Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Appellate Division

In the Case of:	
Life Care Center of Tullahoma	DATE: March 5, 2010
Petitioner,	Civil Remedies No. CR1964
	Board Dkt. No. A-09-115
- v. -	
	Decision No. 2304
Centers for Medicare & Medicaid Services.	

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Life Care Center of Tullahoma (Life Care), a Tennessee skilled nursing facility (SNF), appeals the June 24, 2009 decision of Administrative Law Judge Steven T. Kessel, Life Care Center of Tullahoma, DAB CR1964 (2009) (ALJ Decision). At issue before the ALJ was a determination of noncompliance by the Centers for Medicare & Medicaid Services (CMS) based on a November 2007 health survey of Life Care. After a hearing, the ALJ concluded: (1) Life Care was not in substantial compliance with five Medicare participation requirements, including the requirement that a SNF consult immediately with a physician when there is a significant change in a resident's health status; (2) Life Care's noncompliance began on June 25, 2007 and continued through November 27, 2007; (3) CMS's determination that Life Care's noncompliance during that six-month period placed residents in immediate jeopardy was not clearly erroneous; and (4) the per-day civil money penalty (CMP) imposed by CMS for the period of immediate jeopardy - $6,550 per day for 156 days (for a total of $1,021,800) - was reasonable.

For the reasons discussed below, we affirm the ALJ's findings of noncompliance and CMS's immediate jeopardy determination but reduce the per-day CMP from $6,550 to $4,550 per day.

LEGAL BACKGROUND

In order to participate in Medicare, a SNF must comply with the participation requirements set forth in 42 C.F.R. Part 483, subpart B. 42 C.F.R. § 483.1. State agencies under contract with CMS perform onsite surveys to assess compliance with these requirements. Id. §§ 488.300, 488.305. Deficiencies- or failures to meet participation requirements - are reported by the state survey agency on a standard form called a "Statement of Deficiencies." State Operations Manual (SOM), CMS Pub. 100-07, Appendix P - Survey Protocol for Long-Term Care Facilities (available at http://www.cms.hhs.gov/ Manuals/IOM/list.asp).

CMS may impose enforcement remedies (including CMPs) when it determines, on the basis of survey findings, that a SNF is not in "substantial compliance" with one or more participation requirements. See 42 C.F.R. § 488.402. "Substantial compliance" means a level of compliance such that "any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm." Id. § 488.301. Under the regulations, the term "noncompliance" refers to "any deficiency that causes a facility to not be in substantial compliance." Id.

CMS determines the amount of a CMP based on the "seriousness" of the SNF's noncompliance. See 42 C.F.R. § 488.404. "Seriousness" is largely a function of the deficiency's "scope" (whether it is "isolated," constitutes a "pattern," or is "widespread") and "severity" (whether it has created a "potential for harm," resulted in "actual harm," or placed residents in "immediate jeopardy"). Id. § 488.404(b); SOM, App. P, sec. V. The most serious type of deficiency is one that places residents in "immediate jeopardy." Id. Immediate jeopardy is defined as "a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment or death to a resident." 42 C.F.R. § 488.301.

A deficiency's seriousness is designated in the Statement of Deficiencies by a letter (A-L) that corresponds to a matrix reflecting different combinations of scope and severity. SOM § 7400(E). A "J" designation refers to "isolated" immediate jeopardy-level noncompliance, while a "L" designation refers to "widespread" immediate jeopardy-level noncompliance. Id.

CASE BACKGROUND

On November 27, 2007, the Tennessee Department of Health (state survey agency) completed a health survey of Life Care and thereafter issued a Statement of Deficiencies containing the survey's findings. CMS Ex. 1. The Statement of Deficiencies contained the following 13 findings of immediate jeopardy-level noncompliance:

Survey Tag	Requirement Allegedly Violated	Seriousness
F155	42 C.F.R. § 483.10(b)(4)	J
F157	42 C.F.R. § 483.10(b)(11)	L
F226	42 C.F.R. § 483.13(c)	L
F280	42 C.F.R. § 483.20(d)(3) and 483.10(k)(2)	L
F281	42 C.F.R. § 483.20(k)(3)	L
F309	42 C.F.R. § 483.25	L
F319	42 C.F.R. § 483.25(f)(1)	L
F323	42 C.F.R. § 483.25(h)	J
F326[1]	42 C.F.R. § 483.25(i)(2)	J
F329	42 C.F.R. § 483.25(l)	L
F333	42 C.F.R. § 483.25(m)(2)	J
F353	42 C.F.R. § 483.30(a)	L
F490	42 C.F.R. § 483.75	L

CMS Ex. 1. Based on these findings, the state survey agency recommended the imposition of a $6,550 per-day CMP with an effective date of June 25, 2007. CMS Ex. 41.

In addition to the health survey, Life Care underwent Life Safety Code (LSC) surveys which resulted in findings of non-immediate-jeopardy level noncompliance (findings not at issue in this decision). CMS Exs. 40 & 43.

Subsequent revisit surveys found that Life Care had removed the alleged immediate jeopardy-level noncompliance as of November 28, 2007 and had come back into substantial compliance with all requirements on December 7, 2007. CMS Exs. 44-46.

Based on the health and LSC survey findings, CMS issued a determination of noncompliance and imposed the following CMPs on Life Care: (1) a $6,550 per-day CMP that was effective from

[1] As a result of informal dispute resolution, an independent panel within the state survey agency recommended in February 2008 that tag F326 be rescinded. It is unclear whether this deficiency tag was rescinded.

June 25, 2007 through November 27, 2007; and (2) a $100 per-day CMP that was effective from November 28 through December 6, 2007. CMS Exs. 44-46.

Life Care appealed CMS's determination by requesting a hearing before the ALJ. In its request for hearing, Life Care indicated that it was challenging all 13 immediate jeopardy-level findings of noncompliance from the November health survey. The parties subsequently exchanged documentary evidence, written direct testimony, and pre-hearing briefs that outlined the issues for hearing.

In its pre-hearing brief, CMS asked the ALJ to sustain the $6,550 per-day CMP based on five of the Statement of Deficiencies' 13 findings of immediate jeopardy-level noncompliance. CMS Pre-Hearing Br. at 3. Those five findings were:

- 42 C.F.R. § 483.10(b)(11), tag F157 (failure to consult immediately with a physician about a significant changes in the resident's health status);
- 42 C.F.R. § 483.20(k)(3), tag F281 (failure to provide services that meet professional standards of quality);
- 42 C.F.R. § 483.25, tag F309 (failure to provide necessary care and services);
- 42 C.F.R. § 483.25(m)(2), tag F333 (failure to ensure that residents are free of significant medication errors); and
- 42 C.F.R. § 483.75, tag F490 (failure to administer the facility in a manner that enables effective and efficient use of its resources).

Id. CMS defended these five noncompliance findings by presenting testimony and argument on eight residents - namely, Residents 18, 19, 26, 27, 38, 40, 48, and 56. Id. at 3-23. In discussing the nursing care provided to five of these eight residents, CMS alleged a "systemic collapse" of Life Care's "diabetes protocol." Id. at 11-18. More specifically, CMS contended that Life Care's nursing staff had: (1) failed to consult with the physicians of diabetic residents who displayed signs or symptoms of hypoglycemia (abnormally low concentration of glucose in the blood); (2) failed to follow a general directive to notify a physician if a resident's blood glucose fell below 60 mg/dl or rose above 360 mg/dl; (3) administered

insulin to certain residents without first determining their blood glucose levels; and (4) failed to implement "sliding-scale" insulin orders. Id.

In support of these allegations, CMS submitted written direct testimony from James K. Schmitt, M.D. and three members of the survey team (Jacqueline Denton, R.N., Rhonda Arnold, R.N., and Vickie Crocker, R.N.). Life Care submitted written direct testimony from its medical director, John Patsimas, M.D., and from Annette V. O'Brien, R.N. and John B. Standridge, M.D. All of the parties' witnesses were made available for cross-examination.

On March 12, 2009, the ALJ conducted an in-person hearing during which Life Care cross-examined three of CMS's witnesses, including Dr. Schmitt. (CMS did not cross-examine any of Life Care's witnesses.) The parties then submitted post-hearing briefs.

THE ALJ DECISION

Focusing on the care provided to five residents (18, 27, 40, 48, and 56), and finding (among other things) that Life Care's nursing staff had "disregarded wholesale the express protocols and orders that had been issued to govern the care of diabetic residents," the ALJ concluded that Life Care was not in substantial compliance with the participation requirements in 42 C.F.R. §§ 483.10(b)(11), 483.20(k)(3), 483.25, 483.25(m)(2), and 483.75 from June 25, 2007 through November 27, 2007. ALJ Decision at 2-25. In addition, the ALJ upheld, as not clearly erroneous, CMS's finding that Life Care's noncompliance with those requirements had placed residents in immediate jeopardy. Id. at 25-26. The ALJ further concluded that the amount of the CMP imposed for the six-month period of immediate jeopardy - $6,550 per day for the 156 days from June 25 through November 27, 2007 - was reasonable. Id. at 26-28. Finally, the ALJ declined to address whether CMS had validly imposed the $100 per-day CMP that ran from November 28 through December 6, 2007. Id. at 1.

Life Care filed a timely request for review of the ALJ Decision. In addition to submitting the standard appeal briefs, Life Care submitted a Motion to Submit Supplemental Authority (dated October 16, 2009) and a Second Motion to Submit Supplemental Authority (dated January 28, 2010). The Board hereby grants both motions.

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*, http://www.hhs.gov/dab/divisions/appellate/guidelines/index.html.

DISCUSSION

In its request for review, Life Care generally contends that the ALJ's findings of noncompliance are based on legal errors or are not supported by substantial evidence. More specifically, Life Care contends that the ALJ:

- held it to standards of nursing care not found in the applicable regulations and for which there is insufficient evidence in any event;
- failed to give adequate weight to the testimony of its witnesses;
- made a flawed credibility judgment concerning the testimony of Life Care's medical director; and
- erroneously denied it the opportunity to rebut testimony given and arguments made for the first time during the March 12, 2009 hearing.

Life Care also objects on various grounds to the conduct of the hearing. It contends, for example, that its due process and statutory hearing rights were violated when CMS elected to defend the CMP based on a subset of the noncompliance findings contained in the Statement of Deficiencies. In addition, Life Care asks the Board to overturn or expunge noncompliance findings that CMS elected not to litigate. Life Care also contends that the $6,550 per-day CMP imposed by CMS for the immediate jeopardy-level noncompliance (assuming it existed) is excessive. Finally, Life Care suggests that the ALJ improperly sustained the $100 per-day CMP.

Overall, we conclude that the ALJ's findings of noncompliance - which focus largely on alleged failures by the nursing staff to consult with residents' physicians, effectuate physicians' orders, and comply with standard treatment protocols - are

supported by substantial evidence and legally correct. In addition, we sustain CMS's determination that Life Care's noncompliance was at the level of immediate jeopardy. We also: (1) sustain the ALJ's credibility judgment concerning the testimony of Life Care's medical director; (2) reject Life Care's due process claim and related contentions concerning conduct of the hearing; (3) deny Life Care's request to overturn or expunge survey findings of noncompliance that CMS elected not to rely upon; and (4) find that the ALJ properly declined to determine whether CMS had a basis to impose a $100 per day CMP for the period November 28 through December 6, 2007. Finally, although we affirm the ALJ's findings of noncompliance, we conclude that the amount of the per-day CMP imposed by CMS for Life Care's period of immediate jeopardy-level noncompliance was unreasonable. Accordingly, we reduce CMP from $6,550 per day to $4,550 per day.

A. *The ALJ's conclusion that Life Care was not in substantial compliance with 42 C.F.R. § 483.10(b)(11) is supported by substantial evidence and not legally erroneous.*

Section 483.10(b)(11) of the regulations requires a SNF to "immediately . . . consult with the resident's physician . . . when there is . . . [a] significant change in the resident's physical, mental or psychosocial status (i.e., a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications)" (emphasis added). The regulation defines a "significant change" as "a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications." The requirement to "consult" means that the SNF must engage in a dialogue with the physician about an appropriate response to the significant change or changes. Magnolia Estates Skilled Care, DAB No. 2228, at 9 (2009).

The ALJ concluded that Life Care was noncompliant with section 483.10(b)(11) in its care of Residents 18, 27, 40, and 56. See ALJ Decision at 4-19. Most of the ALJ's analysis focuses on Residents 18, 27, and 40, and so we address his findings regarding those three residents first.

1. Substantial evidence supports the ALJ's finding that Life Care failed to consult immediately with the physicians of Residents 18, 27, and 40 about significant changes in their health status on June 25, July 21, September 11, and October 27, 2007.

The ALJ found that Life Care had a "protocol" that instructed

the nursing staff to notify a diabetic resident's physician when the resident's blood glucose dropped below 60 mg/dl or rose above 360 mg/dl. ALJ Decision at 5-6. The ALJ found that the physician notification protocol appeared in residents' physician orders and was "featured prominently" in treatment administration charts (also known as "flow sheets) for each of its diabetic residents. Id. at 6. In addition, the ALJ found that "[a] decline in a resident's blood sugar level to below 60 mg/dl is a 'significant change' in a resident's condition within the regulatory definition of that term because it is a clinical complication that can cause severe damage or even death." Id. at 7.

The ALJ also found that on the following dates, Residents 18, 27, 40 had episodes of hypoglycemia in which their blood glucose fell below 60 mg/dl:

June 25, 2007 (Resident 27)
July 21, 2007 (Resident 27)
September 11, 2007 (Resident 40)
October 20, 2007 (Resident 18)
October 21, 2007 (Resident 18)
October 24, 2007 (Resident 18)
October 26, 2007 (Resident 18)
October 27, 2007 (Resident 18)

Id. at 8. According to the ALJ, during the June 25, July 21, September 11, and October 27 episodes, the residents in question manifested signs or symptoms of "extreme" hypoglycemia. Id. at 8, 15. The ALJ further found that Life Care did not consult, or consult immediately, with the residents' physician(s) about those episodes, thus depriving the physicians of the "opportunity to direct the care immediately provided" in response to the episodes as well as the "opportunity to consider whether [the residents'] overall treatment regimes . . . were inappropriate or needed to be adjusted." Id. at 8, 17-18.

In short, the ALJ found that: (1) the episodes of hypoglycemia experienced by Residents 18, 27, and 40 constituted "significant changes" in health status within the meaning of section 483.10(b)(11); and (2) Life Care failed to consult immediately with the residents' physicians about those changes, as the regulation required.

We first discuss whether the record supports the ALJ's finding that Residents 18, 27, and 40 experienced significant changes in their health status on the dates in question.

(a) *Residents 18, 27, and 40 experienced episodes of hypoglycemia that constituted significant changes in their health status.*

Life Care's appeal focuses largely on the ALJ's finding that a blood glucose level below 60 mg/dl is a significant change in the resident's health status that necessitates immediate physician consultation. See RR at 23-29. According to Life Care, the ALJ overlooked or ignored expert testimony and other evidence that nursing standards do not require immediate physician consultation when the hypoglycemic resident is not manifesting serious symptoms of that condition and the facility has succeeded quickly in boosting the resident's blood glucose above 60 mg/dl. RR at 27-28, 35-36, 38-39, 41-42, 51. Thus, Life Care contends that it cannot be found noncompliant with section 483.10(b)(11) for failing to consult a physician about "uncomplicated manifestations" of a resident's diabetes, or about "*asymptomatic* low blood sugar that responds unremarkably to standard nursing interventions." RR at 51 (italics in original).

Both parties submitted testimony concerning the proper management of hypoglycemia. Dr. Patsimas, Life Care's medical director, testified that requiring immediate physician notification in every instance in which a diabetic resident's blood glucose falls below 60 mg/dl, regardless of the resident's response to treatment and other clinical circumstances, is infeasible and medically unnecessary. P. Ex. 81, at 4-7. He testified that under a "typical" nursing protocol for diabetic residents, if the hypoglycemic resident is alert and able to swallow, then the nursing staff should attempt to boost the resident's blood sugar, then call the physician if the resident "does not respond as anticipated to the usual treatment." Id. at 4. He further explained:

> When a patient responds as intended and expected to an intervention for hypoglycemia . . . and is asymptomatic, I see no necessity to notify the physician immediately of that result. There are both clinical and practical reasons for my opinion. First, if a patient has responded as expected to an intervention, and is asymptomatic, then it is very unlikely that I would order any additional intervention. The nature of the disease process is that blood sugar tends to be unstable, but the underlying disease cannot treated; rather, the treatment is simply to stabilize the blood sugar. If that response occurs, then no further treatment

ordinarily is needed.

* * *

> My practice, of which the nursing facility's staff is well aware, is that I want to be called (or my Nurse Practitioner should be notified) if a patient exhibits significant symptoms of hypoglycemia or hyperglycemia (such as a seizure) or remains symptomatic after the nurses implement the usual nursing interventions, or the patient does not respond.

Id. at 5, 8 (emphasis added).

Dr. Standridge, Life Care's medical expert, testified that there is no "standard of care that requires that a diabetic patient's physician must be personally notified each time the patient experiences high or low sugar, especially if the condition responds promptly to standard treatment." P. Ex. 79, at 6 (emphasis added). Dr. Standridge indicated that a "correct" interpretation of Life Care's instruction to notify the physician in the event of a blood glucose outside the 60-360 mg/dl range was to call the physician "in an emergency, or if the patient is exhibiting serious symptoms of high or low blood sugar, or if the routine interventions provided by the protocol are not effective." Id. at 9 (emphasis added).

Annette O'Brien, R.N. testified:

> [I]n my opinion as an experienced nurse, I would read the orders in this case to require the nurse to notify the physician, as the facility's policy provides, only when a resident has high or low blood sugar, and that condition does not respond to a routine intervention, or the resident continues to exhibit symptoms following intervention, or the nurse otherwise makes a judgment that something out of the ordinary is occurring.

P. Ex. 80, at 5.

Surveyors Denton, Arnold, and Crocker testified that "[i]f a resident's low blood glucose level [does] not respond to an initial attempt to boost it, professional standards oblige[ ] the nurses to notify/consult with a physician before making the next attempt (especially in situations where a resident displayed symptoms of hypoglycemia) - and industry standards

obliged Life Care to have in effect a policy and procedure making it clear that nurses should consult physicians after making only a simple, initial attempt to boost a resident's blood glucose level (i.e., by giving a resident orange juice with sugar added)." See CMS Ex. 49, at 7 (emphasis added); see also CMS Ex. 47, at 7; CMS Ex. 48, at 6.

Dr. Schmitt, CMS's medical expert, indicated in his direct testimony that he was offering "no opinion regarding the propriety of" Life Care's physician notification protocol. CMS Ex. 50, at 2. On cross-examination, Dr. Schmitt was asked about whether it would be acceptable for a SNF to follow a standard policy that requires the nursing staff to notify or consult with a physician about blood glucose less than 60 mg/dl only if the resident is symptomatic or does not respond adequately to efforts to boost blood glucose. Tr. at 148. Dr. Schmitt replied that although he did not consider that hypothetical policy to be as safe as Life Care's physician notification protocol - which required Life Care to notify the physician in all cases in which the resident's blood glucose fell outside the 60-360 mg/dl range - such a policy would, he said, be "valid" and not fall below the standard of care as long as the policy reflected consideration of "all of the possible outcomes." Tr. at 141-42, 148-49. None of CMS's witnesses testified that professional standards of nursing care required immediate physician consultation in every instance in which a diabetic resident's blood glucose falls below 60 mg/dl, regardless of the resident's response to an initial attempt to boost it above 60 mg/dl.

In light of the testimony from both parties, substantial evidence does not support the ALJ's finding that blood glucose lower than 60 mg/dl always constitutes a "significant change" in health status within the meaning of section 483.10(b)(11). Nevertheless, substantial evidence of record does support the ALJ's findings that: (1) Resident 27 experienced significant changes in her health status on June 25 and July 21, 2007; (2) Resident 40 experienced a significant change in her health status on September 11, 2007; and (3) Resident 18 experienced a significant change in her health status on October 27, 2007. In each of these instances, the resident experienced not only a drop in blood glucose substantially below 60 mg/dl but additional symptoms that necessitated immediate physician consultation under the applicable standard of care and an internal "emergency procedures" policy.

The record shows (and the ALJ found) that:

- Around noon on **June 25, 2007**, Resident 27 had a blood glucose level of 32 and was reportedly lethargic, staring blankly, and mumbling to herself; her extremities were also twitching involuntarily. CMS Ex. 17, at 15.

- At 1:00 a.m. on **July 21, 2007**, Resident 27's blood glucose was at 40 mg/dl, and she was reportedly very groggy and unable to walk. CMS Ex. 17, at 16.

- On 3:00 p.m. on **September 11, 2007**, Resident 40's blood glucose was 28 mg/dl, her skin was cool and clammy, her head was wet with sweat, and she was slow to react to stimuli. CMS Ex. 26, at 19.

- At 6:15 p.m. on **October 27, 2007**, Resident 18's blood sugar was 20 mg/dl, and she concurrently experienced convulsions, diaphoresis, and an inability to speak or swallow. CMS Ex. 12, at 16.

In short, the record shows that on these four occasions, the residents had blood glucose levels significantly below 60 mg/dl and also displayed additional signs or symptoms of hypoglycemia.[2]

Dr. Schmitt testified that "[t]he particular risks of harm associated with a diabetic's experiencing hypoglycemia . . . as established by FSBS [finger-stick blood sugar] test results lower than 60 mg/dl[ ] [are] very serious[.]" CMS Ex. 50, at 3. "[A]t that level of low serum (blood) glucose," he said, "a diabetic is likely to experience sudden onset of grave symptoms, including seizures, coma and death." Id. Dr. Schmitt also testified that the "apparent failure of nurses to notify and consult Resident #27's and Resident #40's physician(s) while these episodes were occurring [on June 25, July 21, and September 11, 2007] was a violation of prevailing standards of care - as well as Life Care's FSBS [i.e., the 60-360 notification] policy - and these failures exposed the residents to a high likelihood of suffering very serious harm, including seizures, coma or death." Id. at 5. The clear implication of

[2] Dr. Patsimas testified that "[c]ommon symptoms of low blood sugar (hypoglycemia) include excessive perspiration, weakness, faintness or dizziness, blurred vision, tremors, tachycardia (racing heartbeat), headache, or even sudden unconsciousness." P. Ex. 81, at 3.

this testimony is that the episodes of hypoglycemia experienced by Residents 27 and 40 were, in Dr. Schmitt's opinion, "significant changes" in health status. Dr. Schmitt's statements concerning the potential dangers posed by blood glucose below 60 mg/dl (seizures, coma, or death), coupled with the severity of the documented episodes of hypoglycemia on June 25, July 21, and September 11, adequately supports a finding that those episodes met section 483.10(b)(11)'s definition of a significant change - being instances of "deterioration in health . . . status" in either life-threatening conditions or clinical complications.

We note that Dr. Schmitt did not express an opinion about the clinical significance of Resident 18's October 27 episode of hypoglycemia. In any event, Life Care concedes on appeal that Resident 18 suffered "serious complications of hypoglycemia" on October 27, a fact that necessitated physician notification even under Dr. Standridge's criteria. See RR at 50; see also P. Ex. 79, at 7.

The ALJ also relied on the undisputed fact that all three residents had physician orders, written by Dr. Patsimas, directing the nursing staff to notify him if the resident's blood glucose dropped below 60 mg/dl. It is reasonable to conclude from these circumstances that Dr. Patsimas wrote the order based upon his medical judgment that blood glucose less than 60 mg/dl was, for these particular residents, a significant medical event requiring his input and direction. As the residents' attending physician in the facility, Dr. Patsimas was, presumably, thoroughly familiar with their clinical condition and thus was in the best position to determine what medical intervention was required under the circumstances. As we noted, Dr. Patsimas testified that he expected to be notified only if the resident exhibited "significant symptoms of hypoglycemia" (or if the resident remained symptomatic after treatment or failed to respond to the initial attempt to boost the resident's blood glucose). However, Dr. Patsimas did not indicate whether he considered the symptoms exhibited by Residents 18, 27, and 40 to be "significant symptoms" under the circumstances. See P. Ex. 81, at 7-8. We find that the ALJ could reasonably infer from this silence that Dr. Patsimas did not disagree with CMS that the episodes of hypoglycemia on June 25, July 21, September 11, and October 27 were serious enough to necessitate immediate physician consultation.

The ALJ's finding that those episodes were significant changes in health status is consistent with Life Care's own "emergency procedures" for diabetic residents who displayed symptoms of

hypoglycemia. During the November survey, surveyors asked Life Care's nursing director for the facility's written policies governing the management of hypoglycemic residents. Tr. at 52-53. In response, Life Care produced a policy, authored by Life Care's corporate parent, entitled "Hyperglycemia & Hypoglycemia." Id.; CMS Ex. 39, at 1. The policy appears under the chapter heading of "Emergency Procedures." CMS Ex. 39, at 1. The Hyperglycemia & Hypoglycemia policy states in relevant part that the physician is to be "immediately notified when any resident who receives insulin exhibits altered behavior or mental/physical state consistent with hyperglycemia or hypoglycemia." CMS Ex. 39, at 1 (emphasis added). On the four occasions discussed, Residents 18, 27, and 40 experienced what could reasonably be called "altered behavior or mental/physical state consistent with" hypoglycemia, including convulsions, inability to swallow, lethargy, blank staring, involuntary twitching, and impaired stimulus response. None of Life Care's witnesses questioned the applicability of the Hyperglycemia & Hypoglycemia policy or claimed that the policy either exceeded the standard of care or was inapplicable to the four episodes of hypoglycemia discussed above.

Testimony from Life Care's witnesses does not persuade us that substantial evidence is lacking for the ALJ's finding that Residents 18, 27, and 40 experienced "significant changes." Dr. Standridge testified that physician notification is required when a resident's hypoglycemia is accompanied by "serious" or "severe" symptoms of that condition: "I believe that the correct interpretation of the order to 'notify the physician' in the event of high or low blood sugar is to call the physician's office, or the on-call physician, for instructions in an emergency, or if the patient is exhibiting serious symptoms of high or low blood sugar, or if the routine interventions provided by the protocol are not effective." P. Ex. 79, at 9 (emphasis added). Dr. Patsimas articulated a similar standard of care. P. Ex. 81, at 4-7. However, neither witness expressly and clearly indicated whether this standard of care obligated Life Care to consult with a physician about the specific episodes of hypoglycemia experienced by Residents 18, 27, and 40. Indeed, Dr. Patsimas expressed no opinion at all about the severity of these residents' symptoms and did not testify that he would not have wanted to be alerted about deviations from normal blood glucose levels of the magnitude experienced by Residents 18, 27, and 40.

Dr. Standridge also avoided this precise issue. For example, he did not express an opinion about the clinical significance of the symptoms that Resident 18 experienced on October 27,

although he admitted that Resident 18 experienced a "significant hypoglycemic episode" on that date. P. Ex. 79, at 14. Dr. Standridge also did not discuss the September 11 episode involving Resident 40 (see id. at 21-22), nor did he comment on the severity of the symptoms experienced by Resident 27 on June 25 (id. at 19). As we discuss later, although Resident 27's treatment records indicate that the nurse practitioner became aware of the June 25 episode on the day it occurred, it is not clear whether she acquired this awareness through verbal consultation with the nursing staff or by reading the resident's chart. See P. Ex. 79, at 19; CMS Ex. 17, at 11 (nurse practitioner's June 25 progress note). Furthermore, Resident 27's records do not indicate precisely when on June 25 the nurse practitioner learned of the episode (which occurred around noon).

Dr. Standridge also failed to clearly and directly comment on whether the symptoms of hypoglycemia exhibited by Resident 27 on July 21 were serious enough to necessitate physician consultation. P. Ex. 79, at 19-20. In addition, he failed to comment on the fact that the nursing staff's initial attempt to boost Resident 27's blood glucose did not succeed in bringing it above the 60 mg/dl threshold, a factor he previously testified was relevant in determining the necessity of physician consultation. Id. at 7, 19-20; see also CMS Ex. 17, at 16 (indicating that the resident's blood glucose was 48 mg/dl after the initial round of treatment). Although Dr. Standridge concluded that there was no need to notify the physician because the nursing staff ultimately succeeded in stabilizing Resident 27's blood glucose, that success does not, in itself, demonstrate that physician consultation was unnecessary. The July 21 episode was Resident 27's second episode of symptomatic hypoglycemia in a one-month period. The ALJ reasonably relied on Dr. Schmitt's testimony that physician consultation was necessary in this instance to give the physician a timely opportunity to adjust medications and ensure that the resident "did not suffer any sort of rebound/lunge of serum glucose levels, leading again to grave risks of . . . seizures, coma or death." CMS Ex. 50, at 5; see also ALJ Decision at 10. Life Care's witnesses did not rebut or even address this testimony.

For the reasons above, we conclude that substantial evidence supports the ALJ's finding that Residents 18, 27, and 40 experienced "significant changes" in their health status on June 25, July 21, September 11, and October 27, 2007 within the meaning of section 483.10(b)(11).[3] Consequently, Life Care was

[3] In the preamble to the final rule that promulgated (Continued. . .)

obligated to "consult immediately" with their physicians about those changes. We now consider whether substantial evidence supports the ALJ's finding that Life Care failed to meet that particular obligation.

(b) Life Care *did not comply with its obligation to consult immediately with a physician about the episodes of hypoglycemia on June 25, July 21, September 11, and October 27, 2007.*

The ALJ found that Life Care did not consult with a physician at all about the June 25 or July 21 episodes of hypoglycemia involving Resident 27, or about Resident 40's hypoglycemia episode on September 11. ALJ Decision at 8, 17. Life Care does not dispute those findings.

As for the October 27 episode involving Resident 18, the ALJ found that Life Care "called" her physician "30 minutes after discovering her in a nonresponsive state" but concluded that this attempted communication did not constitute "immediate" consultation:

> The resident's condition obviously was extremely grave and time was of the essence. In that situation Petitioner's staff was obligated to do exactly what

(Continued. . .)

section 483.10(b)(11), CMS stated: "We recognize that judgment must be used in determining whether a change in the resident's condition is significant enough to warrant notification, and accept the comment that only those injuries which have the potential for needing physician intervention must be reported to the physician." Final Rule, *Medicare & Medicaid; Requirements for Long Term Care Facilities*, 56 Fe.d Reg. 48,826, 48,833 (Sept. 26, 1991) (emphasis added). Citing this passage, the Board has previously stated that the "potential need for physician intervention is a factor in whether notice is required." Park Manor Nursing Home, DAB No. 2005, at 29 (2005), aff'd, Park Manor, Ltd. v. U.S. Dep't of Health & Human Servs., 495 F.3d 433 (7th Cir. 2007); see also Park Manor Nursing Home, DAB No. 1926 (2004). With respect to the four hypoglycemia episodes discussed here, the potential need for physician intervention was shown. See, e.g., CMS Ex. 50, at 3 (Schmitt testimony) (indicating that consultation was necessary to give the physician a timely opportunity to adjust medication and ensure that the resident did not experience a potentially dangerous plunge or rebound of blood glucose).

> the regulation required, and that was to consult with the physician immediately upon discovery of the resident in her hypoglycemic state and not to wait.

ALJ Decision at 17.

In response to that finding, Life Care contends that Resident 18's treatment records do not indicate when the staff "called" the physician, only when he responded. RR at 50. That statement is inaccurate. The nursing progress note for October 27 indicates that Resident 18 was found with severe symptoms of hypoglycemia at 7:15 p.m. and that a blood test showed blood glucose of 20 mg/dl. Id. The progress note then states that the nurse administered medication, fed the resident snacks, and measured the resident's blood glucose for a second time at 7:45 p.m. Id. After reporting this blood glucose value, the nurse wrote that she "[n]otified the physician on call." Id. (emphasis added). The ALJ reasonably interpreted this note, as did the surveyors (see CMS Ex. 48, at 10-11), as indicating the nurse did not attempt to notify the physician until 7:45 p.m., after the second blood test and 30 minutes after Resident 18 was found to have symptoms of hypoglycemia. Life Care failed to establish that this interpretation was unreasonable or that Life Care did, in fact, contact the physician earlier than 7:45 p.m. In addition, Surveyor Crocker testified the nursing staff "violated professional standards of care . . . by apparently working for nearly 30 minutes . . . before consulting a physician for direction and instructions." CMS Ex. 48, at 11. None of Life Care's witnesses testified that waiting 30 minutes was medically appropriate or otherwise satisfied accepted standards of nursing care in these circumstances. We thus find no basis to disturb the ALJ's finding that Life Care failed to consult immediately with Resident 18's physician about her hypoglycemia on October 27.

Life Care submits that the following "context" establishes that its nursing staff complied with the physician consultation requirement in section 483.10(b)(11) as well as with the instruction in residents' treatment record to notify the physician about blood glucose less than 60 mg/dl:

> A nursing facility is not a hospital, where physicians are readily available personally to direct the care of (the acutely ill) patients who may be experiencing even routine clinical problems. Rather, the residents of Petitioner's facility, like those at most nursing facilities, are attended by physicians from the community who maintain office practices,

> attend patients at the local hospital and in local nursing facilities, and the like. Tullahoma is in a rural area, and the few physicians are, as can be imagined, extremely busy. Dr. Patsimas testified that he and his "on call" group of five colleagues have thousands of active patients. Dr. Patsimas points out that for this reason he employs a Nurse Practitioner, Susan Warner, who visits Petitioner's facility four or more times a week to address clinical issues that do not require his personal or immediate attention. By the nature of her practice, [the] Nurse Practitioner . . . is in daily and oral communication with Petitioner's nursing staff, frequently reviews and document in charts, is licensed to provide many orders, and communicates on an ongoing basis with him. That is the current standard of care.

RR at 71-72. In short, Life Care contends that physician consultation was unnecessary because the nursing staff was consulting daily with a nurse practitioner about the condition of its residents. The ALJ rejected this argument because he found no evidence that the nursing staff consulted immediately with the nurse practitioner about the episodes of hypoglycemia experienced by Residents 18, 27, and 40. ALJ Decision at 17-18. In this appeal, Life Care does not specify any evidence of timely - i.e., immediate - consultation with the nurse practitioner about those episodes. Consequently, we reject the argument that the nursing staff's interaction with the nurse practitioner satisfied its regulatory obligation.

(c) *The ALJ did not make certain findings that Life Care attributed to him.*

According to Life Care, the ALJ held that section 483.10(b)(11) required the nursing staff to consult immediately with the physician about abnormally low or high blood sugar before undertaking treatment and regardless of any "protocols, preferences or practices of the attending physician, the resident's history or symptoms, or any other factors." RR at 1, 2, 22, 29. Life Care contends that the ALJ Decision effectively "prohibit[s] a nursing facility and its Medical Director from creating protocols that direct nurses to treat certain instances of high or low blood sugar without first consulting with a physician in every case." Id. at 1. In addition, Life Care asserts that the ALJ held that "nursing facilities must assure that physicians are available instantaneously, '24/7,' for such consultation." RR at 1-2. In reaching these conclusions, says

Life Care, the ALJ improperly rejected expert testimony about the appropriate standard of nursing care and effectively created a "new clinical standard never before announced or published by CMS" that may not be applied in this case without violating the Administrative Procedure Act (APA) or Life Care's right to due process. RR at 2, 22.

This argument is baseless because the ALJ did not make the findings attributed to him. For example, the ALJ did not find that Life Care was noncompliant because it failed to consult a physician before initiating treatment for residents of hypoglycemia. In fact, the ALJ expressly noted that this was not the basis for CMS's allegations of noncompliance. See ALJ Decision at 15.[4] Nor did the ALJ find that the regulations prohibited Life Care from adopting procedures that would permit the nursing staff to initiate treatment before notifying the physician. As the ALJ found, Life Care's suggestion that section 483.10(b)(11) is being applied to prohibit a SNF from following pre-established emergency procedures is "specious" because there is "nothing to prevent [the nursing] staff from initiating emergency measures . . . and simultaneously consulting with the treating physician." ALJ Decision at 17.

Finally, nothing in his decision suggests that the ALJ found Life Care noncompliant with section 483.10(b)(11) because it failed to ensure that a physician was "available instantaneously" for consultation. Moreover, section 483.10(b)(11) does not direct a SNF to ensure physician "availability." Rather, it requires a SNF to make diligent efforts to contact and consult a physician immediately about significant changes in a resident's health status. The ALJ found that Life Care failed to meet that requirement, and the record adequately supports that finding, as we have discussed.[5]

(d) *CMS produced sufficient evidence of applicable professional nursing standards.*

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[4] The ALJ found that the residents' physicians "were never made aware contemporaneously of what the staff was doing for the residents and were never given an opportunity to modify, alter, or redirect treatment." ALJ Decision at 15 (emphasis added).

[5] Life Care is incorrect in suggesting that it has no obligation to ensure the availability of a physician. Section 483.40(d) of the regulations states that "[t]he facility must provide or arrange for the provision of physician services 24 hours a day, in case of an emergency."

Life Care contends that CMS did not make a prima facie showing of noncompliance with section 483.10(b)(11) and other requirements because it did not offer evidence of a "national" nursing standard governing the management of hypoglycemia in the long-term care setting. RR at 24-25, 27-29, 41. According to Life Care, CMS "offered nothing but the opinions of two surveyors, based largely on their recollections of nursing school training years ago, to establish the rigid notification and consultation standards the ALJ adopted." RR at 71.

We reject this contention for two reasons. First, the regulations at issue do not require CMS to prove the existence a single or unitary "national" standard of care governing the treatment of hypoglycemia in the long-term care setting. Section 483.20(k)(3), for example, states that a SNF's services must meet "professional standards of quality" without requiring that the standard have a specific level or breadth of acceptance in the medical community.

Second, Life Care mischaracterizes the record. Contrary to its assertions, the surveyors testified that their opinions were based on more than their nursing school training but on substantial post-graduate clinical experience as well as their experience as surveyors. See CMS Exs. 47, 48, and 49. Furthermore, CMS presented more evidence concerning the standard of care than just the opinions of the surveyors. CMS submitted the testimony of Dr. Schmitt, a licensed physician with extensive experience practicing geriatric medicine in both hospital and long-term care settings. CMS Ex. 50, at 1. Dr. Schmitt testified that Life Care violated "prevailing standards of care" by failing to consult a physician when Residents 27 and 40 had "very low" or "extremely low" blood glucose levels and also displayed symptoms of hypoglycemia. Id. at 4-5. None of Life Care's witnesses testified that the prevailing standard of care required something less than immediate physician consultation in these circumstances. Moreover, Dr. Schmitt's testimony about the prevailing standard of care is corroborated by: (1) the existence at Life Care of the physician notification protocol;[6] and (2) Life Care's Hyperglycemia &

[6] Surveyor Crocker testified (and it is undisputed) that when she asked Life Care for its policies or procedures for reporting abnormal blood glucose tests, Life Care's director of nursing produced a flowsheet which instructed the nursing staff to notify the physician if a resident's blood glucose fell outside the 60-360 mg/dl range. Tr. at 86 (discussing CMS Ex. 39, at 3). Thus, there is no merit to Life Care's contention (RR at 30) that this instruction was not an established facility

(Continued. . .)

Hypoglycemia policy, which instructed the nursing staff to notify the physician immediately if the resident displayed "altered behavior or mental/physical state consistent with hyperglycemia or hypoglycemia." CMS Ex. 39, at 1, 3; Tr. at 52-53, 86.

(e) *The ALJ did not err in rejecting Life Care's interpretation of its physician notification protocol.*

Life Care expends considerable effort in this appeal trying to show that its physician notification protocol did not require what it appears to have required. Life Care submits that under a proper "interpretation" of that protocol, its nursing staff was not, in fact, obligated to notify the physician in every instance in which a resident's blood glucose fell outside the specified range. RR at 35-39. In support of that assertion, Life Care relies on its medical director, Dr. Patsimas, who testified that it was unreasonable to interpret the protocol as requiring physician notification any time a resident's blood glucose fell outside the designated range because: (1) the circumstances of individual residents - including their symptoms and response to treatment - varies greatly; and (2) the standard treatment for hypoglycemia and hyperglycemia is straightforward and quickly effective in most cases. P. Ex. 81, at 3-4.

Life Care further submits that the physician notification protocol should be interpreted in light of the written policy contained in Petitioner's Exhibit 7. RR at 30-33. That policy (last revised in October 2004) is entitled "Diabetic Care" and was authored by Life Care's corporate parent. P. Ex. 7, at 4. Life Care suggests that during the period at issue, it was managing episodes of hypoglycemia and hyperglycemia in accordance with the Diabetic Care policy. RR at 25, 30-33.

As a preliminary matter, Life Care's argument about the meaning of the physician notification protocol avoids the resident-specific compliance issues presented here - namely, whether the episodes of hypoglycemia experienced by Residents 18, 27, and 40 on June 25, July 21, September 11, and October 27 were significant changes in health status that triggered Life Care's obligation to consult with a physician.

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protocol.

The argument is factually unfounded in any event. We find insufficient evidence that Life Care's physician notification protocol meant anything other what it plainly required: physician notification any time a resident's blood glucose fell outside the specified range. Life Care produced no treatment records indicating that the instruction carried - or was actually and properly understood by the nursing staff to carry - qualifications or exceptions. Life Care also failed to proffer testimony from any member of its nursing staff to identify or explain the procedures that the staff followed, or was supposed to follow, in responding to episodes of abnormal blood glucose. Even if the nursing staff followed the Diabetic Care policy during the period at issue, as Life Care alleges, Life Care does not explain why the staff should not have been implementing that policy consistently or in conjunction with other applicable orders, procedures, or nursing care standards. We note that the Diabetic Care policy does not tell the nursing staff not to contact a physician under circumstances addressed by Life Care's physician notification protocol, residents' physician orders, or the Hyperglycemia & Hypoglycemia policy (CMS Ex. 39, at 1).

Although Dr. Patsimas claimed that the nursing staff was "aware" that he should be called only "if a patient exhibits significant symptoms of hypoglycemia or hyperglycemia . . . or remains symptomatic *after* the nurses implement the usual nursing interventions, or the patient does not respond" (P. Ex. 81, at 8), there is no testimony from the nursing staff or medical records to corroborate that claim. If Life Care is claiming that Dr. Patsimas directed the nursing staff to follow the Diabetic Care policy in Petitioner's Exhibit 7, we reject that claim as well. Dr. Patsimas did not testify that he directed the nursing staff to follow the Diabetic Care policy, and there is no documentary evidence that he had instructed the nursing staff to do so.

Life Care's reply brief betrays the weakness of its position on these issues. Life Care states there that "if CMS (or the ALJ) really had any questions whether the protocol [i.e., the Diabetic Care policy] actually was in effect at Petitioner's facility at the time of the survey - which is the only reasonable inference from the evidence - then they simply could have asked Dr. Patsimas whether [the Diabetic Care protocol] was the same protocol he was quoting and describing (or the ALJ could have considered the proffer by Petitioner's Vice President for Nursing [i.e., Sharon Coleman] offered to that effect)." Reply Br. at 8. Of course, if Life Care sought to rebut CMS's evidence that it had not implemented the Diabetic Care policy during the period in question (June through November 2007), then

it was Life Care's burden to produce - and not CMS's or the ALJ's burden to elicit - such evidence.

We reiterate that Dr. Patsimas did not cite or allude to the Diabetic Care policy in his direct testimony. Moreover, we disagree that the record permits only one reasonable inference concerning Life Care's alleged reliance on that policy. CMS presented evidence that Life Care's nursing director failed to produce the Diabetic Care policy in response to the surveyors' request for facility policies and procedures for managing blood glucose. Life Care, on the other hand, failed to produce testimony from any member of its nursing staff about the procedures it was expected to follow. Given these circumstances, the ALJ reasonably concluded (see ALJ Decision at 11) that the nursing staff was not guided by the Diabetic Care policy during the period in question.

Assuming it is reasonable (as Dr. Patsimas testified) for a nurse to notify a physician only if the resident has significant symptoms of hypoglycemia or fails to respond to treatment, then - according to Surveyor Arnold and Dr. Schmitt - prevailing standards of nursing and medical care required that the staff's responses to hypoglycemic episodes be guided by comprehensive written instructions that cover "all of the possible outcomes." CMS Ex. 47, at 6; Tr. at 141-42. Life Care failed to establish that it had adopted, or had instructed its nursing staff to follow, such a policy during the period in question. Instead, it appears that Life Care had a clear and simple instruction to notify the physician in every instance in which a resident's blood glucose fell outside the 60-360 range, regardless of the other clinical circumstances and regardless of the magnitude of the deviation from the designated range. Surveyor Denton testified that surveyors interviewed four physicians responsible for the care of diabetic residents in Life Care. CMS Ex. 49, at 9. She further testified that although one physician "seemed unaware" of Life Care's physician notification protocol, the others (including Dr. Patsimas) "understood the protocol and agreed that Life Care's nurses should have been notifying physicians when FSBS test results were outside the range of 60 mg/dl to 360 mg/dl." Id. It would reasonable to infer from these circumstances that notifying the physician of all instances of blood glucose outside the 60-360 mg/dl range was the response that Life Care and residents' physicians determined to be necessary to protect diabetic residents from harm *given the absence of a comprehensive protocol* for managing hypoglycemia and hyperglycemia.

(f) *The ALJ did not make an improper credibility judgment regarding Dr. Patsimas.*

The ALJ characterized Dr. Patsimas' testimony concerning Life Care's physician notification protocol as "self-serving and not credible" and further stated: "As medical director, [Dr. Patsimas] was responsible for insuring that facility protocols and physicians' orders, including Petitioner's diabetes protocol and his own orders directing notification if blood sugars fell below 60, were carried out by the nursing staff. I view his testimony as an after the fact attempt to justify his failure to discharge his responsibilities." ALJ Decision at 16 n.7.

Life Care contends that the ALJ's credibility findings are improper because the ALJ "did not see any of Petitioner's witnesses, and thus obviously did not have the usual opportunity to evaluate their demeanor, tone of voice, forthrightness, method of responding to pointed or hostile questions, apparent inconsistencies in their testimony, and the like." RR at 40 (emphasis in original). Life Care asserts that deference is owed to an ALJ's credibility judgment only when the ALJ has actually seen and heard the witness. Id.

It is not improper for a finder of fact to make a credibility judgment based on testimony given outside his or her presence. Cf. United States v. Davis, 261 F.3d 1, 39 n.34 (1st Cir. 2001) (rejecting contention that the district court was not in a position to evaluate a witness's credibility because the witness's testimony was submitted by reading excerpts of his deposition into the record); Buckanaga v. Sisseton Indep. Sch. Dist., 804 F.2d 469, 474 (8th Cir. 1986) (holding that "[d]eposition testimony can be assessed by the district court on the basis of credibility"). Furthermore, credibility involves more than simply evaluating witness "demeanor" or other behavior apparent from in-person observation. Ginsu Products, Inc. v. Dart Industries, Inc., 786 F.2d 260, 263 (7th Cir. 1986) ("[F]actors other than demeanor and inflection go into the decision whether or not to believe a witness. Documents or objective evidence may contradict the witness' story; or the story itself may be so internally inconsistent or implausible on its face that a reasonable factfinder would not credit it."). Furthermore, the Board has previously held that an ALJ may consider many factors other than witness demeanor in making credibility judgments, including "witness qualifications and experience, as well as self-interest." Madison Health Care, Inc., DAB No. 2049, at 7-8 (2006). Here, in judging credibility, the ALJ reasonably took into account the fact that Dr. Patsimas was Life Care's medical director as well as other

relevant factors, such as the lack of corroboration by the nursing staff and his silence on key issues, irrespective of whether he gave his direct testimony in person.

(g) *The ALJ did not improperly limit Life Care's opportunity to offer rebuttal testimony.*

Life Care contends that the ALJ erroneously denied its request to present in-person testimony to rebut cross-examination testimony by Surveyors Crocker and Arnold. See RR at 3, 20 n.11 (citing Tr. at 171-188).

At the close of the evidentiary hearing, Life Care requested an opportunity to have Sharon Coleman, Life Care Center's Vice President for Clinical Services, provide rebuttal testimony. Tr. at 172; see also RR at 31 n.15. The ALJ asked Life Care to describe the testimony it wanted to elicit from Ms. Coleman. Tr. at 172. Life Care responded that Ms. Coleman would have confirmed that the diabetes management protocol that Dr. Patsimas said was in effect at Life Care - one that obligated the nursing staff to notify a physician only if standard interventions were unsuccessful in bringing a resident's blood glucose back within the pre-established parameters - was consistent with the written clinical policies of its parent company, Life Care Centers. Tr. at 172-74. Life Care also indicated that Ms. Coleman would testify that the protocol described by Dr. Patsimas and Life Care Center's written policies were "well within the long-term care standard of care" and met the applicable regulatory requirements. Tr. at 173. The ALJ denied Life Care's request, stating:

> I don't think there's anything that you say Ms. Coleman would say that isn't something you already said in your brief, and since you've already said it in your brief, it meant that you had plenty of opportunity to get witnesses to put it in their declarations, if that's what you wanted to do. You clearly anticipated the argument that you were going to make or even the testimony that you would have Ms. Coleman give. So consequently there is literally nothing that you claim, based on what you've said that the witness is going to testify to, that should come as a surprise to you.

Tr. at 178.

We reject Life Care's challenge to this ruling for three reasons. First, Life Care does not dispute the ALJ's rationale

for the ruling. Second, the ALJ's rationale was sound. In essence, Life Care wanted to present cumulative testimony by Ms. Coleman concerning the existence and timing of its obligation to notify or consult a physician about residents with abnormal blood glucose levels. That issue was clearly and prominently raised by CMS in its pre-hearing exchange, and we find no error in the ALJ's finding that Life Care "clearly anticipated" the need for Ms. Coleman's testimony about that issue prior to the hearing.

Third, Life Care's objection to the evidentiary ruling raises an issue that is neither relevant nor material to the ALJ Decision. Life Care asserts that the ALJ should have allowed Ms. Coleman to rebut cross-examination testimony that there was "some standard of care or regulation [that] requires physicians to be available '24/7' for instantaneous consultation with a nursing facility's nurses any time a resident experiences high or low blood sugar, and that this standard controls over the facility's protocols." RR at 9; see also RR at 20 n.11. However, there was no such testimony elicited during cross-examination, as best we can determine.

Even if there were such testimony, it would be immaterial. As previously discussed, the ALJ did not hold Life Care responsible for ensuring the "24/7" availability of physicians, and section 483.10(b)(11) does not impose or establish such an obligation (even though section 483.40(d) does require such availability in the case of an emergency).

(h) *The ALJ's reliance on evidence concerning residents other than the eight residents identified by CMS in its pre-hearing brief was improper.*

In evaluating whether Life Care was noncompliant with section 483.10(b)(11), the ALJ found:

> Petitioner's diabetes protocol was routinely ignored by its nursing staff. On dozens of occasions residents at Petitioner's facility were documented as having blood sugars at below 60 or above 360 and the nursing staff failed to notify - much less consult with - residents' treating physicians. CMS's post-hearing brief, attachment A and exhibits cited therein.

ALJ Decision at 7 (emphasis added). From this passage it is apparent that the ALJ's finding that Life Care "routinely

ignored" its own "diabetes protocol" on "dozens of occasions" is based on evidence summarized in Attachment A to CMS's post-hearing brief. Attachment A lists instances - involving 19 different residents (including Residents 18, 27, and 40) - in which Life Care's nursing staff allegedly failed to comply with an instruction in a resident's medical records to notify a physician if the resident's blood glucose fell outside the 60-360 mg/dl range. Each instance of alleged non-notification is accompanied by a citation to treatment records that CMS submitted in its pre-hearing exchange.

Life Care objected to CMS's submission of Attachment A, but the ALJ overruled the objection, stating:

> [T]here is nothing new referenced in the attachment[.] [I]t recites only evidence that Petitioner did not object to my receiving. Petitioner asserts also that the attachment is offered as an apparent effort to support new or revived allegations of noncompliance that CMS did not previously advocate. That is incorrect. The attachment merely illustrates examples of those contentions that CMS made throughout the case.

ALJ Decision at 7 n.2.

Life Care now reasserts its objection to Attachment A, claiming that it "represented an effort by CMS to resurrect the very allegations that ALJ Kessel had precluded Petitioner from addressing (indeed, that Petitioner specifically had requested leave to address in its own Briefs should CMS ever offer evidence regarding them.)." RR at 4, 9-10, 43 n.18.

The citation to Attachment A is problematic because it suggests that the ALJ based his decision on incidents upon which CMS disclaimed any reliance prior to the hearing. In a section entitled "Statement of Facts that CMS Intends to Prove," CMS presented argument concerning eight residents, including Residents 18, 27, and 40. CMS Pre-Hearing Br. at 23. With respect to the physician consultation requirement, CMS's argument was limited to four of those eight residents. See id. at 3-10. On July 7, 2007, before Life Care filed its pre-hearing exchange, the ALJ held a telephone conference with the parties. According to a Civil Remedies Division staff attorney's notes of this conference, Life Care inquired about the necessity to present evidence concerning survey findings and residents that CMS did not address in its pre-hearing exchange. In response, the ALJ reportedly advised Life Care to focus its

pre-hearing exchange on the eight residents identified in CMS's pre-hearing brief.

In its subsequent pre-hearing brief, Life Care indicated that, although it was not waiving any right to challenge survey findings that CMS had elected not to rely upon, Life Care understood that the scope of the hearing, as settled in the July 7 pre-hearing conference, would be "limited to the examples of alleged noncompliance pressed by CMS in its Prehearing Brief." Pet.'s Pre-Hearing Br. at 18 n.5. At no time prior to, or during, the in-person hearing did CMS dispute this characterization of the results of the July 7 conference or otherwise claim that the hearing was not limited to the "examples of alleged noncompliance" discussed in its pre-hearing brief.

In short, it appears that CMS and the ALJ led Life Care to believe that, absent any request by it to contest survey findings that CMS had elected not to rely upon, a decision on the merits of its hearing request would be based solely on evidence concerning a total of eight residents and that it was, therefore, unnecessary for Life Care to present evidence regarding any other residents. For this reason, we find that it was improper for the ALJ to rely, directly or indirectly, on evidence concerning residents other than the eight residents about whom CMS presented testimony and legal argument.

Attachment A listed 33 alleged failures to comply with Life Care's physician notification protocol involving Residents 18, 27, and 40; only seven of those episodes were discussed in CMS's pre-hearing brief. Attachment A also listed 95 alleged failures to comply with the protocol involving 16 other residents, none of whose clinical circumstances were discussed by the ALJ. Thus, it appears that the ALJ's finding that there were "dozens of occasions" in which Life Care failed to consult with a physician about abnormal blood glucose levels was based largely on incidents that Life Care was led to believe were not at issue in the ALJ proceeding. Accordingly, we disregard that finding in evaluating the ALJ's finding of noncompliance with section 483.10(b)(11) and in assessing the reasonableness of the CMP amount.

(i) Life Care largely mischaracterizes a key issue on appeal.

Many of Life Care's arguments in this appeal obfuscate or mischaracterize a key issue on appeal. Life Care insists that "this case represents an effort by [CMS and the state survey

agency] to create and enforce new nursing and physician standards for the care of diabetic residents in nursing facilities that neither [CMS], nor any other regulatory or professional body, ever has promulgated or even described before." Reply Br. at 2. Later, Life Care asserts that "the threshold issue in the appeal - in fact, as it turned out, the only real issue - was the validity of Petitioner's diabetes protocols themselves." Reply Br. at 4 n.1. However, we see no indication that CMS or the state survey agency was attempting to enforce "new nursing and physician standards." Instead, CMS has sought in this litigation to hold Life Care accountable for noncompliance with regulatory requirements and accepted professional standards in its care of specific residents. The professional standards upon which the ALJ relied were established by expert testimony and other evidence in the record, and those standards were not novel. The "real issue" in this case is whether Life Care's residents received care that met applicable nursing standards and regulatory requirements. While the content of Life Care's protocols is relevant to resolving this issue, their adequacy is neither the sole nor key point.

2. Substantial evidence supports the ALJ's finding that Life Care failed to consult a physician immediately about a significant change in Resident 56's health status.

The ALJ made the following undisputed factual findings regarding Resident 56. The resident, who was 94 years old during the period in question, had a history of severe bradycardia (abnormally slow heartbeat) and hyperkalemia (abnormally elevated serum potassium). ALJ Decision at 9. Those two "problems are linked because abnormally elevated potassium levels can impair heart muscle function, can cause slowed heart beats, and can actually cause the heart to cease beating entirely." Id. (citing CMS Ex. 50, at 6). At 1:55 a.m. on November 4, 2007, Resident 56 "awoke with a sudden onset of shortness of breath and extreme anxiety." Id. Her heartbeat was recorded at 45 beats per minute. Id. Pursuant to a November 2 physician's order, the nursing staff performed a laboratory test called a basic Metabolic Panel (BMP), which found that Resident 56's potassium level was (in the ALJ's words) "critically high." Id. Life Care faxed the BMP test results to Resident 56's physician at 3:35 a.m. but did not contact the physician directly until 6:00 a.m. Id. Upon learning of the resident's condition, the physician ordered her immediate transfer to the hospital for evaluation. Id.

Based on these findings, the ALJ concluded that Life Care had failed to consult immediately with a physician about a significant change in Resident 56's condition on the morning of November 4, 2007. ALJ Decision at 8-9. He also found that the delay in consulting a physician about Resident 56's bradycardia and elevated potassium levels that morning "put this resident at grave risk for adverse consequences," and that "[c]ardiac arrest was a likely outcome for this resident in the absence of immediate and urgent care." Id. at 9.

Life Care does not expressly challenge the ALJ's finding that it failed to consult immediately with Resident 56's physician about a significant change in her health status on November 4. See RR at 63-64. Life Care merely asserts that its "error" was not evidence of any "systemic" failure to meet its obligation to consult with physicians when necessary and that the ALJ disregarded testimony by Dr. Standridge about whether the error caused or was likely to cause harm. RR at 44.

On the issue of harm, Dr. Standridge testified that he saw "no evidence that [Resident 56] suffered any harm or medical distress" as a result of the nursing error, and that Resident 56's elevated potassium level of 6.3 "unlikely . . . caused any harm" in the two-and-one-half hour period between Life Care's receipt of the laboratory test results and its attempt to contact the physician. P. Ex. 79, at 26. However, as the ALJ correctly noted, proof of actual harm is not a legal prerequisite for a finding of noncompliance (or, for that matter, a finding of immediate jeopardy). Stone County Nursing and Rehabilitation Center, DAB No. 2276, at 19 (2009); Meridian Nursing Center, DAB No. 2265, at 13 (2009). Noncompliance exists if has the "potential" to cause more than minimal harm, and it exists at the immediate jeopardy level if it is "likely to cause" death or other serious harm. See 42 C.F.R. § 488.301 (definitions of "immediate jeopardy" and "substantial compliance").

In contrast, Dr. Schmitt testified that "[t]he failure to notify Resident #56's physician of a critically-high serum Potassium level exposed the resident to a high likelihood of suffering grave harm" because "elevated serum Potassium can cause sudden death by cardiac arrest[.]" CMS Ex. 50, at 6 (emphasis added). Life Care did not point to any evidence rebutting Dr. Schmitt's testimony about the likelihood of harm stemming from the nursing staff's error. Moreover, the ALJ could reasonably infer from the fact that Resident 56's physician ordered her immediate transfer to the hospital that the likelihood of serious harm to Resident 56 was substantial. Finally, the relevant issue is

whether the noncompliance is likely to cause serious harm, not whether harm to a particular resident is likely.

We thus affirm the ALJ's conclusion that Life Care's care of Resident 56 on November 4, 2007 evidenced a lack of substantial compliance with section 483.10(b)(11).

B. The ALJ's conclusion that Life Care was not in substantial compliance with 42 C.F.R. § 483.20(k)(3) is supported by substantial evidence and not legally erroneous.

Section 483.20(k)(3) requires a SNF to provide services that "[m]eet professional standards of quality." CMS's interpretive guidelines for this requirement state that "'[p]rofessional standards of quality' mean services that are provided according to accepted standards of clinical practice," and that "[s]tandards may apply to care provided by a particular clinical discipline or in a specific clinical situation or setting." SOM, App. PP (tag F281).

The Board has held that a nursing staff's failure to carry out a physician's order may constitute a failure to meet professional standards of quality under section 483.20(k)(3). Georgian Court Nursing Center, DAB No. 1866, at 8 (2003); Emerald Oaks, DAB No. 1800, at 37 (2001). Failure to comply with a facility-adopted treatment protocol or procedure may likewise constitute a failure to meet professional standards of quality if the protocol reflects either the judgment of an individual physician, or an accepted standard of nursing care, concerning the appropriate treatment to be rendered in a given set of circumstances. Cf. Lake City Extended Care Center, DAB No. 1658, at 11 (1998) (stating that when the SNF's protocol did not reflect the applicable standard of care, the SNF's failure to follow the protocol was not significant, unless the protocol was part of a care plan or was otherwise required under the regulations).

The ALJ found that the evidence that proved Life Care's noncompliance with the physician consultation requirement in section 483.10(b)(11) also proved that Life Care "failed to provide or arrange for services that met professional standards of quality." ALJ Decision at 19. The ALJ indicated that Life Care's failure to meet professional standards of quality had three distinct elements: (1) "[f]ailure to comply with [Life Care's] written diabetes protocol" (namely, the protocol which instructed the nursing staff to notify a physician if a resident's blood glucose fell outside the 60-360 mg/dl range);

(2) "[f]ailure to comply with physicians' orders"; and (3) "[f]ailure to consult with treating physicians about potentially life-threatening medical crises experienced by residents of the facility and the treatment that the staff initiated to address these crises." Id.

Substantial evidence supports the ALJ's conclusion that Life Care did not provide services that met professional standards of quality. The record supports a finding that Life Care violated accepted standards of care when its nursing staff failed to comply with the physician notification protocol. Dr. Schmitt testified that, because it is the proper role of nurses to administer patient care under the supervision of physicians, the nursing staff violated standards of nursing care "each time a diabetic's FSBS test result was lower than 60 mg/dl or greater than 360 mg/dl, without the nurses' notifying the physician in accordance with Life Care's FSBS protocol." CMS Ex. 50, at 2-3. This failure was significant because, as we have discussed (infra text at 23), the existence of that protocol reflects a judgment by Life Care and treating physicians (who incorporated the instruction into resident-specific orders) about the care necessary to ensure the health and safety of diabetic residents in the facility.

Life Care's noncompliance with section 483.20(k)(3) is also evidenced by its failure to follow physicians' orders. Residents 18, 27, 40 each had individual physician orders requiring physician notification about blood glucose test results less than 60 mg/dl. P. Ex. 15, at 4; P. Ex. 35, at 2; P. Ex. 54, at 6. The ALJ found, and Life Care does not dispute, that in seven instances involving these three residents,[7] the nursing staff did not notify a physician about sub-60 mg/dl blood glucose levels. See ALJ Decision at 8. Life Care does not dispute that accepted standards of nursing care required the nursing staff to follow the applicable physician orders by notifying the physicians in those circumstances.

Life Care's failure to consult with a physician about circumstances - namely, a resident with symptomatic hypoglycemia and blood glucose significantly below 60 mg/dl - in which professional standards require such consultation is further evidence that Life Care did not comply with section 483.20(k)(3). See CMS Ex. 50, at 4-5 ("the apparent failure of

[7] Those instances were: October 20, 21, 24, and 26, 2007 (for Resident 18); June 25 and July 21, 2007 (for Resident 27); and September 11, 2007 (for Resident 40). See ALJ Decision at 8.

nurses to notify and consult Resident #27's and Resident #40's physician(s) while these episodes were occurring was a violation of prevailing standards of care").

None of Life Care's witnesses rebutted Dr. Schmitt's opinion that the nursing staff's failure to comply with the physician notification protocol violated standards of nursing care. Instead, those witnesses, including Dr. Standridge, sought to interpret the protocol as requiring physician notification only if the resident displayed serious symptoms of abnormal blood glucose or failed to respond to treatment. See P. Ex. 79, at 4 (asserting that the order or general directive to notify the physician must be "interpreted correctly"); P. Ex. 80, at 2 (discussing what the witness believed was a "reasonable interpretation" of the order). As discussed, however, there is no evidence that the nursing staff either similarly interpreted or actually followed the interpretation of the physician notification protocol advanced by Life Care's witnesses. Nor is there any contemporaneous documentation indicating that a physician or nurse practitioner directed the nursing staff to apply the protocol only when a diabetic resident failed to respond to treatment or exhibited serious symptoms of hypoglycemia or hyperglycemia.

Citing CMS's interpretive guidelines for section 483.20(k)(3), Life Care asserts that CMS was obligated to submit - but failed to submit - evidence that the nursing staff ran afoul of some published standard of care contained in a manual, textbook, article, or guideline. RR at 69-70. "One would think," Life Care says, "that if the rigid standard of care CMS advances were as clear cut as CMS argues, the agency could have offered at least a page or two from a current nursing or medical textbook, etc., to counter Professor Standridge's testimony regarding current standards of care." RR at 70. This contention is unpersuasive because section 483.20(k)(3) does not preclude CMS from establishing the existence of a nursing standard through the testimony of an expert witness, as CMS did in this case. In addition, CMS's interpretive guidelines, which do not have the force of law,[8] do not suggest that CMS must in every case verify

[8] The Board recently reiterated its long-standing explanation that the "SOM, in general, is a compilation of interpretive guidelines, standards of practice, and internal policies directed to the state survey agencies that conduct long-term care facility surveys and that certify facility compliance." Foxwood Springs Living Center, DAB No. 2294, at 8 (2009) (citations omitted). "While the SOM may reflect CMS's interpretations of the applicable statutes and regulations, the

(Continued. . .)

the existence of an applicable clinical standard through published sources.[9]

For these reasons, we affirm the ALJ's conclusion that Life Care was noncompliant with section 483.20(k)(3) because it did not provide services that met professional standards of quality.

C. *The ALJ's conclusion that Life Care was not in substantial compliance with 42 C.F.R. § 483.25 is supported by substantial evidence and not legally erroneous.*

Section 483.25 states that "[e]ach resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being" of the resident, consistent with the resident's comprehensive assessment and care plan. The ALJ found that the facts that proved a violation of the physician consultation requirement in section 483.10(b)(11) also proved a violation of section 483.25. ALJ Decision at 20.

We find no error with the ALJ's conclusion. We have held that the care and services required by section 483.25 include services ordered by the physician or called for by established facility policies, as well as consulting with the physician when necessary. See The Laurels at Forest Glenn, DAB No. 2182, at 6, 20 (2008) (citing cases and affirming a finding by the ALJ that a SNF violated section 483.25 because its nursing staff failed to consult an attending physician when, according to Life Care's own protocol, such consultation was necessary).

(Continued. . .)

SOM provisions are not substantive rules themselves." Id. at 9 (citations omitted).

[9] The interpretive guidelines state that "[s]tandards regarding quality care practices may be published by a professional organization, licensing board, accreditation body or other regulatory agency," and that "[p]ossible reference sources" for standards of practice include current nursing manuals and textbooks, standards published by professional organizations, clinical practice guidelines published by the Agency of Health Care Policy and Research, and current professional journal articles." SOM, App. PP (tag F281) (emphasis added).

Life Care contends, as it did before the ALJ, that this conclusion should be overturned because CMS did not present evidence that a resident failed to achieve his or her "highest practicable" level of function. RR at 69-70. In response to this contention, the ALJ wrote:

> . . . "[A]ctual failure" to achieve a level of function is not a measure of a facility's compliance under [section 483.25]. The issue is whether a facility offers the requisite services – which would include complying with physician orders or internal facility care protocols – not whether, in any case, the services provided caused the resident to achieve some measurable result.

ALJ Decision at 21. We fully agree with the ALJ's analysis. Accordingly, we affirm the ALJ's conclusion that Life Care was not in substantial compliance with section 483.25.

D. *The ALJ's conclusion that Life Care was not in substantial compliance with 42 C.F.R. § 483.25(m)(2) is supported by substantial evidence and not legally erroneous.*

Section 483.25(m)(2) requires a facility to ensure that residents are "free of any significant medication errors." The ALJ concluded that Life Care failed to comply with this requirement in its care of Residents 18 and 48. ALJ Decision at 21-24.

The Board has held that the compliance issue under section 483.25(m)(2) "turns solely on whether [Life Care] made a medication error or errors that were 'significant'" and that "a single medication error can be 'significant.'" Franklin Care Center, DAB No. 1900, at 8; see also Ocean Springs Nursing Center, DAB No. 2212 (2008). "To ensure that residents are free of any significant medication errors as required by section 483.25(m)(2), a facility must administer the right dose of the right med[ication] by the right route to the right patient at the right time." Franklin Care Center at 11 (citation and internal quotations omitted). Section 483.25(m)(2) does not require that a medication error result in actual harm to the resident in order for a SNF to be found in substantial compliance.

In the preamble to the final rule which promulgated section 483.25(m)(2), CMS identified criteria for judging whether a medication error is "significant":

> A significant medication error is judged by a surveyor, using factors which have been described in interpretive guidelines since May 1984. The three factors are: (1) Drug category. Did the error involve a drug that could result in serious consequences for the resident; (2) Resident condition. Was the resident compromised in such a way that he or she could not easily recover from the error; (3) Frequency of error. Is there any evidence that the error occurred more than once. Using these criteria, an example of a significant medication error might be as follows: A resident received twice the correct dose of digoxin, a potentially toxic drug. The resident already had a slow pulse rate, which the drug would further lower. The error occurred three times last week.

56 Fed. Reg. 48,853 (Sept. 26, 1991). These criteria are reflected in CMS's interpretive guidelines for section 483.25(m)(2). SOM, App. PP (tag F333). The interpretive guidelines define a "significant medication error" as "one which causes the resident discomfort or jeopardizes his or her health and safety." Id. The guidelines further state that the "relative significance of medication errors is a matter of professional judgment," and that surveyors should, in determining whether the error was significant, consider (1) the drug's category, (2) resident condition, and (3) frequency of the error. Id.

With these guidelines in mind, we consider whether substantial evidence supports the ALJ's conclusion that Life Care failed to ensure that Residents 18 and 48 were free of significant medication errors.

1. Substantial evidence supports the ALJ's conclusion that Life Care failed to ensure that Resident 18 was free of a significant medication error.

The ALJ found that Life Care administered excessive doses of insulin to Resident 18 (55 units in the morning, and 40 units in the evening) following her admission to Life Care on October 19, 2007. ALJ Decision at 20-21. The ALJ found that these errors were "significant" and "due to a misreading of the hospital transfer form by Petitioner's nursing staff." Id. According to the ALJ, "[t]he nurse who transcribed the insulin dosage failed to comprehend that a superseding and much lower dose had been administered to the resident while she was hospitalized and that this lower dose had not been countermanded or rescinded by later

orders." Id. Life Care now contends that the ALJ misinterpreted the relevant documents and that there is nothing in the record to support a finding that the nursing staff mistranscribed the physician's insulin order. RR at 44-48.

We first consider whether the record supports the ALJ's finding that there was a medication error. The parties point to three documents: (1) the Baptist Hospital "Patient Transfer Form" pertaining to Resident 18's transfer from the hospital to Life Care on October 19, 2007 (CMS Ex. 12, at 21-26); (2) a discharge summary prepared by Susan Briley, M.D., the resident's attending physician in the hospital (P. Ex. 10); and (3) a chart, prepared by Life Care's nursing staff, that shows Resident 18's "admission orders" (CMS Ex. 12, at 27).

The Patient Transfer Form was signed on October 18, 2007 by Dr. Briley. CMS Ex. 12, at 26. Section nine of the Patient Transfer Form is entitled "Medications at Transfer." Id. at 21. The Medications at Transfer section has two subsections, the first entitled "Home Meds Prior to Admission," the second entitled "Current Active Medications." Id. at 21, 23. The lead-in paragraph for these subsections states:

> MEDICATIONS AT TRANSFER: No changes will be made until time of transfer[.] **Check box to continue order**. Note: Meds listed in the "Home Medications Prior to Discharge" section may also appear in the "Current Active Medications" section. Check for duplications and hospital therapeutic substitutions.

Id. at 21 (emphasis added).

The Home Meds Prior to Admission section of the Patient Transfer Form includes the following entries (with a space for the physician to indicate, with a check mark or some other notation, whether the medication would be continued or discontinued:

> Novolog [Insulin] Mix 70/30 40 units sq daily - PM
> indication: Diabetes Last Dose Taken: 9/11 PM
>
> Novolog [Insulin] Mix 70/30 55 units sq daily - AM
> indication: Diabetes Last Dose Taken: 9/11 AM

CMS Ex. 12, at 21 (emphasis added). These entries indicate that prior to her hospitalization, Resident 18 received 55 units of insulin in the morning and 40 units at night. Both entries have handwritten check marks next to them.

Further down the Patient Transfer Form, in the Current Active Medications section, are the following entries:

> 70-30 Human Insulin (100 units/ml) Inj, Notify MD if dose held, If glucose less than 70, notify MD prior to giving Insulin 20 units, sc, qam, Bfast, (10/17/07 08:00 - . .)
>
> **Attn: Variable Time/Dose**
>
> 70-30 Human Insulin (100 units/ml) Inj, notify MD if dose held, If glucose less than 70, notify MD prior to giving Insulin 10 units, sc, qam, Dinner, (10/16/07 17:00 - . .)

CMS Ex. 12, at 25 (emphasis added; bold in original). These entries - which specify insulin dosages substantially less than those in the Home Meds Prior to Admission section - also have check marks next to them (though, as discussed later, a facility witness maintained that the check marks are actually "slashes"). Id. The Current Active Medications section also contains an entry calling for administration of "sliding scale" insulin, but this item is marked "D/C" (i.e., discontinue). Id. at 24.

Upon Resident 18's admission to Life Care on October 19, 2007, its nursing staff prepared a chart that purports to show her then-current physician orders. CMS Ex. 12, at 27. This admission orders chart shows an order for 55 units of insulin in the morning and 40 units in the evening. Id. According to a medication administration record, Resident 18 received 55 units of insulin on the mornings of October 21, 22, 24, 25, 26, and 27, and received 40 units in the evening on October 20 and 21. P. Ex. 17, at 1. Her treatment records also show that on October 22, the nursing staff obtained an order to reduce the evening insulin dose from 40 to 30 units. P. Ex. 18, at 1.

Construing the Patient Transfer Form, Surveyor Vickie Crocker testified that the insulin order in effect on the date of Resident 18's discharge from the hospital was for 20 units in the morning and 10 units at night, and not for the higher doses recorded on Life Care's admission orders chart. CMS Ex. 48, at 10. As a result of this error, said Surveyor Crocker, Resident 18 received "excessive doses of insulin at the rate of 55 units in the morning and 40 units in the evening (in accordance with hospital record marked 'home medications prior to admission')." Id.

In the opinion of Life Care's witnesses, Nurse O'Brien and Dr. Standridge, CMS misconstrued the Patient Transfer Form. Nurse O'Brien testified:

> As I read this "Patient Transfer Form" document, it clearly indicates that Resident [18] was receiving 55 units of insulin in the morning and 40 at night before her hospitalization. There are clear check marks next to the "Novolog 70/30 (55 units) in the A.M.," and "Novolog 70/30 (40 units) in the P.M.," which indicates that Dr. Briley wanted those medications continued at Life Care. This document also indicates that the Resident was on a sliding scale insulin protocol while in the hospital, which would be typical, which Dr. Briley also wanted continued. My experience in the hospital is that every diabetic resident is put on a sliding scale protocol regardless of her previous medication regimen, since the stresses of surgery, medications, illness, etc., make it very difficult to establish a single standard dose of insulin, even if the patient was receiving a standard dose before hospitalization. As I read this document, the last doses of insulin the Resident received at the hospital per the sliding scale protocol were 20 units in the morning before discharge, and 10 units the previous evening.
>
> . . . I see that the physician clearly checked the box next to the "55/40" order on the Transfer Document dated October 18, but only drew a slash through the box next to the report of the "20/10" dose. This is the universal indication that the physician had ordered the former, and acknowledged that her patient had received the latter, and I would expect any nurse to understand that. Thus, the fact that the "55/40" dose was entered into the Resident's skilled admission orders at Life Care was not, as the surveyors state, an "error," since the physician actually did order it. Conversely, I see no indication that the physician ever ordered, or intended to order, 20 units every morning and 10 units every evening at Life Care.

P. Ex. 80, at 9-10. Dr. Standridge made the same points in his written testimony. P. Ex. 79, at 12-14. He also testified that "95 units of insulin daily would [have been] a plausible daily dose, given the resident's weight." Id. at 13.

In short, there is conflicting evidence about the insulin order in effect at the time Resident 18 was discharged from the hospital and transferred to Life Care. Life Care contends that the operative order was for 55 units of insulin in the morning and 40 units in the evening, as shown in the Home Meds Prior to Admission section of the Patient Transfer Form, while CMS submits that the correct order was, in fact, 20 units in the morning and 10 at night, as indicated in the Current Active Medications section of that form.

Although the ALJ agreed with CMS that the Patient Discharge Form is clear about the insulin order in effect when Resident 18 was discharged, we find the form inherently ambiguous. The form does indicate, in the Current Active Medications section, that the resident received 20 units in the morning and 10 at night just prior to discharge. Simultaneously, the Patient Transfer Form seems to instruct a facility to "continue" at transfer any "checked" orders that appear in Home Meds Prior to Admission section. The Home Meds Prior to Admission section lists the orders for 50 and 40 units of insulin, and both of those items are checked. The form instructs the reader to check for "duplications" and "substitutions" in the Current Active Medications section, but it is not clear how the reader should interpret the form if an order is checked in the Home Meds Prior to Admission section (indicating that the physician wants the order continued at transfer) and there is a conflicting, non-discontinued order in the Current Active Medications section.

Nurse O'Brien's and Dr. Standridge's interpretation of the Patient Discharge Form seems to rest in part on a belief that Dr. Briley wanted Life Care to continue a sliding-scale insulin regimen, but we see no indication of this in the Patient Transfer Form or elsewhere. In fact, as indicated, the Patient Transfer Form shows that Dr. Briley specifically discontinued that regimen. CMS Ex. 12, at 24. Moreover, both of Life Care's witnesses overlook the instruction in the Patient Transfer form to check for "duplications" and "substitutions" in the Current Active Medications section when reviewing the orders set out in the Home Meds Prior to Admission section. As for Nurse O'Brien's assertion that the marks next to the 20/10 insulin orders were actually "slashes" rather than "check marks," we agree with the ALJ that this assertion is entirely unfounded (see ALJ Decision at 23) as well as inconsistent with the fact that the persons who completed the Patient Transfer Form routinely used the notation "D/C" to identify discontinued medication orders. See CMS Ex. 12, at 21, 23, and 24.

Because the Patient Transfer Form was ambiguous, it was incumbent on Life Care to resolve the ambiguity before administering insulin to the resident. Surveyor Crocker testified that if the "hospital records were ambiguous in any regard, professional nursing standards obliged Life Care's nurses to note the ambiguity and contact Resident 18's physician to clarify the doses of insulin that were to be given." CMS Ex. 48, at 10. Life Care submitted no evidence to rebut that opinion. Life Care also did not submit any evidence that it contacted Dr. Briley to verify the correct insulin dosage. Dr. Briley's discharge summary indicates that Resident 18's insulin order at discharge was, in fact, for 20 units in the morning and 10 at night, and there is no evidence that this physician order was superseded upon the resident's admission to Life Care. P. Ex. 10, at 5. Consequently, we conclude that substantial evidence supports the ALJ's finding that medication errors occurred when Life Care: (1) inaccurately indicated on its admission orders chart that Resident 18 had a physician's order for 50 units of insulin in the morning and 40 units at night, and (2) administered those erroneous doses, which were twice to four times the amount prescribed.

Apparently as a result of the excessive doses of insulin, Resident 18 experienced episodes of hypoglycemia on October 20, 21, 24, 26, and 27. See CMS Ex. 12, at 12, 14, 16; CMS Ex. 48, at 10 (Crocker Declaration) (testifying that "[i]t seemed to me that Resident #18 reacted almost immediately to the excessive doses of insulin given by Life Care's staff"). The resident's apparent reaction to the excessive doses of insulin supports the ALJ's finding that the medication error was significant.

For these reasons, we affirm the ALJ's conclusion that Life Care was noncompliant with its obligation to ensure that Resident 18 was free of significant medication errors.

2. Substantial evidence supports the ALJ's conclusion that Life Care failed to ensure that Resident 48 was free of significant medication errors.

On August 2, 2007, Resident 48 was discharged from the hospital and readmitted to Life Care with an order for Tegretol, which is an anti-convulsant drug. CMS Ex. 33, at 5, 7. It is undisputed that the discharge order called for administration of one 200 mg dose of the drug each day. RR at 58; see also CMS Ex. 33, at 5, 7. It is also undisputed that Life Care's nursing staff inaccurately transcribed the discharge order, and that as a result Resident 18 received two 200 mg doses of Tegretol - or double the total daily dose actually prescribed - from August 2

though September 13, 2007. RR at 58; see also CMS Ex. 33, at 8 (indicating that 200 mg was to be administered "BID - that is, twice daily). The ALJ found that error to be a "significant" medication error. ALJ Decision at 24. Life Care contends that this finding was not supported by substantial evidence, asserting that the "doses in question were so small that they could not have harmed anyone, and so there was no 'potential for more than minimal harm,' much less 'immediate jeopardy' that could support a huge penalty." RR at 58.

We find substantial evidence that the medication error involving Resident 48 was significant within the meaning of section 483.25(m)(2). As noted, CMS's interpretive guidelines indicate that determining the significance of a medication error is a "matter of professional judgment" and that three general factors should be considered: (1) drug category; (2) condition of the resident; and (3) frequency of the error. Two of those factors are implicated here. First, the error was very frequent. It is undisputed that Resident 48 received double the prescribed daily dose of Tegretol for 43 days. Second, there was undisputed testimony from CMS's witnesses that Tegretol is the type of drug that can cause significant harm if taken in incorrect doses. Surveyor Crocker testified that overdoses of Tegretol can be "extremely dangerous" and "must be carefully titrated and administered at the lowest effective dose to reduce a patient/resident's seizure activity, because excessive amounts of Tegretol can become toxic, leading to brain damage, heart failure, liver damage or other grave harm." CMS Ex. 48, at 15. Dr. Schmitt testified that Tegretol overdoses can cause various non-lethal but "serious complications, including neutropenia (abnormally low number of white blood cells, which exposes patients to increased risks of suffering life-threatening bacterial infections), as well as impaired function of the liver and heart." CMS Ex. 50, at 6. Although Dr. Schmitt conceded on cross-examination that it was "unlikely" that the 400 mg dose received by Resident 48 would have been lethal (Tr. at 168), and that Resident 48 suffered no actual harm (Tr. at 168-69), Dr. Schmitt indicated that the error was nevertheless significant because it increased the risk of "toxicity." Tr. at 169. He also regarded the error as significant because of its potential to interact with other medications and because harmful drug interactions are more likely in older patients (Resident 48 was 75 years old at the time). Tr. at 169; CMS Ex. 33, at 1.

Life Care points to the declaration of Dr. Standridge, who testified that 400 mg per day is the "usual starting dose of Tegretol, which can be increased safely to 800 to 1200 mg per day (the literature reports that doses as high as 1600 mg/day

have been used in adults)." P. Ex. 79, at 23. Dr. Standridge further testified:

> . . . [I]t does appear that when the apparent anomaly was discovered in mid-September, the patient's physician ordered immediate blood tests, which showed that the patient actually had a subtherapeutic level of Tegretol in his blood, which is inconsistent with a 100% overdose for several weeks . . . . The patient's chart also shows no signs or symptoms of overdose, which would include lethargy. In addition, Life Care's staff has informed me that they have obtained the pharmacy billing records for this patient, and those records show that only enough medication for one daily dose was ordered and delivered in August, September and October, 2007.[10]
>
> But even if the patient did receive a double dose, that is, 400 mg/day, that error would not be clinically significant because it is still a low dose. As I stated above, a dose of 200 mg BID [twice per day] is the usual starting dose and can be increased to the usual effective dose of 800 to 1200 mg per day. Thus, the resident did not receive an "overdose," nor was he exposed to jeopardy level risks of harm every time Life Care's staff gave him "double doses."

Id. at 24 (footnote added).[11]

In our view, the ALJ had sufficient reasons to discount Dr. Standridge's testimony. First, Dr. Standridge's testimony does not address whether there were clinical reasons, unique to Resident 48, that would explain why his physician prescribed

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[10] Life Care did not produce its pharmacy billing records for Resident 48, and as Dr. Standridge conceded, Life Care's medication administration records showed that Resident 48 received two 200 mg doses of Tegretol from August 2 through September 13, 2007. P. Exs. 61-70; P. Ex. 79, at 24.

[11] We note that the ALJ paraphrased the content of this testimony without expressly attributing it to Dr. Standridge or acknowledging that it tended to detract from his conclusion. The ALJ's omission is not prejudicial because, as discussed in the text, there is substantial evidence to conclude that the Tegretol error was a significant medication error even if Dr. Standridge's testimony is credited.

less than the "usual starting dose" of 400 mg per day. For that reason, his opinion that 400 mg was not an "overdose" is not persuasive. Second, Dr. Standridge did not refute or even address the testimony by Dr. Schmitt that the medication error was significant notwithstanding the absence of actual harm because of the potential for harmful drug interactions. Third, Dr. Standridge failed to address whether there was a potential for harm from repeated, daily administration of twice the prescribed dose of the drug. His testimony implied that Life Care's error was not significant because it did not cause actual harm or create a certainty of actual harm. P. Ex. 79, at 24 (stressing the absence of signs or symptoms of overdose). Of course, CMS need not prove actual harm to support a finding of noncompliance and, as CMS's interpretive guidelines state, a medication error may be considered significant if it "jeopardizes" - that is, has the potential to harm - the resident's health.

In describing a conversation with one of Life Care's nursing unit managers, Surveyor Crocker testified that when the attending nurse practitioner learned about the medication error in mid-September 2007, she became "very angry" and ordered "stat" (immediate) lab testing to ensure that Resident 48's serum Tegretol level was not toxic. CMS Ex. 48, at 15-16; see also CMS Ex. 33, at 19 (order for serum Tegretol test). Life Care did not deny that this was the nurse practitioner's reaction to the error. It is reasonable to infer from this reaction that the nurse practitioner believed that the medication error had created the potential to cause substantial harm to Resident 48. .

Because we conclude that substantial evidence supports the ALJ's finding that the Tegretol error was significant, we affirm his conclusion that Life Care was noncompliant with its obligation to ensure that Resident 48 was free of significant medication errors.

E. *The ALJ's conclusion that Life Care was not in substantial compliance with 42 C.F.R. § 483.75 is supported by substantial evidence and not legally erroneous.*

Section 483.75 states in its prefatory paragraph that a SNF "must be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident."

The ALJ concluded that Life Care was not in substantial compliance with section 483.75 during the period at issue, stating that the "systemic failure of Petitioner's nursing staff to comply with physicians' orders and with Petitioner's internal protocol can and should be laid at the feet of Petitioner's management," and that Life Care "offered neither evidence nor argument to rebut CMS's assertions of management failure." ALJ Decision at 25. Life Care's appeal is likewise devoid of any argument regarding this alleged deficiency. Life Care merely asserts that no violation of section 483.75 occurs "if there are no underlying clinical deficiencies." RR at 69. As our prior discussion makes clear, the record contains substantial evidence of "underlying" deficiencies. In addition, the Board has held that, in appropriate circumstances, a finding that a SNF was noncompliant with section 483.75 may be derived from findings of noncompliance with other participation requirements. Stone County Nursing and Rehabilitation Center at 15-16 (citing cases). For these reasons, we affirm the ALJ's conclusion that Life Care was not in substantial compliance with section 483.75.

F. *The regulations provided adequate notice of the standard of nursing care that Life Care was required to meet in these circumstances.*

Life Care contends that neither the regulations nor CMS (in its interpretive guidelines or policy statements) provided adequate notice of the standards to which it was held in the ALJ Decision. RR at 12. Relying on Emerald Shores Health Care Associates, LLC, 545 F.3d 1292 (11th Cir. 2009), Life Care contends that CMS must give a SNF fair notice of applicable standards prior to the survey but that, in this case, "CMS offered no evidence that [Life Care] was, or could have been, on notice of the specific clinical standard it (or the ALJ) would enforce." RR at 12. Life Care further contends that CMS "may not cite violations of very general requirements such as the 'professional standards' and 'quality of care' regulations [sections 483.20(k)(3) and 483.25] on the basis of ad hoc, unpublished and unknowable standards." RR at 71. Life Care further contends:

> CMS offered no evidence that it ever has issued regulatory guidance whether every blood sugar issue (or which issues) qualifies as a "significant change of condition" for purposes of [section 483.10(b)(11], nor what "consultation" would be required if that was the case. In the absence of such evidence, CMS must have the obligation to offer as part of its prima facie case of noncompliance evidence regarding some

> authoritative clinical standard that was, or should have been, known by physicians and nurses, as the predicate for such a violation. But CMS did not. Instead, the only evidence regarding clinical standards CMS offered was passing testimony by a surveyor that she based her judgments on otherwise unidentified "standards of practice which I learned in [nursing] school."

RR at 24 (emphasis added).

We reject the apparent premise of this argument, which is that Life Care is being held to a standard that requires immediate physician consultation any time a resident is found to have an abnormal level of blood glucose. That is clearly not what the ALJ found, and we stress that we are affirming the ALJ's findings of noncompliance based on evidence that prevailing standards of care obligated the nursing staff to consult with a physician immediately about the *specific episodes* of hypoglycemia experienced by Residents 18, 27, and 40 on June 25, July 21, September 11, and October 27, 2007.

We also disagree that the regulations failed to provide Life Care fair notice of its obligations to those residents. Section 483.10(b)(11), for example, plainly states that if there is a "significant change" in the resident's health status, then a SNF must consult immediately with the resident's physician. The regulation defines "significant change" as a "deterioration" of health status in "life-threatening conditions" or "clinical complications," and CMS's interpretive guidelines provide illustrative examples of significant changes. In addition, in the preamble to the final rule that promulgated section 483.10(b)(11), CMS noted that the physician consultation requirement was intended to cover situations in which there is a "potential for needing physician intervention." 56 Fed. Reg. 48,833. Life Care does not explain how or why the term "significant change" - as defined in regulation's text and preamble and explained in CMS's interpretive guidelines - should be regarded as vague with respect to the symptomatic episodes of very low blood glucose discussed in this decision.

Moreover, contrary to Life Care's assertion, CMS produced sufficient evidence of a pre-existing standard of care applicable to those episodes, including expert testimony by Dr. Schmitt, physician orders, and Life Care's own Hyperglycemia & Hypoglycemia policy, which directed Life Care to notify a physician immediately about "altered behavior or mental/physical state consistent with hyperglycemia or hypoglycemia." CMS Ex.

39, at 1. We also note that Life Care's medical director, Dr. Patsimas, showed an awareness of the nursing care standard applicable to Residents 18, 27, and 40 when he testified that a physician should be notified when a patient exhibits "significant symptoms of hypoglycemia," as these residents did.

We find Emerald Shores inapposite. The issue in that case involved a regulation requiring a SNF to maintain an "effective" pest control system. In deciding whether the SNF had substantially complied with that regulation, the court found that the term "effective" was too vague because CMS had not issued detailed instructions about how the efficacy of pest controls should be quantified or evaluated and because the "average nursing home administrator" lacks expertise in pest control methods. 545 F.3d at 1300. In contrast, the issue in the present case involves an aspect of nursing home administration - the management of diabetic residents - about which a SNF is expected to have expertise and knowledge of relevant standards of nursing care and how those standards should be applied in various circumstances. See Social Security Act § 1819 (d)(4)(A) (stating that a SNF "must operate and provide services in compliance with . . . accepted professional standards and principles which apply to professionals providing services in such a facility"); 42 C.F.R. § 483.75(b) (requiring facilities to provide services in compliance "with . . . accepted professional standards and principles"). To the extent that a Medicare participation requirement in Part 483, such as the physician consultation requirement, governs the quality of a resident's health care, the requirement can and should be interpreted to incorporate, and require adherence to, relevant professional standards of nursing care. Cf. John J. Kane Regional Center - Glen Hazel, DAB No. 2068, at 11-12 (2007) (holding that the obligation under section 483.25 to provide "necessary care and services" implicitly requires the SNF to ensure that its services meet professional standards of quality).

For these reasons, we hold that Life Care had adequate and timely notice of the standards to which it is being held in this proceeding.

G. *Life Care's contention regarding the allocation of evidentiary burdens is without merit.*

In its October 16, 2009 Motion to Submit Supplemental Authority, Life Care contends that the ALJ violated section 556(d) of the

APA because, in accordance with the Board's Hillman decision,[12] he allocated the ultimate burden of persuasion concerning the dispositive compliance issues to Life Care. Section 556(d) provides, among other things, that the "proponent of the rule or order has the burden of proof." According to Life Care, the decision in Grace Healthcare of Benton v. Dept. of Heath and Human Services, 589 F.3d 926 (8th Cir. 2009) "structured its analysis in terms of Section 556(d)" and "strongly suggested that the Board's traditional assignment of the burdens of proof and persuasion to petitioners challenging Government action is inconsistent with" section 556(d). Pet.'s Motion to Submit Supp. Auth. at 1-2.

Contrary to Life Care's protestation, the court in Grace did nothing of the sort. The court did not reassign the burden of persuasion or "structure[ ] its analysis in terms of Section 556(d)." Instead, the court rendered its decision based on an analysis of whether the Board's decision was "supported by substantial evidence in the administrative record as a whole." 589 F.3d at 931-35. In fact, the court expressly stated that the burden of proof issue had not been raised. Id. at 933 n.7.

We note that in prior cases, the Board has addressed and rejected the same APA argument made by Life Care in this case. Batavia Nursing and Convalescent Center, DAB No. 1904, at 15 (2004), aff'd, Batavia Nursing & Convalescent Center, 129 Fed. App'x 181 (6th Cir. 2005); Universal Healthcare/King, DAB No. 2215, at 26 (2008). We see nothing in Life Care's motion that persuades us to reconsider the Board's prior holdings on this issue.

H. *The ALJ did not violate Life Care's due process or other rights by receiving the parties' direct testimony in writing.*

In its initial pre-hearing order, the ALJ directed the parties to submit their direct testimony in writing.[13] Life Care now

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[12] Hillman Rehabilitation Center, DAB No. 1611 (1997), aff'd, Hillman Rehabilitation Ctr. v. U.S. Dep't of Health and Human Servs., No. 98-3789 (GEB) (D.N.J. May 13, 1999).

[13] The ALJ's pre-hearing order directed the parties to collect and submit written direct testimony of any individual whose testimony advanced the parties' claims and defenses, and provided guidance regarding the information which should be included in that testimony. Acknowledgment and Initial Pre-Hearing Order at 3 (Jan. 31, 2008) (directing Life Care to submit the "complete written direct testimony of any proposed

(Continued. . .)

contends that the ALJ's pre-hearing order impaired its statutory right to a hearing and constitutional right to due process, asserting that "it is inappropriate to require the use of written testimony for fact witnesses in any case involving the sort of 'quasi-criminal' penalties at issue here." RR at 2, 18-21; Pet.'s Second Motion to Submit Supp. Auth. at 2.

The Board has previously upheld the discretion of the ALJ to receive direct testimony in written form "so long as the right to effective cross examination is protected and no prejudice is alleged and shown." Laurels at Forest Glenn at 9 (2008), citing 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).

Life Care does not contend that its right to effective cross-examination was impaired in this case, nor does Life Care contend that the written direct testimony in this case prejudiced its ability to raise any issue or prove any fact bearing on its compliance status or the reasonableness of the CMP amount. We note that the ALJ's pre-hearing order did not bar Life Care from seeking permission to introduce in-person witness testimony if Life Care believed that it would otherwise be deprived of a full and fair opportunity to present its case. We further note that Life Care did not ask the ALJ for permission, on that ground, to elicit in-person testimony from any witness whose written testimony it had introduced.

Instead of attempting to demonstrate that it was prejudiced by the ALJ's pre-hearing order, Life Care submits that the Board should, as a policy matter, re-evaluate its stance regarding the general use of written direct testimony in light of Melendez-Diaz v. Massachusetts, 557 U.S. ___, 129 S.Ct. 2527 (2009). RR at 18-21. In Golden Living Center - Frankfort, DAB No. 2296 (2009), the Board held that Melendez-Diaz, a criminal case that implicated the Sixth Amendment's Confrontation Clause, is inapplicable to a civil administrative proceeding such as this one, and that even if Melendez-Diaz were applicable, it would prohibit use of a witness's written direct testimony only if the party against whom the written testimony is introduced lacked an opportunity to cross-examine the witness. DAB No. 2296, at 5; see also Austin v. United States, 509 U.S. 602, 608 (1993)

(Continued. . .)

witness" and indicating that such testimony could be used to "offer evidence that is relevant and that is not contained in other exhibits").

(stating that "[t]he protections provided by the Sixth Amendment are explicitly confined to criminal prosecutions"). Golden stressed that the Board's decisions "make clear that testimony proffered in written form before an ALJ may not be relied on if the proponent fails to produce the witness for cross-examination upon request of the opposing party." DAB No. 2296, at 5. As indicated, CMS did not fail to produce for cross-examination any witness whose written direct testimony it introduced.

In its Second Motion to Submit Supplemental Authority, Life Care asserts that the Supreme Court's order in Briscoe v. Virginia,[14] "as illuminated by the [Supreme Court's] oral argument in [that] case, makes clear that the Court intended Melendez-Diaz . . . to be construed and applied broadly to prohibit the Government from relying upon written testimonial evidence in a challenge by a citizen to a punitive sanction." Pet.'s Second Motion to Submit Supp. Auth. at 1. Life Care also asserts that "the discussion throughout the oral argument [in Briscoe] makes clear that the Court did *not* intend its analysis [in Melendez-Diaz] to be limited to the Sixth Amendment Confrontation Clause" and "that the tone of the entire oral argument - as well as the result - makes clear that the Court did *not* intend Melendez-Diaz to be construed and applied narrowly." Id. at 4 (italics in original).

Briscoe is irrelevant, in part because the Supreme Court did not address the merits of that appeal. Instead, it vacated the judgment of the Virginia Supreme Court and remanded the case for further proceedings consistent with Melendez-Diaz. Moreover, Briscoe, like Melendez-Diaz, concerns a criminal prosecution, not a civil proceeding such as this one. Even if it were proper to be guided by the statements of Supreme Court Justices made during oral argument (which, of course, we do not find), there is nothing in the transcript of the Briscoe oral argument that compels or otherwise supports a conclusion that a majority of the Supreme Court intends to extend the holding in Melendez-Diaz to civil administrative proceedings or would conclude that use of written direct testimony in these circumstances violates the APA or Due Process Clause.

In its first Motion to Submit Supplemental Authority, Life Care conflates its arguments regarding the burden of proof and written direct testimony in an effort to show that it was deprived of its constitutional and statutory (APA) rights to due process. Pet.'s Motion to Submit Supp. Auth. at 4-9. Life Care

[14] Briscoe v. Virginia, No. 07-11191, 2010 WL 246152 (U.S. Jan. 25, 2010).

claims that CMS's regulations, coupled with the pre-hearing procedures typically used by ALJs (and approved by the Board), "significantly restrict any petitioner's ability to prepare a defense to CMS's allegations." Id. at 4-5. For example, says Life Care, "[p]etitioners are not permitted to obtain any meaningful evidentiary discovery, much less to engage in any prehearing inquiry into CMS's theory of the case." Id. at 5. Life Care also asserts that the Board has "[e]xacerbat[ed] this limitation on the petitioner's ability to prepare a defense" by permitting an ALJ "to create a *new* basis for a sanction - as the ALJ did in this case - during, or even after the hearing, even to the extent of basing a sanction on a ground never asserted by CMS." Id. at 5 (emphasis added, italics in original).

This argument is devoid of any reference to the circumstances of this case. Life Care makes no attempt to demonstrate (and has not demonstrated) that the procedures used by the ALJ deprived it of an adequate opportunity to litigate any specific claim supporting the noncompliance findings at issue or any other issue bearing upon the validity of the remedy imposed. Life Care also fails to specify the factual basis for its suggestion that the ALJ "created a new basis" for the remedy during or after the hearing.

Because Life Care has not identified any issue of which it was not reasonably and timely notified, or demonstrated any prejudice as a result of the ALJ's reliance upon written direct testimony, Life Care has not established a deprivation of due process.[15]

I. *The ALJ did not preclude Life Care from challenging noncompliance findings that CMS elected not to rely upon,*

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[15] The APA "requires procedural fairness in the administrative process." Rapp v. U.S. Dep't of Treasury, 52 F.3d 1510, 1519 (10th Cir. 1995). Section 554(b)(3) provides that "[p]ersons entitled to notice of an agency hearing shall be timely informed of . . . the matters of fact and law asserted." 5 U.S.C. § 554(b)(3). However, "[a]s long as a party to an administrative proceeding is reasonably apprised of the issues in controversy, and is not misled, the notice is sufficient." Savina Home Indus., Inc. v. Secretary of Labor, 594 F.2d 1358, 1365 (10th Cir. 1979). In order to establish a violation of section 554(b)(3), a party must demonstrate that it "had sustained prejudice from the allegedly insufficient notice." St. Anthony Hosp. v. U.S. Dept. of Health and Human Services, 309 F.3d 680, 708 (10th Cir. 2002) (citations omitted).

nor did the ALJ err in not overturning or expunging those noncompliance findings.

In its pre-hearing brief to the ALJ, CMS stated that there was "no need for it to present detailed arguments and evidence supporting each and every jeopardy-level deficiency listed in" the Statement of Deficiencies for the November 2007 health survey because "[a] single jeopardy-level deficiency establishes the basis for a CMP in the range of $3,050 to $10,000 per day, and only a portion of Petitioner's many deficiencies are needed to support its CMP of $6,550 per day." CMS Pre-Hearing Br. at 3. Consequently, CMS informed Life Care and the ALJ that it had decided to limit its case-in-chief to a defense of five of the Statement of Deficiencies' 13 immediate jeopardy findings (namely, the findings at tags F157, F281, F309, F333, and F490).

Life Care contends that CMS's "litigation tactics" impaired its right to challenge the nine immediate jeopardy findings that CMS elected not to rely upon (and which the ALJ did not address). RR at 4, 8, 14-17. Life Care further contends that these nine unaddressed noncompliance findings should be "stricken from the record." RR at 14. In support of that request, Life Care submits that the unaddressed noncompliance findings have caused, or will cause, harm because "the mere *citation* of a deficiency now has significant - in some cases, catastrophic - regulatory consequences." RR at 4 (italics in original). In particular, Life Care asserts that CMS "uses the 'existence' of citations - whether challenged or not - as the basis for a new series of enforcement initiatives, including 'Five Star' public ratings, 'Special Focus Facility' designations that subject facilities to enhanced survey and enforcement activities, and the like, all of which are designed and intended to cause adverse effects on facilities (and actually are doing so)." RR at 16. Life Care also asserts that "[i]t is a matter of public record that CMS designated [Life Care] as a 'Special Focus Facility' on the basis of the *original* citations in this case, and the consequence of those citations is that CMS will publicly designate Petitioner as a 'One Star' or 'poor performing' facility for many years to come under its public rating system." RR at 16-17. According to Life Care, CMS permits no appeal of those ratings, "and so the effect of 'withdrawing' such citations from review in this appeal is to insulate such findings from any review, regardless of their accuracy." RR at 17.

Because these assertions are either factually unsupported or legally meritless, we conclude that Life Care was not deprived of its due process rights concerning the nine unaddressed

noncompliance findings. According to notes of the July 7, 2007 pre-hearing conference contained in the appellate record, Life Care inquired about the necessity to present evidence on noncompliance findings that CMS had elected not to rely upon. The notes further indicate that in view of CMS's decision to narrow its case-in-chief, the ALJ advised Life Care to focus on the eight residents and five noncompliance findings about which CMS had presented argument and testimony.

In its July 18, 2008 pre-hearing brief, Life Care acknowledged that CMS had narrowed its case-in-chief and stated that it would respond to the survey findings that CMS had elected to rely upon. Pet.'s Pre-Hearing Br. at 6. Later in that brief, Life Care asserted:

> [A]s Petitioner noted during the telephone Prehearing Conference on July 7, 2008, the practical and legal effect of CMS's tactical narrowing of the allegations it is pressing in this appeal is to leave Petitioner no means to challenge literally hundreds of allegations of wrongdoing that have no support whatsoever. Petitioner suggests that the notion that an agency is entitled to shield its public allegations of wrongdoing from meaningful review may be a reflection of the current political ideology about the Executive Branch's prerogatives, but Petitioner suggests that such tactics are fundamentally unfair . . . . The record of this case should reflect, as does Petitioner's Request for Hearing (and its informal dispute resolution evidence) that Petitioner disputes the accuracy and appropriateness of virtually every citation, and strongly objects to such litigation tactics.
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> * * *
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> Petitioner addressed every cited example of alleged noncompliance in its Request for Hearing (and addressed all at informal dispute resolution), and is prepared to do so at the hearing if necessary. As Petitioner understands the Court's ruling during the Prehearing Conference on July 7, 2007, the Court has ordered the parties to address in their evidence and briefs the citations they press or defend, respectively, and so the hearing will be limited to the examples of alleged noncompliance pressed by CMS in its Prehearing Brief. Petitioner wishes to make clear that by submitting evidence and argument directed only to those examples, it does not intend

> to concede that any citation in the Statement of Deficiencies is inaccurate, or that it is waiving its defense to any such citation.

Id. at 6, 18 n.5 (emphasis added). CMS never disputed Life Care's statements about its understanding of the ALJ's pre-hearing ruling concerning the scope of the hearing.

In our view, the statement in this passage that CMS's "litigation tactics" left Life Care with "no means to challenge" noncompliance findings that CMS elected not to rely upon lacks foundation. Life Care was not, of course, obliged to submit to CMS's litigation tactics but could have presented evidence on any of the 13 immediate jeopardy findings in the Statement of Deficiencies. Life Care asserts that during the July 7 pre-hearing conference, the ALJ "ordered the parties to address . . . the citations they press and defend, respectively[.]" The ALJ did not issue a written order summarizing the results of the July 7 conference. However, assuming Life Care has accurately characterized the ALJ's oral order, it did not preclude Life Care from "defending" itself against any noncompliance finding that it wished to challenge. Although Life Care understood the July 7 conference to have resulted in a narrowing of the issues, that outcome stemmed from facility's apparent decision to accede to CMS's "tactical narrowing" of CMS's case-in-chief, and not from restrictions imposed by the ALJ on Life Care's case-in-chief. Life Care's statement that it was prepared "if necessary" to present evidence on noncompliance findings that CMS had elected not to rely upon indicates that Life Care - for tactical reasons of its own - waived or deferred its opportunity to present such evidence. At no later point did Life Care advise the ALJ that it was "necessary" for it to present additional evidence concerning noncompliance findings that CMS had elected not to rely upon.

Life Care asserts in this appeal that it "specifically requested leave on numerous occasions throughout the case - including in its post-hearing briefs - to address all of CMS's allegations," including allegations that CMS elected not to rely upon. RR at 17. "The only reason it did not offer such evidence," says Life Care, "is that the ALJ precluded Petitioner from doing so." RR at 17-18. However, the post-hearing brief contains no request to present evidence on noncompliance findings that CMS had elected not to rely upon, and Life Care does not identify any other occasion - pre-hearing or post-hearing - on which it asked the ALJ for permission to present such evidence. Furthermore, we see no indication that Life Care objected to any ruling by the ALJ concerning the scope of the hearing. Life Care objected

only to CMS's "litigation tactics," indicating that it "wished to make clear" that it did not "concede" the accuracy or truth of any noncompliance findings that CMS did not address in its pre-hearing exchange. Pet.'s Pre-Hearing Br. at 5; see also Pet.'s Post-Hearing Br. at 8. For these reasons, we reject Life Care's contention that it was precluded from challenging the nine unaddressed findings of immediate jeopardy.

We also reject Life Care's suggestion that CMS's "litigation tactics" were improper in themselves. According to Life Care, the court in Grace Healthcare of Benton found it improper for CMS to defend the reasonableness of the amount of a CMP based on fewer than all of the findings of noncompliance appealed by the SNF. RR at 14-18; Pet.'s Motion to Submit Supp. Auth. at 3. In Grace, the court reviewed a decision in which the Board upheld a remedy based on one of six immediate jeopardy-level findings appealed by the SNF. The court overturned the Board's decision because, in its view, the Board had "made no fact-specific analysis of the immediate jeopardy issue" and cited no facts that the regulatory violation in question "increased the risk of abuse, neglect, or mistreatment of Resident #1 or its other residents." 589 F.3d at 935.

Contrary to Life Care's contention, Grace did not find that it was improper for the ALJ or the Board to uphold a remedy based on fewer than all of the findings of noncompliance appealed by the SNF. In fact, the court expressly held that it was not rejecting the principle, consistently applied by the Board, that an ALJ may decline to consider or rule on noncompliance findings that are immaterial to the outcome of the appeal. 589 F.3d at 935. Grace merely found that the principle had been "misapplied" in that case (evidently because the court thought that certain immediate jeopardy-level findings appealed by the SNF but not addressed by the ALJ or the Board were, or may have been, necessary to support the immediate jeopardy determination). Id.

Finally, we deny Life Care's request to overturn or expunge the nine noncompliance findings of noncompliance that CMS elected not to litigate and which were not addressed in the ALJ Decision. As an initial matter, we are unaware of (and Life Care does not cite to) any statute or regulation that would authorize the Board in these circumstances to expunge (or to direct CMS to expunge) a survey finding of noncompliance absent a decision by the ALJ or the Board on the finding's merits. Moreover, it is important to note that neither party has conceded its respective positions on the merits of these findings. CMS, in fact, presented documentary evidence to

substantiate them and claimed (without further elaboration) that this evidence constituted a prima facie case of noncompliance. CMS Pre-Hearing Br. at 3. For its part, Life Care took pains to advise the ALJ in its pre-hearing brief that it was reserving its objections to the nine unaddressed noncompliance findings and would later, "if necessary," present evidence to support them. Pet.'s Pre-Hearing Br. at 18 n.5. Life Care did not subsequently ask the ALJ for leave to present evidence on the unaddressed noncompliance findings, nor has Life Care asked us to remand the case for a hearing on those findings.

Life Care argues that Grace requires the Board to grant its request. According to Life Care, Grace "specifically held that where, as here, a petitioner challenges all of the 'immediate jeopardy' citations that underlie a remedy, the ALJ and Board must either affirm or reverse *all* such citations, **or any citations that are not so resolved should be 'expunged from the agency's public records.'**" Pet.'s Motion to Submit Supp. Auth. at 1 (italics in original, emphasis added).

We do not read Grace as stating such a broad rule. In that case, the status of unresolved deficiency citations became an issue when the SNF claimed that they were publicly accessible and could be used to support damages in a separate third-party civil action. The court's response was a conditional one: the court indicated that if it were true that unaddressed deficiency citations could be used to support private damages claims, then the continued existence of those citations was a "material adverse impact, in which case all findings of immediate jeopardy that are appealed should either be upheld or reversed by the ALJ or the DAB or be expunged from the agency's public records." 589 F.3d at 935. Without further explanation or reasoning, the court then directed the Secretary of HHS to "expunge all references to findings or determinations of immediate jeopardy-level noncompliance by Grace Healthcare with respect to this litigation and [the survey] from the Department's and CMS's agency records that are accessible or available or available by any method or means to the public." Id.

There are two facts that materially distinguish this case from Grace. First, the record here indicates that Life Care acquiesced in CMS's narrowing of the litigation to a subset of the appealed noncompliance findings. In contrast, the parties in Grace litigated all of the appealed deficiency citations. Grace Healthcare of Benton, DAB CR1676, at 3 (2007), aff'd, Grace Healthcare of Benton, DAB No. 2189, at 1-2 (2008), rev'd, 589 F.3d 926. We see nothing in Grace indicating that the court intended to announce a broad rule that requires the Board

or the ALJ to issue a ruling on the merits of every finding of noncompliance appealed by the SNF, regardless of whether the parties themselves ultimately narrowed the scope of the administrative litigation.

Second, Life Care has alleged qualitatively different collateral consequences. Unlike the SNF in Grace, Life Care does not contend that the unaddressed noncompliance findings will increase its exposure to damages in a third-party civil action. Instead, Life Care alleges that there will be adverse "regulatory consequences" - namely, exposure to "enhanced survey and enforcement activities" by CMS or the state survey agency. Such enforcement activities are remedial in nature and are performed to protect Medicare beneficiaries, not to assess damages for negligence or other legal liability. Moreover, Life Care did have an opportunity to avoid these consequences by challenging them in the IDR process, which it did.

For these reasons, we find Grace inapplicable and reject Life Care's request to expunge the unaddressed noncompliance findings. CMS's "litigation tactics" may have altered how Life Care weighed the option to litigate those findings; indeed, Life Care may reasonably have thought that its prospects for reducing or eliminating the CMP were better if only five of the 13 survey findings of noncompliance were at issue. Those tactics did not, however, preclude Life Care from challenging any deficiency citation before the ALJ. In addition, Life Care did not raise the issue of collateral adverse consequences before the ALJ, nor did Life Care submit any evidence of CMS's "enhanced survey and enforcement activities" and how those activities might affect Life Care under these circumstances. Finally, Life Care has not shown that the enhanced regulatory scrutiny would not have occurred but for the continued existence of the unaddressed noncompliance findings.

J. *The ALJ committed no error in concluding that CMS's immediate jeopardy determinations were not clearly erroneous.*

A SNF is in a state of "noncompliance" with Medicare participation requirements if it has one or more deficiencies that have the potential to cause more than minimal harm. 42 C.F.R. § 488.301 (definitions of "noncompliance" and "substantial compliance"). "Immediate jeopardy is defined as a situation in which a SNF's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." 42 C.F.R. 483.301. CMS's determination about the seriousness of

the SNF's noncompliance must be upheld unless it is clearly erroneous. 42 C.F.R. § 498.60(c). Under that standard, the SNF has a heavy burden to overturn the immediate jeopardy determination. Edgemont Healthcare, DAB No. 2202, at 20 (2008) (citing cases); Daughters of Miriam Center, DAB No. 2067, at 7 (2007).

After concluding that Life Care was noncompliant with five participation requirements, the ALJ concluded that CMS had committed no clear error in determining that this noncompliance had created a situation of immediate jeopardy. ALJ Decision at 25-26. The ALJ made specific findings to support that conclusion, stating, among other things, that "[t]he failure of Petitioner's nursing staff to consult with residents' treating physicians about the hypoglycemic crises sustained by residents #s 18, 27, and 40 certainly put these residents at a high likelihood of suffering serious harm[.]" Id. at 25. Interspersed with those findings are some sweeping characterizations of Life Care's nursing care. We disagree with some of those characteristics: we do not, for example, think that the record supports the ALJ's assertion that Life Care's nursing operations were "anarchic." We nevertheless sustain CMS's immediate jeopardy determination as to each of the citations at issue (tags F157, F281, F309, F333, and F490) because Life Care has not met its burden of demonstrating that those determinations are clearly erroneous. In this appeal, Life Care essentially takes the position that CMS did not prove the existence of any noncompliance, much less immediate jeopardy-level noncompliance. Life Care could have contended, in the alternative, that the immediate jeopardy determination associated with a particular deficiency should be overturned in the event that the Board upheld the underlying finding of noncompliance. However, Life Care did not take that alternative position with respect to any of the noncompliance findings at issue in this appeal. Indeed, Life Care's appeal briefs are devoid of discussion of the regulatory prerequisites for a finding of immediate jeopardy.

Life Care occasionally remarks that residents suffered no actual harm from the noncompliance (see, e.g., RR at 75 and Reply Br. at 3) but, as we have noted, the existence of actual harm is not a prerequisite for a finding of immediate jeopardy. Stone County Nursing & Rehabilitation Center at 19. Moreover, we find substantial evidence in the record supporting CMS's immediate jeopardy determinations. See, e.g., CMS Ex. 50, at 4-5 (Schmitt declaration) (testifying that Life Care's failure to consult with a physician about Resident 27's and Resident 40's episodes of hypoglycemia "exposed the residents to a high likelihood of

suffering very serious harm"); id. at 5 (testifying that the nursing error regarding Resident 56, given her history of hyperkalemia and bradycardia, "exposed the resident to a high likelihood of suffering grave harm, including cardiac arrest and sudden death"); CMS Ex. 48, at 10 (Crocker declaration) (noting that the medication error involving Resident 18 probably resulted in repeated episodes of hypoglycemia, including one in which the resident suffered convulsions and became non-responsive); CMS Ex. 48, at 15 (Crocker declaration) (stating that the facility's failure to prepare a medication error report concerning the Tegretol administration error "created a very strong likelihood that another serious medication error could arise again for Resident #48). Accordingly, we affirm the ALJ's conclusion that CMS's determinations of immediate jeopardy were not clearly erroneous.

K. *The amount of the civil money penalty imposed by CMS for Life Care's period of immediate jeopardy-level noncompliance is not reasonable; a $4,550 per-day CMP for that period is reasonable.*

If CMS finds noncompliance at the level of immediate jeopardy, the regulations authorize it to impose a per-day CMP in the range of $3,050 to $10,000 per day. 42 C.F.R. § 488.438(a)(1)(i). Here, CMS imposed a $6,550 per-day CMP for Life Care's immediate jeopardy-level noncompliance. CMS Exs. 42-44. This CMP was in effect from June 25, 2007 through November 27, 2007. Thus, the total amount of the penalty for this period was $1,021,800 ($6,550 multiplied by 156 days).

As Life Care concedes (RR at 72) and the ALJ found (ALJ Decision at 27), the magnitude of the aggregate penalty reflects two factors (among others): (1) the seriousness of the noncompliance; and (2) the duration of the noncompliance, as determined by CMS.

Regarding the second factor, Life Care asserts that "CMS never made clear why" the CMP became effective on June 25 but concedes that this starting date correlates with Resident 27's first episode of hypoglycemia and Life Care's response to that episode (see infra text at 7-18). RR at 72. Life Care contends, however, that its "response to Resident #27's hypoglycemic episode was no different than dozens of similar episodes, so it is hard to see how that episode put [it] on notice that the response on that date was particularly problematic or required correction." RR at 72 (emphasis added).

In claiming that it lacked notice of its June 25 noncompliance,

Life Care implies that a CMP may be imposed only for dates after CMS or the state survey agency notifies the SNF of noncompliance. This is incorrect. The regulations provide that a "per day civil money penalty may start accruing as early as the date that the facility was first out of compliance, as determined by CMS or the State." 42 C.F.R. § 488.440(a)(1). On its face this provision permitted CMS to impose a CMP for noncompliance that existed prior to the November 2007 health survey. Pinehurst Healthcare & Rehabilitation Center, DAB No. 2246, at 35 (2009). Moreover, in this context, Life Care may not reasonably complain that it lacked notice of noncompliance. A SNF is expected to be in substantial compliance with Medicare participation requirements at all times. 42 C.F.R. §§ 488.3(a)(i), 488.20 (requiring periodic surveys to verify continued compliance). Here, Life Care should have known that its failure to consult with a physician despite Resident 27's low blood glucose and other symptoms did not comply with the regulatory requirements.

For these reasons, and based on our discussion in the previous sections, we affirm the ALJ's finding that Life Care's immediate jeopardy-level noncompliance began on June 25, 2007. We also affirm the ALJ's finding that after June 25, 2007, Life Care did not remove that noncompliance until November 28, 2007.[16] In view of these findings, we conclude that CMS was legally authorized to impose a per-day CMP of between $3,050 and $10,000.

We now turn to the issue of whether the per-day CMP chosen by CMS from that range is reasonable. In deciding whether the CMP amount is reasonable, an ALJ may consider only those factors specified in the regulations. 42 C.F.R. § 488.438(e), (f). Those factors are: (1) the SNF's history of noncompliance; (2) the SNF's financial condition; (3) the factors specified in 42 C.F.R. § 488.404 (e.g., the severity and scope of the

[16] Section 488.454(a) provides that "alternative remedies," such as a per-day CMP, continue to accrue until "[t]he facility has achieved substantial compliance, as determined by CMS or the State based upon a revisit or after an examination of credible written evidence that it can verify without an on-site visit." In addition, section 488.454(e) states that an alternative remedy may terminate on a date prior to a revisit survey if the SNF "can supply documentation acceptable to CMS or the State survey agency that it was in substantial compliance" on that earlier date and was capable of remaining in substantial compliance. Life Care does not contend that the noncompliance that began on June 25, 2007 ceased any sooner than November 28, 2007.

noncompliance); and (4) the SNF's degree of culpability, which includes neglect, indifference, or disregard for resident care, comfort or safety. 42 C.F.R. § 488.438(f). The ALJ reviews the reasonableness of the CMP de novo, based on the facts as found on the record before the ALJ. Emerald Oaks, DAB No. 1800 (2001); CarePlex of Silver Spring, DAB No. 1683 (1999). "[W]hether the CMP amount is reasonable is a legal conclusion to be drawn from the application of regulatory criteria to the facts of the case." Cedar Lake Nursing Home, DAB No. 2288, at 14 (2009).

The ALJ found that the per-day CMP amount chosen by CMS - $6,550 - was "well supported by the evidence establishing the seriousness of Petitioner's noncompliance." ALJ Decision at 27. The ALJ further found:

> Petitioner's noncompliance was shocking. It tolerated a state of anarchy in its facility in which nurses were free to make treatment decisions that should have been made either by physicians directly or at their instruction. It allowed nurses to defy physicians' orders and to ignore written protocol that had been adopted to establish parameters of care. The anarchic state in Petitioner's facility had severe consequences for residents. Several residents experienced medical crises which put them on the edge of sustaining life-threatening consequences. But, even those alarming events did not prompt Petitioner's staff or management to assume and discharge their responsibilities.

Id. at 27. In addition, the ALJ found "nothing unfair about basing the remedy in this case on the five deficiencies that I have addressed in this decision," finding the remedy to be "amply supported by evidence establishing the egregiousness of these deficiencies." Id. at 28.

We have two reservations about this analysis. First, the ALJ's comments indicate that he sustained the CMP based partly on his finding that there were "dozens" of examples of noncompliance other than the ones that his decision describes. As discussed above, it was improper for the ALJ to rely upon any examples of alleged noncompliance other than the ones involving the eight residents about whom CMS presented evidence and legal argument. See infra text at 26-28 (discussing the ALJ's reliance on Attachment A to CMS's post-hearing brief).

Second, the ALJ's finding that Life Care "tolerated a state of

anarchy . . . in which nurses were free to make treatment decisions that should have been made either by physicians directly or at their instruction" is overblown and inaccurately characterizes Life Care's noncompliance. Life Care was noncompliant largely because its nursing staff - in violation of physician orders, professional nursing standards, and its own physician notification protocol - failed to consult in a timely way with physicians about circumstances in which there was a potential need for the physician to supervise or modify the resident's treatment. The surveyors found that the noncompliance "denied physicians an opportunity to consider adjusting" residents' insulin orders or to order more rigorous monitoring of residents' blood glucose. CMS Ex. 49, at 7-8. In addition, the surveyors found that the nursing staff's failure to comply with the physician notification protocol was problematic because Life Care did not have sufficiently comprehensive written instructions to guide the staff's response to hypoglycemic episodes. Id. at 6-7. However, neither the surveyors nor Dr. Schmitt (CMS's medical expert) testified that nurses had, in fact, made treatment decisions or initiated interventions that should have been ordered first by the resident's physician, or that nurses were developing treatment plans and protocols for residents without physician input.

Notwithstanding these reservations, we find that a consideration of the relevant regulatory factors supports a CMP above the regulatory minimum of $3,050 per day. Life Care's immediate jeopardy-level noncompliance involved five residents and multiple failures to comply with the most basic of nursing standards - the obligation to act under a physician's supervision. See CMS Ex. 50, at 3 ("it is the role of nurses to administer patient care under the supervision of physicians"). Furthermore, given Life Care's failure to establish that the actions of its nursing staff were being governed during the relevant period by sufficiently comprehensive protocols for managing episodes of hypoglycemia and hyperglycemia, it is reasonable to infer that an element of Life Care's noncompliance - specifically, its failure to consult with the physicians about hypoglycemic and hyperglycemic episodes - had the potential to affect diabetic residents other than the ones whom the ALJ discussed. We thus conclude that Life Care's noncompliance with the physician consultation requirement was widespread. While the noncompliance with the medication error requirement was isolated, the two deficiencies were related in that they both involved a lack of sufficient attentiveness by facility staff to physician orders.

We find Life Care culpable for its noncompliance. For our

purposes, culpability "includes, but is not limited to, neglect, indifference, or disregard for resident care, comfort or safety." 42 C.F.R. § 488.438(f)(4). The record here reveals acts or omissions that satisfy one or more definitions of culpable conduct, including gross inattentiveness (e.g., the two-to-three hour delay in notifying Resident 56's physician about her abnormal potassium level), carelessness (e.g., the failure to correctly identify Resident 18's insulin order at the time of admission), lack of diligence in complying with physician orders, and evidence of seeming unconcern about the source of a significant medication error (see Surveyor Crocker's testimony concerning Life Care's failure to prepare a report on Resident 48's medication error (CMS Ex. 48, at 15)).

As to the other regulatory factors, CMS submitted no evidence of prior history of noncompliance by Life Care, while Life Care submitted no evidence of its inability to pay the CMP imposed by CMS.

For its part, Life Care does not frame its objection to the CMP amount in terms of the relevant regulatory factors. Instead, Life Care raises issues that the Board has rejected in prior decisions. Life Care contends that an ALJ "must actually evaluate whether any proposed CMP actually has a remedial purpose - namely, that it "motivate[s] a noncompliant facility to correct deficiencies and not repeat them." RR at 73. Life Care suggests that there is no basis to find it needed motivation to come into compliance because CMS produced no evidence that the nursing staff or medical director were "clueless" or "indifferent" about a compliance issue or "had any way to anticipate the critiques of Petitioner's longstanding diabetes protocols[.]" RR at 74. In these circumstances, says Life Care, "[i]t is hard to see how imposition of a huge *retroactive* penalty would motivate a nursing facility to adopt specific clinical policies that CMS has never required or even recommended." Id. (italics in original).

Imposition of a CMP does not require proof that Life Care was ignorant of, or indifferent to, its regulatory obligation, only that it was not, in fact, in substantial compliance with participation requirements.[17] Furthermore, the regulations do not require the ALJ to evaluate or otherwise establish a nexus

[17] If Life Care is contending here that it was not culpable, we reiterate that under section 488.438(f)(4), culpability may be shown by circumstances other than staff members' subjective "indifference" or ignorance.

between the amount of a CMP and a specific remedial purpose.

Under its regulations, which are binding on the Board, CMS may impose a CMP in the upper range of $3,050 to $10,000 per day if it validly determines that a SNF is in a state of immediate jeopardy-level noncompliance. See 42 C.F.R. § 488.408(e)(2)(ii). Those regulations also authorize CMS to impose a CMP for noncompliance that arises prior to the survey in which the noncompliance is identified. Id. § 488.440(a)(1). Here, CMS established the legal prerequisites for a $3,050-to-$10,000 per-day CMP - namely, the existence at Life Care of immediate jeopardy-level noncompliance between June and November 2007. We are therefore bound to sustain CMS's decision to impose an upper-range CMP for that period and may not reduce the CMP to zero or to an amount below that range. 42 C.F.R. § 488.438(e); Magnolia Estates Skilled Care, DAB No. 2228, at 28-29 (2009). Although we may assess whether the amount imposed within the applicable range is reasonable, we are legally prohibited from considering factors other than those specified in regulations. See id. §§ 488.438(e)(3), 488.438(f).

Life Care also relies on Dr. Standridge's opinion that the remedy was disproportionate to the severity of the noncompliance alleged by the surveyors in the Statement of Deficiencies and suggests that this opinion is supported by a Tennessee legislative report which indicates that the state survey agency issues a "disproportionate number" of immediate jeopardy citations. RR at 75. Life Care did not submit a copy of that report for the record. Even if Life Care had submitted a copy of the report, the alleged comparative severity of citations from the state survey agency would not be relevant to our consideration because it is not one of the listed regulatory factors that govern the scope of our review. In any case, our conclusions are based on the record as developed before us, not merely on state surveyors' findings and opinions.

Finally, Life Care suggests that the ALJ was obligated to reduce the CMP amount because CMS did not rely upon a substantial number of noncompliance findings during the ALJ proceeding - findings that ostensibly supported the decision to set the CMP amount at $6,550 per day. RR at 72-73. As the Board has consistently held, an ALJ "may . . . find the CMP amount selected by CMS to be reasonable based on fewer deficiencies than those upon which CMS relied to impose the penalty." The Residence at Salem Woods, DAB No. 2052, at 11 (2006). In this case, CMS did not pursue a number of widespread, immediate jeopardy-level deficiencies. In our view, the remaining findings, while serious, do not suffice to support the entire

amount of the per-day CMP.

Based on our consideration of the record here in light of the relevant factors, including our previously discussed reservations concerning the ALJ's analysis, we find that a $4,550 per-day CMP is reasonable for the period from June 25 through November 27, 2007.

L. *The ALJ properly determined that Life Care did not appeal the findings of noncompliance that led to the imposition of the $100 day CMP.*

The ALJ declined to determine whether a basis existed for CMS to impose the $100 per-day CMP that ran from November 28 through December 6, 2007, finding that "CMS's determination to impose [that remedy] was administratively final." ALJ Decision at 1. Life Care now asserts that the basis for the $100 per-day CMP "remains uncertain," and that the ALJ "had no authority simply to sustain it sua sponte." RR at 6-7 & n.2. Life Care asserts that the ALJ sustained the $100 per-day CMP "without ever saying what it related to." Id.

We do not agree that the basis for the $100 per-day CMP was uncertain, as Life Care alleges. CMS's December 18, 2007 letter to Life Care states that a revisit survey was performed on December 12, 2007 to determine whether Life Care had corrected its "health deficiencies," a reference to the immediate jeopardy-level findings from the November 2007 health survey. CMS Ex. 44. The December 18 letter further states that Life Care "removed the immediate jeopardy" as of November 28 and corrected the LSC deficiencies as of December 5, 2007. While the December 18 letter could be interpreted as indicating that Life Care's "health deficiencies" persisted from late November to early December 2007 at a level lower than immediate jeopardy, the letter also plainly states that Life Care was noncompliant with LSC requirements during that approximately one-week period. Thus, the December 18 letter alerted Life Care that CMS had imposed the $100 per-day CMP based in whole or part on the LSC survey findings.

CMS's adoption of the LSC findings as a basis for the $100 per-day CMP constituted an initial determination of noncompliance that was final and binding on Life Care unless it timely requested a hearing on that determination. 42 C.F.R. §§ 498.3(b)(13), 498.20(b). The only request for hearing in the record before us is the hearing request filed by Life Care on January 23, 2008. Life Care did not challenge the LSC survey findings in that hearing request. Life Care merely stated that

the "status of the $100 per day CMP . . . is not clear" and it was reserving the right to appeal that remedy "to the extent that [the remedy] was imposed solely because of any LSC deficiency[.]" Request for Hearing at 3 (emphasis added).

In its June 18, 2008 pre-hearing brief, CMS clarified that the bases for the $100 per-day CMP were the deficiencies found during the November 2007 LSC survey. CMS's Pre-Hearing Br. at 3 n.3. After receiving that information, Life Care did not seek further clarification from CMS or ask the ALJ for leave to amend its pending hearing request to include a challenge to the LSC deficiencies.[18] Life Care also made no attempt to file a second hearing request on the theory that CMS's clarification regarding the $100 per-day CMP constituted an appealable initial determination.

Citing correspondence indicating that CMS had "waived" certain LSC requirements, Life Care suggests that it did not understand the impact of that decision on the validity of the $100 per-day CMP. RR at 7 n.2. However, Life Care does not explain how the waiver, assuming it occurred, affected its decision about whether or not to appeal the LSC survey findings.[19] Because there is no evidence that Life Care timely appealed CMS's determination to impose the $100 per-day CMP, we conclude that the ALJ committed no error in declining to determine whether there was a basis for that remedy.[20]

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[18] To the extent that such an amendment would have been deemed to be an untimely request for hearing, Life Care could have sought an extension of the filing deadline under 42 C.F.R. § 498.40(c).

[19] Life Care does not suggest that the waiver operated to rescind or overturn the LSC survey findings that were the basis for the $100 per day CMP.

[20] The record is unclear about the proper duration of the $100 per day CMP. According to CMS's December 18 letter, a revisit survey found Life Care in substantial compliance with LSC requirements "as of" December 5, 2007. CMS Ex. 44, at 2. CMS later indicated that the $100 per day CMP had remained in effect *through* December 6, 2007, which, it appears, was one day after Life Care achieved substantial compliance. Life Care did not raise this issue on appeal.

CONCLUSION

Based on the foregoing analysis, we affirm the ALJ's determination that from June 25, 2007 through November 27, 2007, Life Care was not in substantial compliance - at the level of immediate jeopardy - with requirements in 42 C.F.R. §§ 483.10(b)(11), 483.20(k)(3), 483.25, 483.25(m)(2), and 483.75. However, we vacate section II.B.3 of the ALJ Decision and in its place substitute our analysis and conclusion concerning the reasonableness of the CMP amount. Based on our analysis of the evidence relating to the applicable regulatory factors, we conclude that a $4,550 per-day CMP is reasonable for Life Care's 156 days of immediate jeopardy-level noncompliance.

/s/
Judith A. Ballard

/s/
Leslie A. Sussan

/s/
Stephen M. Godek
Presiding Board Member