents and/or their legal representatives had consented to the administration of the PPV.

Furthermore, even assuming the facts relied on by Alexandria established that it had some policies and procedures, this would not prove compliance. As the ALJ observed, a facility's responsibilities under section 483.25(n) are not limited to establishing and maintaining policies and procedures that ensure that each resident or legal representative is provided an opportunity to consent to, or refuse, the vaccination. The regulation also requires the facility to actually offer the PPV to each resident unless it is medically contraindicated or the resident has already been immunized and to document this information. The record does not establish that the residents for whom consent had been obtained were in fact offered the PPV between October 15, 2006 and February 23, 2007. Neither does it establish that during that time the facility had determined (and documented) that these residents should not receive the

pneumococcal immunization due to medical contraindication or refusal, as required under the regulation. Nor is there evidence showing that the facility had imminent plans, prior to the survey, to provide the vaccine to these residents. In fact, Alexandria did not provide evidence that it ever provided PPV immunizations to any of its residents before the survey. Thus, even if Alexandria had established a policy and procedures to educate all of its residents and obtain their consent, the ALJ could reasonably decline to infer that these measures "would have resulted in administration of the PPV" at some indeterminate future date. Such limited policy and procedures would not have satisfied the requirements and objectives of the rule. Indeed, as the ALJ concluded, obtaining residents' consent to immunization would be pointless if the PPV is not given to each eligible resident "in a timely fashion." ALJ Decision at 10.

We further find curious Alexandria's reliance on the survey finding that it had failed to have a program to offer the PPV to ten out of seventeen sampled residents who were eligible to receive it. P. Br. at 10-11, citing P. Ex. 30, at 21 (SOD). Alexandria infers from this finding that "[seven] residents had been offered and/or received the PPV vaccine, and thus a [PPV] procedure or policy existed at Alexandria . . . ." Id. But Alexandria offers no evidence to show that the facility had in fact offered and administered the vaccine to the seven residents. Indeed, the surveyor interviews found that "no pneumococcal vaccines had been given in the facility." CMS Ex. 1, at 22. In any event, the regulation requires the facility to have policies and procedures in place to ensure that *each* eligible resident is offered and given an opportunity to refuse the PPV, not merely a fraction of the resident population.

We also reject Alexandria's contentions that the ALJ erred in "basing [the] finding of non-compliance on the fact that certain residents had not received the PPV vaccine when those residents had been at the facility less than 30 days or refused to consent to the PPV"; in rejecting as irrelevant evidence that five of the nine residents at issue had received the vaccine either within the past five years or after they had turned 65; and in failing to address the argument that two of the nine residents did not suffer from pneumonia between October 15, 2006 and February 23, 2007, and had not consented to the administration of the PPV. P. Br. at 11-17.

The ALJ's determination that the facility failed to substantially comply with section 483.25(n) was not based on findings that certain residents did not receive the vaccine or findings that particular residents contracted pneumonia because they had not been vaccinated. Rather, he concluded that the facility failed to substantially comply with the regulation because the evidence "clearly demonstrated that there was no systematic and comprehensive policy in place," as required by section 483.25(n). ALJ Decision at 8.

We agree. Alexandria's arguments about the individual residents do not show that the facility was making (and documenting) timely assessments of each resident's eligibility to receive the PPV, nor do they address whether the facility had the necessary policies and procedures in place prior to the February survey to ensure that each of the other PPV regulation requirements were met. Indeed, to support its argument that it was not required to offer the PPV to two residents who were at the facility for less than 30 days, Alexandria cites the facility policy adopted *after the survey* that the PPV "only needs to be administered within the 1st 30 days of the residency after consent is obtained." P. Br. at 11, citing P. Ex. 30, at 38.

In addition to being irrelevant, Alexandria's argument that five of the nine residents had previously received the PPV is not supported by the record. The facility's own immunization records for Residents 3, 6, and 20 show no prior administration of PPV to those residents, and the "minimum data set" assessments of Residents 3, 6, 10, 12 and 20 state that "the resident[s'] PPV status was not up to date" because the PPV had "not been offered" to them. CMS Ex. 6, at 9, 13; CMS Ex. 7, at 10-13, 15; CMS Ex. 10, at 10-12; CMS Ex. 12, at 10-12; CMS Ex. 18, at 7-8.

Further, the facility and survey documents show that *after* the February 2007 survey began, the facility audited its records to determine each resident's eligibility to receive the vaccine, obtained the requisite consent for the eligible residents, and administered PPV to those eligible. CMS Ex. 1, at 37. Seven of the nine residents discussed by the ALJ (Residents 3, 6, 7, 10, 11, 12 and 17) were determined to be eligible, provided consent and were vaccinated. CMS Ex. 6, at 8-10; CMS Ex. 7, at 10, 15, 16; CMS Ex. 10, at 9, 16; CMS Ex. 12, at 13-14; CMS Ex. 24, at 1-2; P. Ex. 6, at 57; P. Ex. 9, at 5-7. Of the remaining two, one (Resident 13) had been discharged prior to the survey, and

the other (Resident 20) had died before the survey. CMS Ex. 13, at 1-8. CMS Ex. 18, at 3, 25.)

Accordingly, we uphold the ALJ's determination that Alexandria failed to comply substantially with the requirements of section 483.25(n).

3. The ALJ's determination that Alexandria failed to comply substantially with 42 C.F.R. § 483.75(o)[6] is supported by substantial evidence and free of legal error.

Section 483.75 of the regulations sets forth the administration requirements for long term care facilities. The regulation provides that -

> A facility must be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.

The quality assessment and assurance (QAA) requirement at subsection 483.75(o) provides in part--

> (1) A facility must maintain a quality assessment and assurance committee consisting of--
>
> (i) The director of nursing services;
>
> (ii) A physician designated by the facility; and
>
> (iii) At least 3 other members of the facility's staff.
>
> (2) The quality assessment and assurance committee--
>
> (i) Meets at least quarterly to identify issues with respect to which quality assessment and assurance activities are necessary; and
>
> (ii) Develops and implements appropriate plans of action to correct identified quality deficiencies.

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[6] FFCL B.1.c. of the ALJ Decision states: "Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.75(o)(1)." ALJ Decision at 11. As reflected in the ALJ's discussion of the deficiency, however, Alexandria's noncompliance additionally involves subsection 483.75(o)(2) of the regulation. Thus we modify the FFCL to correct the technical error.

CMS defines "quality assessment" to mean "an evaluation of a process and/or outcomes of a process to determine if a defined standard of quality is being achieved." SOM App. PP, F520. "Quality assurance" is defined as "the organizational structure, processes, and procedures designed to ensure that care practices are consistently applied and the facility meets or exceeds an expected standard of quality." Id. The term "quality deficiency" in section 483.75(o) "is meant to describe a deficit or an area for improvement," and it "is not synonymous with a deficiency cited by surveyors." Id. The SOM states that the purpose of QAA "is continuous evaluation of facility systems." Id. Each facility's QAA committee is to discern "issues and concerns . . . with facility systems," to correct "inappropriate care processes," and to develop a plan of action to correct problems and monitor the corrections' effectiveness. Id.

The ALJ upheld CMS's determination that Alexandria failed to substantially comply with section 483.75(o) because Alexandria's QAA committee had failed to develop and implement plans to address the need to administer the PPV to residents. The SOD pointed specifically to Alexandria's "failure to identify a need to offer vaccination to four residents" who, according to the SOD, had been treated for pneumonia between October 15, 2006 and the time of the survey. The ALJ rejected Alexandria's argument that the noncompliance determination should be reversed because it asserted that none of the four residents cited in the SOD needed to be vaccinated or would have benefited from the PPV. These contentions, the ALJ determined, did "not address the question of whether [Alexandria's QAA] committee was doing what it was required to do." ALJ Decision at 11.

Alexandria argues before us that the ALJ's finding should be reversed since the facility "had in place policies and procedures for obtaining consent for administration of PPV." P. Br. at 17. To support this argument, Alexandria cites its contentions made in opposition to the deficiency involving section 483.25(n) of the regulations. Alexandria also repeats the argument it made before the ALJ that the noncompliance determination should be reversed since the four residents identified in the SOD had not needed, or would not have benefited from, the PPV.

We have already rejected the contention that Alexandria had developed and implemented the required PPV policies and procedures. We also agree with the ALJ that arguments that the

four identified residents either had not actually contracted pneumococcal pneumonia or did not need the PPV vaccine due to earlier vaccination miss the point.

We conclude that substantial evidence on the record supports the ALJ's determination that Alexandria's quality assurance committee was not doing what was required of it under section 483.75(o), e.g., to review facility records and information, identify potential and actual quality deficiencies, and develop corrective action plans. Multiple facility records, including Alexandria's infection control log, reflect that the four residents had been treated or monitored for pneumonia during the relevant period. See, e.g., CMS Ex. 1, at 21, 23, 25, 34; P. Exs. 3, at 15, 19, 26, and 5, at 15. Other medical records indicated that these residents had not received or been offered the PPV. CMS Ex. 6, at 9, 14; CMS Ex. 10, at 10-12; CMS Ex. 15, at 31, 42, 77, 85; CMS Ex. 18, at 8. Furthermore, a "Monthly Resident Infection Analysis" form dated December 8, 2006 and signed by Alexandria's Medical Director and DON, stated that "[r]espiratory infections have increased." CMS Ex. 1, at 87-89. This evidence should have alerted the facility QAA committee to a more widespread problem needing its attention.

The DON acknowledged to the surveyor that, despite this well-documented problem with respiratory illnesses, the facility had no PPV policy or procedures in place, although "the topic had been discussed with the facility Medical Director in Utilization Review." CMS Ex. 1, at 87-89, 91-92, 94. The Medical Director also "acknowledged he had not participated in the development of policies at the facility specific to the pneumococcal vaccine nor had he written specific orders to offer/administer the vaccine to individual residents." Id. Thus, substantial evidence on the record shows that Alexandria's QAA committee did not respond to a quality deficiency and did not develop a plan of action to correct the problem.

Accordingly, we uphold the ALJ's determination that Alexandria failed to substantially comply with the requirements of section 483.75(o).

4. *The ALJ did not err in concluding Alexandria had not shown that CMS's immediate jeopardy determination was clearly erroneous.*

Alexandria argues that even if the Board concludes that the facility failed to substantially comply with the regulations addressed in the ALJ Decision, "the ALJ erred in finding that the deficiencies [rose] to the level of immediate jeopardy." P. Br. at 26. Alexandria contends that, as reflected in its arguments responding to each alleged deficiency,

> . . . no resident was facing or suffering from immediate jeopardy to his or her health or safety based on the alleged deficiencies given the actions that were being taken by Alexandria Place to care for and assess the Residents and the documentation in the medical records of the Residents who are referenced in the survey.

Id.

A CMS determination of immediate jeopardy - that a facility's noncompliance caused or was likely to cause "serious injury, harm, impairment, or death to a resident" - must be upheld on review unless the facility shows the determination to have been "clearly erroneous." 42 C.F.R. §§ 488.301, 498.60(c)(2). As numerous Board decisions have explained, the facility therefore has a "heavy burden" to meet in challenging an immediate jeopardy. Magnolia Estates Skilled Care, DAB No. 2228, at 23 (2009) and authorities cited therein.

The ALJ found that Alexandria did not carry its burden of proof with respect to any of the three deficiencies he addressed, and we agree. With respect to the quality of care deficiency, the medical literature and other evidence on professional standards of care for PICC lines, along with Resident 19's records discussed above amply support the ALJ's conclusion that failing to change Resident 19's dressing for more than three weeks "created a high probability" of PICC line infection. ALJ Decision at 12. The facility provided no evidence showing that CMS's determination that the noncompliance under section 483.25 posed immediate jeopardy was clearly erroneous. Further, Alexandria's claim that its care for, and assessment of, the resident mitigated the potential harm posed by the noncompliance has no merit. It was the very inadequacies of Alexandria's care and assessments of Resident 19 that created the likelihood of serious harm. Further, the staff's apparent failure to understand, verify, and implement physician orders and follow professional care standards in handling this resident's dressing

indicates that any resident coming to the facility with a PICC line was likely to be at risk too.

Likewise, we concur in the ALJ's finding that there was "a high probability of harm to residents" posed by Alexandria's noncompliance with sections 483.25(n) and 483.75(o) of the regulations. As reflected in the preamble to the pneumococcal immunization rule, nursing facility residents are "at high risk of contracting invasive pneumococcal disease, with a high risk of resultant complications, hospitalizations, and deaths." 70 Fed. Reg. 58,836; see also SOM App. PP, F334. Alexandria's failure to develop a comprehensive immunization policy and to implement systematic procedures to carry out that policy was thus likely to result in serious harm to facility residents. In turn, the failure of Alexandria's QAA committee to identify and address the facility's failure to have a comprehensive policy and systematic procedures for the administration of pneumococcal immunization allowed the situation to continue unaddressed, increasing the likelihood that facility residents would contract preventable, serious illnesses and death. Alexandria has not presented any persuasive evidence that its actions made serious harm unlikely.

Accordingly, we sustain the ALJ's determination that CMS's determinations of immediate jeopardy were not clearly erroneous.

5. *The ALJ did not err in upholding the duration of remedies imposed by CMS.*

Section 488.454(a)(1) provides that once a facility has been found out of compliance, remedies continue until --

> The facility has achieved substantial compliance, as determined by CMS or the State based upon a revisit or after an examination of credible written evidence that it can verify without an on-site visit; or . . . CMS or the State terminates the provider agreement.

42 C.F.R. § 488.454(a); see also 42 C.F.R. § 488.440 (providing that a per day CMP accrues until the facility achieves substantial compliance or the provider agreement is terminated). The Board has held that the facility "has the burden of proving that it achieved substantial compliance on a date earlier than that determined by CMS." Sunbridge Care and Rehabilitation for Pembroke, DAB No. 2170 at 36 (2008).

The ALJ upheld CMS's determination that the facility's noncompliance began on October 15, 2006 at the immediate jeopardy level and that Alexandria's noncompliance continued at a severity level less than immediate jeopardy from February 22, 2007 through March 25, 2007.

Regarding the starting date, the SOD states that Alexandria's noncompliance with section 483.25(n) posed immediate jeopardy beginning October 15, 2006, "when this regulation went into effect."[7] CMS Ex. 1, at 20. The SOD is less explicit on how the starting dates of the other two deficiencies at issue were determined. However, the deficiency under section 483.75(o) arises from the QAA committee's failure to identify the problems causing noncompliance with section 483.25(n). Alexandria has not offered any reason to think the starting date for that deficiency was any different from that for the noncompliance in section 483.25(n).

Alexandria does argue with respect to the finding of noncompliance under section 483.25 that immediate jeopardy could not begin before one week after Resident 19's readmission with the PICC in place (December 29, 2006) when any dressing change would be called for by the discharge instructions. P. Br. at 9. Alexandria asserts that no resident other than Resident 19 had a PICC line. The ALJ did not make an express finding as to when Alexandria's noncompliance with section 483.25 began, but resolving this issue could not make any difference because the immediate jeopardy was present from October 15, 2005 based on the other noncompliance and the amount of the CMP was the minimum possible for immediate jeopardy.[8]

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[7] As noted above, the effective date of the final rule was October 7, 2005, while CMS issued detailed guidance in the SOM concerning this provision effective October 15, 2006. Presumably, the surveyors were referring to the latter effective date.

[8] Alexandria suggests in the alternative that the Board should adopt the per-instance penalty of $2,000 that the State agency had recommended for this deficiency instead of the per-day CMP proposed by CMS. Id. CMS's decision to impose a per-day CMP, as opposed to another type of remedy, such as a per-instance CMP, is a choice committed to CMS's discretion by the

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As to the ends of the CMP periods, Alexandria has presented no evidence showing that it abated the immediate jeopardy posed by its noncompliance with sections 483.25(n) or 483.75(o) any earlier than February 22, 2007, nor has it provided evidence showing that it took corrective action sufficient to achieve substantial compliance with the participation requirements any earlier than March 26, 2007. Based on a revisit survey of the facility conducted on April 12, 2007, CMS determined that Alexandria had come into substantial compliance with all program participation requirements only as of March 26, 2007. CMS Ex. 8, at 8. Alexandria asserts that it did take some corrective actions even before the surveyors arrived but does not establish that these measures sufficed to abate the immediate jeopardy or achieve substantial compliance prior to the dates upheld by the ALJ.

We therefore find no reason to disturb the ALJ's determinations on the duration of the CMPs.

6. The ALJ did not err in finding that the amounts of the CMPs imposed were reasonable.

As noted, the factors that CMS may consider in determining the amount of a CMP are established by regulation. 42 C.F.R. §§ 488.438(f), 488.404. These factors are the facility's history of noncompliance (including repeated deficiencies), its financial condition, its degree of culpability for the cited deficiencies, the seriousness of the noncompliance, and the relationship of one deficiency to the other deficiencies resulting in noncompliance. Id. "The absence of culpability," however, "is not a mitigating circumstance in reducing the

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regulations and is not subject to review. Kenton Healthcare, LLC, DAB No. 2186, at 28 (2008); 42 C.F.R. §§ 488.408 (listing per-day and per-instance CMPs as separate and distinct remedies from among which CMS may choose); 488.408(g)(2) (a facility may not appeal the choice of remedy, including the factors considered by CMS or the State in selecting the remedy); 498.3(d)(11) (the choice of remedy to be imposed on a provider is not subject to appeal); see also 42 C.F.R. § 488.438(e)(2) (where a basis for imposing a CMP exists, the ALJ cannot review CMS's exercise of discretion to impose a CMP).

amount of the penalty." 42 C.F.R. § 488.438(f)(4). As also noted, CMS's choice of remedy is not subject to appeal, but the facility may contend that the amount of a CMP imposed by CMS is unreasonable based on the factors specified in the regulations. 42 C.F.R. §§ 488.438(f), 488.404. An ALJ may not consider any factors other than those specified by regulation in reviewing the penalty amount. 42 C.F.R. § 488.438(f); 42 C.F.R. § 488.438(e)(3).

Alexandria argues that the CMPs imposed by CMS were both "unreasonable and unconstitutional." P. Br. at 25. Alexandria contends that "the ALJ arbitrarily ignored" the State agency's recommended per-instance penalties of $2,000 each for the deficiencies involving sections 483.25 and 483.75(o), and $4,000 for the deficiency involving section 483.25(n). P. Br. at 25-26. Alexandria asserts that the total of over $400,000 in per-day CMPs imposed by CMS is "improper, disproportionate, and not justified." P. Br. at 26.[9]

The State agency's March 9, 2007 notice to Alexandria made clear that the State agency was only "recommending" the per-instance penalties. CMS Ex. 28 at 2. CMS was not required to adopt the State agency's recommendation. Rather, as discussed above, the decision to impose a remedy for noncompliance and the choice of remedy are matters committed to CMS's discretion and are not subject to review by the ALJ or the Board. 42 C.F.R. §§ 488.408, 488.408(g)(2); 498.3(d)(11); see also 42 C.F.R. § 488.438(e)(2).

Alexandria next contends that the penalties imposed by CMS were

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[9] Alexandria repeats here its claim that any noncompliance did not rise to the level of immediate jeopardy but we have already rejected this and do not address it again. Alexandria also objects to the ALJ's failure to consider the other deficiencies addressed in the SOD. P. Br. at 18. The Board has held that an ALJ has discretion, as an exercise of judicial economy, not to address findings that are immaterial to the outcome of an appeal. Magnolia at 30; Grace Healthcare of Benton, DAB No. 2189, at 5 (2008); Western Care Management Corp. d/b/a Rehab Specialties, DAB No. 1921, at 19 (2004)). In this case, the additional deficiency citations were not material to the outcome of the case since, as discussed below, the deficiencies addressed suffice to support the CMPs.

excessive based on the factors set forth in section 488.438. Alexandria asserts that (1) in the past seven years, the only immediate jeopardy citations it has received have been those at issue in this case; (2) the PPV immunization requirements were new; (3) the facility "responded to the immediate jeopardy allegations as soon as they were identified;" and (4) the facility was not accused here of any deliberate disregard of federal law or of abuse or neglect of the residents. P. Br. at 27. Alexandria contends that the facility is locally owned and operated, that the penalty will pose significant hardship, and that, given current economic conditions, it will not be able to obtain a loan to pay the penalty and stay in business. We reject all of these contentions.

As to the immediate jeopardy CMP, $3,050 per day was the *minimum* amount that CMS was permitted to impose under section 488.438(a)(1). As such, the per-day amount is reasonable *as a matter of law*, regardless of Alexandria's history of noncompliance, financial condition and other factors. Final Rule, Medicare and Medicaid Programs; Survey, Certification and Enforcement of Skilled Nursing Facilities and Nursing Facilities, 59 Fed. Reg. 56,116, 56206 ("[W]hen the administrative law judge or State hearing officer (or higher administrative review authority) finds noncompliance supporting the imposition of the civil money penalty, he or she must remedy it with some amount of penalty consistent with the ranges of penalty amounts established in section 488.438."); Sheridan Health Care Center, DAB No. 2178, at 44 (2008).

Alexandria's arguments do not undercut the ALJ's finding that the $150 per-day CMP was reasonable for the facility's ongoing noncompliance. As the ALJ observed, the penalty amount of $150 per day is at the low end of the penalty range -- only five percent of the maximum amount allowed by regulation. ALJ Decision at 14. Furthermore, substantial evidence supports the ALJ's conclusion that the seriousness of these deficiencies justified the $150 per-day amount. The evidence discussed above about vulnerability of the long-term care facility population to preventable pneumococcal pneumonia and other respiratory illnesses, together with the evidence of the facility's QAA committee's failure to take action, supports the ALJ's conclusion that the ongoing noncompliance posed "a significant risk" to all of Alexandria's residents until all corrective actions were implemented and substantial compliance was achieved.

Furthermore, we find no error in the ALJ's rejection of Alexandria's arguments on their merits. The only evidence that Alexandria cites with respect to its history of noncompliance is the declaration of a facility manager, who states that in "the past seven years the highest deficiency received was two 'G' level deficiencies in 2005." P. Ex. 31 at 2, ¶ 9. If anything, two prior G level deficiencies - showing actual harm that is not immediate jeopardy -- provide some support for a CMP greater than the minimum amount. The PPV final rule was, as noted, published and effective October 7, 2005, so Alexandria had ample time to come into compliance. Alexandria does not explain why the absence of findings of "deliberate disregard for the federal statutes and regulations," or a citation "for abuse and neglect" is relevant. P. Br. at 28. If they are meant to suggest the absence of culpability, the regulation makes clear that this may not be used as a mitigating circumstance to reduce the amount of a CMP. 42 C.F.R. § 488.438(f)(4).

We also find no error in the ALJ's evaluation of Alexandria's claim of financial hardship. Alexandria cites the declaration of a facility manager, who states:

> Alexandria Place is not part of a national chain and its profits cannot cover such a large penalty. . . . Taking this amount of money away from the facility impacts the benefits to be provided to the nursing home residents. $400,000 is roughly equivalent to 8.5 nurses' salary for a year or 21 CNAs. The penalty administered is nothing more than an unwarranted punishment that in no way enhances the residents' quality of care.

P. Ex. 31, at 9-10, ¶ 30. The ALJ could reasonably decline to give weight to general assertions in the declaration that do not document that the financial condition of the facility renders it unable to pay the penalty. Moreover, more than 90 percent of the total penalty amount is generated by the $3,050 per-day amount (which we have already noted cannot legally be reduced), and by the determination of the duration of the immediate jeopardy (which we have upheld).

Finally, Alexandria argues that the total amount of the penalties assessed in this case violates the Eighth Amendment's

prohibition against excessive fines.[10] Alexandria argues that it "is grossly disproportionate to the gravity of the alleged offense." P. Br. at 28. Alexandria relies on Hudson v. United States, 522 U.S. 93, 109 (1997), in which the Supreme Court stated in dicta that the Eighth Amendment protects against excessive civil fines, and United States v. Bajakajian, 524 U.S. 321, 333 (1998), in which the Court held that a criminal fine could violate the Eighth Amendment, if it was "grossly disproportionate to the gravity of the offense." P. Br. at 28. Alexandria further alleges that facilities in CMS Region IV have been assessed disproportionately high penalties.[11]

As explained above, the governing regulations do not permit the ALJ or the Board to change the per-day amount of a CMP where it is at the minimum amount, as the CMP for the immediate jeopardy period was here. We have also upheld the ALJ's determination that the penalty amount imposed for the remaining period of noncompliance was reasonable. Thus, we find Alexandria's contention that the penalties imposed in this case violate the Eighth Amendment or are otherwise excessive factually wrong.[12]

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[10] The Excessive Fines Clause of the Eighth Amendment states: "Excessive bail shall not be required, nor excessive fines imposed, nor cruel and unusual punishments inflicted." U.S. Const. amend. VIII.

[11] Alexandria references a March 28, 2008 letter from the American Health Care Association to CMS, a copy of which is attached to the request for review, to explain its allegation. We are faced here with determining whether CMS is authorized under law to impose the penalties at issue, not with reviewing the performance of particular regional offices. Given our conclusions that CMS had a basis here to impose remedies for the periods in question and that the per-day amounts were either legally compelled or reasonable in fact, we see no relevance to the AHCA letter in this proceeding.

[12] Furthermore, having determined that the ALJ appropriately reviewed a CMP under the governing regulatory factors, the Board does not have the authority suggested by Alexandria to set aside the limitations on its own review authority and reduce the amount. Sentinel Medical Laboratories, Inc., DAB No. 1762, at 9 (2001)(finding it "well established that administrative forums, such as this Board and the

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We also find no merit in Alexandria's argument that the CMPs imposed in this case are unreasonable compared to the CMPs assessed in other Board cases. The total amount of the CMPs is largely a function of the 130 days in which Alexandria's noncompliance presented an immediate jeopardy to its residents. As discussed, the decision to impose a per-day CMP was a choice committed to CMS's discretion by the regulations, and the per-day amount was at the legal minimum. The total amount of penalties in other cases in which a minimum per-day immediate jeopardy CMP was imposed will depend on the duration of the immediate jeopardy.

As to the non-immediate jeopardy amount, as noted, the regulations give CMS considerable discretion in the amount of a CMP it is permitted to impose based on the regulatory factors in a given case. It would be almost impossible to make any true comparisons of different cases since the underlying facts of noncompliance vary considerably, as do the other factors. Alexandria provided no factual basis for its claim that the $150 per-day amount was somehow excessive compared with other

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Department's ALJs, do not have the authority to ignore unambiguous statutes or regulations on the basis that they are unconstitutional"), aff'd sub nom., Teitelbaum v. Health Care Financing Admin., No. 01-70236 (9th Cir. Mar. 15, 2002), reh'g denied, No. 01-70236 (9th Cir. May 22, 2002). In any event, the constitutional concerns raised by Alexandria would not apply to civil penalties that are remedial in nature. See Austin v. United States, 509 U.S. 602, 610 (1993); Korangy v. U.S.F.D.A., 498 F.3d, 272, 277 (4th Cir. 2007)(Civil fines serving remedial purposes do not fall within the reach of the Eighth Amendment. . . If the civil penalty is punitive and thus subject to the Eighth Amendment, it will be found constitutionally excessive only if it is "grossly disproportional . . ."). Nursing home enforcement CMPs are clearly remedial in nature, since their purpose "is to ensure prompt compliance with program requirements." 42 C.F.R. § 488.402(a); see also Kenton at 32; Sunbridge at 37-38; Regency Gardens Nursing Center, DAB No. 1858, at 11 (2002)(purpose of CMP "is not to punish individual violations but to pursue attainment and maintenance of a state of substantial compliance with federal requirements.").

similarly-situated facilities. In any case, the assertion is not relevant to the issue before us which is whether the amount is reasonable in light of the regulatory factors in this case. We have determined that it is.

Accordingly, we affirm the ALJ's conclusion that CMS's determination to impose CMPs of $3,050 per day during the period of Alexandria's immediate jeopardy level noncompliance is reasonable as a matter of law. We further sustain the ALJ's determination that CMPs of $150 per day for the period of Alexandria's non-immediate jeopardy level noncompliance are reasonable.

Conclusion

For the reasons set out above, we sustain the ALJ Decision. We affirm and adopt each of the findings of fact and conclusions of law set forth therein, except FFCL B.1.c., which we modify to read:

> Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.75(o).

/s/
Judith A. Ballard

/s/
Sheila Ann Hegy

/s/
Leslie A. Sussan
Presiding Board Member