Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
The Laurels at Forest Glenn,	)	Date: October 30, 2007
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-06-666
	)	Decision No. CR1681
Centers for Medicare & Medicaid Services.	)	
	)	

DECISION

The Laurels at Forest Glenn (Petitioner or facility) is a skilled nursing facility, located in Garner, North Carolina, that participates in the Medicare program. On June 27 and 28, 2006, the North Carolina Department of Health and Human Services (State Agency) investigated a complaint about the facility's response to a diabetic resident's extreme hypoglycemic episode. Based on the results of that investigation, the Centers for Medicare and Medicaid Services (CMS) determined that, from June 22 through August 8, 2006, the facility was not in substantial compliance with two Medicare requirements, 42 C.F.R. § 483.10(b)(11) (notification of change) and 42 C.F.R. § 483.25 (quality of care). CMS also determined that, from June 22 through 27, 2006, the facility's deficiencies posed immediate jeopardy to resident health and safety. CMS imposes a civil money penalty (CMP) of $3050 per day for each day of immediate jeopardy, and $50 per day for each day of substantial noncompliance that was not immediate jeopardy. Petitioner appeals.

For the reasons set forth below, I sustain CMS's determinations.

I. Background

The Social Security Act (Act) sets forth requirements for nursing facility participation in the Medicare program, and authorizes the Secretary of Health and Human Services to promulgate regulations implementing the statutory provisions. Act, § 1819. The

Secretary's regulations are found at 42 C.F.R. Part 483. To participate in the Medicare program, a nursing facility must maintain substantial compliance with program requirements. To be in substantial compliance, a facility's deficiencies may pose no greater risk to resident health and safety than "the potential for causing minimal harm." 42 C.F.R. § 488.301.

The Secretary contracts with state survey agencies to conduct periodic surveys to determine whether skilled nursing facilities are in substantial compliance with program participation requirements. Act, § 1864(a); 42 C.F.R. § 488.20. The regulations require that each facility be surveyed once every twelve months, and more often, if necessary, to ensure that identified deficiencies are corrected. Act § 1819(g)(2)(A); 42 C.F.R. §§ 488.20(a); 488.308.

In this case, following the June 27-28 complaint investigation/survey, the State Agency's surveyors concluded that the facility was not in substantial compliance with federal requirements for nursing homes participating in the Medicare and Medicaid programs, and that its deficiencies posed immediate jeopardy to resident health and safety. Specifically, they found that the facility did not meet federal requirements under: 42 C.F.R. § 483.10(b)(11) (Tag F-157 - Notification of Changes) and 42 C.F.R. § 483.25 (Tag F-309 - Quality of Care). Petitioner's Exhibit (P. Ex.) 1; CMS Exhibits (CMS Exs.) 2, 10, 18.[1]

CMS has agreed with the State Agency's recommendations and imposes a CMP of $3050 per day for each day of immediate jeopardy, June 22–27, 2006 ($3050 x 6 days = $18,300), plus $50 per day for the period of noncompliance that did not pose immediate jeopardy, June 28–August 8, 2006 ($50 x 42 days = $2100) (total CMP = $20,400). CMS Ex. 5, at 2; CMS Ex. 8, at 2; Transcript (Tr.) at 8.[2]

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[1] The State Agency subsequently affirmed these findings following an informal dispute resolution proceeding. CMS Ex. 4.

[2] From the documents submitted, I could not initially determine which dates of alleged noncompliance were in controversy. At the opening of the hearing, I asked the parties to identify the period in dispute, which, remarkably, neither counsel seemed prepared to do. ("That's a good question, Judge. I haven't actually focused on that.") After some discussion, and input from an employee of the State Agency, the parties agreed that June 22 through August 8 were the relevant dates. Tr. at 1-8. Based on an August 9 survey, additional penalties were apparently imposed for the period August 9 through September 22, 2006 (CMS Ex. 5), but Petitioner has not appealed that survey:

(continued...)

Petitioner timely requested a hearing, and the case was assigned to me. The hearing convened on June 6, 2007, in Raleigh, North Carolina. Mr. Joseph L. Bianculli appeared on behalf of Petitioner, and Ms. Sonia G. Burnett appeared on behalf of CMS. I have admitted into evidence CMS Exs. 1-18 and P. Exs. 1-41.[3]

The parties filed initial (opening) briefs and submissions. Following the hearing, they filed closing briefs (CMS Cl. Br and P. Cl. Br.). Petitioner filed a reply brief.

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[2](...continued)

MS. BURNETT: [T]hat [August 9] revisit is not at issue in this case.

JUDGE HUGHES: Because it was not appealed or because –

MS. BURNETT: It was not appealed.

JUDGE HUGHES: It was not appealed. So, then, I'm only concerned about the period from June 22nd through August 8th?

MR. BIANCULLI: That is correct.

Tr. at 7-8. Yet, in their briefs, the parties seem to have forgotten this explicit representation and agreement; each refers, without explanation, to penalties imposed through September 22, 2006. P. Cl. Br. at 6; CMS Cl. Br. at 3. Inasmuch as I have before me no hearing request for the August 9, 2006 revisit survey, I consider only the facility's compliance through August 8.

[3] Petitioner objected to admission of CMS Ex. 17, which is a policy issuance from the American Medical Directors Association (AMDA). CMS objected to P. Ex. 28, which is *the same* policy issuance from the AMDA. CMS also objected to the admission of P. Ex. 30, which are guidelines from the American Diabetes Association, even though CMS included *these same* guidelines in its own exhibits, CMS Ex. 13, at 13, 14. The parties were not able to explain why they objected to the admission of documents that they had included among their own exhibits. Inasmuch as neither party had a legitimate objection, I admitted all of the documents. Order and Setting of Hearing Date (April 18, 2007).

II. Issues

The issues before me are:

- Whether, from June 22 through August 8, 2006, the facility was in substantial compliance with 42 C.F.R. §§ 483.10(b)(11) (notification of changes); and 483.25 (quality of care);

- If the facility was not in substantial compliance from June 22 through 27, 2006, did its deficiencies then pose immediate jeopardy to resident health and safety?

Tr. at 8. I do not consider whether the amount of the CMP is reasonable. CMS has imposed the statutory and regulatory minimum per day amounts so the penalty is reasonable as a matter of law. *See, e.g.*, *Hermina Traeye Memorial Nursing Home*, DAB No. 1810, at 16 (2002).

III. Discussion

A. From June 22 through August 8, 2006, the facility was not in substantial compliance with 42 C.F.R. § 483.10(b)(11) nor with 42 C.F.R. § 483.25.[4]

Under the statute and the "quality of care" regulation, each resident must receive, and the facility must provide, the necessary care and services to allow a resident to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the resident's comprehensive assessment and plan of care. Act, § 1819(b); 42 C.F.R. § 483.25.

The regulations also require that the facility consult the attending physician immediately whenever there is a significant change in a resident's status or whenever there is 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." 42 C.F.R. § 483.10(b)(11); *Georgian Court Nursing Center*, DAB No. 1866, at 18-19 (2003).

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[4] My findings of fact and conclusions of law are set forth, in italics and bold, in the discussion captions of this decision.

This case centers around the facility's treatment of one of its residents. Resident 1 (R1) was a 73-year-old man who fell at his home, fracturing his cervical spine and his right arm. He also had diagnoses of Type 2 (non-insulin dependent) diabetes, chronic renal insufficiency, hypertension, and coronary artery disease. Among his medications, R1 took the oral medications, Avandia and Amaryl, for his diabetes. P. Exs. 7, 11, 21.

R1 was hospitalized following his accident, and, during his hospitalization, he experienced episodes of hypoglycemia (abnormally low blood sugar). At the time of his discharge from the hospital, his hospital physician characterized his condition as "good," but, because of his recurring hypoglycemia, recommended that his blood sugar be monitored. P. Exs. 4, 7; Tr. at 18-19. The facility's Director of Nursing (DON), Linda Wood, acknowledges the hospital's advice "that the nursing facility should monitor him to be aware of 'serious' hypoglycemia." P. Ex. 39, at 2 (Wood Decl.).

Immediately following his hospitalization, R1 was admitted to the facility on June 19, 2006. Assessments made at the time of his admission describe R1 as alert but confused. His speech was clear and his memory intact, although he was depressed and angry. P. Ex. 14, at 1. He wore a cervical collar. P. Ex. 40, at 2; Tr. at 33. According to the facility's progress notes, on the night of his admission, R1 was alert, verbal, and able to answer questions appropriately, although he became increasingly agitated when not allowed to get out of bed. Staff gave him Percocet.[5] P. Ex. 21, at 1.

According to one of the facility's assessments, which has a reference date of June 21, 2006, R1's memory was "ok." He could recall the location of his room, and the names and faces of staff. He knew that he was in a nursing home. He had no problems with altered perception or awareness, and no episodes of disorganized speech. He had periods of restlessness, and his mental functions varied over the course of the day. He could make himself understood, and was usually able to understand others. In contrast to his earlier assessment, this one says that he displayed few indicators of depression, anxiety or sadness – the only block marked indicates that, within the preceding five days, he had exhibited "sad, pained, worried facial expressions." Further, these indicators (sad/pained/worried expressions) were easily altered, according to the assessment. P. Ex. 26, at 2. He exhibited no behavioral symptoms. He experienced pain, sometimes excruciating pain, daily. P. Ex. 26, at 3-4.

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[5] R1 was prescribed Percocet for pain. P. Ex. 24, at 4; *see also* P. Ex. 34. As the state surveyor Patrick Campbell pointed out, the note suggests no complaints of pain, but he got two Percocet anyway. Tr. at 40; P. Ex. 21, at 1. Percocet is not an appropriate treatment for agitation. Tr. at 41; P. Ex. 34; *see also* P. Ex. 21, at 3 (Resident very agitated. PRN Percocet given).

Consistent with the June 21 assessment, the facility's rehabilitation manager told Surveyor Campbell that, when R1 participated in physical therapy on June 20 and 21, his speech was clear and he was responsive; he even joked around with her. Tr. at 61.

1. Facility staff inadequately monitored R1's blood sugar levels.[6]

The facility and Petitioner's physician, Dr. Bernard Bennett (who was also the facility's medical director), seem to have given short shrift to consideration of R1's diabetes. His admission care plan includes no instructions for managing diabetes, even though the plan's format contains a discrete section titled "Diabetes." The form contains a specific place to fill in how often blood sugar should be checked, but that line (and indeed the entire section) is left blank. P. Ex. 17, at 2. Similarly, Dr. Bennett provided no specific guidance for monitoring R1's blood sugar level or for responding if those levels were abnormal. Indeed, although Dr. Bennett examined R1 on June 21, 2006, his report does not mention diabetes. He simply describes R1 as sitting in a chair in no apparent distress, and characterizes the resident as "stable" with no neurologic deficit. P. Ex. 22.[7]

Notwithstanding the absence of a written diabetes assessment or physician order for monitoring his blood sugar, R1's medication administration record (MAR) indicates that blood sugar checks should be performed a minimum of four times per day: at 7:30 a.m; 11:30 a.m; 4:30 p.m.; and 9:00 p.m. But no finger stick tests were recorded for the day of R1's admission, June 19. Nor were levels recorded at 7:30 a.m. on June 20. The first blood level recorded following R1's admission was taken at 11:30 a.m. on June 20. P. Ex. 24, at 3; P. Ex. 1, at 16; CMS Ex. 2, at 16; Tr. at 72. So, even though R1's hospital physician had pointed out the need for careful monitoring, and the facility knew that he had "serious hypoglycemia," it did not even begin to test blood levels until late morning

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[6] I address below Petitioner's argument that the facility may not here be held accountable for this and other deficiencies.

[7] Dr. Bennett apparently refused to testify in this matter. I am frankly skeptical (as was Petitioner) of Dr. Bennet's claim that state law precluded him from discussing the matter with the nursing facility of which he was the medical director. Petitioner asked that I issue a deposition subpoena so that counsel could depose Dr. Bennett in advance of the hearing and submit his deposition testimony, but the regulations do not grant me the authority to issue such a subpoena. Although Petitioner suggested that Dr. Bennett might be subpoened to testify at the hearing, it neither asked me to issue a subpoena for the hearing, nor otherwise satisfied the regulatory requirements for its issuance. 42 C.F.R. § 498.58.

on his second day there.[8] Nor did the facility test R1's blood sugar level at 11:30 a.m. on June 22, 2006. Had staff done so, they would have found that it was dangerously low. *See* discussion *infra*.

2. Facility staff did not follow the facility's protocol for notifying the physician of R1's low blood sugar levels.

The parties dispute whether the facility provided its staff guidance for notifying an attending physician of a resident's abnormal blood sugar levels. CMS points out that R1's medical record includes no instructions for calling his physician in the event of an abnormal blood sugar reading. Another facility document, titled "Observations to Report to the Physician" does not mention blood sugar levels, although it instructs staff to "report changes . . . to the physician as soon as possible, but no later than one hour after the observation of a significant or life threatening change in condition, and four hours for an observed change in condition." CMS Ex. 17, at 10.

Petitioner claims that specific instructions for monitoring or responding were unnecessary since Dr. Bennett had in place for all of his diabetic residents a standing order for the administration of insulin should blood sugar levels exceed certain parameters. P. Ex. 38; P. Ex. 41, at 2 (Bishop Decl.). A copy of this order was placed in R1's chart. But this order does not resolve CMS's objections because it addresses episodes of *hyper*glycemia only; it says nothing about hypoglycemia, and, in any event, says absolutely nothing about notifying the physician of any abnormalities. P. Ex. 38; *see* CMS Ex. 18, at 1 (Campbell Decl. ¶ 4); Tr. at 42, 47-48.

Petitioner also produces a document that was not in R1's chart, but which Petitioner characterizes as its protocol for treating hypoglycemia. The document includes parameters for consulting a physician about abnormally low blood sugar levels. P. Ex. 29. The document includes a description of the "usual symptoms" of mild, moderate, and severe hypoglycemia, and the accompanying blood sugar levels. It instructs specific treatments for each level. For mild hypoglycemia (blood sugar levels of 50-70 mg/dl), staff should give the resident 10-15 grams of a simple carbohydrate (e.g., 4 ounces of

[8] Petitioner argues, without much support, that R1 had a "pattern" of low blood sugar in the morning. P. Cl. Br. at 10. If this were so, and staff knew it, its failure to measure his 7:30 a.m. blood level would have been all the more indefensible.

orange or apple juice). For moderate hypoglycemia (blood sugar levels of less than 50 mg/dl), staff are instructed to administer 20 grams of a simple carbohydrate (e.g., 6 ounces of orange or apple juice). For severe hypoglycemia (usually 20 mg/dl or less), staff are to administer Glucagon[9] intramuscularly or subcutaneously. P. Ex. 29.

Fifteen minutes after administering the treatment, staff are instructed to re-test for blood sugar levels. If the resident's blood sugar level has not risen above 70 mg/dl, staff are to re-administer the prescribed treatment, and to re-test after an additional fifteen minutes. "**If glucose has not risen to 70 mg/dl, call the physician immediately.**" (Emphasis in original) P. Ex. 29.

According to Surveyor Campbell, he specifically asked but found no staff member who even knew where to find this protocol. Tr. at 50. This seems likely inasmuch as the protocol was not followed. S*ee* discussion *infra*. Moreover, according to Lori Bishop, R.N., who was the Unit Manager for R1's unit, staff were only required to contact the physician "immediately" in a life-threatening situation, a position that seems at odds with this protocol (unless the facility considers life-threatening prolonged episodes of hypoglycemia) and the position articulated by DON Wood. Tr. at 143.

DON Wood stated in her written declaration that

> Our policies and procedures . . . provide typical protocols . . . for responding to low blood sugar, including providing sugary foods, remeasuring blood sugar, and, where the blood sugar level does not rise within a certain time, to call the physician.

P. Ex. 39, at 3 (Wood Decl.) When questioned about the policy for notifying the doctor, DON Wood replied that staff would normally notify the doctor if blood levels were "out of the limit." She defined "out of the limit" as "typically . . . somewhere around 70 or below." Tr. at 97-98.

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[9] Glucagon is a medication that increases blood glucose.

But staff did not call the physician, even when blood sugar levels fell – and remained – well below 70.[10] At 7:30 a.m. on June 21, R1's blood sugar was 48. The facility had no orange juice, but gave him a can of Ensure. When re-tested half an hour later, his blood sugar was still 48.[11] Nobody called the physician. P. Ex. 32;[12] P. Ex. 1, at 17; Tr. at 98-100.

Not one shred of evidence suggests that any staff ever notified the physician of these blood sugar levels. Nevertheless, Petitioner characterizes the documentation as simply "not clear," and says that Dr. Bennett probably knew about the blood levels when he visited later in the day, but he considered the matter too insignificant to warrant any mention. P. Cl. Br. at 13-14. I note first that the facility's protocol, by itself, establishes that the facility had determined that a blood sugar reading below 70 – that stays below 70 half an hour after treatment – is very significant and requires *immediate* physician involvement. Moreover, no facility witness has claimed that the physician was ever notified; no document suggests that the physician was notified; and Dr. Bennett's June 21, 2006 note does not even mention R1's diabetes, much less his episodes of hypoglycemia.

In any event, even if staff had advised Dr. Bennett some time later, the protocol directed them to notify him "**immediately**" when the 8:00 a.m. blood level came in so low, but they failed to follow that protocol.

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[10] According to R1's MAR, his 4:30 p.m. readings on June 20 and 21 showed mild hypoglycemia (63 and 62 respectively). According to both the written protocol and DON Wood's testimony, the physician should have been consulted. I find no evidence in the nurses notes or elsewhere that staff offered the protocol-prescribed treatment, retested, or contacted the physician. *See* P. Ex. 21, at 2, 3 (no mention of blood levels in nurses notes).

[11] DON Wood incorrectly states that R1's blood sugar "came right up" after he ate breakfast and a carbohydrate-rich supplement. P. Ex. 39, at 4. Petitioner's records establish that it remained at the same low level, even after he took the supplement.

[12] Petitioner presents a typed statement, signed by Wanda Seymour, describing these events. Although it says on its face that it was written on June 28, 2006, Ms. Seymour's signature is dated July 27, 2006. P. Ex. 32. An undated, hand-written version of this statement can be found at CMS Ex. 13, at 86.

Because staff did not consult the attending physician when, according to the facility's own protocol, such consultation was necessary, the facility was not in substantial compliance with 42 C.F.R. § 483.10(b)(11), and it was not providing R1 necessary care and services, in violation of 42 C.F.R. § 483.25.

3. Facility staff delayed for hours notifying the attending physician of a significant change in R1's condition.

On the morning of June 22, 2006, R1's condition changed. According to his MAR, his 7:30 a.m. blood sugar level was 93, which is within normal range. However, by 8:00 a.m., according to a nurses note, his speech was slurred and the nurse had "difficulty understanding some of his conversation." His pupils were 3 cm and sluggishly reactive to light; on the other hand, he displayed no seizure activity, and denied pain or discomfort. P. Ex. 21, at 4. At 8:30, according to the note, he complained of thirst. He took water, with coughing. Staff attempted to feed him breakfast, but he coughed as he took sips of fluid and small bites of food. He was unable to eat, drink, or take his medication, and was hyper-extending his neck. P. Ex. 21, at 4; Tr. at 86.

Staff did not contact his physician nor re-test his blood sugar.

When his wife came to the facility at about 11:00 a.m., she was extremely upset by his appearance. He was gurgling; his head was back; his eyes were glassy; "he looked like he'd had a stroke." P. Ex. 21, at 4; P. Ex. 41, at 2-3 (Bishop Decl.). She insisted that the facility call 911.

> [H]is wife was next to him extremely distraught, crying, very, very excited, saying that there was something wrong with her husband. He appeared to be shaking. He was having trouble getting speech out.

Tr. at 132-133.

Shortly before noon, Unit Manager Bishop decided to call for an ambulance. Fortuitously, a team of paramedics arrived at the facility at about the same time. According to their report, they were there to pick up another resident, but that individual had already been taken to the hospital. A staff member (presumably Unit Manager Bishop) said to them "but we have another one you may as well take since you are here." CMS Ex. 13, at 69; P. Ex. 41, at 2-3.

At 11:56 a.m., the paramedics found R1 in a wheelchair with "snoring respiration," and "unresponsive to physical stimuli." CMS Ex. 13, at 46, 66, 69; Tr. at 67-68. They immediately assessed him and noted "hypoglycemia" on their event chronology report. Though dry, his skin was "pale/ashen." They took his blood glucose level at 12:01 p.m. and it registered 20 mg/dl. Within minutes, the paramedics began administering intravenous dextrose. R1 then became responsive and "'back to baseline' per staff." CMS. Ex. 13, at 46, 66. However, he became sleepy again, so they administered more dextrose. The paramedics took him to the emergency room, and he was subsequently admitted to the hospital. CMS. Ex. 13, at 46-50; P. Ex. 21, at 4. His hospital physicians took him off his oral hypoglycemic medications. CMS Ex. 13, at 51.

In response to this compelling evidence, Petitioner argues that it was not required to consult with R1's physician because R1's condition did not change significantly on the morning of June 22. Moreover, according to Petitioner, even if R1's condition changed significantly, staff had no reason to suspect low blood sugar; they reasonably attributed R1's changed demeanor to pain medication and/or another cause, and, before consulting the physician, they decided to monitor his changes.

I reject Petitioner's argument that R1 did not undergo a significant change within the meaning of 42 C.F.R. § 483.10(b)(11). Nor am I persuaded that the facility was not required to consult the physician because staff did not suspect hypoglycemia, but attributed R1's changed demeanor to some other cause, such as his pain medication and/or restless night. The regulation requires that the facility consult the physician when there is a significant change, regardless of its cause.[13]

Unit Manager Bishop claims that it was not necessary to contact R1's physician because nothing life-threatening was going on. Tr. at 143. But this is not the regulatory standard. "Significant" does not mean "life-threatening." Nor does the regulation require a medical emergency. The regulation mandates consultation with the resident's physician when there is –

> (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); [or]

[13] Where a medication causes these types of adverse consequences – inability to eat, drink, or swallow, altered mentation, unintelligible speech – the physician must be consulted so that he/she can consider treatment changes.

> (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).

42 C.F.R. § 483.10(b)(11). Drafters of the regulation emphasized that "in all cases, whether or not there is a medical emergency," the facility must immediately consult the attending physician. 56 Fed. Reg. 48826, 48833 (September 26, 1991). As the drafters explained, a "significant change" could be life-threatening, but it could also involve clinical complications, such as the development of a stage II pressure sore or onset of delirium.

The changes to R1 fall well within the regulatory definition. In fact, as all parties now agree, the change in Petitioner's condition was potentially life-threatening, and it resulted in his hospital physicians significantly altering his treatment; not only did he require multiple ampules of dextrose, he was also permanently taken off his oral hypoglycemic medications. CMS Ex. 13, at 55.

Moreover, even assuming that facility staff could not reasonably have suspected that R1 was suffering from hypoglycemia (which I find highly questionable), they should have recognized the need to consult his physician. Petitioner acknowledges that, on the morning of June 22, R1 did not "look good" and that his speech was difficult to understand, but claims that these were not significant departures from his usual appearance. According to Petitioner, R1 had not looked good from the time of his admission, because his face was bruised, and his speech was always difficult to understand, because of his cervical collar.

R1's face was bruised, but his assessments establish that, until the morning of June 22nd, his speech was clear and understandable, and his memory was intact. P. Ex. 14; P. Ex. 21, at 1; P. Ex. 26. He was able to eat, drink, swallow, and take his medications without difficulty. P. Ex. 33. The facility's rehabilitation manager, who had worked with R1 on the 20th and 21st, described him as a joker. When she heard the administrator refer to him as non-verbal, she said that "you got to be looking at the wrong guy[;] he's fine . . . ." Tr. at 61.

On June 22, staff recognized that R1 had undergone a significant change. They told the paramedics, that R1 was found "with altered mentation this a.m.[;] originally responding to voice with garbled, unintelligible responses, now unresponsive to voice." CMS Ex. 13, at 69.[14]

Petitioner acknowledges, as it must, that R1's wife noticed immediately that something was terribly wrong with her husband, but suggests that only someone close to him would have seen the changes. I disagree. These were not subtle changes, detectable only to one who was intimately familiar with R1. The changes she saw in her husband were so dramatic and disturbing, that, as Unit Manager Bishop testified, she panicked when she saw him. Tr. at 132-133.

Petitioner's witness, Karen Becton, R.N., testified that when she saw R1, shortly after 7:00 a.m. on June 22, he appeared "more restless and uncomfortable" than he had two days earlier (when she had last seen him). P. Ex. 40, at 2. He was agitated; he was hyper-extending his neck; and his speech was slurred, "obvious" symptoms of stroke, according to Nurse Becton. P. Ex. 40, at 3. Moreover, he had previously been able to eat and drink without any apparent difficulty, but, on the morning of the 22nd, he could not even swallow. *See* P. Ex. 33 (on the mornings of June 21 and 22, R1 ate breakfast and drank); Tr. at 85 ("he would go coughing and gagging as though he was having difficulty. That was a change . . . .").

Nurse Becton first testified that she did not consider these significant changes because R1's vital signs were normal, "and he was alert." Tr. at 85-86. But then she said that slurred speech, gagging, and inability to consume water or take medication *were* significant changes. Tr. at 85-87. Then, on re-direct, she said that "when I think of the whole picture, he remained alert, the vitals did not show a change," so she decided not to consult the physician, but to continue monitoring him. Tr. at 87-88. (Unfortunately, her "monitoring" did not include checking his blood sugar levels.)

Thus, Nurse Becton appears to agree that R1's condition changed, but claims that the changes were not significant because he was "alert." Sometime after 8:30 a.m., however, he was no longer alert. But Nurse Becton still did not consult his physician, because she thought he might have been sedated by the Percocet. Tr. at 87, 89.

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[14] According to the paramedics' prehospital report, R1's history of non-insulin dependent diabetes was "not disclosed by staff." CMS Ex. 13, at 69.

Nurse Becton claims that she was not concerned about R1's blood sugar because his 7:30 a.m. reading was 93, "higher than the previous two mornings." P. Ex. 40, at 3 (Becton Decl.). DON Wood makes a similar claim: that his "normal pattern was to have low blood sugar in the early morning," and that "this same pattern repeated during the early morning hours of both June 20 and June 21." P. Ex. 39, at 3 (Becton Decl.). But, as discussed above, there were no early morning blood levels recorded on June 20. No level was taken until 11:30 a.m. P. Ex. 24, at 3; P. Ex. 1, at 16. So staff could not reasonably have relied on any such June 20 reading.

And Petitioner is incorrect in asserting that R1 displayed no symptoms of hypoglycemia. He did not display all of the symptoms listed in the facility's protocol, but he displayed many of them: shakiness, anxiety and irritability (symptoms of mild hypoglycemia); sleepiness, lack of coordination, altered behavior (symptoms of moderate hypoglycemia); and inability to take by mouth (symptom of severe hypoglycemia). P. Ex. 29; Tr. at 64-67. Moreover, staff should also have recognized that some people have no symptoms of hypoglycemia, and may lose consciousness without ever knowing that their blood sugar levels are dropping. P. Ex. 30, at 1. I note also that when the paramedics observed R1, they *immediately* suspected hypoglycemia, and, within minutes, were testing his blood sugar. CMS Ex. 13, at 70 ("11:56 paramedic assessment . . . hypoglycemia . . . 12:01 Blood Glucose . . . mg/dl 20.").

In this case, the facility twice failed to consult R1's attending physician about a significant change in his condition, and it was therefore not in compliance with 42 C.F.R. § 483.10(b)(11). Because the facility's inaction also meant that it was not providing R1 necessary care and services, its failure to notify puts it out of compliance with the quality of care regulation, 42 C.F.R. § 483.25, as well. The facility also failed to provide R1 "necessary care and services" for treatment of his diabetes "in accordance with [his] comprehensive assessment and plan of care." As the evidence shows, the facility did not assess his diabetes. Though aware if his "serious hypoglycemia," the facility skipped all of his blood sugar tests for the day of his admission and the first test of the following day. It did not test his blood sugar as called for in his MAR even when he was displaying significant symptoms of hypoglycemia. Independent of the facility's failure to consult the attending physician, these failures establish the facility's noncompliance with quality of care requirements.[15]

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[15] Petitioner dismisses the "quality of care" regulation as "catchall," suggesting that the only important finding here was failure to notify. P. Cl. Br. at 7, 25. I disagree. While a facility that fails to comply with the quality of care requirements often has deficiencies under other regulations, that hardly negates the significance of quality of care

(continued...)

B. 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.

Petitioner offers a perplexing argument about the nature of *de novo* review, culminating in the assertion that

> CMS plainly based its action on the conclusion that Petitioner's staff did not appropriately identify and respond to [R1's] developing (*hypo*glycemic) illness during the morning in question – *not* that the Resident's attending physician's "standing orders" for sliding scale insulin (for *hyper*glycemia) were not sufficiently individualized; or that a nurse failed to do a blood sugar check a day or two before the Resident became ill; or that Petitioner's staff failed to contact the Resident's physician the preceding morning when his blood sugar was measured as low. These matters did not support the sanction CMS imposed, which focused on Petitioner's staff's acts and omissions *after* the Resident's blood sugar was determined to be normal on the morning of June 22, 2006.

P. Cl. Br. at 3.

Petitioner received ample notice from both the State Agency and CMS that the penalties imposed were based on the findings enumerated in the Statement of Deficiencies (CMS Form 2567). P. Ex. 2; CMS Exs. 8, 10.

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[15](...continued)
findings. Indeed, while compliance with all Medicare long term care requirements is important, the quality of care regulation is particularly important because it encompasses the purpose of skilled nursing care. Medicare pays for placement in skilled nursing facilities in order for residents to receive the quality of care described in the regulation.

This is not even a situation in which CMS has asked me to look beyond the four corners of the Statement of Deficiencies, which I am empowered to do. *Pacific Regency Arvin*, DAB No. 1823, at 9 (2002); *Regency Gardens Nursing Center*, DAB No. 1858, at 15-16 (2002). Rather, Petitioner's argument simply disregards the contents of that document. CMS Ex. 2; P. Ex. 1. All of the issues Petitioner characterizes as "not supporting the sanction," are specifically listed there in support of the sanction.

The Statement of Deficiencies cites the regulatory requirements that were not met, and then explains why those requirements were not met. In its explanations, it includes (among other deficiencies) all of the matters that Petitioner now argues are not before me. The Statement of Deficiencies talks about the problems with the physician's "standing orders" for sliding scale insulin (P. Ex. 1, at 2, 11, 14); it talks about staff's failure to test blood sugar on the days prior to the significant change in R1's condition (P. Ex. 1, at 3, 16); it talks about the staff's failure to contact the attending physician on the morning prior to the significant change in R1's condition (P. Ex. 1, at 4-5, 17). *See also* CMS Ex. 11 (Summary of Survey Findings); CMS Ex. 12 (Review of Survey Material, July 6, 2006).

C. CMS's determination that the facility's deficiencies posed immediate jeopardy to its residents was not clearly erroneous.

I next consider whether CMS's immediate jeopardy finding was "clearly erroneous." Immediate jeopardy exists if the facility's noncompliance has caused or is likely to cause "serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301. CMS's determination as to the level of a facility's noncompliance – which includes its immediate jeopardy finding – must be upheld unless it is "clearly erroneous." 42 C.F.R. § 498.60(c).

The Board has observed repeatedly that the "clearly erroneous" standard imposes on facilities a "heavy burden" to show no immediate jeopardy, and has sustained determinations of immediate jeopardy where CMS presented evidence "from which '[o]ne could reasonably conclude' that immediate jeopardy exists." *Barbourville Nursing Home*, DAB No. 1962, at 11 (2005) (citing *Florence Park Care Center*, DAB No. 1931, at 27-28 (2004) (citing *Koester Pavilion*, DAB No. 1750 (2000)). Here, the facility has not satisfied its burden.

Petitioner concedes that R1's diabetic crisis "could have caused harm" but argues no connection between the facility's actions (or inactions) in this regard and potential harm to a resident. P. Cl. Br. at 35. In fact, R1's trip to the emergency room and subsequent hospitalization were directly related to the facility's general inattention to his diabetes and its deficient response to his changed condition on the morning of June 22. Moreover,

Petitioner's multiple shortcomings in assessing, planning, and managing R1's diabetes, as well as its overall failure to give its staff clear direction for consulting the physician about a resident's abnormal blood sugar levels, placed the facility's diabetic residents at immediate risk for serious injury, harm, or even death.

I am therefore not able to find clearly erroneous CMS's determination that the facility's deficiencies posed immediate jeopardy to resident health and safety.

IV. Conclusion

For all of the reasons discussed above, I find that, from June 22 through August 8, 2006, the facility was not in compliance with program requirements, specifically, 42 C.F.R. §§ 483.25 (quality of care) and 483.10(b)(11) (notification of changes). From June 22 through 27, 2006, its deficiencies posed immediate jeopardy to resident health and safety. Because CMS has imposed the statutory and regulatory minimum per day penalty amounts, I also sustain the $3050 per day CMP for the period of immediate jeopardy, and the $50 per day CMP for the period of noncompliance that did not pose immediate jeopardy.

/s/
Carolyn Cozad Hughes
Administrative Law Judge