Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

In the Case of:	DATE: December 16, 2008
Ocean Springs Nursing Center,	
Petitioner,	Civil Remedies CR1778 App. Div. Docket No. A–08-109
- v. -	Decision No. 2212
Centers for Medicare & Medicaid Services.	

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Ocean Springs Nursing Center (Ocean Springs), a skilled nursing facility located in Ocean Springs, Mississippi, requested review of the decision of Administrative Law Judge (ALJ) Steven T. Kessel in Ocean Springs Nursing Center, DAB CR1778 (2008) (ALJ Decision). The ALJ sustained the determination of the Centers for Medicare & Medicaid Services (CMS) imposing a civil money penalty (CMP) of $7,500 against Ocean Springs. The ALJ found that Ocean Springs failed to comply substantially with the requirement at 42 C.F.R. § 483.25(m)(2), which states that facilities "must ensure that . . . [r]esidents are free of any significant medication errors." The ALJ also determined that the CMP of $7,500 imposed by CMS was reasonable.

As a preliminary procedural matter and for the reasons discussed below, we decline to admit into the record a witness statement proffered by Ocean Springs on appeal. On the merits, we affirm the ALJ Decision. While we conclude that the ALJ used an incorrect legal standard to determine whether Ocean Springs

substantially complied with section 483.25(m)(2), we also conclude that this error does not require remand or reversal. Applying the correct legal standard to the undisputed facts, we sustain the determination that Ocean Springs failed to substantially comply with 42 C.F.R. § 483.25(m)(2). Finally, we affirm the ALJ's finding that the CMP of $7,500 was reasonable.

Applicable law

The regulatory requirements for long-term care facilities that participate in the Medicare and Medicaid programs are set forth at 42 C.F.R. Part 483. Among the requirements, 42 C.F.R. § 483.25(m) provides:

> *Medication Errors*. The facility must ensure that–
> (1) It is free of medication error rates of five percent or greater; and
> (2) Residents are free of any significant medication errors.

Facility compliance with the participation requirements is determined through a survey and certification process. Sections 1819 and 1919 of the Social Security Act; 42 C.F.R. Parts 483, 488, and 498.[1]

Section 488.301 of the regulations defines terms used in the facility survey and certification regulations. "Deficiency" is defined as a facility's "failure to meet a participation requirement specified in the Act or [42 C.F.R. Part 483]." 42 C.F.R. § 488.301. The term "substantial compliance means 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. The regulation defines "noncompliance" as "any deficiency that causes a facility to not be in substantial compliance." Id. "Immediate jeopardy" is defined as "a situation in which the provider's noncompliance . . . has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." Id.

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

CMS enforces the participation requirements, in part, by imposing remedies on facilities that are not in substantial compliance. See 42 C.F.R. Part 488, subpart F. CMS selects the appropriate remedy, if any, based on the "seriousness of the deficiencies." 42 C.F.R. § 488.404(a). Where noncompliance poses immediate jeopardy to resident health or safety, CMS may impose a per instance CMP in the range of $1,000 to $10,000. 42 C.F.R. § 488.438(a)(2). The criteria for determining the amount within that range include the seriousness of the noncompliance, the facility's history of noncompliance, the facility's degree of culpability, and the facility's financial condition. 42 C.F.R. §§ 488.404, 488.438(f).

Standard of review

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

Background

The following undisputed facts are drawn from the ALJ Decision and the record below.

Based on a complaint survey completed by the Mississippi Department of Health (State agency) on April 20, 2007, the State agency determined that Ocean Springs had past noncompliance with the requirement at 42 C.F.R. § 483.25(m)(2) that posed immediate jeopardy. On March 20, 2007, a Licensed Practical Nurse (LPN 1) was working as a substitute on the South Hall of the Ocean Springs facility administering medications. ALJ Decision at 3; CMS Ex. 5, at 4; Ocean Springs Prehearing Br. at unnumbered page (unnumbered) 2. A resident in a wheelchair (Resident 1) passed by LPN 1 in the hallway. CMS Ex. 1, at 2-3; Ocean Springs Ex. 2; Ocean Springs Ex. 11 ¶ 3. LPN 1, believing Resident 1 to be Resident 2, greeted Resident 1 using Resident 2's name and summoned the resident to the medication cart. Ocean Springs Ex. 11 ¶ 3. Resident 1 responded by saying, "good morning," and going to the medication cart. Id. LPN 1 then administered to Resident 1 multiple medications to treat hypertension that had been ordered for Resident 2. CMS Ex. 1, at 2-3; CMS Ex. 12; Ocean Springs Ex. 2. As a consequence of the medication errors, Resident 1 required hospitalization for profound hypotension,

which the hospital treated with intravenous anti-hypotensive medications.

CMS issued a determination to impose a per instance CMP of $7,500 for Ocean Springs' noncompliance based on the State agency survey findings and section 483.25(m)(2) of the regulations. Ocean Springs appealed the CMS determination. In the proceedings below, the parties filed cross-motions for summary disposition. The ALJ subsequently decided the case on the parties' written submissions and the admitted evidence after the parties indicated that they would be willing to forego an in-person hearing.

Analysis

1. New Evidence

Under the regulations governing Board review of ALJ decisions, the Board may admit evidence into the record in addition to that introduced at the ALJ hearing if the Board considers the additional evidence relevant and material to an issue before it. 42 C.F.R. § 498.86. In deciding whether to admit additional evidence, the Board considers whether the proponent of the new evidence has shown good cause for not producing it during the ALJ proceeding. See Guidelines.

Ocean Springs asks the Board to admit into the record a two-page, signed statement by LPN 1, which Ocean Springs submitted with its Reply Brief. Ocean Springs states that this evidence is "to address the issue of [LPN 1's] familiarity with residents and the requirements of the job." Ocean Springs Reply at unnumbered 3, n.2. Ocean Springs contends that it did not present the evidence below since LPN 1's "competency to pass medications was never made an issue by CMS." Id. However, Ocean Springs submits, the ALJ Decision "is predicated entirely upon the fact that [LPN 1] posed an 'extreme risk' to residents . . . due to her lack of familiarity with the residents she served on the unit and the job requirements for medication passes." Id. Ocean Springs asks the Board to admit the evidence "in order to rectify [Ocean Springs'] deprivation of due process and a patently false conclusion by the ALJ about [LPN 1's] competency and familiarity with residents." Id.

CMS opposes the admission of the evidence, arguing that it is neither relevant nor material to an issue before the Board and that Ocean Springs failed to show it had good cause for not producing the evidence below. CMS argues that Ocean Springs itself attempted to make LPN 1's competence an issue in this case and that, consequently, its claim of surprise is incorrect. CMS

further contends that the question whether LPN 1 was sufficiently experienced and qualified to pass medications is not legally relevant. The only relevant issues in this matter, CMS argues, are: 1) "did [Ocean Springs'] staff give Resident 1 the wrong medications[;]" and 2) "if so, was this significant?" CMS Opposition to New Evidence at 5. CMS also argues that the ALJ's explanation as to why the medication error occurred is dicta since it is "not necessary to his holding." Id.

Ocean Springs has not shown good cause for not introducing the statement during the ALJ proceedings. Throughout those proceedings, Ocean Springs argued (as it does now) that it substantially complied with 42 C.F.R. § 483.25(m)(2) because LPN 1 acted reasonably under the circumstances, and that she followed accepted nursing practices, consistent with facility policy, when she mistakenly administered medications ordered for Resident 2 to Resident 1. See, e.g., Ocean Springs Pre-Hearing Br. at unnumbered 7-9; Ocean Springs Motion for Summary Disposition ¶¶ 9-10. To support this argument, Ocean Springs submitted, among other things, evidence to show that LPN 1 was an experienced, competent and "exemplary employee," and that she was familiar with both Resident 1 and Resident 2. Ocean Springs Pre-Hearing Br. at unnumbered 1-2; Ocean Springs Exs. 1, 9 ¶ 2, 11 ¶ 2. This evidence includes two sworn declarations by LPN 1, which in part address her competence and work at Ocean Springs ("in various capacities for over fourteen years[;] [c]urrently [as] a charge nurse in the facility") and the bases of her familiarity with Residents 1 and 2. Ocean Springs Exs. 11 ¶ 1, 12 ¶ 1. We also note that CMS submitted evidence, discussed in the ALJ Decision and cited in Ocean Springs' own prehearing brief, showing that LPN 1 was working as a substitute in administering medications on the South Hall on March 20, 2007, and that LPN 1 acknowledged confusing the identities of Residents 1 and 2. ALJ Decision at 3, citing CMS Ex. 1, at 2; CMS Ex. 5, at 4; Ocean Springs Prehearing Br. at unnumbered 2. Thus, Ocean Springs' argument on appeal that it was unaware that the ALJ might address the nurse's competence to pass medications or her familiarity with the residents is belied by the record.

In any event, admission of the additional evidence would not alter the outcome of our decision. As we explain in detail below, we conclude that the ALJ did not apply the correct legal standard for determining whether Ocean Springs substantially complied with 42 C.F.R. § 483.25(m)(2). Under the correct standard, it is unnecessary to resolve whether the nurse who made the medication error was sufficiently trained and experienced to administer medications, or whether she was so familiar with the residents that she was not required to have taken further steps

to verify the identity of the resident to whom she administered medications on March 20, 2007.

Accordingly, we decline to admit the proffered statement into the record because Ocean Springs has not shown good cause why it did not submit this evidence below and since the statement addresses issues that are immaterial to the outcome of this case.

2. Ocean Springs failed to comply substantially with 42 C.F.R. § 483.25(m)(2).

As set forth above, 42 C.F.R. § 483.25(m)(2) states that a "facility must ensure that . . . [r]esidents are free of any significant medication errors." The ALJ interpreted section 483.25(m)(2) to "impose[] a burden on a facility to take all reasonable measures to ensure that residents are not victims of medication errors." ALJ Decision at 3. Applying this standard, the ALJ concluded that "the actions of the nurse who mis-administered medications to Resident #1 clearly were not reasonable," and that "[t]here was obvious negligence here." Id. at 3-4. The ALJ further rejected Ocean Springs' argument that CMS had imposed strict liability because "receipt of a single dose of the wrong medication by a resident cannot be the basis for finding a violation." Id. at 3, quoting Ocean Springs Motion for Summary Disposition at ¶ 8. The ALJ stated, "that the negligence constituted a single event does nothing to diminish its significance." ALJ Decision at 4.

On appeal, Ocean Springs acknowledges that "[t]he use of the word 'ensure' in the regulation suggests [that] the occurrence of any significant medication error in a nursing home constitutes a violation of the regulation[.]" Ocean Springs Br. at unnumbered 4. However, Ocean Springs contends, finding it noncompliant with section 483.25(m)(2) holds the facility to a strict liability standard, which contravenes prior Departmental Appeals Board and federal court decisions. Those decisions, Ocean Springs argues, "make clear that a single significant misadministration of a medication, or the occurrence of any other event proscribed by one of the sections of 42 C.F.R. § 483.25 do not, of themselves, establish a violation of the regulation." Id., citing Tri-County Extended Care Center, DAB No. 1936, at 7 (2004), aff'd, Tri-County Extended Care Ctr. v. Leavitt, No. 04-4199 (6th Cir. Dec. 14, 2005); Aase Haugen Homes, Inc., DAB No. 2013 (2006); Crestview Parke Care Ctr. v. Thompson, 373 F.3d 743 (6th Cir.

2004).[2] Rather, Ocean Springs submits, a "[p]etitioner's burden is to prove that its staff acted reasonably in trying to achieve the outcomes described in the regulation," notwithstanding any actual adverse consequences. Reply at unnumbered 2, citing Woodstock Care Center, DAB No. 1726 (2000), aff'd, Woodstock Care Ctr. v. U.S. Dep't of Health and Human Servs., 363 F.3d 583 (6th Cir. 2003). Ocean Springs also cites the recent Court of Appeals decision in Emerald Shores Health Care Associates v. HHS, 545 F.3d 1292 (11th Cir. 2008), rev'g Emerald Shores Health and Rehabilitation Center, DAB No. 2072 (2007), to support its argument.

We conclude that the ALJ erred in construing, and Ocean Springs misunderstands, the legal standard established under section 483.25(m)(2) of the regulations. The regulation itself plainly states that a facility "must ensure" freedom from "significant medication errors." Construing this language, the Board has previously held that it is unnecessary to find that a facility "engaged in improper acts or failed to act prudently or that there was a pattern of medication errors . . . in order to conclude that [the facility] failed to substantially comply with section 483.25(m)(2)." Franklin Care Center, DAB No. 1900, at 8 (2003). The Board observed that the *Federal Register* preamble to the final regulation makes clear that compliance with section 483.25(m)(2) "turns solely on whether [the facility] made a medication error or errors that were 'significant' and that a single medication error can be 'significant.'" Id. The preamble provides:

> Since medication errors vary in their significance (e.g., from significant errors such as a double dose of a potent cardiac drug like digoxin to a small error in the dose of an antacid like milk of magnesia), we have based

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2. Ocean Springs also cites the ALJ Decisions in Northeastern Ohio Alzheimer's Research Center, DAB CR1092 (2003), and Living Center West, DAB CR988 (2002), to support its contentions. The Board is not bound to follow ALJ decisions. Further, Northeastern involved section 483.25(h)(2), which, as we discuss below, involves a different legal standard than section 483.25(m)(2), and Living Center West is inapposite because it involved missed doses of medications, not medications administered to the wrong resident. Furthermore, it predates Franklin Care Center, in which the Board clearly held that compliance with section 483.25(m)(2) turns exclusively on whether the facility made a "significant" medication error.

> sanctions on two different criteria. First, **if a facility has a significant medication error, then it is sanctioned**. This policy satisfies consumers, who maintain that a five percent tolerance in medication errors is too lenient and that **one medication error could be disastrous for a resident**. Second, a facility is sanctioned if it has an error rate of five percent or greater. This satisfies providers who maintain that there must be some tolerance of errors because all systems have some errors. . . .

56 Fed. Reg. 48,826, at 48,853 (1991)(emphasis added). Accordingly, the Board concluded in Franklin Care Center, a facility will be found noncompliant "if there is **either** a significant medication error or an error rate in excess of the five percent rate determined to be tolerable 'because all systems have some errors. . . .'" Id. at 9 (emphasis added).

The preamble to the final rule also discussed the meaning of the term "significant medication error" as follows:

> A significant medication error is judged by a surveyor, using factors which have been described in interpretive guidelines since May 1984. The three factors are: (1) Drug category. Did the error involve a drug that could result in serious consequences for the resident (2) Resident condition. Was the resident compromised in such a way that he or she could not easily recover from the error (3) Frequency of error. Is there any evidence that the error occurred more than once[.]

Id.; see also State Operations Manual (SOM), Appendix PP, section 483.25 (discussing the three factors considered to determine whether an error is "significant").

Applying the appropriate legal standard established under the regulation and elucidated in the *Federal Register* preamble to the facts presented in this case, we conclude that Ocean Springs failed to comply substantially with 42 C.F.R. § 483.25(m)(2). Ocean Springs acknowledges that on March 20, 2007, LPN 1 "passed hypertension medications to Resident 1 that had been ordered for Resident 2." Ocean Springs Br. at unnumbered 1; see also CMS Exs. 1, 5-7, 14-17. These medications included Norvasc

(Amlodipine Besylate), Prinivil (Lisinopril), Catapres (Clonidine), and Trandate (Labetalol). CMS Ex. 1, at 6-7; CMS Ex. 5, at 3; CMS Ex. 6, at 5-7. The medications, the record also shows, were prescription drugs that could result in serious consequences to a resident for whom the drugs had not been prescribed. CMS Exs. 14, at 1 ("Do not give Norvasc to [people for whom it has not been prescribed] It may harm them."); CMS Ex. 15, at 4-9 (Contraindications, Warnings and Precautions); CMS Ex. 16, at 1-2 (Drug Interactions); CMS Ex. 17 at 2 (Drug Interactions, Side Effects and Precautions). Further, Ocean Springs does not dispute that, as a consequence of this error, "Resident 1 experienced profound hypotension that required her to be hospitalized and treated in that hospital's intensive care unit with intravenous anti-hypotensive medications." ALJ Decision at 3, citing CMS Ex. 1, at 1, 5-6; CMS Ex. 5, at 17-19.

Thus, the surveyor's determination that the administration of drugs to Resident 1 was a "significant medication error" is fully consistent with the meaning of the term as defined in the preamble. The type of drugs administered to Resident 1 was such that the error resulted in serious consequences for the resident. Moreover, Resident 1 was so compromised that she could not easily recover from the medication error. Indeed, the consequences were so grave that the resident required hospitalization in an intensive care unit and the administration of other drugs to counter the effects of the erroneously administered medications. CMS Ex. 1, at 5-6; CMS Ex. 5, at 17-25. Furthermore, the error involved the erroneous administration of four drugs to treat hypertension, each of which had potentially very serious consequences if administered to the wrong person. Thus, the error involving Resident 1 can properly be considered a "significant medication error" based on the category of the drugs administered or the resident's condition. The error might also be considered "significant" based on the frequency of the error given the number of drugs erroneously administered to Resident 1.

Ocean Springs' reliance on prior Board and federal court decisions to support its interpretation of the applicable legal standard is misplaced. The cited decisions did not involve the specific regulation at issue here, with its unambiguous language and regulatory history, nor did they address analogous factual circumstances. For example, the Woodstock, Tri-County, and Aase Haugen decisions involved section 483.25(h)(2), which provides that a "facility must ensure that . . . [e]ach resident receives adequate supervision and assistance devices to prevent accidents." The Board has explained in the cited and other decisions that an element of reasonableness is inherent in the language of section 483.25(h)(2). However, the Board has also

consistently held that while the regulation does not make facilities "guarantors of [the] favorable outcomes" sought by the regulation, it does require facilities "to take all reasonable steps to ensure that a resident receives supervision and assistance devices that meet his or her assessed needs and mitigate foreseeable risks of harm from accidents." Golden Age Skilled Nursing and Rehabilitation Center, DAB No. 2026 at 11 (2006), citing Woodstock Care Ctr. v. Thompson, 363 F.3d at 590 (a facility must take "all reasonable precautions against residents' accidents").

In construing section 483.25(h)(2), the Board has taken into account not only the language of the regulation, but also the "obviously difficult task" of foreseeing and preventing every type of accident. Woodstock at 28. Given the myriad variables that may contribute to or cause a resident accident, and the fact that a facility cannot always foresee or control all of those variables, it would be unreasonable to sanction a provider for a resident accident regardless of the circumstances. In contrast, "[t]o 'ensure that residents are free of any significant medication errors,' as required by section 483.25(m)(2), a facility must administer the 'right dose' of the 'right med[ication]' by the 'right route' to the 'right patient' at the 'right time.'" Franklin Care Center at 11 (quoting hearing transcript). "This," the Board concluded in Franklin Care Center, "is not reasonably considered 'an obviously difficult task' since, unlike the prevention of accidents such as patient falls, this task does not typically involve any factors outside the facility's control." Id. Thus, the language of section 483.25(h)(2) and the practicalities of its implementation distinguish Woodstock and its progeny from the immediate matter.

Ocean Springs mistakenly cites the Sixth Circuit decision in Crestview as support for its position that it should not have been cited for noncompliance with section 483.25(m)(2) because, in Ocean Springs' view, LPN 1 acted reasonably, albeit, mistakenly. In Crestview, the court construed the lead-in language of 42 C.F.R. § 483.25, which requires a facility to provide "necessary care and services" to enable a resident "to attain or maintain" the resident's "highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care." The term "practicable," the Crestview court held, "suggests that a reasonableness standard inheres in the regulation." 373 F.3d at 754. Like the term "adequate" in section 483.25(h)(2), the court continued, "'practicable' intimates that it is possible for a petitioner to show that there was a justifiable reason for [a] violation of section 483.25." Id. Ocean Springs misreads the

court's holding. As the Board stated in Tri-County Extended Care Center, DAB No. 2060 (2007), "[t]he [Crestview] court did not find . . . that a facility must do for the resident only what is "practicable" for it to do under the circumstances." DAB No. 2060 at 4, 5. Moreover, the Crestview court stated that it reached its conclusion about the suggested meaning of section 483.25 "lacking any other guidance from HHS aside from its statements in Woodstock and progeny." 373 F.3d at 754. In Tri-County, the Board provided guidance, holding that the word "practicable" in the lead-in language of section 483.25, "refers to the resident's condition, not to the care and services that the facility must provide." DAB No. 2060, at 5 (2007), citing Ridge Terrace, DAB No. 1834, at 8 (2002). Indeed, while apparently overlooked by the Crestview court, the Board's decision in Ridge Terrace had already provided such guidance by holding that the "highest practicable" language in section 483.25 "means that a facility must provide care and services so that a resident attains the highest level of well-being the resident is capable of attaining, not that a facility is excused from providing such care and services if it is not practicable to monitor its staff to ensure compliance." DAB No. 1834 at 8. We also note that the case before the Sixth Circuit in Crestview, like the other cases on which Ocean Springs relies, did not involve section 483.25(m)(2), and the Sixth Circuit decision shows no awareness of the Board's Franklin Care Center decision construing section 483.25(m)(2) in light of its very precise language.

Finally, the court decision in Emerald Shores involved an entirely different regulation from the quality of care provision on significant medical errors at issue in this case. The Court considered whether the regulatory requirement at section 483.70(h)(4) that a facility must "maintain an effective pest control program so that the facility is free of pests and rodents" was sufficiently clear to support the Board's conclusion that a facility in which a resident received multiple fire ant stings was not in substantial compliance. The Court concluded that, under the circumstances present in that case, the term "effective" was too vague given that CMS had not issued detailed instructions on pest control programs and given the Court's view of the "average nursing home administrator's lack of expertise in pest control methods." Emerald Shores at 9-10, 15, 17. The Court's view of the pest control provision offers no useful analogy to the case now before us. As we have explained, the language at 42 C.F.R. § 483.25(m)(2) is not vague. Moreover, the accurate distribution of medications is unquestionably an essential element of resident care in which nursing homes are expected to have expertise.

Accordingly, applying the appropriate legal standard, we conclude that Ocean Springs failed to comply substantially with 42 C.F.R. § 483.25(m)(2).

In any event, the circumstances surrounding the medication error in this case belie Ocean Springs' characterization of LPN 1's actions as reasonable and consistent with accepted professional practices and facility policy. The Statement of Deficiencies (SOD) (which summarizes the surveyor's observations, interviews, record review and policy review), the surveyor's notes and worksheets, and copies of facility records support the conclusion that LPN 1's actions were unreasonable and inconsistent with principles of medication administration that Ocean Springs itself accepted. CMS Exs. 1, 5, 6, 10, 12. The SOD shows that LPN 1 told the surveyor that "she should have made a positive identification of the resident prior to administering medications and had been trained to do this." CMS Ex. 1, at 3. Further, according to the SOD, LPN 1 "reported that identification was usually made by calling the resident's name, looking at the arm band and looking at the photo on the M[edication] A[dministration] R[ecord]." Id.; see also Ocean Springs Ex. 3, at 3. Another facility nurse interviewed by the surveyor "revealed that nurses were in-serviced at least once yearly on the five (5) rights of medication administration"[3] and "stated that residents were supposed to be identified prior to medication administration by checking their arm band and looking at the photo on the MAR." Id. at 4; see also CMS Ex. 10.

Ocean Springs claims that its policy requires only that a nurse "positively identify" a resident and that it is not necessary to consult the name on the resident's armband or a photograph in the resident's record if the resident's identity is not in doubt. Ocean Springs Exs. 8 ¶ 3, 10 ¶ 4. However, the facility's written resident identification policy states under the heading, "Policy Interpretation and Implementation," that "[t]he person

[3] CMS's briefs below and on appeal state that the five "rights" of medication administration are: "the right resident; the right medication; the right dose, the right route; and the right time." CMS Prehearing Br. at 4; CMS Reply at 4. To support this statement, CMS cites CMS Exhibit 10, a medication administration observation report which includes a hand-written listing titled "5 Rights of Med Administration." Ocean Springs does not dispute CMS's statement or Exhibit 10, which are consistent with the discussion of the five "rights" of medication administration in Franklin Care Center at 11.

administering the drug(s) **must verify** the resident's identity before administering the medication." Ocean Springs Ex. 4 (emphasis added).

The circumstances here do not reasonably support a conclusion that LPN 1 verified the resident's identity. LPN 1 administered the drugs as the resident was passing in the hallway. Thus, there were no physical markers, such as a room or bed number, that might have helped decrease the chances of misidentification. LPN 1 appears to have relied solely on the fact that Resident 1 made a verbal response ("good morning") and approached the medicine cart when LPN 1 called out "Hey Mrs. [Resident 2's name]." However, Resident 1 could have been responding to the greeting while not hearing or focusing on the name.

Also, while Ocean Springs asserts that LPN 1 was familiar with both the resident for whom the medications were prescribed and the resident to whom she wrongly gave the medications, LPN 1 said in a written statement that the residents "look alike." Ocean Springs Ex. 3; see also Ocean Springs Ex. 11 ¶ 2. LPN 1 also told the Director of Nursing that "the two [residents] look alike with the same hairstyle and both are amputees." Ocean Springs Ex. 2. Further, LPN 1 told the surveyor that "both residents favored physically, both were amputees, had short brown hair and the same build . . . ." CMS Ex. 1, at 3. Thus, by her own admission, the nurse could not have made a positive identification that the resident to whom she gave the medications was the resident for whom the medications were prescribed without taking additional steps to verify the resident's identity.

Finally, Ocean Springs' argument that it is sufficient to identify an alert resident solely by addressing the resident by name and receiving an affirmative response from that individual assumes that the resident is "more than capable and willing of letting a nurse know . . . if she has been misidentified." Ocean Springs Ex. 8 ¶ 4. Thus, Ocean Springs in effect contends that Resident 1 misled LPN 1 because "Resident 1 did not correct [LPN 1's] misidentification." Ocean Springs Ex. 8 ¶ 5; see also Ocean Springs Ex. 11 ¶ 3. Ocean Springs' assumption, however, is plainly flawed since it fails to take into account factors such as whether a resident accurately hears or understands a nurse's greeting or whether a resident believes that it is necessary and appropriate to correct a nurse.[4] Ocean Springs' suggested

[4] We note that Resident 1 told the surveyor that she did ask LPN 1 "why there were so many pills," but

(continued...)

"sufficient" identification method is not sufficient because it unnecessarily shifts control over, and responsibility for, the proper administration of medications from the facility and its staff to the resident herself. This transfer of responsibility is neither reasonable nor justifiable when the facility has more reliable means (such as checking armbands and MAR photographs) to verify resident identities. It also is inconsistent with the facility's own policy, which puts on the facility an affirmative duty to "verify" the resident's identity, not to assume it. Ocean Springs Ex. 4.

Thus, we reject Ocean Springs' contention that the facility and its employees acted reasonably in attempting to meet the desired outcome of the medication error rule when LPN 1 erroneously administered medications prescribed for Resident 2 to Resident 1.

3. The ALJ's determination that the per-instance CMP of $7,500 was reasonable is not erroneous.

An ALJ must make an "independent determination" about whether the amount of the CMP imposed by CMS is reasonable. CarePlex of Silver Spring, DAB No. 1683, at 16 (1999). That determination is guided by the regulatory factors specified at 42 C.F.R. §§ 488.438(f) and 488.404, which include the facility's history of noncompliance (including repeated deficiencies), its financial condition, its degree of culpability (which includes neglect, indifference, or disregard for resident care, comfort or safety) for the cited deficiencies, and the seriousness of the noncompliance. When a penalty is imposed for an instance of noncompliance, the penalty must be in the range of $1,000 to $10,000. 42 C.F.R. § 488.438(a)(2).

In this case the ALJ determined that the per-instance CMP of $7,500 assessed by CMS was reasonable "given the injury caused by the error and the misjudgment that the error revealed." ALJ Decision at 6. The ALJ cited the "extremely serious" nature of

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[4] (...continued)
took them after the nurse responded "that they were all hers." CMS Ex. 1, at 2. LPN 1 told the surveyor she "did not recall the resident asking anything about the medications." Id. The nature of Resident 1's assertion, regardless of whether it is true in this case, illustrates how nursing home residents depend on, and are vulnerable to, decisions and actions by staff to ensure resident safety, including the safe administration of medications.

the medication error and its consequences to the resident as well as the "palpable failure on the part of Petitioner to recognize that putting a nurse into a situation where she would be asked to perform acts that were not part of her daily routine could pose extreme risk to residents if appropriate safeguards – even safeguards that exceeded the facility's ordinary routine – were not employed." Id. The ALJ also noted that Ocean Springs had not presented any evidence showing that its financial condition precluded it from paying the CMP amount.

Ocean Springs disputes the ALJ's conclusions about the seriousness of the noncompliance and the facility's culpability, arguing that LPN 1's "mistake, though it was unfortunate and produced an adverse outcome for Resident #1, was nonetheless excusable." Ocean Springs Br. at unnumbered 13.

We find no error in the ALJ's conclusion that the medication error was "extremely serious." Undisputed record facts establish that the medication error resulted in the need to hospitalize Resident 1 to stabilize her blood pressure. Indeed, physicians who treated her at the hospital characterized the resident at the time of her arrival in the emergency room as "markedly hypotensive" and "profoundly hypotensive." CMS Ex. 5, at 18, 20. Further, after initially administering Dopamine to the resident, the treating physician "still didn't get a decent pressure," and consequently ordered a second medication, a "high dose of Neo-Synephrine," which "got her pressure up at last." Id. at 18. Resident 1 was subsequently "admitted to the ICU" with her condition "[g]uarded but improving." Id. at 19.

We also find no error in the ALJ's assessment of Ocean Springs' culpability. The nurse who erroneously administered Resident 2's medications to Resident 1 was an employee of the facility, and it is well-settled that a long-term care facility is responsible for the deeds of its employees. See, e.g., Burton Health Care Center, DAB No. 2051 (2006); Northeastern Ohio Alzheimer's Research Center, DAB No. 1935 (2004); Cherrywood Nursing and Living Center, DAB No. 1845 (2002) (and cases cited therein).[5] We also agree with the ALJ that the fact that LPN 1 was a substitute on the unit where the medication error occurred "imposed a duty on her supervisors and Petitioner's management to exercise extra caution to assure that the nurse provided

[5] "[T]he absence of culpability," in any event, "is not a mitigating circumstance in reducing the amount of the penalty." 42 C.F.R. § 488.438(f)(4).

medications correctly to residents." ALJ Decision at 5. Ocean Springs suggests that such extra caution was not necessary due to LPN 1's work history, which included duties on the unit where she usually worked and where Resident 1 had previously resided for a period of time. Ocean Springs Br. at unnumbered 10-11, 14. However, even assuming those duties included passing medications on another unit, that fact would not obviate the facility's responsibility to exercise caution when assigning LPN 1 (or any other nurse) to pass medication on a different unit to assure that the nurse can accurately identify the residents on that unit. Indeed, if LPN 1 was used to seeing Resident 1 on the unit where LPN 1 usually worked, not on the unit where she was a substitute, this would seem to underscore the risk of her misidentifying Resident 1 since she would not be used to seeing her in the new location. The record reveals no evidence that Ocean Springs' management anticipated or prepared LPN 1 to mitigate the risk for error associated with passing medications as a substitute in a unit other than the one in which she routinely worked.

Ocean Springs contends that the CMP is unreasonable in light of the facility's "undisputed outstanding history of regulatory compliance in the three annual surveys that preceded the one in this case." Ocean Springs Br. at unnumbered 14; Ocean Springs Exs. 5-7. While the ALJ Decision does not discuss the evidence that Ocean Springs submitted to show its compliance history, we find on review of the prior survey reports that Ocean Springs, in fact, was cited for deficiencies found during the prior surveys, albeit not for medication errors. Thus, we question Ocean Springs' characterization of its compliance history as "outstanding." In any event, the Board has previously "held that although a 'history of noncompliance' is one of the factors to be considered, the absence of a history of noncompliance is not a mitigating factor." Western Care Management Corp., d/b/a Rehab Specialties Inn, DAB No. 1921, at 93 (2004), citing Franklin Care Center, DAB No. 1900 (2003) and 42 C.F.R. § 488.438(f).

Accordingly, we find no error in the ALJ's analysis in determining that a per-instance CMP of $7,500 was reasonable.

Conclusion

For the reasons stated above, we affirm the ALJ Decision and uphold his determination imposing a per-instance CMP in the amount of $7,500.

/s/
Leslie A. Sussan

/s/
Constance B. Tobias

/s/
Sheila Ann Hegy
Presiding Board Member