### Department of Health and Human Services

### DEPARTMENTAL APPEALS BOARD

**Appellate Division** 

In the Case of:	) )	DATE: June 23, 2008
The Laurels at Forest Glenn,	) ) )	
Petitioner,	) ) )	Civil Remedies CR1681 App. Div. Docket No. A-08-39
- v	) )	Decision No. 2182
Centers for Medicare & Medicaid Services.	, ) )	

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

The Laurels at Forest Glenn (Laurels), a nursing facility located in Garner, North Carolina, requested review of the decision by Administrative Law Judge (ALJ) Carolyn Cozad Hughes in <u>The Laurels at Forest Glenn</u>, DAB CR1681 (2007)(ALJ Decision). The ALJ Decision upheld the determination by the Centers for Medicare & Medicaid Services (CMS) to impose on Laurels a civil money penalty (CMP) of \$3,050 per day for the period June 22, 2006 through June 27, 2006, and a CMP of \$50 per day for the period June 28 through August 8, 2006.

The ALJ Decision accurately and thoroughly describes the legal and procedural background of this appeal, as well as the undisputed facts. Therefore, we do not repeat them here. Furthermore, the ALJ thoroughly addressed most of Laurels' arguments on appeal. We agree with the ALJ that these arguments have no merit. We address the major arguments below.<sup>1</sup> Our decision first explains why we determine that Laurels' allegations of legal error in the ALJ Decision mischaracterize the proceedings below and are unfounded. Next, we describe our reasons for concluding that the ALJ's factual findings contested by Laurels are supported by substantial evidence on the record as a whole. Finally, we explain why we uphold the ALJ's conclusion that CMS's determination that Laurels' noncompliance with the program participation requirements posed immediate jeopardy to facility residents from June 22, 2006 through June 27, 2006 was not clearly erroneous.

CMS imposed the statutory and regulatory minimum per-day penalty amounts for the immediate jeopardy period of noncompliance (\$3,050 per day) and for the non-immediate jeopardy period of continuing noncompliance (\$50 per day). Furthermore, Laurels did not challenge the duration of either period of noncompliance. Therefore, we sustain without further discussion the ALJ's conclusions on the amount and duration of each CMP imposed.

Accordingly, we uphold the ALJ Decision and adopt each of the ALJ's findings of fact and conclusions of law.

#### 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 for Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's Participation in the Medicare and Medicaid Programs, http://www.hhs.gov/dab/guidelines/prov.html; <u>see also</u> <u>Batavia Nursing & Convalescent Inn</u>, DAB No. 1911, at 7 (2004), <u>aff'd</u>, <u>Batavia Nursing & Convalescent Ctr. v. Thompson</u>, 143 Fed.Appx. 664 (6th Cir. 2005).

<sup>&</sup>lt;sup>1</sup> Although some specific points made by Laurels may not be discussed in detail in this decision, we considered all of the arguments in the parties' briefs in reaching the conclusions set forth herein. To the extent that any contention is not explicitly addressed, the ALJ Decision adequately covered the issue.

#### Discussion

1. Laurels' arguments that the ALJ Decision contains errors of law are without merit.

# A. The ALJ did not address matters beyond the scope of her review.

Laurels argues, as "a threshold administrative law issue," that the ALJ erred in sustaining the CMPs based on aspects of the care and treatment of a resident (R1) on which neither the North Carolina State Survey Agency (State agency) nor CMS relied to support their determinations of noncompliance. P. Br. at 2-6; P. Reply Br. at 1-3. According to Laurels, the "gist" of CMS's determination that Laurels did not substantially comply with the physician notification requirement at 42 C.F.R. § 483.10(b)(11) or the quality of care requirement at 42 C.F.R. § 483.25 is that "staff failed to notify [R1's] attending physician [of], and to seek treatment for, a 'documented change in [R1's] physical condition' that occurred during the morning of June 22, 2006." P. Br. at 2. Laurels points out that, in addition to addressing this issue, the ALJ found that: 1) "Facility staff inadequately monitored R1's blood sugar levels" at various points during his stay; and 2) "[f]acility staff did not follow the facility's protocol for notifying the physician of R1's low blood sugar levels" on June 21. ALJ Decision at 6-10. In so doing, Laurels contends, the ALJ "took it on herself to canvass [R1's] entire chart," and cited "evidence regarding various events . . . that allegedly occurred on June 19, 20 and 21, as well as June 22" to support her conclusions that Laurels was not in substantial compliance with the regulations. P. Reply Br. at 2; P. Br. at 3. Laurels acknowledges that the State agency's statement of deficiencies (SOD) found during the survey "does recite various events that occurred on June 19, 20 and 21." P. Br. at 3. However, Laurels says, the SOD includes these events (listed under both the physician notification and quality of care citations) only to establish "the context for the alleged violations . . . [of] June 22." Id. at 3, 32. Thus, Laurels argues that it did not have notice "of the actual factual basis for the sanction." P. Br. at 4; see also P. Reply Br. at 1.

Laurels made similar arguments in the proceedings below, and section III.B. of the ALJ Decision addressed them. P. Posthearing Br. at 2-4; ALJ Decision at 15-16. The ALJ stated:

In determining whether the facility was in substantial compliance with the quality of care and notification of changes regulations, I may consider all relevant evidence, including evidence of R1's treatment prior to the morning of June 22, 2006.

ALJ Decision at 15. The ALJ determined that Laurels' argument in its post-hearing brief about the limited scope of her review "disregard[ed] the contents of the [SOD]," which included "all of the matters" Laurels argued were not before her. <u>Id.</u> at 16. Specifically, the ALJ noted, the SOD addressed R1's physician's "standing orders" for sliding scale insulin, staff failure to monitor R1's blood sugar at various points throughout his stay, and staff failure to notify the physician on June 21, 2006 of R1's episode of hypoglycemia<sup>2</sup> that morning. ALJ Decision at 16. Thus, the ALJ determined, Laurels "received ample notice" that it was within the ALJ's authority to consider and issue findings related to these and other matters. <u>Id.</u> at 15.

We concur with the ALJ, and we conclude that Laurels' contentions about the scope of review misrepresent CMS's determination, the survey findings set forth in the SOD, the proceedings below, and the ALJ's actions. Here, the July 13, 2006 CMS determination notified Laurels that the decision was "[b]ased on the findings of the June 28, 2006 survey." P. Ex. 2, at 1-2. The determination notice explicitly referenced the SOD, noting that it had previously been furnished to Laurels by the State agency. Id. at 1. The relevant findings in the SOD regarding noncompliance included but were not limited to Laurels' failure to notify R1's physician of a significant change in R1's condition on the morning of June 22, 2006. Rather, the SOD set out numerous findings relating to R1's care and treatment from June 19, 2006 (when he was discharged from the hospital where he received treatment for injuries sustained in a fall and for episodes of hypoglycemia) to June 22, 2006 (when R1 was readmitted to the hospital for hypoglycemia).

Specifically, the SOD described R1's June 19 hospital discharge summary, which stated that R1 had experienced episodes of hypoglycemia during the hospitalization and that he should have "finger sticks checked" at the rehabilitation facility to ensure that he not experience significant episodes of hypoglycemia there. P. Ex. 1, at 3, 15. Thus, the SOD set a context establishing that Laurels should have been aware at the time of R1's admission of his recent history of hypoglycemia, the need to

<sup>&</sup>lt;sup>2</sup> Hypoglycemia is abnormally low blood glucose, which, if not treated quickly, can cause an individual to pass out, and can cause problems such as brain damage. P. Ex. 30; Tr. at 73.

address this risk in R1's care plans, and the need to monitor R1 for this condition.

The SOD also cited Laurels' policies and protocols for "Finger Stick Blood Sugar" checks and "Observations to Report to the Physician," as well as R1's physician's "standing orders" for sliding scale insulin, all of which were in effect during the entire period of R1's stay at the facility. Further, the SOD listed, among other things, the following findings:

- While R1's "medication administration record (MAR) for June 2006 listed blood sugar checks to be done" at four specified times daily, "[n]o physician's order was found for blood sugar checks." P. Ex. 1, at 3, 16.
- "No blood sugars levels were recorded on the MAR on 6/19/2006." <u>Id.</u> at 3, 16.
- "[R1's] blood sugar level on 6/20/2006 at 7:30 a.m. was not recorded." <u>Id.</u> at 3, 16.
- "The only nurse's note written for 6/21/2006 was timed for 6:00 AM. The nurse #1 wrote, 'Alert and confused. Resident very agitated through the night. Trying to get O[ut] O[f] B[ed]. (2) Percocet (narcotic pain medication) given.'" <u>Id.</u> at 4, 16-17. However, on June 28, the facility provided an undated, written statement from Nurse #1 stating that on June 21, "around 7:30 AM . . ., Nurse #5 reported that [R1] had a blood sugar 'in the 40's. She went to the nourishment room to look for some orange juice. I went to the D-cart (D-Hall) and got a can of ensure. At that point (Nurse #5) stated that there was nothing available to give to the resident. I told her that I would give him a can of ensure.'" <u>Id.</u> at 4-5, 17.

In an interview with Surveyor Patrick Campbell, R.N. (the Surveyor) on June 28, 2006, "[n]urse #5 stated that she cared for [R1] on 6/21/2006 and checked his blood sugar at 7:30 AM. 'I took his sugar and it was low. I had a co-worker give him Ensure (supplement). I checked his sugar again in 30-45 minutes and it was the same reading. I figured it hadn't had time to go up. He was talking to me. He said he felt fine. I would call the doctor if a patient was unresponsive and needed to be sent out.'" Id. at 5, 17.

"On 6/21/2006, [R1's] physician completed an untimed initial physical exam. [R1's] history of being diabetic was not noted. Current treatment and monitoring of diabetes was not documented." <u>Id.</u> at 5, 18.

As discussed below, especially when considered in light of Laurels' own policies, these findings clearly raised questions about whether, during the period June 19-21, Laurels was adequately monitoring R1's blood sugar levels and about why it appeared that R1's physician was not aware R1's blood sugar was, and remained, low on the morning of June 21. Accordingly, Laurels' contention that the ALJ addressed matters beyond the scope of CMS's determination because she made findings relating to events and omissions that occurred on June 19, 20, and 21, and about which Laurels had no notice, is simply wrong.

Further, we reject Laurels' suggestion that the only issue before the ALJ was whether Laurels complied with the physician notification requirement on June 22, 2006 since CMS's allegations concerning the quality of care requirements at section 483.25 of the regulations were the same as the allegations made under the physician notification requirement at section 483.10(b)(11). P. The quality of care requirement at 42 C.F.R. § 483.25 Br. at 32. 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 wellbeing" of the resident, consistent with the resident's comprehensive assessment and care plan. Such care and services, the Board has found in prior cases, include not only notifying a resident's physician of the resident's condition in prescribed circumstances, but also monitoring and adequately documenting the resident's condition, following established facility policies, providing care consistent with the resident assessment and care plan and with professional standards of quality, and ensuring the sufficiency of care plans and orders. See, e.q., Sheridan Health Care Center, DAB No. 2178 (2008); Spring Meadows Health Care Center, DAB No. 1966, 16-20 (2005); Omni Manor Nursing Home, DAB No. 1920 (2004), aff'd, Omni Manor Nursing Home v. Thompson, 151 Fed.Appx. 427 (6th Cir. 2005).

Therefore, although the same findings were cited in the SOD under section 483.10(b)(11), notification of changes, and section 483.25, quality of care, the ALJ could properly consider any of those findings relevant both to whether the facility substantially complied with the physician notification requirement at section 483.10(b)(11) and whether it substantially complied with the broader quality of care requirements at section 483.25. Moreover, Laurels itself submitted testimony, evidence and argument in the proceedings below that addressed the matters cited by the ALJ about which Laurels now contends it had no notice. For example, Laurels submitted prefiled testimony relating to whether staff sufficiently monitored R1's blood sugar levels throughout his stay. <u>See, e.g.</u>, P. Ex. 39, at 2-3; P. Ex. 40, at 2; P. Ex. 41, at 2. Laurels' exhibits include the SOD as well as the following: R1's attending physician's orders, which contained the directive "may use standing orders;" Laurels' assessments and plans of care for R1; the facility's policy titled "Treating Hypoglycemia;" the progress notes from the entire period of R1's stay at Laurels; and the MAR showing when R1's blood sugar levels were taken from June 19 through June 22, 2006. P. Exs. 1, 14, 16, 17, 19-24, 26, 29.

Further, at the hearing, counsel for Laurels cross-examined the Surveyor about the physician orders in R1's record and the facility's policies for monitoring hypoglycemia and for notifying the physician of a resident's low blood sugar levels. Tr. at 42-50. The ALJ's questions of the Surveyor also made clear that whether staff measured R1's blood levels throughout the course of his stay and whether staff followed the facility's hypoglycemia policy on June 21, 2006 were central to the question whether the facility was in compliance with the program participation requirements, notwithstanding Laurels' counsel's assertion that "[t]he resident didn't get sick on the 21<sup>st</sup>." Tr. at 48-50.

Moreover, Laurels discussed these issues in its post-hearing, closing brief. For example, Laurels addressed the facility's hypoglycemia policy at page 11 of its post-hearing brief; responded to the ALJ's inquiries into the sufficiency of the physician's standing orders for hyperglycemia at pages 11-13 of its post-hearing brief; and addressed the question whether R1's physician was provided notice of R1's low blood sugar readings on the morning of June 21 at pages 8, 13 and 14 of its post-hearing brief. Thus, we reject Laurels' argument that it was denied adequate notice and sufficient opportunity to address all of the grounds cited by the ALJ to support her determination.

We also reject Laurels' argument that "the Board effectively has reduced CMS's 'burden' to establish a prima facie case essentially to reciting the [SOD], which . . . may include a lengthy narrative, which an ALJ ultimately may decide is or is not material to some violation, [and that the appellant] . . . is reduced to guessing what factual allegations it must defend against." P. Br. at 4. As the Board has previously concluded, "an SOD may function both as a notice document and as evidence of the facts asserted therein." Oxford Manor, DAB No. 2167, at 2 (2008), <u>citing</u> <u>Pacific Regency Arvin</u>, DAB No. 1823 (2002). Further, the Board has determined that --

> if a finding in an SOD is not disputed, CMS need not present evidence in support of the finding. Batavia Nursing and Convalescent Center, DAB No. 1904 (2004), aff'd, Batavia Nursing and Convalescent Center v. Thompson, 129 Fed.Appx. 181 (6<sup>th</sup> Cir. 2005). If a finding in an SOD is disputed, the issue once both parties have presented their evidence, as they did here, is whether the petitioner showed substantial compliance by a preponderance of the evidence. Id. Mere denial by a petitioner If the petitioner presents no is not enough. evidence to rebut CMS's evidence of noncompliance or if the evidence on which the petitioner relies is irrelevant or unreliable or outweighed by evidence to the contrary, the petitioner has not met its burden.

Oxford Manor at 2-3. Furthermore, the ALJ did not rely on the SOD alone to support her findings of noncompliance, as Laurels suggests. Rather, the ALJ also relied on the testimony of the Surveyor as corroborating the findings documented in the SOD, as well as testimony of Laurels' own witnesses and evidence submitted by both parties. <u>See, e.g.</u>, ALJ Decision at 5-14, citing Tr. at 18-19, 33, 40-42, 47-48, 61, 67-68, 72, 85-89, 97-100, 132-33, 143; P. Exs. 4, 7, 11, 14, 17, 21-22, 24, 26, 29, 32, 34, 38-41; CMS Exs. 2, 13, 17.

Finally, we note that, even if the SOD had not by itself provided clear notice to Laurels as to the legal and factual bases for the noncompliance findings, the ALJ would not have erred in developing and evaluating the evidence as she did. An ALJ's review of a CMS determination of facility noncompliance is a "de novo" proceeding. SunBridge Care and Rehabilitation for Pembroke, DAB No. 2170, 26-27 (2008). It is the responsibility of the ALJ to develop a complete and sound record; the ALJ must "inquire[] fully into all of the matters at issue, and receive[] in evidence the testimony of witnesses and any documents that are relevant and material." 42 C.F.R. § 498.60(b). As the Board has stated in prior decisions, the ALJ must determine whether "the evidence as it is developed before the ALJ" supports the findings of noncompliance, "not . . . how CMS evaluated the evidence as it stood at whatever point CMS made its assessment." Emerald Oaks, DAB No. 1800, at 13, 16 (2001). Thus, the ALJ hearing is not simply a "review [of] how or why CMS decided to impose

remedies," nor is it "restricted to the facts or evidence that were available to CMS when it made its decision." <u>Beechwood</u> <u>Sanitarium</u>, DAB No. 1906, at 28-29 (2004), motions granted in part and denied in part, <u>Beechwood v. Thompson</u>, 494 F.Supp.2d 181 (W.D.N.Y. 2007). Instead, the hearing provides a "fresh look by a neutral decision-maker at the legal and factual basis for the deficiency findings [underlying the remedies]." <u>Id</u>.

Based on the evidence and testimony submitted before the hearing, the ALJ inquired into matters that were relevant and material to whether Laurels' care for R1 was consistent with the physician notification and quality of care program participation requirements, as was her responsibility under the governing regulations. The ALJ concluded that Laurels' noncompliance with the regulations involved several aspects of the treatment and care provided to R1 throughout his brief stay. That the ALJ reached these conclusions did not, however, introduce unrelated issues or immaterial aspects of R1's care into the proceedings or change the fundamental reasons for the deficiency citations.

Accordingly, Laurels' contention that the ALJ addressed matters beyond the scope of her review is without merit.

### B. The ALJ's requirement that the parties submit written testimony before the hearing did not deny Laurels a fair hearing.

Laurels also contends that it was denied a fair hearing because the ALJ required the parties to submit written testimony before the hearing. P. Br. at 4. Consequently, Laurels says, it was forced to "freez[e]" its defense before finding out what issues the ALJ thought were important. <u>Id</u>.

Section 498.47(a) of the regulations states that "[a]t any time before the hearing, the ALJ may call a pre-hearing conference for the purpose of [among other things] delineating the issues in controversy." In addition, the September 26, 2006 pre-hearing order in this case stated that "[i]f a party believes that there is a need for a pre-hearing conference it may request one . . . " Pursuant to 42 C.F.R. §§ 498.47 - 498.50, and on the ALJ's own motion, a pre-hearing conference in this case took place on April 16, 2007, after each party had submitted a copy of the SOD as a proposed exhibit. To the extent that it was unclear to Laurels what aspects of the SOD would be at issue, at any time prior to, or during the pre-hearing conference, Laurels could have requested clarification of the issues. Yet, it did not do so. Moreover, the Board has previously reviewed and approved the use of written direct testimony, so long as the right to effective cross examination is protected and no prejudice is alleged and See Vandalia Park, DAB No. 1940, at 28-29 (2004), aff'd, shown. Vandalia Park v. Leavitt, No. 04-4283, 2005 WL 3334522 (6th Cir. Dec. 8, 2005); Pacific Regency Arvin, DAB No. 1823, at 7-8 (2002). The ALJ's pre-hearing order stated that the parties "must exchange as a proposed exhibit the complete written direct testimony of any proposed witness," and that "[g]enerally, [the ALJ] will accept the witness' written direct testimony as a statement in lieu of in-person testimony." Acknowledgment and Initial Pre-Hearing Order, dated September 26, 2006, at 3. Laurels did not object to this order at the time. Neither the filing of the direct testimony nor the ALJ's pre-hearing order, moreover, prevented Laurels from providing testimony or arguments at the hearing to address the issues about which it claims not to have had notice, nor was Laurels foreclosed from responding to these issues in its post-hearing brief, as it in fact did.

Accordingly, we conclude that Laurels was not denied a fair hearing because the ALJ required the parties to submit written testimony before the hearing.

## C. The ALJ did not erroneously interpret the physician notification requirement at 42 C.F.R. § 483.10(b)(11).

The "notification of changes" regulation at 42 C.F.R. § 483.10(b)(11) provides:

(i) A facility must immediately inform the resident; consult with the resident's physician; and if known, notify the resident's legal representative or an interested family member when there is--

(A) An accident involving the resident which results in injury and has the potential for requiring physician intervention;

(B) 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);

(C) A need to alter treatment significantly (i.e., a need to discontinue an existing form of treatment due to adverse consequences, or to commence a new form of treatment); or

(D) A decision to transfer or discharge the resident from the facility . . . .

The ALJ held that "[d]rafters of the regulation emphasized that 'in all cases, whether or not there is a medical emergency,' the facility must immediately consult the attending physician." ALJ Decision at 12, citing 56 Fed. Reg. 48,826, 48833 (September 26, 1991). Further, the ALJ concluded, "a 'significant change' could be life-threatening, but it could also involve clinical complications. . . ." Id.

Laurels argues that the ALJ erroneously interpreted the regulation and CMS's statement in the Federal Register preamble to the rule as requiring nurses to notify physicians immediately, regardless whether the situation involves an emergency. P. Br. Laurels argues that the regulation "requires immediate at 33. notification only in the case of life-threatening changes." P. Reply Br. at 6; P. Br. at 33-34. According to Laurels, "there is a significant difference under the regulation between symptoms that need to be reported to a physician NOW (symptoms of heart attack, stroke, etc.), and those that might have to be reported in due course, depending on what happens." P. Reply Br. at 8 (emphasis in original). Laurels also asserts that the ALJ misread language in the preamble, which, according to Laurels, does not address the time period in which the facility must consult with the physician or "the nurse's professional judgment to monitor a resident while changes unfold." P. Br. at 33.

These contentions disregard the plain language and structure of 42 C.F.R. § 483.10(b)(11), CMS's interpretation of the notification regulation, and the full discussion of the requirement in the Federal Register preamble to the final rule. The requirement at section 483.10(b)(11)(i), that the facility "immediately . . . consult with the resident's physician," modifies each of the four types of circumstances described in subsections 483.10(b)(11)(i)(A)-(D), including: 1) when there is a "significant change in the resident's . . . status" (483.10(b)(11)(i)(B)); and 2) when there is "[a] need to alter treatment significantly" (483.10(b)(11)(i)(c))(emphasis added). The regulation also defines the term "significant change in . . . status" to mean "a deterioration in health, mental, or psychosocial status in *either* life-threatening conditions or clinical complications." 42 C.F.R. 483.10(b)(11)(i)(B) (emphasis added). CMS's official interpretation of the regulation, set forth in the CMS State Operations Manual (SOM)(and discussed similarly in the preamble), reads:

> For purposes of §483.10(b)(11)(i)(B), lifethreatening conditions are such things as a heart attack or stroke. Clinical complications are such things as development of a stage II

pressure sore, onset or recurrent periods of delirium, recurrent urinary tract infection, or onset of depression. A need to alter treatment "significantly" means a need to stop a form of treatment because of adverse consequences (e.g., an adverse drug reaction), or commence a new form of treatment to deal with a problem (e.g., the use of any medical procedure, or therapy that has not been used on that resident before).

SOM, App. PP;<sup>3</sup> <u>see also</u> 56 Fed. Reg. at 48,833. Thus, the ALJ correctly observed that the regulation does not limit the term "significant change in . . . status" to mean only a "life threatening condition," nor does it equate the term "significant change" with "medical emergency." ALJ Decision at 11. Rather, the regulation directs the facility to consult with the physician immediately not only where a resident's "significant change" is in a "life-threatening" condition, but also when the change involves non-emergency clinical complications such as the development of a stage II pressure sore, the onset of delirium, or a need to alter treatment significantly.

In addition, the ALJ's reliance on the preamble to the final rule to support her interpretation of the regulation was not misplaced. CMS stated in the preamble that it had received several comments in response to the earlier regulation with comment period, published on February 2, 1989 (54 Fed. Reg. 5316), and that the rule needed to be rewritten because it produced an unintended result. Specifically, as initially drafted, the rule provided that "in a medical emergency or in the case of a competent individual the facility does not have to . . . contact the resident's physician and the legal representative or family to notify them of the changes." 56 Fed. Reg. 48,826, 48,832-33 (1991). To prevent this unintended result, CMS stated in the preamble to the 1991 final rule:

> We are clarifying the wording of this provision to indicate that in all cases, whether or not there is a medical emergency, the facility must notify the resident; his or her physician; and any legally-appointed representative or an interested family member, if known.

<sup>&</sup>lt;sup>3</sup> The SOM, with which nursing facilities are familiar, is available at http://www.cms.hhs.gov/manuals/downloads/ som107ap\_pp\_guidelinesltcf.pdf.

Id. The preamble then addressed public comments received about the time limit for providing such notification. CMS stated that the February 1989 draft of the rule gave the facility "up to 24 hours in which to notify the resident's physician and the legal representative or family." Several commenters, however, objected to the 24-hour period because "a resident could be dead or beyond recovery in that time . . . . " In response, CMS stated: "We agree and have amended the regulation to require that the physician and legal representative or family be notified immediately." Id. It is important to recognize that CMS did not restrict the immediate notification requirement to situations involving life-threatening emergencies. To the contrary, the requirement applies to each type of circumstance wherein the physician is to be consulted. Accordingly, Laurels' suggestion that the preamble says nothing about the time period in which the facility must notify the physician of the patient's status in non-emergency circumstances is simply wrong.

Finally, we note that Laurels argues that the ALJ failed to recognize that under the regulation, when a nurse reasonably believes that "a resident *might* be developing some change from his baseline, but it is not immediately clear that the problem is either 'significant' or 'life threatening,' . . . then it may well be appropriate for a nurse to delay notification to the physician while she monitors the resident to determine more fully what actually is occurring . . . " P. Br. at 35, citing Tr. at 143-144, 105; see also P. Br. at 38-39.

The preamble introducing the final rule, as well as prior Board decisions, have addressed the role of professional nursing judgment under the notification of changes regulation. Specifically, CMS stated in the preamble:

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.

56 Fed. Reg. at 48,833 (emphasis added). Citing this passage from the preamble, the Board has previously observed, "[t]he regulatory history acknowledges that nursing judgment may be involved in evaluating what is significant for a particular resident, gives examples of `life-threatening conditions' (heart attack and stroke), and supports a conclusion that the potential need for physician intervention is a factor in whether notice is required." <u>Park Manor Nursing Home</u>, DAB No. 2005, at 29 (2005), <u>aff'd</u>, <u>Park Manor, Ltd. v. U.S. Dep't of Health & Human Servs.</u>, 495 F.3d 433 (7th Cir. 2007); <u>see also</u> <u>Park Manor Nursing Home</u>, DAB No. 1926 (2004).

In this case, the ALJ recognized the role of professional nursing judgment in interpreting and applying the regulatory standard for physician notification. The ALJ Decision discusses Laurels' argument that nursing staff thought that changes in R1's demeanor on the morning of June 22 resulted from the effects of R1's pain medication, underlying injuries and lack of sleep and made a professional judgment to monitor R1's condition further before contacting the physician. ALJ Decision at 11. The ALJ rejected this argument, however, based on the evidence and testimony (which we discuss below) which shows that Laurels' nursing staff did not exercise reasonable professional judgment in evaluating and responding to R1's condition on the morning of June 22. Id. at 12-13.

Accordingly, we find no error in the ALJ's legal interpretation of the physician notification requirement at 42 C.F.R. § 483.10(b)(11).

2. The ALJ's factual findings are supported by substantial evidence on the record as a whole.

A. The ALJ's finding that "[f]acility staff inadequately monitored R1's blood sugar levels" (FFCL III.A.1.) is supported by substantial evidence on the record as a whole.

Laurels argues that the ALJ's discussion of the finding that facility staff inadequately monitored R1's blood sugar levels "is misleading and incomplete in several material respects." P. Br. at 13. Laurels contends that the ALJ "[f]or some reason" criticized R1's physician<sup>4</sup> "apparently because he did not write a note about [R1's diabetes or hypoglycemia] during his June 21 visit . . . and because he characterized [R1's] condition as 'stable.'" P. Br. at 13-14, quoting ALJ Decision at 6. Laurels argues that the ALJ's "opinions about [the physician] have no basis in the record, and also are unrealistic and unfair." P. Br. at 14. Laurels says that R1 was admitted to Laurels "for

<sup>&</sup>lt;sup>4</sup> The physician was also the Medical Director of the facility, and in that capacity, was responsible for the "implementation of resident care policies" and the "coordination of medical care in the facility." 42 C.F.R. § 483.75(i).

rehabilitation of his serious injuries . . . not his apparently stable diabetes, for which he already had a medication order that apparently was effective." <u>Id</u>. Further, Laurels contends, "It is neither fair nor useful in regulatory terms for [the] ALJ to criticize [the doctor] for not anticipating [R1's] subsequent blood sugar problems . . . ." <u>Id.</u> at 14-15. Moreover, Laurels submits, R1's doctor "uses a standard protocol for all his diabetic residents that provides for routine administration of insulin (for *hyperglycemia*) on a 'sliding scale' based on specific blood sugar parameters" and the protocol's parameters were correctly entered onto R1's MAR. P. Br. at 15 (emphasis in original), citing P. Exs. 24, 38-39; Tr. at 114.

These contentions have no merit. The ALJ based the finding that facility staff inadequately monitored R1's blood sugar levels on the following evidence and testimony:

- R1's June 19, 2006, hospital discharge summary, which stated that R1 had type 2 diabetes mellitus, that during his June 15-19 hospital stay R1 experienced "episodes of hypoglycemia," and that R1 "should have some finger sticks checked at the rehab facility to assure that he does not have significant hypoglycemia there" (ALJ Decision at 5-6; P. Ex. 4);
  - Laurels' admission care plan for R1, which "include[d] no instructions for managing diabetes, even though the plan's format contain[ed] a discrete section titled 'Diabetes,' [and had] "a specific place to fill in how often blood sugar should be checked, . . . [which was] left blank" (ALJ Decision at 6-7; P. Ex. 17);
  - The physician's examination report of June 21, which did not mention R1's diabetes and which described R1 as "stable" (ALJ Decision at 6; P. Ex. 22);
    - R1's MAR, which indicated that blood sugar checks should be made at four specified times daily (ALJ Decision at 6; P. Ex. 24, at 3; P. Ex. 1, at 16; CMS Ex. 2, at 16; Tr. at 72); and
    - The MAR, SOD, and the Surveyor's testimony, which evidenced that no checks were performed "until late morning on [R1's] second day" at the facility and that no check was performed at 11:30 a.m. on June 22, 2006 (<u>id.</u>).

Based on all of the evidence and testimony cited, the ALJ determined that Laurels' staff collectively failed to monitor sufficiently R1's blood sugar levels. ALJ Decision at 6-7. We have carefully reviewed the entire record, including the evidence and testimony cited by the ALJ to support this finding. We conclude that the ALJ Decision accurately describes the evidence and testimony on which it relies and that the ALJ's finding is based on substantial - indeed overwhelming - evidence.

Further, we conclude that the ALJ properly addressed the physician's June 21 examination report and the absence of physician orders relating to R1's risk for hypoglycemia in the context of evaluating whether Laurels substantially complied with the program participation requirements cited in the SOD. It was Laurels' responsibility under the quality of care regulation to coordinate and communicate effectively with the attending physician and to ensure that staff had sufficient quidance to provide R1 all of "the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being." 42 C.F.R. § 483.25. In R1's case, those services included monitoring the resident for episodes of "significant hypoglycemia," which the hospital discharge summary clearly identified. P. Ex. 4. Accordingly, the ALJ appropriately considered all of the documents in R1's chart, including the physician's orders and notes on which Laurels' staff would have relied, to assess whether the facility substantially complied with the participation requirement. Thus, the ALJ reasonably cited the absence of any physician order or report addressing R1's risk of hypoglycemia, together with the other referenced evidence and testimony, to support the conclusion that the facility did not substantially comply with the quality of care requirement.

Moreover, as the ALJ noted, while R1's MAR indicated that his blood sugar levels should be checked at four specified times daily, the notation in the MAR alone did not ensure that staff adequately monitored R1's blood sugar levels, as evidenced by the fact that no blood sugar readings were taken until the late morning of June 20<sup>th</sup>, R1's second day at the facility. In addition, while the parameters of the physician's "standard protocol" or "standing orders" for the administration of insulin were entered on the MAR, as Laurels submits, those parameters address how much insulin should be administered in the event a patient experiences hyperglycemia. As the ALJ observed, the standing orders do not address how to treat hypoglycemia, for which R1 was at an identified risk. ALJ Decision at 7. We also reject Laurels' allegations that the ALJ's assessments of the physician's report and orders were "unrealistic" and "unfair." P. Br. at 14. While the physician's report and orders, as well as the facility's assessments and care plans, properly addressed the primary purpose of R1's admission to the facility (rehabilitation associated with the injuries R1 sustained in a fall on June 15, 2006), as Laurels argues, the facility nevertheless was responsible for ensuring that R1 received all of the necessary care and services he required during his stay. To that end, it was not reasonable for the report, orders and care plans to focus on R1's recent injuries to the exclusion of addressing R1's diabetes, his recent history of, and risk for, experiencing episodes of hypoglycemia, and the consequent need to monitor R1's blood sugar levels and be prepared to respond to abnormally low levels. Furthermore, Laurels' characterization of R1's diabetes as "apparently stable," and its suggestion that R1's post-hospitalization episodes of hypoglycemia could not have been anticipated, are squarely contradicted by the hospital discharge summary, which notes that R1's blood sugar levels were not stable and forewarned any reader of that document that R1 might experience episodes of hypoglycemia at the rehabilitation facility.

Laurels also argues that the ALJ "consistently confuse[d]" the terms "hyperglycemia" (abnormally high blood sugar) with "hypoglycemia" (abnormally low blood sugar), as exemplified by the ALJ's "critique" of the doctor's "hyperglycemia protocols." P. Br. at 13. These protocols, Laurels says, "have nothing to do with" R1's condition on the morning of June 22 "or . . . any other issue in this case." <u>Id</u>. Laurels further contends that the ALJ "confuse[d] cause and effect" by writing that when R1 returned to the hospital on June 22, "the hospital physicians discontinued his 'hypoglycemic medications' (i.e., his diabetes medications that worked to *reduce* his blood sugar)." P. Br. at 13, citing ALJ Decision at 11, citing CMS Ex. 13, at 51.

These contentions have no merit. The ALJ properly recognized that "hypoglycemia" refers to "abnormally low blood sugar" and used the terms "hyperglycemia," "hypoglycemia," and "hypoglycemic" correctly and consistently throughout the ALJ Decision. <u>See, e.g.</u>, ALJ Decision at 5-8, 11. Further, it was Laurels' records that show that, as the ALJ noted, a copy of the physician's "standing order" for hyperglycemia was placed in R1's chart. It was Laurels that claimed that "specific instructions for monitoring or responding [to R1's hypoglycemia] were unnecessary" because the standing order was in place for all of the doctor's patients. ALJ Decision at 7, citing P. Exs. 38, 41; <u>see also</u> P. Post-hearing Br. at 10-12. Thus, the ALJ appropriately addressed the relevance and sufficiency of the protocols in response to Laurels' own actions and arguments.

Furthermore, as described above, Laurels itself relies on the fact that staff entered the parameters of the standing orders onto R1's MAR to challenge the ALJ's finding that facility staff did not adequately monitor R1's blood sugar levels, thus undercutting its simultaneous contention that the protocols "have nothing to do with . . . any . . . issue in this case." P. Br. at 13.

Lastly, in using the term "hypoglycemic medications" to describe the medications that R1 had been taking, the ALJ did anything but confuse cause and effect. In fact, the ALJ used the correct adjective "hypoglycemic" to describe the medications that R1 had been taking as agents that worked to reduce blood sugar; the ALJ did not use the noun "hypoglycemia" to modify "medications," which would describe medications used to treat the condition of hypoglycemia itself. The term "hypoglycemic agent" appears in the hospital records cited by the ALJ. ALJ Decision at 12, citing CMS Ex. 13, at 55.

Accordingly, we conclude that the ALJ's finding that Laurels' staff inadequately monitored R1's blood sugar levels is supported by substantial evidence on the record as a whole, and we reject Laurels' contentions that the ALJ's discussion of this factual finding is materially misleading and incomplete.

> B. The ALJ's finding that "[f]acility staff did not follow the facility's protocol for notifying the physician of R1's low blood sugar levels" (FFCL III.A.2.) is supported by substantial evidence on the record as a whole.

The Board has previously held that CMS may reasonably rely on a facility's policy relating to the care and treatment of its residents as evidencing the facility's understanding of what must be done to attain or maintain residents' highest practicable physical, mental, and psychosocial well-being, as required by section 483.25. <u>Spring Meadows</u> at 16-20. Such a policy "is also evidence of the standard of care the facility expect[s] its staff to provide" and of professional standards of care. <u>Oxford Manor</u> at 5-6. Consequently, the Board has decided, a facility's failure to follow or implement its own resident care policy may constitute a deficiency under section 483.25. <u>Id</u>.

Laurels submits, as it did below, that it uses a written protocol that provides detailed instructions for the treatment of hypoglycemia and, in appropriate cases, notification of the physician. P. Br. at 15-16. Laurels argues that the ALJ was wrong to "apparently decide[] that [Laurels'] staff was unaware of these procedures because the Surveyor testified that no one could provide him a copy of the written protocol during the survey." P. Br. at 16. Laurels questions the reliability of the Surveyor's statement: "But we do not know who [the Surveyor] asked, or in what context." <u>Id</u>.

Further, Laurels contends, it was not reasonable for the ALJ to "infer[] that the policy was ineffective" on the grounds that Laurels "could not produce evidence that its staff had communicated a low blood sugar reading to [the physician] on June 21, and because [the physician] did not mention the matter in a written report of an examination of [R1] he wrote that day." P. Br. at 16, citing ALJ Decision at 6. Laurels contends that the physician was notified of R1's episode of hypoglycemia since staff recorded in R1's chart the two consecutive low blood level readings of the morning of June 21, and since the physician "did visit [R1] later that same day, where the ordinary course would be to review [R1's] . . . medical record . . . . " P. Br. at 17-18; see also P. Reply Br. at 4. Laurels asserts that the physician did not mention R1's low blood sugar levels on the morning of June 21 in his written report because these readings were "consistent with the pattern [R1] demonstrated at the hospital," of low blood sugars in the morning, followed by normal levels in the afternoon. Id. Consequently, Laurels submits, "the fair inference seems to be that [the doctor] did not consider [R1's] low blood sugar that morning to be significant." Id. at 18.

We reject these arguments. First, we note that the ALJ did not decide "that [Laurels'] staff was unaware of [the facility's hypoglycemia] procedures because the Surveyor testified that no one could provide him a copy of the written protocol during the survey," as Laurels argues. P. Br. at 16. Rather, the ALJ stated that "[a]ccording to [the Surveyor], he specifically asked but found no staff member who even knew where to find this protocol." ALJ Decision at 8, citing Tr. at 50. The ALJ then wrote: "This seems *likely* inasmuch as the protocol was not followed." Id. (emphasis added). Thus, the ALJ determined that it was likely that those individuals whom the Surveyor asked about the policy could not locate it. The ALJ then noted that the testimony of the Unit Manager about the facility's notification policy "seem[ed] at odds" with the written protocol and the testimony of the Director of Nursing. Id., citing Tr. at

97-98, 143; P. Ex. 39, at 3. Therefore, the ALJ did not conclusively determine that all Laurels employees were unaware of the hypoglycemia policy, nor was it necessary for the ALJ to make such a finding to reach the conclusion that the facility failed to follow its hypoglycemia protocols.

We also reject Laurels' contention that it was unreasonable for the ALJ to infer that the hypoglycemia protocol for physician notification was not followed. As the ALJ Decision explains, Laurels' protocol for treating hypoglycemia includes a list of common hypoglycemia symptoms, guidelines for treating low blood sugar levels, and instructions for "after treatment, . . . follow[ing] up," which provide in part:

> If blood sugar has not risen above 70 mg/dl, treat as indicated in the chart. Wait 15 minutes and test blood sugar again. <u>If glucose</u> <u>has not risen to 70 mg/dl, call the physician</u> <u>immediately.</u>

P. Ex. 29 (emphasis in original); ALJ Decision at 7-8. The ALJ concluded that the facility failed to implement the notification requirement on the morning of June 21, when R1's "blood sugar levels fell -- and remained -- well below 70." ALJ Decision at 8-9; P. Exs. 1, 24, 32; Tr. at 98-100. Specifically, R1's blood sugar level at 7:30 a.m. was 48, and after staff gave R1 a can of Ensure to drink, R1's blood sugar level was re-tested at 8:00 a.m. and was unchanged. The ALJ then explained: "Not one shred of evidence suggests that any staff ever notified the physician of these blood sugar levels. . . . no facility witness has claimed that the physician was ever notified; no document suggests that the physician was notified; and [the physician's] June 21, 2006 note does not even mention R1's diabetes, much less his episodes of hypoglycemia." ALJ Decision at 9. Accordingly, the ALJ concluded that the facility violated 42 C.F.R. §§ 483.10(b)(11) and 483.25 "[b]ecause staff did not consult the attending physician when, according to the facility's own protocol, such consultation was necessary." ALJ Decision at 10.

The evidence and testimony cited in the ALJ Decision support the ALJ's findings. First, the SOD and MAR establish, and Laurels does not dispute, that staff recorded R1's blood sugar as below 70 at 7:30 a.m.; that after administering carbohydrates to R1, staff remeasured R1's blood sugar level at 8:00 a.m. and found it unchanged; and that R1's blood sugar levels were not again checked until 11:30 a.m. P. Exs. 1, 24, 32. Further, after our own review of the testimony and evidence, we concur with the ALJ that the record is devoid of any affirmative evidence showing

that Laurels' staff contacted R1's physician to notify him of the consecutive low blood sugar level readings on the morning of June Indeed, according to the SOD and the Surveyor's testimony, 21. the nurse caring for R1 during the morning of June 21 told the Surveyor that she "would call the doctor if a patient was unresponsive and needed to be sent out," but that R1 on the morning of the 21st was talking to the nurse and "said he felt fine." P. Ex. 1, at 5, 17. Thus, the nurse in effect admitted that she did not notify R1's physician of the low blood sugar level reading. We also note that even if we found that the facility had appropriately and timely notified the physician (which we do not), the lack of documentation of the notice would itself violate Laurels' policies addressing "finger stick blood sugar" monitoring and "observations to report to the physician," which expressly provide that when notice is given, the nurse must document in the patient's progress notes the time and date that the physician was notified. P. Ex. 1, at 2, 15; CMS Ex. 17, at 10.

Accordingly, in light of the lack of evidence or testimony demonstrating that Laurels timely notified R1's physician of the resident's episode of hypoglycemia on June 21, as well as the attending nurse's admission, we conclude that it was altogether reasonable and logical for the ALJ to infer that Laurels failed to follow its own hypoglycemia protocol for immediate physician notification.

We also reject Laurels' contention that the ALJ should have inferred that the physician was notified of R1's early morning episode of hypoglycemia at the time the physician visited R1 on June 21<sup>st</sup> on the assumption that he would then have looked at R1's chart, which included the MAR recordings of the blood sugar As the ALJ observed, even if the doctor had read R1's levels. chart later in the day, as Laurels submits, this would not have fulfilled the facility's obligation under its own protocol to have called the doctor "immediately" after the 8:00 a.m. blood sugar level test. ALJ Decision at 9. Moreover, Laurels provided no explanation why it was not possible to notify the physician earlier. In addition, even if, in the ordinary course of a visit with a facility resident, a doctor may be expected to review the resident's chart, that expectation alone does not satisfy the facility's responsibility, under its own policy, to affirmatively notify the doctor of the resident's hypoglycemia.

Finally, we reject Laurels' strained explanation of why, if the physician became aware of R1's June 21 episode of hypoglycemia when he visited the resident later that day, he did not mention it in the June 21 examination report. The bases of that

argument, that R1's blood sugar levels fluctuated consistently (low in the mornings and increasing after breakfast and during the day), that the doctor and staff providing care to R1 were aware of that pattern, and that, consequently, the doctor considered the morning episode of hypoglycemia insignificant, are belied by the facility's failure to measure R1's blood level at 7:30 a.m. on June 20<sup>th</sup>; the fact that R1's recorded blood sugar levels on June 20 were highest at 11:30 a.m. (109) and significantly lower in the afternoon and evening (at 4:30 p.m. the level was 63, and at 9:00 p.m. it was 74); and by the fact that staff appeared unprepared to treat R1's June 21 morning episode of hypoglycemia with any of the recommended forms of carbohydrates listed in the facility's hypoglycemia protocols (e.g., orange juice or apple juice). P. Exs. 1, 24, 29. As evidence that Laurels itself submitted shows, after finding that R1's blood sugar level was "in the 40's," the nurse caring for R1 "went to the nourishment room to look for some orange juice [but found] nothing available to give to the resident;" another nurse then gave a can of Ensure to R1 to drink as a substitute. P. Ex. 1, at 4-5, 17; P. Ex. 32; CMS Ex. 13, at 86. Thus, the "fair inference" is not that the physician considered R1's low blood sugar on June 21 not to be significant, as Laurels alleges, but that the physician simply did not consider R1's low blood sugar at all.

Accordingly, we find that substantial evidence on the record as a whole supports the ALJ's determination that Laurels failed to follow its own protocol for notifying the physician of R1's low blood sugar levels.

C. The ALJ's factual findings relating to R1's "baseline" physical, mental and psychosocial status, and "significant change in condition" on the morning of June 22, 2006 are supported by substantial evidence on the record as a whole.

Laurels argues that the ALJ disregarded evidence and testimony establishing that R1's physical and mental status on the morning of June 22, "was not significantly different from his [true] clinical baseline," which the ALJ mischaracterized. P. Br. at 7. With respect to R1's baseline status, Laurels submits that before the morning of June 22, R1 was only partially oriented; had cognitive loss; was depressed and angry; and "persistently was noted to be agitated, resistant to care, attempting to get out of bed, and not sleeping well." P. Br. at 12, citing Tr. at 80; P. Exs. 14, 17, 20. Moreover, Laurels says, R1 "wore a large cervical collar" that "interfered with his speech and made him hard to understand." P. Br. at 12-13, citing P. Exs. 19, 20, 25; Tr. at 25. Laurels also argues that the Percocet that R1 was taking to relieve pain impaired his cognition, speech and ability to swallow. P. Br. at 12, 19, 23 citing P. Exs. 14, 16, 19, 24, 39; Tr. at 30, 41.

Laurels further contends that the ALJ substituted her own, unfounded, opinion for the informed professional judgment of experienced staff, who reasonably assessed R1's condition on the morning of June 22 and concluded that R1 had not experienced a "significant change" in physical or mental status. P. Br. at 6-7, 17. Laurels acknowledges that the nurse attending to R1 observed on the morning of June 22 that R1's speech was "slurred" or "sluggish," he had difficulty swallowing, and he was "demanding," "uncomfortable," "restless" and "hyperextending, or trying to stretch his neck for two hours or so." Yet, Laurels contends, the nurse reasonably attributed these symptoms to the pain from R1's injuries, the Percocet that R1 was taking, and R1's lack of sleep. P. Br. at 20-24, 27, 36, 39, citing P. Exs. 21, 40, Tr. at 87-88, 92. Further, Laurels argues, R1's blood sugar level at about 7:30 a.m. was within normal limits, he was not diaphoretic, and "he exhibited no other signs or symptoms of any blood sugar problem." P. Br. at 20, citing P. Ex. 24; Tr. at 83; see also P. Br. at 38. Laurels also says that the ALJ ignored the testimony of the Unit Manager for R1's unit, who testified that during her 8:45 and 10:00 a.m. rounds she saw and spoke with R1 and "observed nothing unusual or inconsistent with his previous demeanor." P. Br. at 24, citing P. Ex. 41; Tr. 132. "The bottom line," Laurels argues, "is that [R1] suffered an insidious or hidden diabetic crisis sometime before 11 A.M. on June 22, 2006 that was masked by his other symptoms, his sleepless night, and the intended and expected effects of his pain medication." P. Reply Br. at 3.

We disagree. First, the ALJ Decision itself shows that the ALJ took into account the evidence and testimony about R1's baseline status that Laurels contends she ignored. The ALJ Decision notes that: the assessments of R1 on admission described the resident "as alert but confused . . . depressed and angry," and that "[h]e wore a cervical collar" (ALJ Decision at 5, citing P. Exs. 14, 40; Tr. at 33); progress notes on the night of June 21 stated that R1 "became increasingly agitated when not allowed to get out of bed" (ALJ Decision at 5, citing P. Ex. 21); R1 "had periods of restlessness, and his mental functions varied over the course of the day" (ALJ Decision at 5, citing P. Ex. 26); that he "had exhibited 'sad, pained, worried facial expressions'" (id.); and that "[h]e experienced pain, sometimes excruciating pain, daily" (id.). Thus, the ALJ recognized that before June 22, R1's physical and mental status was compromised, that at times R1 was

confused, depressed, angry and agitated, and that he experienced, and showed symptoms of, extreme pain.

Contrary to Laurels' arguments, however, the ALJ's additional findings that R1 was perceptive, responsive, and able to communicate effectively before the morning of June 22 are also substantiated by the record. ALJ Decision at 5-6. The ALJ accurately described R1's minimum data set, the form used by the facility for resident assessment and care screening, as providing that R1 had "no episodes of disorganized speech" and "could make himself understood." ALJ Decision at 5, citing P. Ex. 26. Further, the ALJ noted, the evidence showed that before June 22<sup>nd</sup>, R1's "speech was clear and understandable," "his memory was intact, " and "[h]e was able to eat, drink, swallow, and take his medications without difficulty." ALJ Decision at 12, citing P. Exs. 14, 21, 26, 33; ALJ Decision at 5, citing P. Exs. 14, 21, 26, 40. Moreover, the ALJ cited to evidence that R1 had participated in rehabilitation on the 20<sup>th</sup> and 21<sup>st</sup>, and the rehabilitation manager had described R1 as a "joker." ALJ Decision at 12, citing Tr. at 61.

In sum, substantial evidence on the record as a whole supports the ALJ's descriptions of R1's baseline physical and mental status, which varied over the course of his first three days at Laurels. As the ALJ further concluded, even accounting for those variations, there is no documentation in the record showing that at any time prior to June 22 R1 was unresponsive or shaking, that his speech was slurred, sluggish, and unintelligible (even though he wore a cervical collar), that he was hyperextending his neck, that he was unable to drink, eat, swallow or take medications, or that the Percocet he was taking had been causing any such adverse effects. Accordingly, we reject Laurels' contentions that the ALJ Decision mischaracterizes R1's baseline condition.

We also conclude that the ALJ's finding that on the morning of June 22, 2006, R1 experienced a significant change from his baseline physical and mental status within the meaning of the physician notification regulation is supported by substantial evidence on the record as a whole. The ALJ Decision accurately describes the evidence, including the contemporaneous nursing notes from the morning of June 22, which demonstrate that R1 presented numerous symptoms and behaviors that were objectively, markedly different from his baseline status: at 8:00 a.m., R1's speech was slurred, the nurse had trouble understanding his speech, he was hyperextending his neck, and his pupils "were 3 cm and sluggishly reactive to light;" by 8:30 "he complained of thirst," yet he had difficulty drinking or eating and was unable to take his 9:00 a.m. medications because he was "coughing and choking too much;" at approximately 11:00-11:20 a.m., R1's wife came to visit R1 and found him "gurgling," "his head was back," "his eyes were glassy," and he "appeared to be shaking." ALJ Decision at 10, citing P. Exs. 21, 41; Tr. at 86, 132-33; <u>see also</u> P. Ex. 1, at 7-9, 20.

The ALJ's conclusion that these symptoms together manifested a significant change in R1's condition, which Laurels' staff recognized as such, is well-founded. First, the paramedics' prehospital report, cited by the ALJ, states that Laurels' staff told the paramedics that R1 had "altered mentation this a.m.[,] originally responding to voice with garbled, unintelligible responses, now unresponsive to voice." ALJ Decision at 13, citing CMS Ex. 13, at 69. Second, while the nurse caring for R1 on the morning of June 22 initially testified that she considered R1's restlessness, agitation and slurred speech not to be significant because R1's vital signs were normal and "he was alert," the nurse later testified that R1's slurred speech, gagging while trying to eat, and inability to drink water or take medication were significant changes. ALJ Decision at 13, citing P. Ex. 40, at 2-3; P. Ex. 33; Tr. at 85-87. Yet, the ALJ noted, the nurse said on re-direct examination that, considering "the whole picture, he remained alert, the vitals did not show a change," so she did not contact the physician but continued to monitor R1. ALJ Decision at 13, citing Tr. at 87-89.

"Thus," the ALJ aptly summarized, the nurse "appear[ed] to agree that R1's condition changed, but claim[ed] [during the hearing] that the changes were not significant because he was 'alert.'" ALJ Decision at 13. However, the ALJ continued, "[s]ometime after 8:30 a.m. . . he was no longer alert" but the nurse still did not call the physician. <u>Id.</u> citing Tr. at 87-89. Thus, the ALJ logically concluded that, even accepting the nurse's own opinion as to what symptoms would have evidenced a "significant change" in R1's status, by the time R1 was no longer alert sometime after 8:30 a.m. and before 11:00 a.m. -- his status had "significantly changed," yet the facility still did not notify the physician, as required under 42 C.F.R. § 483.10(b)(11), until his wife arrived and became "extremely distraught" by his appearance. ALJ Decision at 10, citing Tr. at 132-133.

Furthermore, we note that Laurels' own facility policy on "observations to report to the physician" sets forth a list of examples of such changes that includes some of the very signs and symptoms that R1 presented during the morning of June 22, including: "Appetite . . . failure to eat a meal, (may be diabetic); . . . report any difficulty the resident may have swallowing, chewing or feeding self;" "Delirium . . . failure to respond; " and "Mental Disturbance (change in mental status) anxiety . . . restlessness; trembling . . . failure to answer questions; rambling conversation; shaky voice." CMS Ex. 17, at Moreover, that the nurse caring for R1 on the morning of 10-11. June 22 reacted to the symptoms and signs presented by the resident by repeatedly "check[ing] [his] vital signs, pupils, and hand strength to rule out any neurological problem," in itself demonstrates that she considered the changes she observed to be important. P. Br. at 22, P. Ex. 40, at 2-3. Accordingly, we reject Laurels' argument that the ALJ merely substituted her own, unfounded clinical judgment for that of the professional staff caring for R1 on the morning of June 22, 2006. The EMS report, nursing notes, witness testimony and the facility's own policy support the conclusion that both objectively, and as understood by the nurse caring for him, R1 experienced a significant change in physical and mental status on the morning of June 22.

We also reject Laurels' contention that the ALJ should have found that, during the morning of June 22, staff reasonably attributed R1's symptoms and behaviors to his underlying injuries, the pain medication he was taking, and his lack of sleep. The nurse caring for R1 repeatedly checked his vital signs that morning because, she testified, "agitation and slurred speech could be the sign of a neurological problem such as a developing stroke or transient ischemic attack." P. Ex. 40 at 3. Thus, the ALJ could reasonably infer from the nurse's own actions that she viewed changes in R1's condition as most likely attributable to a neurological problem. Moreover, Laurels submitted no contemporaneous documentation from the morning of June 22 indicating that at the time staff considered R1's symptoms and behaviors attributable to the Percocet or to lack of sleep. In light of this, the ALJ could reasonably determine that the nurse's testimony about what she thought at the time was not reliable.

Substantial evidence in the record also supports the ALJ's rejection of Laurels' argument that staff had no reason to suspect that R1 was experiencing an insidious episode of hypoglycemia since R1's blood sugar at about 7:30 a.m. was within normal limits, he was not diaphoretic, and "he exhibited no other signs or symptoms of any blood sugar problem." P. Br. at 20, citing Tr. at 83. As the ALJ Decision explains, Laurels' own facility policy on hypoglycemia establishes that many of the symptoms that R1 presented (shakiness, anxiety, irritability, sleepiness, altered behavior, and inability to take by mouth) are symptoms of abnormally low blood sugar. ALJ Decision at 14, citing P. Exs. 29; Tr. at 64-67. Moreover, according to the American Diabetes Association publication that Laurels itself

submitted into the record, "[s]ome people have no symptoms of hypoglycemia ["hypoglycemia unawareness"], and [t]hey may lose consciousness without ever knowing their blood sugar levels were dropping." P. Ex. 30. Thus, Laurels' staff could not have reasonably relied on the fact that R1 was not exhibiting all of the classic symptoms of low blood sugar. In addition, as the ALJ also noted, "when the paramedics observed R1, they *immediately* suspected hypoglycemia, and, within minutes, were testing his blood sugar." ALJ Decision at 14, citing CMS Ex. 13, at 70.

Finally, as Laurels correctly notes, the ALJ did not specifically address the testimony of the Unit Manager on duty during the morning of June 22 that she "saw [R1] . . . in the hallway in the doorway of his room, " that she "gave him a morning greeting and he responded in the same manner to [her]," that she again saw him "later in the morning and smiled at him," and that "while [she] did not assess him in detail, [she] observed nothing unusual, considering his condition." Tr. at 132; P. Ex. 41, at 2. The ALJ's role as the finder of fact is to evaluate the credibility of witnesses, to decide what testimony to believe and what weight to assign. In this case, the Unit Manager's general statements about R1's condition on the morning of June 22 are admittedly based on brief encounters and limited observations. These statements stand in marked contrast to the EMS report, the facility's policies, and most importantly, the testimony of, and detailed notes made by, the nurse responsible for caring for R1 on the morning of the 22<sup>nd</sup> who, according to her own testimony "spent a great deal of time with this gentleman." Tr. at 87. Based on the ALJ's in-depth discussion of the evidence and testimony addressing specific aspects of R1's symptoms and behaviors, it is reasonable to infer that the ALJ gave little weight to the Unit Manager's generalized testimony, and we find no error in the ALJ's doing so.

Accordingly, we uphold the ALJ's finding that on June 22, 2008, R1 experienced a "significant change" in physical and mental status requiring immediate consultation with R1's physician under 42 C.F.R. § 483.10(b)(11)(i)(B).

# 3. The ALJ did not err in concluding that CMS's determination that immediate jeopardy existed from June 22 through June 27, 2006 was not clearly erroneous.

Laurels argues that the ALJ erred in concluding that CMS's determination that Laurels' noncompliance with the program requirements posed immediate jeopardy to facility residents' health and safety from June 22 through June 27, 2006 was not "clearly erroneous" (the standard that applies under the

regulation at 42 C.F.R. §§ 488.301 and 498.60(c)). Laurels contends on appeal, as it did before the ALJ, that there was no causal connection between any alleged act or omission by the facility and any threat to R1's health and safety. P. Br. at 44; ALJ Decision at 16, citing P. Post-hearing Br. at 35. While Laurels acknowledges that R1's "hypoglycemic crisis [on the morning of June 22, 2006] could have caused harm . . . there also is no question that it was, in fact, insidious." P. Br. at 44.

We disagree. The ALJ Decision accurately states that CMS's determination of immediate jeopardy, that the facility's noncompliance caused or was likely to cause "serious injury, harm, impairment, or death to a resident," will be upheld unless the facility shows the determination to have been "clearly erroneous." ALJ Decision at 16, citing 42 C.F.R. §§ 488.301, 498.60(c). As the ALJ further noted, the standard imposes a "heavy burden" on facilities to show no immediate jeopardy, and the Board has sustained a determination of immediate jeopardy where CMS presented evidence from which "[o]ne could reasonably conclude that immediate jeopardy exists." ALJ Decision at 16, citing <u>Barbourville Nursing Home</u>, DAB No. 1962, at 11 (2005)(citing Florence Park Care Center, DAB No. 1931, at 27-28 (2004)(citing Koester Pavillion) DAB No. 1750 (2000)). Laurels' argument that there was no "causal connection" between the facility's alleged noncompliance and the existence of serious injury or threat of injury to facility residents is premised on what it alleges is an undisputed "fact" that R1's episode of hypoglycemia on the morning of June 22, 2006, was "insidious." As described above, however, substantial evidence and testimony on the record support the ALJ's determination that R1's hypoglycemia on the morning of June 22 was not hidden or masked by R1's underlying injuries, pain medication or lack of sleep. Moreover, we concur with the ALJ that Laurels' failures to assess, plan, monitor and manage R1's diabetes, as well as its failure to ensure that its staff notified attending physicians of significant changes in residents' status "placed the facility's diabetic residents at immediate risk for serious injury, harm, or even death." ALJ Decision at 17.

Accordingly, we conclude that the ALJ did not err in concluding that CMS's determination that immediate jeopardy existed from June 22 through June 27, 2006 was not clearly erroneous.

### <u>Conclusion</u>

For the reasons stated above, we affirm the ALJ Decision and affirm and adopt each of her findings of fact and conclusions of law.

/s/ Leslie A. Sussan

/s/ Constance B. Tobias

/s/

Judith A. Ballard Presiding Board Member