Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

In the Case of:	DATE: January 14, 2008
Premier Living and Rehab Center,	
Petitioner,	Civil Remedies CR1602 App. Div. Docket No. A-07-117
- v. -	Decision No. 2146
Centers for Medicare & Medicaid Services.	

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Premier Living and Rehab Center (Premier), a North Carolina nursing facility, appealed the May 29, 2007 decision of Administrative Law Judge (ALJ) Carolyn Cozad Hughes which upheld the determination of the Centers for Medicare & Medicaid Services (CMS) to impose a civil money penalty (CMP) of $178,150. Premier Living and Rehab Center, DAB CR1602 (2007) (ALJ Decision). The CMP was based primarily on CMS's determination that three Premier nurses administered ten excess doses of morphine to a resident and that Premier failed to recognize this mistake and address it. CMS determined that Premier was not in substantial compliance with Medicare program participation requirements from September 24 through December 15, 2005. For the first 58 days of that period, CMS determined that Premier's deficiencies posed an immediate jeopardy to resident health and safety and imposed a CMP of $3,050 per day. During the last 25 days, CMS determined, Premier had abated the immediate jeopardy but had not achieved substantial compliance so the CMP was reduced to $50 per day.

For the reasons explained below, we sustain the ALJ Decision in its entirety.

Standard of review

Our standard of review on a disputed conclusion of law is whether the ALJ decision is erroneous. 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. Guidelines -- Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's Participation in the Medicare and Medicaid Programs (Guidelines), ¶4(b), (at http://www.hhs.gov/dab/guidelines/prov.html); Batavia Nursing and Convalescent Inn, DAB No. 1911, at 7 (2004), aff'd, Batavia Nursing & Convalescent Ctr. v. Thompson, 143 F. App'x 664 (6th Cir. 2005); Hillman Rehabilitation Center, DAB No. 1611, at 6 (1997), aff'd, Hillman Rehabilitation Ctr. v. U.S. Dep't of Health and Human Servs., No. 98-3789 (GEB) at 21-38 (D. N.J. May 13, 1999).

Applicable Law

Premier's participation in Medicare is governed by sections 1866 and 1819 of the Social Security Act (Act) and by federal regulations at 42 C.F.R. Parts 483 and 488. To participate in the Medicare program, a nursing facility must maintain substantial compliance with program requirements. "Substantial compliance" means that a facility's deficiencies may pose no greater risk to resident health and safety than "the potential for causing minimal harm." 42 C.F.R. § 488.301.

The participation requirements with which CMS found Premier not to be in substantial compliance are set out at 42 C.F.R. § 483.20(k)(3)(i) (services must meet professional standards of quality) and 42 C.F.R. § 483.25(l)(1) (residents must be free from unnecessary drugs).

Under applicable regulations an "immediate jeopardy" deficiency is one that causes, or is likely to cause, a resident or residents of a facility to experience serious injury, harm, or death. 42 C.F.R. § 488.301. CMS's determination that a deficiency constitutes immediate jeopardy "must be upheld unless it is clearly erroneous." 42 C.F.R. § 498.60(c)(2); Woodstock Care Center, DAB No. 1726, at 9 (2000), aff'd, Woodstock Care Center v. Thompson, 363 F.3d 583 (6th Cir. 2003).

ALJ Decision

The ALJ found that three nurses administered ten doses of morphine to R1 over the course of three days, each of which was ten times larger than prescribed. ALJ Decision at 5-6.[1] The ALJ found that federal and state law, standards of nursing practice and facility policy all required close monitoring of narcotics, including maintenance of individual narcotic records (INRs) as well as medication administration records (MARs) tracking each time a dose is given and recording the remaining amount of medication. Id. at 5. The ALJ found that R1's INR showed ten occasions on which several different nurses recorded that they administered 1.0 milliliter doses (rather than the prescribed dose of 0.1 milliliter) and, on each occasion, also recorded that the remaining amount in the bottle was correspondingly reduced by 1.0 milliliter. Id. at 5-6. The ALJ concluded that this evidence on its face established that the nurses administered unnecessary medication and failed to meet professional standards in that they did not follow the physician's orders and did not comply with professional standards for ensuring accurate dosing especially of narcotics. Id. at 6-7. The ALJ also found corroborating evidence that multiple overdoses were administered and that multiple systems failed to prevent the repeated errors. Id. at 6-7, 10-13. In addition, the ALJ found the subsequent investigation of the discrepancies in the medication records to be inadequate. Id. at 7-14. Finally, the ALJ found that these deficiencies posed immediate jeopardy between September 24 through November 20, 2005, and that Premier was not in substantial compliance through December 15, 2005. Id. at 17-18.[2]

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[1] We set forth here key findings and conclusions that underlie the ALJ Decision, but do not intend this summary to substitute for the ALJ's Findings of Fact and Conclusions of Law (FFCLs).

[2] The ALJ at some points refers to November 20th as the last day of immediate jeopardy, and, elsewhere, refers to November 21 as the last day. Compare ALJ Decision at 1 with ALJ Decision at 2, 18. This confusion originates in CMS's correspondence with Petitioner, which identifies both days as the last day of immediate jeopardy. Compare P. Ex. 2, at 1 with id. at 2. CMS never disputed the ALJ's calculation of the amount of the CMP based on a duration of 58 days (September 24th through November 20th) of immediate jeopardy and 25 days of continued noncompliance thereafter. We therefore accept this determination as to the duration.

Background and issues[3]

The North Carolina Department of Health and Human Services (State agency) conducted a complaint survey of Premier on November 14-15 and 21, 2005. The surveyors concluded that Premier was not in substantial compliance with the following two participation requirements: 42 C.F.R. § 483.20(k)(3)(i) (services must meet professional standards of care) and 42 C.F.R. § 483.25(l)(1) (residents must be free from unnecessary drugs). The surveyors also concluded that the deficiencies constituted immediate jeopardy. Premier submitted a plan of correction (POC) alleging that it would achieve substantial compliance by December 16, 2005. P. Ex. 3. The State agency returned for a revisit on January 9, 2006 and confirmed that Premier achieved substantial compliance by the date alleged.

Premier concedes that a medication error was committed in relation to the administration of excessive morphine to a nonverbal 82-year old resident (R1). R1 suffered from metastasized cancer and was being treated as a hospice patient. It is undisputed that R1 was prescribed 2 milligrams (mg) of morphine by mouth every two hours. It is also undisputed that, based on the concentration of morphine being used by Premier, that dose translated into 0.1 milliliter (ml) of liquid to be taken from a 30-milliliter opaque bottle with a see-through strip marked in increments of 2 cc's (2 ml's). CMS Ex. 2, at 9; CMS Ex. 24, at 1. The parties agreed that this amount was extremely small and difficult to measure accurately.[4]

R1's INR shows that on ten consecutive occasions over the period from September 24 through September 26, 2005, three different nurses recorded that they had administered 1 ml of morphine to R1 -- ten times the prescribed dose each time. On the INR, the nurses also documented the remaining amount in the morphine

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[3] The ALJ Decision contains a full discussion of the facts with record citations, which we summarize here with citations omitted, identifying areas of dispute before us. See ALJ Decision passim.

[4] Premier repeatedly refers to the dosage as "unusually small" or "extremely low." See, e.g., Premier Br. at 1, 6 n.1, 44, 53-54; Premier Reply Br. at 15. These references are misleading; there is no evidence in the record that a 2 mg dose of morphine was "small." What was undisputed was that the amount of liquid required to be administered to achieve a 2 mg dose when using an extremely concentrated formulation was tiny.

bottle after each of these doses as being reduced by a corresponding 1 ml. CMS asserts that the nurses administered ten overdoses; Premier asserts that one nurse administered one overdose followed by nine transcription errors in recording doses.[5]

It is undisputed that the Director of Nursing (DON), Lisa Morlan, and the Premier Administrator instituted some investigation of this incident. On September 26, the DON instructed unit manager Crystal Coleman to investigate after RN Coleman told her that the narcotic count for R1 was "off." P. Ex. 42, at 2-3 (Morlan Decl.). "A day or two later," Nurse Coleman told the DON that a Nurse Godwin had made an error and would be counseled about it the next time she was on duty. Id. at 3. At that time, the DON concluded that this "was the end of the matter." Id. Subsequently, R1's son filed a complaint, which went to Premier's Administrator and the State agency, alleging that on a different occasion his mother's medication was signed out but not administered to her. Id. The Administrator, after consulting with the DON, ordered a complete audit of R1's narcotic records which was performed by five registered nurses on October 4. They reported that the amount in the bottle was "off by 0.9 ml," which the DON believed reflected a single erroneous dose of 1.0 ml instead of 0.1 ml by one nurse. Id.

It is undisputed that two medication error reports were also prepared but one of them was not retained. The existing medication error report, signed by the Administrator on October 6, states that the error consisted of "wrong dose" and specifies that "morphine given at 1 cc instead of 0.1 cc per g [gastric feeding] tube x 9 doses." P. Ex. 34, at 1.

Premier concedes that "at least one, and perhaps as many as ten," incorrect doses of morphine were administered to R1, and that morphine can be dangerous in an excessive dose. See, e.g., Reply Br. at 2. Premier nevertheless argues that the DON and Administrator reasonably concluded based on an adequate investigation that a single error occurred and that no "systemic" problem existed with narcotic medications. Id. at 3. Premier

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[5] Occasionally in the record, witnesses or counsel spoke as if the issue were whether one or nine overdoses were administered. It is evident from the complete context that the parties dispute whether only one actual overdose occurred or whether all ten entries reflected actual overdoses. Thus, nine doses are in dispute, not eight.

argues that, as a matter of law, neither of the cited regulations should be applied under the circumstances here. Id. at 13.

Further, Premier contests the duration of the immediate jeopardy period. Premier argues that its response sufficiently addressed the problem as Premier reasonably understood it. Id. at 15. In addition, Premier argues that later medication errors and other events after the in-servicing should not be a basis to find that substantial compliance had not been achieved. Id. at 15-16. Premier further argues that the ALJ ignored its evidence allegedly showing that the amount of the penalty imposed is unreasonable because Premier is unable to pay it. Id. at 21.

Finally, Premier raises a number of objections about the procedures used by the ALJ in hearing the case. Id. at 16-21.

Premier timely requested a hearing before the ALJ, which was held on October 25, 2006.

Analysis

1. Substantial evidence in the record supports the ALJ's findings that narcotic overdoses were repeatedly administered to R1 and that the medication errors were not adequately investigated.

We find the ALJ Decision as a whole thorough, reliable and persuasive. We find that ALJ discussed all the relevant evidence in appropriate detail. The inferences which the ALJ drew were reasonable and were based on facts supported by substantial evidence. She was not obliged to draw the inferences for which Premier advocates from the facts she found on the record before her. We therefore discuss the major areas in dispute on appeal below, but adopt without repeating the remainder of the ALJ's discussion of the evidence and analysis. This decision should therefore be read in conjunction with the ALJ Decision.

Substantial evidence in the record, viewed as a whole, supports the ALJ's central findings that ten overdoses of morphine were administered to R1.

First, the ALJ was entitled to consider the INR on which three nurses recorded ten overdoses as a clinical record providing competent evidence of these overdoses.[6] INRs are particularly

[6] We make this obvious point because Premier repeatedly (continued...)

persuasive clinical evidence since, as the ALJ explained, they document the closely monitored handling of narcotics required by law, professional standards, and facility policies. ALJ Decision at 5.

> The INR lists the patient's name, the strength and ordered dosage of his/her medication, the amount of medication initially provided, and the amount remaining after each administration. CMS Ex. 35, at 8 n.6 (Guay Decl.); CMS Ex. 36, at 4 (Benson Decl. ¶ 9). The administering nurse consults the INR for the patient's name, medication, route of administration and dosage. The nurse notes the amount of medication before the dose is given. After administering the ordered dose, the nurse measures and records the amount remaining. P. Ex. 35; Tr. 32.
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> Standards of nursing practice also require that licensed nurses perform a narcotic count at each shift change, when the narcotic keys change hands. The facility policy reflected this standard, requiring that the nurse coming on duty and the nurse going off duty make the count together, and document and report to the DON any discrepancies. CMS Ex. 36, at 4 (Benson Decl. ¶ 9); CMS Ex. 19; Tr. 105.

ALJ Decision at 5. Thus, the repeated 1 ml doses and the corresponding decreases of morphine documented by the nurses on the INR were required to be reviewed and confirmed by visual observation of the bottle by multiple nurses.

Second, the ALJ reasonably relied on a medication error report on this incident.[7] ALJ Decision at 10, citing P. Ex. 34; CMS Ex. 8.

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[6](...continued)
makes such assertions as "[the ALJ's] material finding and conclusion not only have no evidentiary support in the record, but they are contrary to largely undisputed clinical evidence." Premier Br. at 3; see also id. at 7, 12, 16; P. Reply Br. at 7.

[7] Premier seeks to discredit the findings in the medication error report by arguing that the portion reporting multiple overdoses was completed before the three nurses had been questioned and, therefore, "does not reflect information learned later in the investigation, and is not a complete or reliable basis for decision." Premier Br. at 22. Premier cites no
(continued...)

Licensed Practical Nurse Mattress McAllister, who discovered the error, prepared the medication error report, which states that "morphine was given at 1 cc instead of 0.1 cc per g tube x 9 doses." CMS Ex. 8, at 1. An attached handwritten note from the same nurse repeats that the resident was given morphine "at 1 cc instead of 0.1 cc as ordered starting in 9/24/05 ending in 9/26/05 at 4:30 am x 9 doses." Id. at 2. The Administrator signed this error report on October 6, 2005.

Third, the ALJ reasonably relied on Premier's audit of R1's narcotic record conducted on October 4, 2005. The Administrator ordered this audit after R1's son filed a written complaint, which he also sent to the State agency, alleging that a nurse had signed out his mother's pain medication and failed to administer it.

The nurse auditors reported to the DON that R1's count was off by 0.9 milliliters. P. Ex. 42, at 4. They arrived at this figure by reviewing the last entry on R1's narcotic count (the 123rd dose, administered at 6:30 AM on October 4, 2005) which stated that 8.3 milliliters remained in the bottle. ALJ Decision at 9-10. The nurse auditors poured the remaining liquid narcotic into a measuring vessel and determined that only 7.4 milliliters was actually in the bottle. ALJ Decision at 10. They concluded that 7.4 ml was 0.9 less than the total of 8.3 ml recorded on the INR, so that an error of 0.9 existed. This finding was reported to the DON who considered it consistent with RN Coleman's original report that a single dose was administered that was 0.9 ml greater than the correct dose of 0.1 ml. P. Ex. 42, at 4.

While Premier cites this audit, its result plainly supports the ALJ's finding. Assuming, as Premier does, that only one overdose occurred, then considerably more narcotic was unaccountably missing from the bottle than the 0.9 ml difference reported in the audit. As the ALJ explained, removing 123 doses of 0.1 ml from the initial volume of 30 ml should have left 17.7 ml, yet only 7.4 ml were present at that point.[8] ALJ Decision at 10. Had

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[7](...continued)
evidence in support of its representations. Further, the Administrator signed the report on October 6, long after the nurses had been interviewed and also after the physical reconciliation of the contents of the bottle on October 4 disclosed the large volume of missing narcotic. CMS Ex. 8.

[8] The ALJ did this calculation but then subtracted the last recorded amount (8.3 ml) instead of the actual measured
(continued...)

the nine doses recorded as 1 ml after the first admitted error merely reflected nurses' transcribing the 1 ml amount incorrectly from the one above while actually administering the correct 0.1 ml dose, then the actual amount remaining in the bottle should have been about 8 ml more than the recorded amount. Instead, the remaining amount (7.4 ml) was almost a milliliter less than the recorded amount (8.3 ml).[9] We agree with the ALJ that this physical evidence is compelling corroboration that the overdoses were actually administered rather than merely recorded incorrectly.[10]

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[8](...continued)
amount (7.4 ml) from the 17.7 ml that should have remained in the bottle to find a discrepancy of 9.4 ml. Using the actual measured amount would show an even larger discrepancy of 10.3 ml. In either case, the amount missing from the bottle is clearly more consistent with the recorded ten overdoses than a single overdose and thus corroborates that R1 was given doses ten times larger than what was ordered by her doctor on ten different occasions.

[9] Perhaps a simpler way to consider the discrepancy is to remember that a 30-milliliter bottle should have yielded 300 doses of 0.1 ml each. By the time of the audit, 123 doses were recorded with 7.4 ml left in the bottle (or 74 doses). That accounts for 207 doses, leaving 93 doses missing and unaccounted for. Although Premier claims that the "viscosity of the liquid" or the difficulty in measuring small doses accurately or some initial discrepancy in the amount delivered in the bottle might explain the disappearance of nearly a third of the bottle (Premier Br. at 17-20), we agree with the ALJ that attributing the disappearance of almost a third of the contents of the bottle to such causes "strains credulity." ALJ Decision at 13.

[10] We note that the DON's November statement recognizes that the audit supports the conclusion that 10 overdoses were actually administered. She states:

> On November 11th, 2005, a complaint survey team entered the building and began to interview the staff and review the records having to do with this resident and her order for morphine. At this time, I pulled the narcotics sign out sheets and made some interesting discoveries that I had been unaware of previously.
>
> The findings included:

(continued...)

Premier nevertheless bases its case before us, as it did before the ALJ, on the claim that only one excess dose was actually administered and the other nine entries in the INR showing excess doses were mere "transcription errors." Premier Br. at 3. In support of this claim, Premier relies on its own investigations and on assertions that it is impossible to accurately determine the number of overdoses retroactively based on the existing evidence. Id. More generally, Premier repeatedly asserts that the ALJ ignored material clinical and other evidence, but frequently fails to identify specifically the evidence on which it relies for these assertions or to explain why that evidence should have altered the ALJ's conclusions.

While Premier relies on its own investigations, it identifies no evidence related to those investigations which would have required the ALJ to reach a different finding. The elements of those investigations on which Premier relies are the statements of two nurses and the audit finding about the contents of the morphine bottle on October 4.

As explained above, the audit findings are actually inconsistent with Premier's contention that only one overdose was administered. Additionally, the evidence as to the nurses' statements is unpersuasive.[11] Premier represents that two of the

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[10](...continued)

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2. The more important issue that I found was that the count from the initial med errors on the 24th through the 26th had not been reconciled and on 9-26-05 at 8:30 should have been 23.5 ml if only one nurse had made the med error. I was disturbed to find out that using the count that was written down of 15.9 ml, the count at the end of the sheet was only 0.7 ml off. This means that if the count was adjusted to show that all nurses who signed off as giving 1.0 ml had actually giving [sic] 1.0 ml instead of the physician ordered dose of 0.1 ml, the count would be accurate.

CMS Ex. 13, at 1.

[11] Premier objects to the ALJ's finding that "staff repeatedly misrepresented their actions." Premier Br. at 4, quoting ALJ Decision at 4. Premier complains that the ALJ did

(continued...)

three nurses who recorded that they administered overdoses subsequently denied that they had actually done so. Premier Br. at 16. Premier did not call those nurses as witnesses in this proceeding. The evidence in the record as to these denials are a statement of the DON that the two nurses denied giving the overdoses (CMS Ex. 13, at 2; CMS Ex. 42, at 5) and a statement by the surveyor that one of the two nurses to whom she was able to speak denied administering any overdoses (Tr. at 48-49; CMS Ex. 2, at 2). The ALJ reasonably rejected Premier's argument that she should disregard the INR, the medication error report, and the physical evidence concerning the contents of the bottle on October 4 on the basis of this hearsay evidence. She could reasonably infer from Premier's decision not to present those nurses as witnesses that their testimony would either be inconsistent with Premier's claims or would not be credible in light of the clinical and physical evidence in the record.[12]

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[11](...continued)
not expressly identify these misrepresentations, but we find the ALJ made evident that she disbelieved the two nurses' denials of having administered overdoses. ALJ Decision at 11-13. Further, the ALJ could reasonably have considered RN Coleman's representation to the DON of the outcome of investigatory steps she had not in fact taken to be another misrepresentation. See ALJ Decision at 8; P. Ex. 42, at 7 (in which the DON states that RN Coleman "reported to me that she had conducted a complete investigation when she really had not.").

[12] Indeed, we note that the DON's statements indicate that, after reviewing the INR in the course of the November 2005 survey for the first time, she did not regard the nurses' denials as credible. In her November 15, 2005 statement, she says:

> Of the 3 nurses who were initially asked if they had mis-documented or if they had really given the wrong dose, only one of them admitted to the med error, the other 2 insisted they had put the decimal point in the wrong place. These two nurses will be called in and have performance conference conducted ASAP. It is important to convey to these nurses that med errors happen, but owning up to our mistakes is one of the most important facets of nursing. We must always keep in the mind that the outcome to the resident is of higher importance that our own pride or fear of reprimand.

CMS Ex. 13, at 2.

Therefore, we conclude that Premier's claim that the "clinical evidence is inconsistent with a conclusion that ten erroneous doses actually were administered" is completely without foundation. Premier Reply Br. at 4.

The ALJ's conclusion that the Premier's investigations were wholly inadequate also rests on substantial evidence in the record. On September 26, 2005, RN Coleman reported to the DON that one nurse had given R1 one dose of 1.0 ml of morphine instead of 0.1 ml of morphine and that "a few other nurses had done 'copy-cat' charging and had written 1.0 ml but had only given the correct dose of 0.1 ml." CMS Ex. 13, at 1. The DON "instructed Nurse Coleman to conduct a further investigation, to reconcile the Resident's narcotic record, and to complete the medication error report initiated by M. McAllister." P. Ex. 42, at 2-3. "A day or two later," Nurse Coleman told the DON that a Nurse Godwin had made an error and would be counseled about it the next time she was on duty. Id. at 3. At that time, the DON concluded that this "was the end of the matter." Id. The DON, who is responsible for such investigations, did not talk with any of the nurses, did not understand that RN Coleman had never reconciled RN's narcotic count, and did not review the INR documenting multiple overdoses. CMS Ex. 13; P. Ex. 42, at 2-4.

The DON blames RN Coleman for misleading her into believing that appropriate steps were taken to reconcile the narcotics records when they were not. CMS Ex. 13, at 1; P. Ex. 42, at 4, 7. Far from exonerating the facility, the DON's testimony suffices in itself to establish that the investigation undertaken when the error was first discovered was not complete or adequate. The facility is responsible for the actions of RN Coleman as well as those of the DON. See Royal Manor, DAB No. 1990, at 12 (2005) and citation therein. The DON accepted RN Coleman's report that only one nurse and one overdose were involved. CMS Ex. 42, at 3. The DON admits in her declaration (Id. at 4, 7) that RN Coleman did not in fact review the INR or reconcile the narcotic medication counts as she had claimed to the DON. P. Ex. 35, at 1-2. Her failure to do so would have been obvious to the DON had she herself looked at the INR which on its face plainly shows the same erroneous dose administered ten times by three different nurses over a three-day period. P. Ex. 25, at 1-2.

Yet no further investigation was undertaken until October 4, 2005, after R1's son filed a complaint, which went to Premier's Administrator and the State agency, alleging that on a different occasion his mother's medication was signed out but not administered to her. Id. At that time, the DON learned that Nurse Coleman had not in fact reconciled R1's narcotic count the

prior week as she had been instructed to do (Id. at 4) and Premier's Administrator ordered a team of registered nurses to audit the narcotic records of R1 and other residents. Thus, only after this complaint triggered fears that state surveyors might come into the facility did the administration reopen the investigation to determine the actual amount of narcotics remaining and how the doses had been handled and administered.[13]

As discussed above, the audit of R1's narcotic records was performed by five registered nurses who reported that the amount in the bottle was "off by 0.9 ml," which the DON interpreted as supporting the view that only a single erroneous dose of 1.0 ml instead of 0.1 ml was administered. Id. This interpretation is unreasonable on its face. The facility failed to recognize that, if the bottle actually contained what the INR said, except for being off by a small amount, then the overdoses recorded on the INR had actually occurred. As noted, the ALJ pointed out that the results of the audit should have made that conclusion obvious, yet the facility not only fails to explain why it disregarded that conclusion but continues even now to insist that only one error occurred.

Premier argues that "CMS does not dispute – because it cannot – that Petitioner's staff actually believed after they investigated the matter, and continued to believe at the time of the hearing, that there was only one administration error, and they reacted accordingly." Premier Reply Br. at 10. Premier then asserts that this "is the crux of the case, and requires that Judge Hughes' findings of fact be reversed as unsupported by substantial evidence." Id. This argument encapsulates the fundamental confusion that pervades Premier's briefing on appeal. The crux of the case is not determining what Premier's staff "believed" but whether the staff complied with applicable standards in caring for the residents. The ALJ properly focused on what the weight of the evidence showed about the mishandling of R1's narcotics and the inadequate response of the facility when the overdosing was discovered, not on the state of mind of the facility staff.

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[13] The DON and Administrator agree about their concern about a state investigation although each attributes the origin of that concern to the other. ALJ Decision at 8-9, n.5, and record citations therein.

We conclude, for the reasons set out above, that the ALJ's factual findings are supported by substantial evidence in the record as a whole.[14]

2. The ALJ's factual findings suffice to support her legal conclusion that Premier was not in substantial compliance with the two participation requirements at issue.

Having found that substantial evidence supported the ALJ's factual findings, we turn to Premier's legal argument that these facts do not support the deficiency findings. Premier asserts that CMS's "interpretation and application of both" cited regulations are "unreasonable." Premier Br. at 11.

Section 483.25(l)(1) provides as follows:

> Each resident's drug regimen must be free from unnecessary drugs. An unnecessary drug is any drug when used:
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> (i) In excessive dose (including duplicate drug therapy); or
> (ii) For excessive duration; or
> (iii) Without adequate monitoring; or
> (iv) Without adequate indications for its use; or
> (v) In the presence of adverse consequences which indicate the dose should be reduced or discontinued; or
> (vi) Any combinations of the reasons above.

The ALJ held that administering ten times the ordered amount of morphine must be considered an excessive dose and doing so ten times constitutes excessive duration. ALJ Decision at 6. CMS's expert witness, David Guay, Pharm. D., a pharmacy professor specializing in the care of elderly patients, testified that the

[14] We note that, although some specific points made by Premier may not be discussed in detail in this decision, all of the arguments in its appeal briefs were considered in reaching our conclusions. To the extent that any of Premier's contentions are not explicitly addressed, the ALJ Decision adequately covered the subject. The Board's role is not to reweigh the evidence and reevaluate the testimony but rather to ascertain whether the factual findings are supported by substantial evidence in the record as a whole, and, as we do below, determine whether the ALJ committed any of the asserted prejudicial legal errors.

doses "were excessive" and "created a high likelihood of serious harm." CMS Ex. 35, at ¶ 18. He explained that –

> applicable standards of practice provide for a maximum increase [of morphine] which should not exceed a doubling of the individual's current dose (i.e., a 100% increase in the current dose) on a single occasion, even in individuals who have developed a tolerance of the opoids and may be taking a very high dose of them.

Id. The overdoses in question increased R1's prescribed dosage by 900%.[15]

Despite the explicit language of the regulation barring excessive doses and excessive duration in the administration of "any drug," Premier argues that this regulation applies only to certain types of drugs. Premier points to CMS's Interpretive Guidelines for this regulation, which it argues "focus very specifically on *appropriate use* of 'psychopharmacological drugs, drugs contraindicated in the elderly, and adverse drug interactions." Premier Br. at 48 (emphasis in original), citing P. Ex. 38. The Interpretive Guidelines do provide detailed guidance to surveyors about how to assess the appropriate use of numerous specific psychoactive drugs and the risks of their use as restraints compared to their potential benefits, about drugs with particular dangers for the elderly, and about interactions between common but dangerous drugs. P. Ex. 38. These topics involve complex judgments about difficult pharmaceutical and medical decisions, so the level of detail on these topics is understandable. Indeed, the second subsection of this regulation provides specific requirements for facilities to avoid and reduce the use of antipsychotic drugs as much as clinically possible. 42 C.F.R. § 483.25(l)(2). Nothing in the guidance suggests, however, that the administration of doses of other drugs in excessive amounts

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[15] CMS argues that Premier was also not in compliance with section 483.25(l)(1) because it failed to monitor R1 adequately in that its staff did not recognize that the reduced respirations might be caused by overdoses of morphine and did not seek a concentration of morphine that could be measured out more easily. CMS Post-Hearing Br. at 2, 8-9, 31-35. Premier objects that these allegation were "new" and unfounded. Premier Br. at 48-49. We need not resolve whether R1's morphine was administered without monitoring, since we agree with the ALJ that R1 received unnecessary drugs by virtue of the repeated overdoses.

or frequencies, in violation of physician orders, is somehow excluded from the plain language of the regulation.

Section 483.20(k)(3) relates to the provision of services to a resident under a comprehensive care plan and reads as follows:

> The services provided or arranged by the facility must –
>
> (i) Meet professional standards of quality; and
> (ii) Be provided by qualified personnel in accordance with each resident's written plan of care.

Premier acknowledges that this regulation "is worded broadly in terms of the necessity for all services to be provided according to accepted professional practices (as set forth in manuals, textbooks, clinical studies, etc.)" and that the Interpretive Guidelines for this provision indicate that "'errors in medication administration *technique*' (emphasis added) might be covered" under it. Premier Br. at 49 (emphasis in original). Nevertheless, Premier asserts that the provision cannot be applied to medication errors, citing the Interpretive Guidelines. Id. The guidance suggests questions for the surveyors to consider including the following: "Are there errors in the techniques of medication administration? (Cite actual medication errors at §483.25(m).)" Premier Post-Hearing Br., Att. C at 2 (emphasis in original). From this language, Premier concludes that surveyors are being instructed that they "should not cite actual medication errors under this tag, but rather under the more specific 'medication error' regulation." Premier Br. at 49-50.

Premier's conclusion is unwarranted for two reasons. First, even if we agreed that the citation required error in medication technique, as opposed to an error in the medication administered, the factual evidence discussed above and in the ALJ Decision amply demonstrates that Premier's staff's techniques in handling highly concentrated narcotics were flawed. This evidence includes the staff's undisputed and repeated failures to visually verify the amount of narcotic remaining in the bottle, as admittedly required by standards for handling of narcotics. Second, we do not agree that the language in guidelines on which Premier relies bars surveyors from citing breaches of professional standards relating to medication errors. Instead, we read the guidelines as merely recommending that surveyors cite the medication error regulation when applicable.

On our first point, we note that the ALJ identified numerous failures on the part of Premier's staff to comply with nursing

practices for the measuring, handling, tracking, and safeguarding of narcotics. Specifically, as the example mentioned, Premier never asserted that its nurses visually checked the contents of the narcotics bottle at every administration and at every shift change, and did not deny that such visual checks were required by professional standards. Instead, Premier merely argued that such checks would have been pointless where the amounts being removed were so small that the change in the level would not have been perceptible, so it was reasonable to merely record the amount remaining by subtracting the amount administered from the prior total. Premier Br. at 17-18. The testimony of CMS's expert witness, David Guay, Pharm.D., makes clear that the difficulty of perceiving precisely the removal of a small amount does not excuse the failure to make visual checks. CMS Ex. 35, at 9. He contended instead that the fact that the facility received such a concentrated formulation of morphine should itself have triggered concerns by the nurses, precisely because the dosage would require such fine measurement to avoid medication errors. Id. Such concerns were especially salient because morphine is an opoid which nurses are specifically trained to use with great care. Id. We need not decide, however, whether the nurses should have followed the pharmacy expert's preferred course of communicating with the physician and hospice staff about obtaining a more dilute solution of morphine. Dr. Gray goes on to opine that, if the nurses determined to use the solution as provided, it was their obligation to ensure the correct dosages. Id. at 10. Premier presented nothing that would undercut the conclusion that professional standards required the nurses to administer only accurate doses and track the narcotics accurately, whether or not the concentrated solution made that task more difficult.

In any case, the claim that visual checking would have been pointless is not persuasive as a practical matter. While the result of removing individual doses of 0.1 milliliter from the bottle would indeed be difficult to visualize, repeated visual inspection of the bottle by the nurses would have quickly revealed that much larger amounts than 0.1 milliliter must have been taken out to account for the drop in the level of narcotic beginning on September 24.[16] And this visual check was required to be performed both after each administration and at the end of

[16] The surveyor testified that "[t]he administration of 1.0 cc instead of 0.1 cc of medication to Resident # 1 on several occasions would have produced a noticeable reduction in the liquid level in the bottle that should have been sufficient to alert staff to a problem." CMS Ex. 36, at ¶ 19.

each shift, as the ALJ pointed out. ALJ Decision at 13. Given that the total liquid missing from the bottle due to the overdoses amounted to almost a third of the total contents, we find no error in the ALJ's conclusion that the failure to visually doublecheck the narcotic administration was "wholly inconsistent with standards of quality for dispensing and tracking narcotics," and hence indeed evidenced the facility's failure to meet professional standards of care. Id.

As to our second point, that medication errors may, in an appropriate case, support a noncompliance finding under the professional standards regulation, we note first that the language of the regulation itself makes no exception for breaches of professional standards that involve medication errors. Furthermore, reading the guidance cited by Premier as a whole makes clear that the advice to cite medication errors under 42 C.F.R. § 483.25(m), which appears as a parenthetical to one of the suggested probe questions, is not intended to preclude also citing such events under 42 C.F.R. § 483.20(k)(3) where they reflect breaches of professional standards. In the body of the discussion, the guidance explains that "professional standards of quality" means "services that are provided according to accepted standards of clinical practice" in any "particular clinical discipline or in a specific clinical situation or setting." Premier Post-Hearing Br., Att. C at 1. This broad language certainly does not exclude professional standards applicable to nurses' handling and administration of narcotics or other medications. The guidance also notes that if a deficiency has occurred which caused a negative resident outcome related to the failure to meet professional standards of care, "it should be cited under the appropriate quality of care or other relevant requirement." Id. at 2. The medication error provision is one of the quality of care requirements. We do not read the guidance to mean that deficiencies in professional standards that cause actual harm should only be cited under other relevant regulatory provisions, but rather that where a deficit in professional standards is bad enough to actually impact the outcome for a particular resident, it should appropriately also be cited under the particular substantive provision relating to the provision of that kind of care to the resident.

We thus reject Premier's position that the only appropriately applicable regulatory provision is section 483.25(m).[17] The

[17] Section 483.25(m) requires that the facility maintain a medication error rate below 5 per cent and that

(continued...)

reason Premier takes this position is evidenced by the large amount of argument Premier devotes to explaining why the circumstances here, as Premier sees them, would not have violated that section. See, e.g., Premier Br. at 47-52. Premier's arguments in this regard are neither persuasive nor relevant. We have already explained that the facts found here were appropriately cited under the two provisions relied on by CMS. We need not consider whether those facts could also make out a deficiency under the medication error provision.

We conclude that the ALJ did not err in finding Premier out of substantial compliance with the two cited provisions.

3. CMS's determination that the deficiencies posed immediate jeopardy is not clearly erroneous.

In opposing immediate jeopardy, Premier stresses its view that R1 suffered no actual harm from the overdose(s) and was not even likely to do so. However, the ALJ made clear that 42 C.F.R. § 488.301 does not require her to find that R1 suffered actual harm in order to conclude that CMS could, without clear error, determine that the facility's errors created a likelihood of serious injury or harm. Id. The Board has consistently held that "[e]ven in the context of immediate jeopardy, CMS need only determine that serious harm was likely, not that it necessarily occurred." Briarwood Nursing Center, DAB No. 2115, at 12 (2007), citing Southridge Nursing and Rehabilitation Center, DAB No. 1778 (2001) (upholding immediate jeopardy determination despite the lack of serious actual harm and noting that it was merely "fortuitous" that such harm did not occur) and Daughters of Miriam Center, DAB No. 2067 (2007).

Premier does not deny, and the record fully supports, the conclusion that morphine in excessive doses can potentially be serious, even life threatening. CMS's expert testified that the doses in this case "created a high likelihood of serious harm." CMS Ex. 35, at ¶ 18. Even if we accepted (which we do not) Premier's claim that R1 did not suffer actual harm from the overdoses, the ALJ could reasonably conclude that R1 was subjected to the likelihood of serious harm and that the systemic breakdowns that permitted the overdosing to continue over three days undetected and uncorrected meant that the facility was equally likely to mishandle narcotics prescribed to other residents with potentially serious or even fatal consequences.

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[17](...continued)
residents be free of any "significant" medication errors.

The ALJ also relied as evidence of systemic failures on two other episodes of mishandling of narcotics that were identified by the surveyors involving other residents. ALJ Decision at 15. Furthermore, the ALJ reasonably concluded that the investigation was repeatedly mishandled and the facility administrators remained oblivious to the "seriousness of the overdosage until the time of the survey." ALJ Decision at 17.

As to whether R1 suffered actual harm, Premier argues that the ALJ erred by disregarding R1's physician's opinion which was "the only specific clinical evidence on point in the record." Premier Br. at 6. Premier relies on Dr. Thigpen's telephone comment when told about the error, recorded on the error report, that there was "no harm done," and on the physician's later declaration. CMS Ex. 8, at 1; P. Ex. 44, at 3. Dr. Thigpen's declaration states that he understood that a single medication error was discovered, that a narcotic overdose "potentially can be a serious matter," but that he did not believe "that this patient suffered any adverse consequence from the one or more erroneous doses she received." P. Ex. 44, at 3. He pointed out that the resident likely had built up tolerance because she had previously received "considerably larger doses of morphine" and asserted that the reported "respiratory depression and congestion" were "the direct consequence of her cancer filling the interstitial spaces in her lungs." P. Ex. 44, at 3-4.

The physician's opinion was <u>not</u> the only relevant evidence. In fact, the nurses preparing the medication error report, who directly observed R1 during the time and after the time she was overdosed, recorded that the outcome of the error for the resident was decreased respiration and "resident extremely lethargic." CMS Ex. 8, at 1. Dr. Thigpen offered no opinion as to why the resident became notably more lethargic after she received ten narcotic overdoses and the ALJ could reasonably infer that the likely cause was the effect of the overdoses. ALJ Decision at 16 (noting that these problems resolved after the nurses began withholding the morphine after the overdosing).[18]

[18] The representation in the medication error report that the morphine was withheld to counteract the prior overdoses is confirmed by the entries on the INR. They reflect that on September 26 R1 did not receive morphine doses scheduled for 10:30 AM, 12:30 PM, 2:30 PM, 4:30 PM, 6:30 PM, and 10:30 PM, and that on September 27 she did not receive doses scheduled for 12:30 AM, 2:30 AM, 4:30 AM and 6:30 AM. P. Ex. 35, at 2.

Premier also relies on a summary timeline purporting to show that changes in R1's respiratory decline began before the first overdose and began irregularly improving only a day after the last (disputed) overdose. Premier Br. at 34; Premier Post-Hearing Br., Att. A.[19] The timeline graphs the respiration rate recorded for R1 by facility and hospice staff at variously spaced intervals from September 22 through September 28, 2005. The rate fluctuated between 7 and 20 respirations per minute, and the changes do not strictly conform to either the surveyor's or Premier's characterization of the relationship between the overdoses and changes in respiratory status.[20] Perhaps for that

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[19] A prior version of the same timeline was offered at the hearing but excluded by the ALJ, a ruling which Premier calls clearly erroneous. Tr. 66-73; Premier Br. at 33, n.30; Premier Post-Hearing Br., Att. A. Premier's counsel sought to use that version to cross-examine the surveyor, Ms. Benson, who had testified based on her review of the nurses' notes and the medication records that "when the resident was receiving the one milliliter of morphine, that she actually had a decline in the respiratory rate. And once the error was discovered, it once again appeared that her respiratory rate went back up." Tr. 66. Counsel had not previously shown the summary timeline to counsel for CMS, so the ALJ permitted a break for CMS counsel to review the document. Tr. 67-70. CMS counsel objected after review that the summary did not constitute "an accurate representation of this resident's respiratory rate during the time period at issue." Tr. 71-73. The ALJ then accepted Premier counsel's representation that he was "prepared to talk from the nursing notes and from the INR" and indicated that he should proceed in that way rather than using the challenged summary. Tr. 72-73. Premier attached to its post-hearing brief a new version of the timeline which it asserts contains all the information missing from the original version from "certain hospice and medication notes" and still supports Premier's view of the respiratory changes overall. Premier Br. at 33-34. We find no error in the ALJ's handling of the original version at the hearing. In any case, no prejudice could have occurred when the original documents from which the summary was purportedly compiled were available for Premier's use at the hearing and when Premier itself now admits that data in the record was omitted from the hearing version.

[20] Overall, the summary provides some support for the view that the overdoses were associated with some respiratory decrease. R1's respiratory rate was at or above 10 until the

(continued...)

reason, the ALJ did not rely on the summary timeline in evaluating whether CMS's determination of immediate jeopardy was clearly erroneous, but simply noted that Premier's position was "inconsistent with the surviving medication error report" prepared by R1's nurses. ALJ Decision at 16.

We conclude that CMS's determination of immediate jeopardy was not clearly erroneous.

4. The ALJ did not err in disregarding Premier's contention that it was financially unable to pay the CMP.

Premier argues that the ALJ committed "clear error" by having "simply ignored" the evidence Premier presented to show that its finances made the total amount of the penalty ($178,000) unreasonable. Premier Br. at 60. Premier cites section 488.438(f)(2) which includes "the facility's financial condition" among the factors CMS is to consider in setting the amount of a CMP.

The ALJ did not ignore evidence about Premier's finances but instead explained that the per-day CMP amounts imposed were the minimums permitted for the levels of noncompliance found during the relevant periods. ALJ Decision at 19. Since CMS had no discretion to reduce the per-day amount below $3,050 for immediate jeopardy, or $50 for lower level findings, the regulatory factors that guide CMS's discretion in imposing a CMP greater than the minimum are irrelevant here.

5. The ALJ did not err in concluding that the duration of the CMP was consistent with statutory and regulatory requirements.

The ALJ concluded that the duration of the CMP from September 24 through December 15, 2005, was consistent with statutory and regulatory requirements. ALJ Decision at 17-18. Premier strongly objects to this conclusion, based on its alleged

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[20](...continued)
first overdose, with two exceptions (at 4:30 and 6:30 AM on September 24, 2005), and most readings were between 15-20. Premier Post-Hearing Br., Att. A. From the first overdose until the afternoon of September 27 (the day after the last overdose), R1's rate never reached 15, and eleven of 20 readings were below 10. Id. From the time of the last overdose on the morning of September 26th until that evening, R1's respiration rate was flat at the lowest point of all, around 7.

inability to pay and on its assertions of having corrected any deficiencies almost immediately.

The regulatory factors governing the amount of CMP have no relation to the duration of the CMP, which rests entirely in the hands of the facility which must abate the immediate jeopardy (as it did here on November 21, 2005) in order to reduce the CMP amount to the lower range and achieve substantial compliance (as it did here on December 16, 2005) in order to end the CMP accumulation. Therefore, Premier's arguments about its inability to pay the CMP are irrelevant to the appropriate duration.

Premier contends that it eliminated any noncompliance by "no later than" October 7, 2005, "well before the survey." Premier Br. at 56. As the ALJ held, once a facility has been found to be out of substantial compliance, it remains so until it affirmatively demonstrates that it has achieved substantial compliance once again. Id. at 17, and citations therein. The ALJ's conclusion that Premier did not make such a showing for dates earlier than those determined by CMS (which are mentioned above) is supported by substantial evidence.

In this case, the ALJ found that Premier's administration did not ascertain the scope or causes of the mishandling of R1's narcotics until the survey. ALJ Decision at 18. We agree with the ALJ that this fact is telling evidence that the inservice training provided to the facility nurses in October was not adequate to prevent recurrence. Id. Premier argues that its staff "did *something* to identify the scope of, and to address, what they perceived to be a problem," given that the DON "obviously believed, even during the survey, that her conclusion that there had been only one error was correct." Premier Br. at 57, and n.42 (emphasis in original). Thus, Premier asserts that its nurses were retrained in a manner "appropriate to the perceived problem," had R1's pain medication order changed, and "did take steps to assure that at least one apparent part of the problem with liquid narcotics (the opaque bottle) would not recur (by instructing the pharmacy not to supply such medications in such packaging)." Id. at 56.

This argument essentially concedes the inadequacy of what was done, since the training was based on the erroneous idea that one nurse made one error in calculating one dose. The facility plainly failed to address the repeated and undetected errors not found by its flawed investigation, the failure of its nurses to abide by the failsafe provisions for handling narcotics, or the problem in handling highly concentrated liquid narcotics (which went well beyond the opacity of the bottle).

Premier also claims that CMS "extended" the immediate jeopardy period based on other incidents which were not themselves cited as deficiencies. Premier Br. at 57-58. The ALJ did not "extend" the immediate jeopardy period. The period of immediate jeopardy continued by law until Premier established abatement. The "other incidents" included the facility accepting another opaque bottle of narcotic (resulting in measuring problems) even after it claimed to have instructed the pharmacy not to send narcotics in opaque bottles and the discovery of another recorded overdose involving a different resident which had never been noticed or investigated by staff despite their retraining. CMS is not required to find additional deficiencies for the CMP to continue to run until the facility successfully makes the required showings, as the ALJ noted. The relevance that the ALJ attributed to these events is that they corroborated CMS's conclusion that the corrective steps taken by Premier before the survey had plainly not been adequate to address the systemic failures or to prevent recurrences of the same type of problems. ALJ Decision at 17-18. Contrary to Premier's assertions, the ALJ was not required to determine whether the circumstances of each later episode would independently support a deficiency finding in order to properly consider the events for the stated purpose.

We therefore conclude that the CMP was reasonable in per-day amount as a matter of law and that the duration of the remedy was supported by substantial evidence in the record as a whole.

6. The ALJ committed no material error in procedure.

Premier makes a number of arguments related to the procedures used by the ALJ to hear the case.

Before explaining why none of these arguments have merit, we set out these procedures. On receipt of the case, the ALJ issued an order requiring CMS, within four months, to file a list of its proposed exhibits, all of its proposed exhibits, a list of its proposed witnesses, copies of prior written statements by any proposed witnesses, and a pre-hearing brief. Order of February 10, 2006, at 2. The next month, Premier was required to file the same types of documents. Id. The order required each party to "exchange as a proposed exhibit the complete written direct testimony of any proposed witness" (Id. at 3) and to make their witnesses available for cross-examination at the hearing (Id. at 8). At the hearing, CMS did not cross-examine any of Premier's witnesses (the DON, Dr. Thigpen, the Administrator, and an owner of Premier). Premier cross-examined a surveyor and Dr. Guay. At the conclusion of the cross-examination, Premier elected not to

present rebuttal testimony. Tr. at 181-182. The parties filed post-hearing briefs.

Premier argues that the ALJ erred by "prohibiting any of Petitioner's witnesses from speaking even to contest the surveyor's live testimony or *new charges CMS first addressed at the hearing . . .*" Premier Br. at 2 (italics in original). Premier does not provide any record citation to support this allegation. In its reply brief, Premier responds to CMS's contention that the issue was waived by pointing to the following statements in the ALJ's order and notice of hearing (Hearing Order) dated August 24, 2006:

> Witnesses: CMS will produce both Ann Benson, R.N. and David Guay for Petitioner to cross-examine. Petitioner will only need to produce Douglas K. Pennington for CMS to cross-examine. Petitioner requested that all witnesses attend the hearing to be examined in-person. That request was denied.

Hearing Order at 2.[21]

At the hearing, the following colloquy occurred between Premier's counsel and the ALJ, after counsel questioned the surveyor about what she was told by Premier staff members:

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[21] Premier also submitted as an attachment with its reply brief handwritten notes dated August 18, 1006 which purport to be Premier's counsel's record of an unrecorded telephone conference on that date. Premier Reply Br. at 17-18, and Att. B. The notes read as follows in their entirety:

> Premier
>
> 8/18/06 Judge Hughes
> Leslie Connery
>
> CMS does not plan to cross-X any W's except Pennington
>
> Denies request to produce W's live
>
> Hearing in Raleigh 9/13 Wed

Premier Reply Br., Att. B. CMS did not object to our receipt of this attachment. We review it simply for what light it might shed on procedural developments before the ALJ since it does not constitute evidence on the merits of the case.

> JUDGE HUGHES: . . . [O]ne of the problems, of course, in all this, is there never seems to be any – the principals, the principal people don't seem to offer their testimony. Why didn't – it would have been really helpful if you'd brought in the testimony of the nurses who made the actual errors. But you didn't. And do we have Crystal Coleman's testimony?
>
> MR. BIANCULLI: No, but, Judge, I will remind you that I actually made a motion that we be allowed to bring in live testimony from the people who participated, and that motion was denied.
>
> JUDGE HUGHES: No, no. That was not exactly it. Your motion was that we just do it on direct. You never put these people on your witness list. Are you suggesting that these people would have been here testifying if we – you know, if for some reason you are unable to get the declaration, then it's appropriate to come in and say this particular witness is unwilling to cooperate, so I can't put in a written declaration, but I want to present this witness' testimony. That has happened to me . . . on many, many occasions, and I've always allowed the person to subpoena the witness and do direct examination. You didn't ask for that. You just said, "I think we should do all direct," and I said no.
>
> MR. BIANCULLI: Right. I mean, I'm on record in many, many cases in saying I don't mind –
>
> JUDGE HUGHES: That's different. You didn't even put the people on your witness list, which is a completely different – how the evidence comes in is a completely different issue as to whether or not you even put the people on your witness list, and you didn't do it. And all I'm saying is, you know, that creates a problem for you.
>
> MR. BIANCULLI: Understood. . . .

Tr. 84-85. The motion or request referenced in the hearing appears to have been the one denied in the Hearing Order. Premier's counsel did not dispute the ALJ's characterization of the motion and denial at the hearing. Premier's counsel did evidently seek to have all direct testimony presented orally rather than through written direct statements. The ALJ denied that blanket request. Nothing in the record or the transcript

indicates that Premier preserved any exception to the denial of its request.

Certainly, neither the Hearing Order nor the colloquy can fairly be described as "prohibiting Premier's witnesses from speaking." Premier's witnesses provided direct testimony in writing, and CMS was free to cross-examine them, but chose not to do so.[22] The same procedures applied to CMS's witnesses, who were required to submit their written direct first.

Premier makes no argument that the general use of written direct testimony in administrative hearings is somehow improper or impermissible. In any case, the Board has addressed such arguments before and concluded as follows:

> We find no evidence that Lutheran was deprived of a fair hearing by the ALJ's use of written direct testimony or any of the other procedures (or the ALJ's conduct) that Lutheran challenges. The Board has previously reviewed and approved the use of written direct testimony, so long as the right to effective cross examination is protected. See Vandalia Park, DAB No. 1940 (2004). Lutheran had the opportunity to cross-examine any of the witnesses for whom CMS submitted written direct examination and, in fact, chose to cross-examine two of those witnesses. We find no basis for Lutheran's assertion that requiring the parties to submit direct testimony in writing before the hearing prevented it from presenting its case "through the mouth of its employees and representatives." Lutheran was free to present its case through written direct testimony of any competent employee or other witness and, in fact, submitted such testimony for seven witnesses.

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[22] Indeed, CMS suggests that Premier's request that direct testimony all be presented in person arose only after Premier became aware that CMS did not intend to cross-examine most of Premier's witnesses. CMS Br. at 14. Premier denies this, but both counsel's notes and the Hearing Order which record Premier's request also record CMS's waiver of cross-examination of all witnesses except Mr. Pennington. Premier Reply Br., Att. B; Hearing Order at 2. At the hearing, CMS withdrew its request to cross-examine Mr. Pennington. Tr. at 181.

Furthermore, the ALJ's Initial Pre-hearing Order states:

> A party must exchange as a proposed exhibit the complete written direct testimony of any proposed witness. Generally, I will accept that witness' written direct testimony as a statement in lieu of in-person testimony. [emphasis added]

> The word "generally," indicates to us that the order does not foreclose a party's moving for permission to present a particular witness's direct testimony in-person if the party feels that is necessary to assure a fair hearing.

Lutheran Home at Trinity Oaks, DAB No. 2111, at 24 (2007); accord Vandalia Park, DAB No. 1940, at 28-29 (2004), aff'd, Vandalia Park v. Leavitt, No. 04-4283, 2005 WL 3334522 (6th Cir. Dec. 8, 2005) (written directs commonly used in both court and administrative contexts) and Pacific Regency Arvin, DAB No. 1823, at 7-8 (2002) (written directs not prejudicial where cross-examination in person is preserved). The same language quoted by the Board in Lutheran also appears in the Pre-Hearing Order issued by the ALJ in the present case. Pre-Hearing Order, dated February 10, 2006, at 3. The ALJ's comment at the hearing that she has permitted live testimony by witnesses when a party made a particularized showing that a written declaration was unobtainable further reinforces that the ALJ's denial of the general request for all testimony to be oral was not tantamount to precluding any oral direct testimony. See Tr. 84.

Yet Premier does not assert, and the record dose not disclose, that Premier offered any showing that in-person testimony from any particular witness was necessary to fairly present its case. Further, Premier was not entitled to rely on CMS's cross-examining its witnesses in order for them to provide testimony on which Premier wished to rely to establish its case-in-chief, which it has to present only after CMS has presented its case-in-chief. We see no basis to Premier's claim that CMS obtained "a tactical advantage unrelated to determination of the truth" by waiving cross-examination in order to deprive Premier of the "voices" of its witnesses. Premier Reply Br. at 18.

Premier argues that the use of written direct testimony, while having merit for some purposes, is inappropriate "in a case like this where witness credibility was so important." Premier Reply Br. at 18; see also Premier Br. at 39 ("the effect [of written direct] is to foreclose the traditional evaluation of a fact witness' memory, demeanor, credibility, etc."). We see no such

foreclosure here. Tellingly, Premier chose not to offer testimony, written or oral, from any witness with first-hand knowledge of most of the events at issue.[23] None of the nurses who committed, discovered, or investigated the overdoses or who treated R1 during the relevant time were listed as witnesses by Premier. The DON who did testify was away from the facility when the overdoses were administered, delegated all investigatory efforts to others, and admitted that she did not get personally involved in "the details of Resident#1's medication error" until the survey because she considered the matter not "especially serious." P. Ex. 42, at 7. The Administrator stated that she had no personal involvement until a week after the overdoses, when she had an audit performed in response to R1's son's complaint about the later episode. P. Ex. 43, at 2. Premier complains that the ALJ referred to Dr. Thigpen's written testimony as "unconvincing," without having heard him in person to assess credibility. Premier Reply Br. at 18. The ALJ's comment, however, went specifically to Dr. Thigpen's statement that he had understood that the discrepancy discovered was that "a weekend nurse apparently had administered 1.0 rather than 0.1 milliliters of morphine." ALJ Decision, at 11, n.9, quoting P. Ex. 44, at 3. She discounted the physician's claim as to having known only of one error not based on his personal credibility, but based on contemporaneous documents showing that Premier's staff reported to him "multiple instances of overdosing throughout the weekend of September 24 - 26." ALJ Decision, at 11, n.9. The only other witness proffered by Premier, Mr. Pennington, testified exclusively about Premier's inability to pay the CMP amount, which we have found to be irrelevant here. While the ALJ certainly evaluated the content of the witness declarations in light of the documentary and other evidence of record, it is not at all clear, and Premier has failed to show, that the personal credibility of any of the witnesses making factual assertions was central to any of the ALJ's conclusions.

Premier mistakenly relies on a Sixth Circuit case which remanded a case after an ALJ granted summary judgment against a nursing home. Crestview Parke Care Center v. Thompson, 373 F.3d 743 (6th Cir. 2004). The Court concluded that some material facts remained in dispute so a hearing should be provided to adjudicate them. The decision did not address the use of written direct testimony at administrative hearings. The Court simply refers to the need for an in-person or oral hearing as opposed to reaching

[23] The ALJ apparently was referring to this choice by Premier when she noted that none of the "principal people" were on Premier's witness list. Tr. at 84.

decision on a summary judgment motion when there are genuine disputes of material fact.

We turn next to Premier's claim that the requirement to produce written direct testimony prior to the in-person hearing denied Premier the opportunity to present testimony to "contest the surveyor's live testimony." Premier Br. at 2. As in Lutheran, we first observe that nothing in the ALJ's orders here precluded a party from seeking to present appropriate rebuttal testimony. Premier made no such request on the record. Furthermore, at the close of the in-person hearing, after consultation with his client representative, Premier's counsel expressly declined to offer any rebuttal evidence. Tr. 181-82.

Premier had the surveyor's written declaration well in advance of the in-person part of the hearing and exercised its right to cross-examine the surveyor in person. Premier has not shown that, either after receipt of the declaration or after cross-examination, it made any request to present additional testimony or witnesses to respond to any new or surprising matter. We thus find no support for Premier's assertion that the ALJ was in some way "freezing" its evidence "long before a hearing." Premier Reply Br. at 20.

Premier shifts from its argument that the ALJ precluded its witnesses from testifying to a further contention that the ALJ allowed "CMS to advance a new theory of liability after [Premier submitted] . . . written evidence," and failed to give Premier an "opportunity to submit new evidence or argument . . . to address that theory." Premier Reply Br. at 20. Premier states that the "substantive issue" which it was "raising in this regard" was whether CMS contended that "the evidentiary elements necessary to establish a violation of the 'professional standards' regulation are the same as those necessary to establish a violation of the 'unnecessary drugs' regulation it originally cited, or what part of its evidence or argument apply to each (or both)." Id. Premier argues that in the absence of a clear statement from CMS in this regard "*the ALJ* has an obligation to allow Petitioner to submit evidence and argument necessary to address (i.e., demonstrate compliance) with that new mixed legal/factual claim." Id. at 21 (italics in original).

It is difficult to understand how Premier can allege that it was confronted by a "new theory of liability" to which it lacked sufficient opportunity to respond. In its pre-hearing brief, CMS made its position clear. CMS contended that multiple members of Premier's staff made "numerous departures from applicable standards of nursing practice that resulted in this resident's

receipt of ten times" the prescribed amount of morphine, that Premier "failed to identify these medication errors promptly and to conduct a thorough investigation for the purpose of determining how and why they transpired," and that "these multiple failures constitute violations of the federal requirements regarding adherence to professional standards of quality (42 C.F.R. § 483.20(k)(3)(i)) and unnecessary drugs (42 C.F.R. § 483.25(l)(1)) . . . ." CMS Pre-Hearing Br. at 2. This brief was submitted on June 16, 2006 in compliance with the ALJ's Pre-Hearing Order, which expressly required that such briefs "contain any argument that a party intends to make including any argument that is not explicitly stated in a notice document such as a hearing request or a survey report." Pre-Hearing Order at 4. This brief was thus the appropriate time for CMS to present its argument that the identified facts constituted not only a violation of the "unnecessary drug" provision (as an excessive dose of morphine) but also a violation of the "professional standards" provision (in respect to the actions of the staff). Premier was not required to submit its pre-hearing brief accompanied by its exhibits and written direct testimony until July 17, 2006, and thus had ample time to present any relevant evidence or argument in relation to both alleged regulatory violations.

Furthermore, Premier fails to identify any occasion between its receipt of CMS's pre-hearing brief and the close of the case before the ALJ at which it requested an opportunity to present any "additional" witnesses or evidence (that is to say, witnesses not on its witness list or exhibits not on its exhibit list) relating to either of the cited regulations. Instead, Premier argued to the ALJ that CMS should have cited it under the "medication error" provision at 42 C.F.R. § 483.25(m) and not under the original "unnecessary drug" provision. Premier Post-Hearing Br. at 39-43. Premier contends that it could have shown that the morphine overdosing here was not a "significant" error as required under that regulation. Id. That Premier would rather have joined issue on a regulatory citation to which it believed it had an adequate defense hardly demonstrates that the ALJ somehow failed to provide Premier with sufficient opportunity to present its case in defense of the two citations with which Premier knew it was actually confronted. Premier did note to the ALJ that CMS had not amended the survey report or notice imposing remedies to add immediate jeopardy under the "professional standards" citation in those documents. Premier Post-Hearing Reply Br. at 22, n.7. Premier does not show, however, why such an amendment would be required so long as Premier had, as we have found it did, notice well before its evidence was to be submitted

that CMS was charging Premier with failing to comply with that regulatory provision.

Conclusion

For the reasons explained above, we affirm the ALJ Decision in its entirety.

/s/
Judith A. Ballard

/s/
Constance B. Tobias

/s/
Leslie A. Sussan
Presiding Board Member