

**Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division**

Lakeport Skilled Nursing Center
Docket No. A-11-105
Decision No. 2435
January 13, 2012

**FINAL DECISION ON REVIEW OF
ADMINISTRATIVE LAW JUDGE DECISION**

Lakeport Skilled Nursing Center (Lakeport) requests review of the decision by Administrative Law Judge (ALJ) Keith Sickendick in *Lakeport Skilled Nursing Center, Inc.*, DAB No. CR2385 (2011)(ALJ Decision). The ALJ concluded that Lakeport was not in substantial compliance with the Medicare participation requirement at 42 C.F.R. § 483.25 (Tag F309) from October 27, 2008 through December 21, 2008. The ALJ further concluded that the determination by the Centers for Medicare & Medicaid Services (CMS) that Lakeport's noncompliance was at the immediate jeopardy level was not clearly erroneous. The ALJ concluded that the following enforcement remedies are reasonable: a civil money penalty (CMP) of \$5,000 for October 27, 2008 and a CMP of \$1,000 per day from October 28, 2008 through December 21, 2008 (for a total CMP of \$60,000); and a denial of payment for new admissions (DPNA) from December 20, 2008 through December 21, 2008. Finally, the ALJ concluded that Lakeport was ineligible to conduct a Nurse Aide Training and Competency Evaluation Program (NATCEP) for a period of two years beginning October 28, 2008.

On appeal, Lakeport does not take exception to the ALJ's factual findings regarding Lakeport's failures to clarify and/or to follow physicians' orders in caring for five of its residents who had been diagnosed with diabetes mellitus. The physicians' orders related to matters such as how often to test the residents' blood sugar levels, what to do if the levels were outside of an acceptable range, and when to notify the resident's physician. Lakeport's appeal is limited to two statements in the ALJ Decision, which Lakeport mistakenly describes as "Findings of Fact No. 2 and 3 that violation of F-309 caused more than minimal harm to the sample residents and that immediate jeopardy to health of the residents resulted therefrom" Request for Review (RR) at 2. Lakeport argues that "these findings were based on causation testimony from registered nurses who are not qualified to render such testimony" and that the ALJ committed prejudicial error by admitting this testimony. *Id.*

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

The ALJ Decision

The ALJ Decision contains the following numbered statements, to which the ALJ referred as his “conclusions of law”:

- 1. Petitioner violated 42 C.F.R. § 483.25 (Tag F309) from October 27, 2008 through December 21, 2008.**
- 2. Petitioner’s violation of 42 C.F.R. § 483.25, posed a risk for more than minimal harm.**
- 3. Petitioner has not shown that the determination that the violation posed immediate jeopardy on October 27, 2008, was clearly erroneous.**
- 4. There is a basis for the imposition of an enforcement remedy.**

ALJ Decision at 5-6.

Since Lakeport did not take exception to the first and last conclusions, we affirm them without further discussion.

In a section of the decision titled “Facts,” under the subheading “Harm,” the ALJ Decision states:

The government’s and [Lakeport’s] witnesses acknowledge a risk for harm due to both hyperglycemia (high blood sugar) and hypoglycemia (low blood sugar). In this case, the evidence supports a finding that high or low blood sugar for [the five residents at issue] is denoted by the parameters set by the physician for notifying him or her. The testimony indicates that the most significant risk is related to hypoglycemia, when a resident may suffer brain damage and/or enter a coma.

Id. at 13, *citing* Tr. at 308-14, 437-38, 480-83, 502-03, 510-11, 547, 552-54.

Under the heading “Analysis,” the ALJ Decision refers to testimony by Surveyor Barbara Ebert about why she expanded a survey of the facility (initiated after a complaint involving Resident 2) to cover additional residents, concluding that immediate jeopardy existed on October 27 and was abated as of October 28. *Id.* at 14. It also refers to testimony by John Motter, RN, Nurse Consultant for CMS, that he reviewed the Statement of Deficiencies (SOD) on behalf of CMS and that “he concurred with the deficiency citation and the immediate jeopardy determination,” which he testified was supported by “the multiple failures of [Lakeport’s] staff to follow physicians’ orders.”

Id. The ALJ also mentions Nurse Motter’s testimony that “a resident who suffers hypoglycemia is at risk for entering a coma, and a resident experiencing hyperglycemia is also at risk for symptoms.” *Id.* Elsewhere in the “Analysis” section, the ALJ Decision says:

Furthermore, there is no dispute among the experts who testified that the **hypoglycemic** incidents pose a risk for more than minimal harm due to the potential for brain damage and coma. The evidence also shows that **hyperglycemic** incidents pose a risk for more than minimal harm due to the potential for damage to the eyes, kidneys, and nerves.

Id. at 15 (emphasis added).

The ALJ then went on to address the testimony of Lakeport’s two expert witnesses: Susan Acquisito, RN, and Bennett G. Zier, M.D. *Id.* at 16-18. Nurse Acquisito was qualified at the hearing as an expert in the area of nursing standards of practice, and Dr. Zier was qualified as an expert in the area of geriatric medicine and internal medicine. *Id.* at 16, n.12.

The ALJ said he did “not find credible or weighty the opinions of Nurse Acquisito that none of the residents were at risk for serious harm due to staff’s failures to comply with physicians’ orders.” *Id.* at 16. The ALJ explained that Nurse Acquisito had no treatment relationship with the five residents at issue, that her knowledge of the residents was limited to Lakeport’s records, and that her “opinions expressed during testimony are inconsistent.” *Id.* With respect to Dr. Zier, the ALJ stated that he did not find Dr. Zier’s testimony that there was no actual harm and no immediate jeopardy to be credible. *Id.* at 17. The ALJ gave reasons for this determination, including the following:

Dr. Zier agreed that hypoglycemia presents a risk for brain damage. He did not explain how brain damage is not serious harm. He also did not address how failures of staff to follow physicians’ orders in administering insulin and responding to the low blood sugars of these residents did not place the residents at risk for hypoglycemia and related serious harm.

Id.

The ALJ found that Lakeport had failed to rebut CMS’s *prima facie* showing that Lakeport’s violation of section 483.25 posed a “risk for more than minimal harm” and had failed to show that “the declaration of immediate jeopardy was clearly erroneous.” *Id.* In support, the ALJ gave the following additional reasons for these conclusions:

The evidence that Resident[s] 2, 4, 5, and 6 had low blood sugar readings in October is not disputed. The evidence shows multiple instances that staff failed to act in compliance with physicians' orders to treat the residents' low blood sugars. The experts agree that low blood sugar may cause brain damage.

Id.

Lakeport's arguments on appeal

As indicated above, Lakeport mistakenly asserts that the ALJ found that Lakeport's noncompliance "caused" more than minimal harm to its residents. Lakeport's arguments on appeal are premised, in part, on this mistaken assertion.

In its request for review, Lakeport contends that "CMS did not introduce evidence from a physician that **harm was caused** to any resident, let alone [that] immediate jeopardy **to a resident's health** result[ed] from a violation of regulations." RR at 3 (emphasis added). Lakeport argues that the ALJ erred by allowing "CMS' two nurses to testify as to medical causation of injury or likelihood of injury due to the care of sampled diabetic residents" and thus by failing to act as the "gatekeeper" for expert testimony envisioned by Federal Rule of Evidence (FRE) 702, as amended in response to the Supreme Court's decision in *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 589 (1993). *Id.* at 4. According to Lakeport, testimony from the two nurses amounted to diagnoses of the residents, a matter beyond their expertise, and should have been excluded. *Id.* at 5. In support, Lakeport cites to California statutes on the practice of nursing and the practice of medicine, an advisory opinion from the California Office of the Attorney General, and cases applying FRE 702. *Id.* at 5-8.

Lakeport also asserts that the ALJ did not follow Federal Rule of Civil Procedure (FRCP) 703, which Lakeport says "requires a foundational showing," that is, it requires that "the witness testify about the facts or data upon which the particular expert bases his or her opinion" *Id.* at 9. Lakeport asserts that both Nurse Motter and Nurse Ebert failed to testify about any bases for their opinions. *Id.* More specifically, Lakeport asserts that there was "absolutely no foundation" for Nurse Motter's conclusion "that violations of regulations caused the sampled patients harm, and that Nurse Motter's opinion was based only on his interpretation of the regulation. *Id.* Neither witness, Lakeport contends, applied the medical facts "to the resulting health of the sampled residents." *Id.*

On the other hand, Lakeport asserts, it offered "the only competent and admissible testimony in this entire matter as to medical causation." *Id.* at 10. According to Lakeport, Dr. Zier is the only witness the ALJ found to be qualified by education and experience to provide opinion testimony in the area of general medicine and internal medicine. *Id.* at 11. Unlike CMS's witnesses, Lakeport contends, Dr. Zier "rendered

foundational testimony arriving at his opinions.” *Id.* Lakeport cites to testimony by Dr. Zier that Resident 2 was never in immediate jeopardy, that missing “a single dose of insulin” would not result in harm to Resident 3, that Resident 4 “was not in immediate jeopardy,” and that Dr. Zier did not see any potential for serious harm with any of the residents not being administered medication as ordered. *Id.*

Lakeport concludes that “CMS did not meet their burden of proof on establishing that immediate jeopardy was present based upon the erroneous admissibility of incompetent testimony that lacked foundation, because nurses cannot testify as to a diagnosis.” *Id.* at 12.

Analysis

Lakeport’s arguments misstate the relevant issues and otherwise have no merit, for the following reasons.

Contrary to what Lakeport argues, the ALJ did not in fact conclude (and was not required to conclude) that Lakeport’s staff caused actual harm to any resident. A facility must be in “substantial compliance,” which 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.” 42 C.F.R. § 488.301 (emphasis added). Noncompliance, on the other hand, is “any deficiency that causes a facility to not be in substantial compliance.” *Id.* Lakeport points to testimony that its staff did not, in fact, cause more than minimal harm to any resident, but even assuming Lakeport established a lack of actual harm, that is not sufficient to show that the facility was in substantial compliance. *See, e.g., Oaks of Mid City Nursing and Rehabilitation Center*, DAB No. 2375, at 17 (2011)(rejecting facility’s contention that CMS may not cite noncompliance unless it finds that actual harm resulted from the facility’s failure). Although Lakeport takes exception to the ALJ’s second general conclusion -- that Lakeport’s failures “posed a risk for more than minimal harm,” Lakeport does not point to any testimony or other evidence in the record showing that the facility’s noncompliance did **not** have the potential for more than minimal harm to a resident.¹ The ALJ also was not required to find any actual harm in order to uphold CMS’s immediate jeopardy determination. “Immediate jeopardy” is a situation in which a

¹ Lakeport describes Dr. Zier’s testimony on page 545 of the transcript as testimony that “there was no potential for **serious** harm with any of the sampled residents.” RR at 11 (emphasis added). Under the regulations, harm may be “more than minimal” without being serious. Moreover, the transcript shows that the question to which Dr. Zier responded “Yes” was whether he was indicating that he “didn’t see any potential for serious harm with any of these residents not being administered medication as ordered.” Tr. at 545. The facility’s failures went beyond failing to administer medication as ordered, however.

facility's noncompliance "has caused, or is likely to cause, serious injury, harm, impairment, or death of a resident." 42 C.F.R. § 488.301. Contrary to what Lakeport suggests, the ALJ was not required to find immediate jeopardy with respect to a particular resident. Where a facility's noncompliance is **likely** to cause serious harm to a **resident**, immediate jeopardy exists, regardless of whether any particular resident has already suffered serious harm or is likely to suffer serious harm.

Lakeport's reliance on the federal rules is also misplaced. Neither FRE 702 nor FRCP 703 applies to this administrative proceeding under 42 C.F.R. Part 498.² In fact, section 498.61 specifically permits an ALJ to receive evidence "even though inadmissible under the rules of evidence applicable to court procedure."

In any event, the ALJ did assume a "gatekeeper" role in determining whether to permit testimony from CMS's witnesses that they were not qualified to give or that was without foundation. *See, e.g.*, Tr. at 97, 138-40 (ALJ rulings that certain matters not within the scope of Nurse Ebert's expertise), 312 (ALJ upholding an objection based on lack of a foundation). Nor did the ALJ Decision rely on testimony that the witnesses were not qualified to give or that was without foundation. Both witnesses (especially Nurse Motter) had extensive nursing experience. Tr. at 49-51, 297-98.

Moreover, both witnesses testified about the foundation for their testimony. Nurse Ebert, the surveyor, based her testimony on the facility documents she reviewed (including charts for five residents), her interviews during the survey, her familiarity from caring for diabetic patients with the signs and symptoms of hypo- and hyperglycemia, and her consultation with her supervisors. Tr. at 52-141. Nurse Motter testified that he had reviewed the documents related to the survey. Tr. at 298-300. He testified that his basis for concurring in the immediate jeopardy determination was—

the number of cases where – or examples provided where the physicians were not informed based on the critical thresholds that they gave, that they had written as the orders; medications that were not documented to have been given; medication that when those critical thresholds are met that were not being provided for the residents.

Tr. at 300. He also testified that he has cared for patients with diabetes. Tr. at 300-01.

² The ALJ did not, as Lakeport alleges, state that he was adopting the federal rules for these proceedings, instead referring to them as "guidelines." Tr. at 8-9. An ALJ may, of course, refer to such rules to guide the determination about what weight to give evidence even if they do not govern the admissibility of evidence. Lakeport mistakenly relies on the procedural guidelines sent out to parties in civil remedies cases (part of which Lakeport submitted as Exhibit A). The guidelines state that an ALJ may modify the procedures set out in those guidelines, but it does not follow that the ALJ here had the authority (or intended) to modify the explicit regulatory provision governing the admissibility of evidence.

In testifying about the **risk** of serious harm, these nurses were not diagnosing the residents (or engaging in the unauthorized practice of medicine), as Lakeport alleges. Instead, they were relying on the physicians' diagnoses, on the physicians' orders evidencing the physicians' judgments about when residents' blood sugars were too low (or too high) and required action, on standards of nursing practice, and on the witnesses' own experience with diabetic patients. Indeed, Lakeport did not object at the hearing to their qualifications to testify about immediate jeopardy.

Lakeport is also mistaken in arguing that CMS had the burden to show that immediate jeopardy existed as a result of the noncompliance. Instead, under the regulation at 42 C.F.R. § 498.60(c)(2), the ALJ was bound to uphold CMS's determination regarding the level of noncompliance unless it was "clearly erroneous." The Board has held that this regulation places the burden on the facility -- a heavy burden, in fact -- to upset CMS's finding regarding the level of noncompliance. *Barbourville Nursing Home*, DAB No. 1962 (2005), *aff'd*, *Barbourville Nursing Home v. U.S. Dept. of Health and Human Servs.*, 174 F. App'x 932 (6th Cir. 2006).

Lakeport did not meet that burden. The ALJ determined not to give any weight to Dr. Zier's opinion on immediate jeopardy because the ALJ found that testimony not credible, a determination to which we defer.³ The ALJ observed Dr. Zier testifying and also noted in his decision factors relevant to credibility. For example, the ALJ noted that Dr. Zier's conclusions related to Resident 2 relied in part on evidence from a period after the survey, that Dr. Zier did not explain how brain damage (which he agreed was a risk from hypoglycemia) is not serious harm, and that Dr. Zier did not address how staff failures to follow physician orders in responding to low blood sugars did not increase the risk for hypoglycemia. ALJ Decision at 17. An ALJ may appropriately consider such factors in assessing credibility. *Hillman Rehabilitation Center*, DAB No. 1663, at 19 n.12 (1998), *aff'd*, *Hillman Rehabilitation Ctr. v. U.S. Department of Health & Human Servs.*, No. 98-3789 (GEB)(D.N.J. May 13, 1999).

As the ALJ's discussion of Dr. Zier's testimony also indicates, Dr. Zier addressed either individual incidents or individual residents. Tr. at 504-531. At most, he opined that the facility's failures did not place the particular resident being discussed in immediate jeopardy, by which he meant it did not cause immediate harm or the potential for immediate harm or death "by a specific act." Tr. at 513. This testimony is not relevant to

³ The ALJ also said he did not find Nurse Acquisito's opinions on the lack of harm and lack of immediate jeopardy to be credible or weighty. ALJ Decision at 16. Lakeport does not rely on her testimony on appeal.

the issue under the regulatory definition: whether the facility's noncompliance – evidenced by repeated failures to follow physician orders with respect to multiple residents – was likely to cause serious harm to a resident if not corrected. As the Board has held, immediate jeopardy exists if a facility's noncompliance is likely to cause serious injury, harm, impairment, or death if not corrected, even if the surveyors did not observe or identify a particular resident who was actually threatened with harm during the survey. *Hermira Traeye Memorial Nursing Home*, DAB No. 1810, at 7 (2002), *aff'd sub nom. Sea Island Comprehensive Health Care Ctr. v. U.S. Dep't of Health & Human Servs.*, 79 F. App'x 563 (4th Cir. 2003); *see also Royal Manor*, DAB No. 1990, at 8 (2005) (“demonstrated incompetence of the facility's response” to a life-threatening emergency was likely to harm other residents with a similar medical emergency).

Contrary to what Lakeport suggests, moreover, the ALJ's two conclusions that Lakeport challenges on appeal were not based only on the nurses' testimony regarding harm. ALJ Decision at 14-18. He also relied on his findings about multiple instances of staff failure to clarify and/or to follow a physician's order for what to do when a resident's blood sugar was above or below the parameters set by the resident's physician and/or for when to administer insulin. ALJ Decision at 17. These instances related to five diabetic residents in the facility. The ALJ also discussed resident care plans, including instructions for actions if blood sugar levels were outside of the parameters set by the residents' physicians. Tr. at 8, 10. These instructions indicate that the facility itself recognized the dangers of hypo- and hyperglycemia for at least some residents. In addition, the ALJ relied on testimony of Lakeport's own witnesses acknowledging the serious dangers of hypoglycemia. Tr. at 437, 480-81, 502, 537-40, 547. On appeal, Lakeport does not dispute these facts underlying the ALJ's rationale. Yet, these facts support CMS's determination that Lakeport's noncompliance was likely to cause serious harm to a facility resident. Indeed, multiple instances of staff members failing to follow physicians' orders, and thus failing to meet standards of nursing practice, also posed a risk to residents other than the five residents cited and posed a risk to residents even if they did not have diabetes, increasing the likelihood of serious harm if the noncompliance was not corrected.

Accordingly, we reject Lakeport's arguments that the ALJ admitted testimony from CMS witnesses that was beyond their expertise and that amounted to diagnoses of the residents beyond the scope of nursing practice. We concur with the ALJ that Lakeport did not show that CMS's determination regarding immediate jeopardy was clearly erroneous.

Conclusion

For the reasons stated above, we affirm the ALJ Decision.

_____/s/
Leslie A. Sussan

_____/s/
Constance B. Tobias

_____/s/
Judith A. Ballard
Presiding Board Member