Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Life Care Center of Tullahoma, (CCN: 44-5238),	)	Date: June 24, 2009
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-08-253
	)	Decision No. CR1964
Centers for Medicare & Medicaid Services.	)	
	)	

DECISION

I sustain the determination of the Centers for Medicare & Medicaid Services (CMS) to impose civil money penalties of $6,550 per day against Petitioner, Life Care Center of Tullahoma, for each day of a period that began on June 25, 2007 and which continued through November 27, 2007.

I do not address additional civil money penalties of $100 per day that CMS imposed against Petitioner during a period that began on November 28 and which continued through December 6, 2007 inasmuch as Petitioner has not offered argument or evidence challenging the imposition of these remedies. CMS's determination to impose them is administratively final.

In its post-hearing brief, Petitioner now asserts that the status of the $100 per day civil money penalties is "not clear." Petitioner's post-hearing brief at 8. I disagree. The record of this case is quite clear: CMS consistently asserted that it was imposing the $100 per day penalties and Petitioner consistently failed to challenge the imposition of these remedies. CMS asserted in a December 18, 2007 remedy notice that it sent to Petitioner that it was imposing the $100 per day civil money penalties for deficiencies that included Life Safety Code deficiencies that had been identified at Petitioner's facility. Petitioner did not challenge any of the Life Safety Code deficiencies in its hearing request. In its pre-hearing brief CMS asserted that Petitioner had not challenged

the $100 per day penalties or the Life Safety Code deficiencies on which they were based. Petitioner did not contest that assertion in its pre-hearing brief nor did it offer evidence to challenge the imposition of these penalties. CMS's pre-hearing brief at 3, n.3; *see* Petitioner's pre-hearing brief.

I. Background

Petitioner is a skilled nursing facility in Tennessee. It participates in the Medicare program and its participation is governed by sections 1819 and 1866 of the Social Security Act (Act) as well as by implementing regulations at 42 C.F.R. Parts 483 and 488. Its hearing rights are governed by regulations at 42 C.F.R. Part 498.

Petitioner requested a hearing to challenge CMS's determination to impose the $6,550 per day civil money penalties that I describe at the inception of this decision. CMS imposed these penalties on the basis of findings of noncompliance that were made during a survey of Petitioner's facility conducted on November 4-26, 2007 (November survey). The case was assigned to me for a hearing and a decision and I held an in-person hearing in Chattanooga, Tennessee, on March 12, 2009. At the hearing I received exhibits from CMS which I identified as CMS Ex. 1 – CMS Ex. 50 and from Petitioner which I identified as P. Ex. 1 – P. Ex. 81. I also received the cross-examination and redirect testimony of several of CMS's witnesses whose testimony had been provided in writing and received as exhibits.

II. Issues, findings of fact and conclusions of law

A. Issues

The issues in this case are whether:

1. Petitioner failed to comply substantially with Medicare participation requirements;

2. CMS's determination of immediate jeopardy level non-compliance is clearly erroneous; and

3. Civil money penalties of $6,550 per day are reasonable remedies for Petitioner's noncompliance.

B. Findings of fact and conclusions of law

I make findings of fact and conclusions of law (Findings) to support my decision in this case. I set forth each Finding below as a separate heading.

1. Petitioner failed to comply substantially with Medicare participation requirements.

In this decision I address CMS's allegations that Petitioner failed to comply substantially with the following Medicare regulations:

- 42 C.F.R. § 483.10(b)(11), which in pertinent part requires a skilled nursing facility staff to consult immediately with a resident's treating physician in the event of a significant change in the resident's physical, mental, or psychosocial status. The regulation defines a significant change to be, for example, deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications. 42 C.F.R. § 483.10(b)(11)(B).

- 42 C.F.R. § 483.20(k)(3), which, among other things, mandates a skilled nursing facility to provide or arrange services that meet professional standards of quality.

- 42 C.F.R. § 483.25, which provides that a skilled nursing facility must provide to each of its residents the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with that resident's comprehensive assessment and plan of care.

- 42 C.F.R. § 483.25(m)(2), which requires a facility to ensure that its residents are free from significant medication errors.

- 42 C.F.R. § 483.75, which directs that a facility be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being for each of its residents.

The allegations of noncompliance that CMS makes concerning 42 C.F.R. §§ 483.25(10)(b)(11), 483.20(k)(3), and 483.25, derive in large measure from the same evidence. I discuss the evidence in detail and the parties' arguments about this evidence as they relate to Petitioner's asserted noncompliance with 42 C.F.R. § 483.25(10)(b)(11). As I discuss, the evidence and the law overwhelmingly support my conclusion that Petitioner failed to comply substantially with this regulation. The same evidence also overwhelmingly supports my conclusions that Petitioner failed to comply substantially with the requirements of 42 C.F.R. §§ 483.20(k)(3) and 483.25. Below, I explain why that is so. However, I do not address additional evidence and arguments offered by CMS as to Petitioner's noncompliance with these two regulations nor do I discuss Petitioner's evidence and rebuttal arguments addressing CMS's additional evidence because it is unnecessary that I do so. The evidence that I discuss in detail is more than sufficient to support findings of noncompliance.

There is evidence which uniquely addresses Petitioner's noncompliance with the requirements of 42 C.F.R. § 483.25(m)(2) and I discuss that evidence in detail. The allegations of noncompliance with 42 C.F.R. § 483.75 derive from allegations of noncompliance with other regulations and I discuss these allegations.

I do not address numerous additional alleged deficiencies that were cited in the November survey report. CMS has not pressed its case concerning these additional alleged deficiencies and argues that the alleged deficiencies that I have just cited are, in and of themselves, sufficient to justify the civil money penalties that CMS determined to impose. I draw no inferences – favorable or unfavorable to Petitioner – from the noncompliance allegations that CMS elected not to pursue.

Petitioner complains bitterly that it is unfair that CMS elected to pursue only some and not all of the deficiency findings that it alleged originally. According to Petitioner: "this tactic is a clear violation of the administrative review provisions of the Social Security Act and regulations, and a deprivation of the Constitutional guarantee that the Government may not impose a penalty, nor deprive citizens of property, without due process of law." Petitioner's post-hearing brief at 8.

I find this argument to be baseless. Petitioner has not shown that it has been harmed in any respect by CMS's election. In electing to rest its case only on five of the many allegations of noncompliance made at the November survey CMS effectively removed all of the other allegations from consideration. For purposes of my decision it is as if those additional allegations were never made. They have absolutely no impact on any of my Findings. Petitioner actually benefits from CMS's election because, by effectively withdrawing the lion's share of allegations from consideration almost at the inception of this case, CMS eliminated any need for Petitioner to defend against them. And, Petitioner took advantage of that election because none of the arguments that Petitioner made in its pre-hearing exchange or the evidence that it offered as part of that exchange address the deficiency allegations that CMS elected not to pursue.

a. Petitioner failed to consult immediately with residents' physicians concerning significant changes in the residents' medical conditions.

A skilled nursing facility must consult immediately with a resident's treating physician whenever there is a significant change in that resident's clinical condition. The obligation of the facility is unambiguously stated in the governing regulation. 42 C.F.R. § 483.10(b)(11)(B). The regulation requires consultation − and not mere notification – and it requires that such consultation take place immediately whenever a significant change is detected and not at some later time or date.

The regulation highlights the role of a nurse in a skilled nursing facility as a primary caregiver who works under the supervision and control of a physician. It is premised on the reality that it is the nurse who will almost always be the first to observe a significant change in a resident's medical condition inasmuch as the nursing staff is present at a skilled nursing facility at all times while the physician is not. But, it is premised also on the reality that a nurse is not an independent contractor who is free to make medical judgments that are within a physician's unique training and authority. Thus, the regulation assures that the nurse functions as the physician's eyes and ears but that he or she also does not overstep the boundaries of his or her professional training and license.

As was testified to by CMS's expert physician, James K. Schmitt, M.D., nurses administer care under the supervision of physicians. CMS Ex. 50, at 3. A nurse may not take matters into his or her own hands and make decisions that must be made by a physician. Aside from violating nursing standards of care such a practice would be very dangerous to the health of the facility resident. *Id.*

Petitioner's nursing staff failed systemically to comply with the consultation requirement. In failing to consult they violated professionally recognized standards of care that put limits on what they could do without physician supervision. The weight of the evidence establishes that:

- Although Petitioner had a protocol for notifying residents' treating physicians in instances of diabetic hypo- or hyperglycemia its nursing staff consistently ignored that protocol. Physicians were not consulted on dozens of occasions about dangerously abnormal resident blood sugar levels.[1]

- The staff failed to consult with residents' treating physicians even when residents were manifesting signs of grave deterioration in their medical conditions. These failures included instances where residents were non-responsive in the presence of extreme hypoglycemia and another instance in which a resident was suffering from a dangerous potassium imbalance and an abnormally slow heartbeat.

[1] Petitioner's medical director, who was the treating physician for many of the residents whose care I discuss explicitly in this decision, employed a nurse practitioner to visit the facility and provide care on his behalf. For purposes of this decision I put the nurse practitioner on the same footing as the physician who employed her. I would not have found Petitioner to be deficient had its staff consulted with the nurse practitioner in those circumstances where physician consultation was obligatory.

- On numerous occasions Petitioner's nursing staff took measures to counter residents' severe hypoglycemia without consulting the residents' treating physicians. Thus, staff was unaware whether a resident's physician would have ordered a different treatment or rejected the treatment opted for by the staff.

Diabetes is a serious medical condition and, if not treated effectively, can cause grave harm to its victims. The condition can be lethal. There are particular risks of harm associated with hypoglycemia (abnormally low levels of sugar in an individual's blood). A decline in a patient's blood sugar to a level of below 60 milligrams per deciliter (mg/dl) is a significant medical event because it can precipitate very grave and even life-threatening medical consequences. At a blood sugar level of below 60 mg/dl an individual is likely to experience the sudden onset of seizures, coma, and death. CMS Ex. 50, at 3.

A decline in a resident's blood sugar level to below 60 mg/dl is a "significant change" in a resident's condition within the regulatory definition of that term because it is a clinical complication that can cause severe damage or even death. Blood sugar levels that low thus require physician consultation by a facility's nursing staff.

At some point Petitioner recognized the need for physician consultation when residents' blood sugar levels fell below 60 because it developed and implemented a protocol for dealing with hypo- and hyperglycemia which required at least notification of physicians of such events. That protocol continued to govern the nursing staff's performance of their duties through the November survey. It instructed the nursing staff to:

NOTIFY MD OF BS LESS THAN 60 AND GREATER THAN 360

in those circumstances where residents were found to be either hypo- or hyperglycemic. CMS Ex. 12, at 12, 13 (capitalization in original). This instruction was featured prominently in the treatment administration record that Petitioner maintained for each of its diabetic residents. *Id.* at 11-13. The protocol was restated in specific orders that physicians gave for residents. P. Ex. 15, at 4; P. Ex. 35, at 2; P. Ex. 54, at 6. It was also restated on other forms that Petitioner used to record care given to residents by its nursing staff. CMS Ex. 39, at 3; P. Ex. 37, at 1.

The diabetes protocol is consistent with another document which Petitioner's staff gave to surveyors during the November survey after the surveyors asked the staff to produce any and all written policies and protocols regarding diabetic care and hypoglycemic crises. Tr. at 53-54, 86-88; CMS Ex. 39. The document that Petitioner's staff gave to the surveyors is evidently part of a larger document entitled "Life Care Centers of America, Inc., Emergency Procedures, Chapter 19." CMS Ex. 39, at 1. It specifies that the resident's:

> [p]hysician is immediately notified when any resident who receives insulin exhibits altered behavior or mental/physical state consistent with hyperglycemia or hypoglycemia.
>
> If attending physician cannot be reached promptly, notify . . . [Petitioner's] medical director. . . .

Id.

Petitioner's diabetes protocol was routinely ignored by its nursing staff. On dozens of occasions residents at Petitioner's facility were documented as having blood sugars at below 60 or above 360 and the nursing staff failed to notify – much less consult with – residents' treating physicians. CMS's post-hearing brief, attachment A and exhibits cited therein.[2]

I find these repeated failures by the nursing staff to consult with residents' physicians to be obvious noncompliance with the regulation's consultation requirement. As I discuss above, a drop in a resident's blood sugar to a level of below 60 is a significant change by any measure because it can precipitate dangerous and even irreversible consequences for that individual. Failure to consult in such circumstances endangered the safety of residents because it meant that nurses were failing to perform their duty to provide critical information to the treating physician. It also endangered the residents' safety because, in failing to consult, the nursing staff frequently made medical judgments that they were not qualified to make.

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[2] Attachment A is a summary prepared by CMS's counsel and based on exhibits that are in evidence. It is advocacy and not evidence, but it documents a great many instances which are illustrated by exhibits in evidence in which residents had blood sugar levels of less than 60 or more than 360 but where Petitioner's nursing staff failed to consult with the residents' physicians. Petitioner objects to my considering the attachment, contending that it has been unfairly ambushed by a new exhibit. I find its objections to be without merit. Petitioner's argument to the contrary, there is nothing new referenced in the attachment, it recites only evidence that Petitioner did not object to my receiving. Petitioner has not identified a single citation in the attachment which it contends to be inaccurate. Petitioner asserts also that the attachment is offered as an apparent effort to support new or revived allegations of noncompliance that CMS did not previously advocate. That is incorrect. The attachment merely illustrates examples of those contentions that CMS made throughout the case.

The failure here is particularly egregious because the nursing staff routinely defied *explicit orders* that had been given to them by residents' treating physicians to consult in the event of blood sugar levels below 60 or above 360. P. Ex. 15, at 4; P. Ex. 35, at 2; P. Ex. 54, at 6. Thus, the staff assumed a role that they had been ordered directly not to assume, and made medical treatment decisions that only physicians were qualified to make.

This wholesale noncompliance with Petitioner's protocol and physicians' orders included instances where residents were manifesting signs of extreme hypoglycemia. These instances involve three of Petitioner's diabetic residents, identified as Residents #s 18, 27, and 40. Each of these residents had a written physician's order directing the staff to notify the physician if blood sugar levels were below 60 or above 360. P. Ex. 15, at 4; P. Ex. 35, at 2; P. Ex. 54, at 6.

Resident # 18 suffered hypoglycemic episodes on October 20, 21, 24, 26, and 27, 2007.[3] CMS Ex. 12, at 12, 14, 16. On October 20 and 26 the resident had blood sugar levels of 39 mg/dl and 47 mg/dl, respectively. *Id.* at 12, 14. On none of these occasions did Petitioner's nursing staff consult with the resident's treating physician. On October 27, 2007 the resident experienced signs of life-threatening hypoglycemia, including a blood sugar level of 20 mg/dl, convulsions, diaphoresis, and an inability to speak or swallow. *Id.* at 16. Then, the staff called the treating physician, but only after 30 minutes had transpired from the staff's discovery of the resident in a nonresponsive state. P. Ex. 18, at 3.

Resident # 27 experienced obvious signs of hypoglycemic crises on two occasions, June 25 and July 21, 2007. On neither occasion did Petitioner's nursing staff consult with the resident's treating physician. On June 25 the resident had a blood glucose level of 32 mg/dl. The resident was reported to be lethargic, staring blankly, mumbling to herself, and her extremities were twitching involuntarily. CMS Ex. 17, at 15. On July 21, the resident's blood glucose level was recorded at 40 mg/dl. The resident was reported to be very groggy and unable to walk. *Id.* at 16.

Resident # 40 displayed obvious signs of a hypoglycemic crisis on September 11, 2007. CMS Ex. 26, at 19. On this occasion the resident's blood sugar was recorded at 28 mg/dl. Her skin was cool and clammy, her head was wet with sweat, and the resident was slow to react to stimuli. *Id.* But, as with the other residents whose care I discuss, Petitioner's nursing staff elected to treat Resident # 40 without consulting with the resident's treating physician.

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[3] As I shall discuss these episodes were likely the consequence of Petitioner's nursing staff administering overdoses of insulin to the resident. The staff failed to consult immediately concerning any of these incidents thus depriving the resident's physician the opportunity to assess whether the incidents were caused by insulin overdoses.

The nursing staff's failures to consult with residents' physicians during medical crises were not exclusively confined to hypoglycemic events. Resident # 56 was an individual who had suffered from severe bradycardia (abnormally slow heart beat) and hyperkalemia (abnormally elevated serum potassium). CMS Ex. 36, at 10-11. The two problems are linked because abnormally elevated potassium levels can impair heart muscle function, can cause slowed heart beats, and can actually cause the heart to cease beating entirely. CMS Ex. 50, at 6. On November 2, 2007, the resident's treating physician ordered that the staff perform a test called a Basic Metabolic Panel (BMP), weekly. The physician additionally ordered that the nursing staff perform a "stat" BMP whenever the resident's pulse was below 50 beats per minute. CMS Ex. 36, at 5.

On November 4, 2007, at 1:55 a.m., the resident awoke with a sudden onset of shortness of breath and extreme anxiety. Petitioner's nursing staff recorded the resident's heart rate at 45 beats per minute. CMS Ex. 36, at 6. A stat BMP was ordered and, at 3:00 a.m., the laboratory reported that the resident's potassium level was critically high. *Id.* at 6, 9. Petitioner's nursing staff faxed the laboratory report to the physician's office at 3:25 a.m. on November 4. However, staff waited until 6:00 a.m., an additional two and one-half hours, before contacting the physician directly. *Id.* The physician, upon learning about the resident's condition, ordered that she be transferred immediately to a hospital emergency room for evaluation.

The delay in consulting with Resident # 56's physician about the resident's bradycardia and elevated potassium levels – as with the failure to consult with other residents' physicians about their hypoglycemic episodes – put this resident at grave risk for adverse consequences. Cardiac arrest was a likely outcome for this resident in the absence of immediate and urgent care. CMS Ex. 47, at 9-10; CMS Ex. 48, at 16-17; CMS Ex. 50, at 6.

Petitioner's staff often took matters into their own hands to address residents' medical crises without any physician input. Physicians were thus deprived of the opportunity to direct the care immediately provided to residents to address their crises. Such unguided treatment decisions pervaded the care that Petitioner's nursing staff provided to Residents #s 18, 27, and 40. For example, Petitioner's staff repeatedly treated the hypoglycemic crises experienced by Resident # 27 without consulting the resident's physician as to which measures would be appropriate. CMS Ex. 17, at 16.

The treatment decisions that the staff made without physician consultation endangered Petitioner's residents. The staff denied the residents' treating physicians the opportunities to: make medication and/or insulin adjustments; direct the amount and type of food or medication to be given; and to monitor the resident's serum glucose levels

after they were boosted. CMS Ex. 50, at 5. Most significantly, the staff received no input from physicians concerning whether and how to monitor residents for possible rebound or plunging of serum glucose levels, which could have caused the residents to suffer seizures, coma, or death. *Id.*

Physicians were also deprived of the opportunity to consider whether their overall treatment regimes for residents were inappropriate or needed to be adjusted. For example, and as I discuss in more detail below, the weight of the evidence in this case proves that Petitioner's staff – as a consequence of its misreading of a hospital discharge report – gave overdoses of insulin to Resident # 18. These overdoses almost certainly contributed to the resident's hypoglycemic episodes. Had Petitioner's staff carried out its obligations and consulted with the resident's physician at the first signs of hypoglycemia, the insulin administration error might have been discovered earlier and the resident might have been spared the ordeal of multiple hypoglycemic episodes.

For the most part Petitioner does not argue that its nursing staff consulted with residents' physicians in the situations that I have described. Rather, it contends that its staff's actions were appropriate and consistent with regulatory requirements despite the staff's failures to consult. I have considered the arguments that Petitioner offered as defenses for its staff's conduct and I find them to be unpersuasive. Petitioner's arguments mainly are of a series of straw men and encompass a collection of statements comprising assertions that are based on fact contentions that are either not supported by, or which mischaracterize, the evidence.

Petitioner begins by arguing that the protocols and the physicians' orders that I have discussed at length in this decision did not really control the nursing staff's care of diabetic residents. It asserts that there were additional protocols that apparently overrode those that I have discussed and which really were Petitioner's guidelines for diabetic care. These other protocols, according to Petitioner, did not require notification of or consultation with treating physicians when residents' blood sugar levels fell below 60.

As support for this argument Petitioner relies on an exhibit entitled "Life Care Centers of America, Inc., Diabetic Care, Chapter 3." P. Ex. 7. Petitioner would have me infer that it is this exhibit which Petitioner used to give primary guidance to its staff for addressing diabetic crises. Petitioner's post-hearing brief at 17-18. The exhibit does not instruct nursing staff to consult with a resident's physician about a hypo- or hyperglycemic episode except when a resident fails to respond to treatment. *Id.* at 6.

Petitioner has established no foundation that would support an inference that the exhibit actually instructed its staff in the performance of their duties and for that reason I find it to be irrelevant. Petitioner's staff did not provide it to surveyors during the November survey when the surveyors explicitly requested that Petitioner furnish them with its

diabetes treatment protocol. *See* Tr. at 53-54, 86-88.[4] None of Petitioner's nursing staff testified that the document actually was relied on by the staff during the events which are the subject of this case.

But, even if the exhibit was utilized at Petitioner's facility during the relevant time period, it is not inconsistent with the protocol requiring physician notification when residents' blood sugar levels fell below 60. Nothing in the exhibit contradicts the instructions given by Petitioner's protocol and physicians' orders that residents' physicians must be notified whenever the residents' blood sugar levels fall below 60. The exhibit mandates physician consultation when a resident's hypoglycemia is unresponsive to treatment but it does not preclude consultation in other circumstances.

Petitioner asserts that the purported protocol in P. Ex. 7 actually was one of three protocols that its staff utilized in treating diabetic residents. Petitioner's post-hearing brief at 18. The second protocol, according to Petitioner, is that which is stated at CMS Ex. 39, at 1. This is the statement, which I have discussed, mandating Petitioner's staff to communicate immediately with a resident's treating physician whenever a resident who is receiving insulin manifests altered behavior or a mental/physical state consistent with hyper- or hypoglycemia. *Id.* But, although Petitioner acknowledges the existence of this instruction, it fails to explain why its staff did not follow it. As I have discussed, CMS offered unchallenged evidence showing that three of Petitioner's residents, Residents #s 18, 27, and 40, on several occasions manifested signs that would have mandated immediate physician consultation pursuant to Petitioner's "second" protocol and yet, staff did not consult.

The third alleged protocol offered by Petitioner is in evidence as CMS Ex. 39, at 3. This, according to Petitioner, is a "blank flow sheet" that matches insulin doses with blood sugar measurements. Petitioner's post-hearing brief at 19. The document contains the explicit instruction which I have discussed telling Petitioner's staff to notify a resident's treating physician whenever the resident's blood sugar level was less than 60 or greater than 360. Petitioner acknowledges that this was indeed a document utilized by Petitioner in providing care to its diabetic residents. But, Petitioner strongly disputes any "interpretation" of the document's instruction that the staff must notify a resident's physician of a resident's blood sugar level of less than 60 or greater than 360. *Id.* According to Petitioner, the correct interpretation of this instruction (and physicians' orders which repeat it) can only be made by weighing the expert testimony of Petitioner's witnesses against the evidence offered by CMS. Petitioner's post-hearing brief at 19.

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[4] What the staff did furnish to the surveyors is the protocol that I have discussed previously.

I disagree that the instructions that Petitioner – and the residents' treating physicians – gave to Petitioner's nursing staff are in any respect ambiguous or subject to interpretation. The requirement of physician notification when a resident's blood sugar level falls below 60 could not be stated more explicitly than it was in the documents utilized by Petitioner for diabetes care or in the orders given by residents' treating physicians. Furthermore, no member of Petitioner's staff testified that anyone interpreted these instructions to require anything other than that which was explicitly stated.[5] For this reason, I conclude that Petitioner's experts' purported interpretations of Petitioner's diabetes are unpersuasive efforts to deny the obvious.

Moreover, no amount of expert opinion can cover up the obvious failure of Petitioner's nursing staff to provide care that complied with regulatory requirements and professionally recognized standards of care. There were residents at Petitioner's facility whose hypoglycemia caused them to manifest grave – even life-threatening – signs, including non-responsiveness and loss of control over their extremities, and even then, Petitioner's staff failed to consult with these residents' physicians.

Petitioner contends that its nursing staff did nothing out of the ordinary in failing to consult with physicians concerning residents' abnormal blood sugar levels. It argues that it would be naïve to find that a facility such as Petitioner's would be obligated to disturb physicians for problems that its nursing staff handled as part of their routine duties. With regard to Petitioner's protocol that required notification of blood sugar levels below 60 and above 360, Petitioner claims that the only reasonable interpretation of this protocol is that it did not obligate the staff to consult in instances where blood sugar was abnormally low or high but where the staff was able to control the problem without physician intervention.

As support for this argument Petitioner relies heavily on the testimony of its expert, John B. Standridge, M.D. P. Ex. 79, at 2-11. I find this witness' testimony not to be persuasive, primarily because it does not address what actually happened at Petitioner's facility. Rather, and in keeping with Petitioner's overall approach to this case, Dr. Standridge premises his testimony on a series of characterizations that are simply unsupported by the evidence of record.

Thus, Dr. Standridge never discusses directly either Petitioner's diabetes protocol or the explicit physician orders that were issued in conformity with that protocol. Nor does Dr. Standridge account for the failure of the staff to explain their noncompliance with the protocol and orders. Indeed, Dr. Standridge does not draw any of his conclusions from first-hand knowledge of what happened at Petitioner's facility.

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[5] Petitioner offered no testimony from any of its nursing staff.

I do not question Dr. Standridge's qualifications as an expert in family medicine or as a director of a long-term care facility. However, as I read his testimony, it is carefully hedged to avoid confronting head on the evidence of noncompliance that is at the heart of this case. Dr. Standridge opines that:

> A citation for not bothering a busy multitasking rural physician for a blood sugar slightly outside the general parameters demonstrates to me, overzealousness on the part of a surveyor, not substandard care. Yet this pattern is repeated throughout the citations [of deficiencies that are at issue]. . . . .

P. Ex. 79, at 4. This assertion is the first of several that are not based on the evidence. This case does not involve "citation[s] for not bothering a . . . physician for a blood sugar slightly outside the general parameters . . ."
The specific incidents of non-consultation cited by CMS and which I have discussed included instances in which residents of Petitioner's facility were hypoglycemic to the extent that they were in imminent danger of severe harm. Some of these residents were so compromised that they suffered from altered mental states, were non-responsive, or displayed uncontrolled movement of their extremities. These residents had blood sugar levels recorded as low as 20 mg/dl. That is a far cry from a slight deviation from acceptable blood sugar parameters. I note, furthermore, that at no point in his testimony does Dr. Standridge explicitly characterize a blood sugar of below 60 as a slight deviation from general parameters. Nor does he ever explain what a slight deviation might consist of.

Indeed, what Dr. Standridge and Petitioner avoid addressing is the fact that Petitioner decided that resident blood sugar levels below 60 were *serious* and not slight changes. That is the whole point of establishing a protocol for physician consultation. If Petitioner and its staff concluded that a blood sugar level of below 60 was not serious, then why have a protocol that explicitly directs consultation in such instances? None of Petitioner's witnesses attempted to answer that question.

Dr. Standrige makes a second incorrect characterization by asserting that:

> Nurses obviously must follow physician orders, but orders must be interpreted correctly, and proper interpretation of an order requires consideration of both the applicable standard of care, as well as the context of the order.

P. Ex. 79, at 4. However, the physicians' orders that Petitioner's nursing staff violated in this case were plainly written. There was neither ambiguity nor "context" to these orders that made them subject to interpretation. This is not a case in which there is evidence showing that a facility staff, when confronted with ambiguous or conflicting orders and

protocols, made informed judgments about how to comply with them. There is no evidence whatsoever to show that the staff ever discussed Petitioner's diabetes protocol or physicians' orders in order to determine their appropriate meaning and application.[6]

Dr. Standridge also asserts that "the surveyors' opinions . . . are based on exaggeration of the seriousness of most high or low blood sugar readings." P. Ex. 79, at 6. This testimony is given to support the apparent argument that the surveyors who conducted the November survey were wrong in concluding that the blood sugar readings that Petitioner's staff failed to report were significant.

This assertion again mischaracterizes CMS's allegations. It was not the surveyors, but Petitioner, who determined that a blood sugar level of below 60 was a significant event that triggered the need for physician consultation. The issue here is whether Petitioner failed to comply with professionally recognized standards of care *as expressed in its own protocol and in physicians' orders*. Moreover, the credible expert testimony in this case – which mirrors precisely that which Petitioner told its staff – is that blood sugar level readings below 60 are significant. CMS Ex. 50, at 3. Dr. Standridge never states in his testimony that he disagrees with that conclusion.

Dr. Standridge asserts that:

> The correct interpretation of the order to "notify the physician" in the event of high or low blood sugar is to call the physician's office, or the on-call physician, for instructions in an emergency, or if the patient is exhibiting serious symptoms of high or low blood sugar, or if the routine interventions provided by the protocol are not effective.

P. Ex. 79, at 9. This is yet another assertion based on a mischaracterization. Petitioner's policy was not to notify the physician in the event of a blood sugar level that was merely "high" or "low." Petitioner adopted, and physicians ordered, a specific protocol with specific trigger numbers in it. Dr. Standridge, his testimony notwithstanding, never explains why the trigger numbers in Petitioners' protocol were unreasonable. Nor does Dr. Standridge reconcile his testimony with the fact that three of Petitioner's residents on

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[6] Petitioner argues that: "As a practical and legal matter it is unclear how Petitioner and its physicians are supposed to be on notice that they cannot rely on what is being taught at the nearby medical school simply because CMS takes a different position to 'win' in a particular enforcement case." Petitioner's post-hearing brief at 21. I am assuming that Petitioner is asserting that Dr. Standridge's testimony mirrors that which he teaches as a member of the faculty of the University of Tennessee Health Science Center College of Medicine, Chattanooga. There is nothing in Dr. Standridge's testimony that suggests that he teaches his students that it is permissible for staff nurses to ignore physicians' explicit written orders.

several occasions were exhibiting serious signs of low blood sugar and, still, Petitioner's staff failed to consult. Indeed, it is reasonable to conclude that Petitioner was noncompliant even if one assesses Petitioner solely based on Dr. Standridge's interpretation of Petitioner's protocol and physicians' orders and the facts of this case.

Another mischaracterization asserted by Dr. Standridge and Petitioner is that CMS premises its case on assertions that the nursing staff initiated emergency treatment of hypoglycemic residents *before* the staff contacted the residents' treating physicians. But, that is not the basis of CMS's case. One can debate whether a phone call to the physician should have been made in each case of hypoglycemia before any treatment was initiated. But, in fact, that question is moot because what happened here is very different. In this case the staff provided emergency treatment (snacks, sugar, glycogen) to hypoglycemic residents *without ever consulting treating physicians*. Thus, the treating physicians were never made aware contemporaneously of what the staff was doing for the residents and were never given an opportunity to modify, alter, or redirect treatment.

Dr. Standridge and Petitioner also suggest that CMS failed to take into consideration a unique aspect of Petitioner's operations that allegedly obviated the need for physician consultation. The allegedly unique aspect is that Petitioner's medical director and other attending physicians at Petitioner's facility rely on the advice and assistance of a nurse practitioner to evaluate and deal with routine issues, including most high and low blood sugar issues, and to communicate with them more significant issues requiring their personal attention. Petitioner's post-hearing brief at 22. Petitioner argues that communications with the nurse practitioner were an acceptable substitute for communications directly with the residents' treating physicians.

As I state above at n.1, I would evaluate this case very differently were there any evidence that Petitioner's staff consulted immediately with the nurse practitioner about residents' hypoglycemic episodes. But there is none. There is not a single record showing a contemporaneous communication with the nurse practitioner during a resident's hypoglycemic episode.

The regulation's requirement that there must be immediate communication with a resident's physician in the event of a significant medical change means exactly what it says. "Immediate" does not mean hours later or the next day. The fact that the nurse practitioner may have been apprised at some point after the fact about the residents' hypoglycemic episodes and the care that Petitioner provided for these residents is not compliance with the regulation's requirement for immediate consultation.

At bottom, Petitioner's arguments devolve into an assertion that it would be unrealistic to expect physicians to become involved with every instance of hypo- or hyperglycemia in a nursing facility such as Petitioner's. Petitioner asserts that it has several dozen diabetic residents at any time. Petitioner's post-hearing brief at 3. According to Petitioner, its medical director, John Patsimas, M.D., practices in rural Tennessee and has many, "perhaps thousands", of active patients. *Id.* Thus, according to Petitioner:

> It is not possible, nor is it desirable, for busy physicians to consult immediately regarding every blood sugar issue experienced by residents of nursing facilities that have nurses available to address such issues according to routine protocols.

Id.

Petitioner attempts to reinforce this argument with Dr. Patsimas' testimony:

> It is not reasonable for a nursing facility to call me, or any of . . . [the residents' treating physicians] about relatively trivial or routine matters at any time, but certainly not in the middle of the night or on weekends (when my nurse or receptionist cannot filter the calls), especially to report about matters that do not require my intervention. . . . There literally would not be enough hours in the day for me to attend to serious matters, conduct my office practice, etc. – not to mention get time off – unless I could rely upon a nursing facility staff's professional judgment about matters such as whether a routine intervention for a high or low blood sugar has produced the intended result.

P. Ex. 81, at 6. But, these assertions once again mischaracterize the record. The failures to consult that are the basis for CMS's assertions of noncompliance were not occasioned by relatively trivial or routine hypoglycemic events. There were instances where residents' blood sugar fell to life-threatening levels and there were no immediate consultations. Moreover, it was Dr. Patsimas, in his role as medical director and the residents' treating physician, who decided that blood sugar levels of below 60 were serious, that such results necessitated physician consultation, and who issued orders to that effect.[7]

[7] Dr. Patsimas' testimony is self-serving and not credible. As medical director, he was responsible for insuring that facility protocols and physicians' orders, including Petitioner's diabetes protocol and his own orders directing notification if blood sugars fell below 60, were carried out by the nursing staff. I view his testimony as an after the fact attempt to justify his failure to discharge his responsibilities.

The "physicians were too busy to be bothered" argument is offensive. Petitioner agreed to comply with Medicare participation requirements when it applied to qualify for Medicare reimbursement for residents of its facility. That agreement included doing whatever was necessary to assure that all Medicare participationrequirements were complied with scrupulously. Petitioner cannot justify failure to comply on the grounds that the physicians with whom it dealt – especially its medical director – were too busy to provide requisite care. Nor can it excuse providing care of a second-rate and inferior quality by contending that its circumstances are somehow unique.

Petitioner argues additionally that the care it provided to Residents #s 18, 27, 40, and 56 complied with all relevant Medicare participation requirements. As to Resident # 18, Petitioner argues that calling the resident's physician on October 27, 2007, 30 minutes after the resident was discovered in convulsions due to hypoglycemia, complied with the regulation's requirement for immediate consultation. I disagree. The resident's condition obviously was extremely grave and time was of the essence. In that situation Petitioner's staff was obligated to do exactly what the regulation required, and that was to consult with the physician immediately upon discovery of the resident in her hypoglycemic state and not to wait.

Petitioner contends that, on the morning of October 27 its nursing staff was faced with an "either or" situation. According to Petitioner, *either* the staff could have immediately initiated treatment in order to address the resident's critical hypoglycemia *or* it could have consulted with the treating physician and waited to begin caring for the resident until consultations were concluded. It argues that it made the right choice – to treat Resident # 18 – given that time was of the essence and should not now be penalized for making that choice.

However, this "either or" construct is specious because Petitioner's argument ignores the obvious. There was nothing to prevent Petitioner's staff from initiating emergency measures on that occasion and *simultaneously* consulting with the treating physician. Petitioner has not asserted that its staff was so limited on the 27th that a nurse could not have called the physician while another nurse simultaneously began providing emergency care to the resident.

Petitioner makes a somewhat similar argument concerning the care that its staff gave to Resident # 27. With respect to that resident's hypoglycemic episode of June 25, 2007 – when the resident's blood sugar level fell to 32 mg/dl and the resident was observed to have lost control of her extremities among other things – Petitioner contends that the staff in fact consulted with the nurse practitioner who represented Dr. Patsimas. Petitioner's

post-hearing brief at 42. However, the nurse practitioner's note which Petitioner cites as support for this contention shows only that the nurse practitioner became aware of the resident's hypoglycemic event hours after the fact. P. Ex. 39, at 2. It does not document any consultation much less immediate consultation.[8]

As respects Resident # 40, Petitioner's argument seems to be that failure to consult with the resident's physician for the resident's hypoglycemic episode on September 11, 2007 should not be regarded as evidence of a deficiency because the overall diabetes care that Petitioner's staff gave to the resident was good. Petitioner's post-hearing brief at 46-48. Petitioner argues also that the resident had uncontrolled diabetes, seemingly asserting that the resident's hypoglycemic episode was not a major event when viewed in that context. And, finally, Petitioner contends that CMS's assertions of noncompliance are exaggerated because the resident ate her entire breakfast on the morning of September 11. *Id.*

But, Petitioner has offered nothing to counter persuasive evidence showing that the resident's hypoglycemic episode on September 11 mandated immediate physician consultation. It is no exaggeration to characterize the event of that morning as potentially life-threatening. On the morning of September 11 the resident's blood sugar fell to a level of 28 mg/dl and the resident showed signs of confusion. Petitioner's own protocol, the resident's physician's orders, and commonly accepted nursing standards of care all demanded that the resident's physician be consulted immediately. Petitioner's failure to provide necessary care on that date is not excused by the resident's possibly uncontrolled diabetes or the ostensibly good care that may have been provided to the resident on other dates and occasions.

In the case of Resident # 56, Petitioner avers that it makes no excuse for the nursing staff's failure to consult immediately with the resident's treating physician on November 4, 2007, when the resident experienced an episode of bradycardia coupled with elevated serum potassium levels. However, according to Petitioner, this lapse is not evidence of any systemic problem at Petitioner's facility. Additionally, according to Petitioner, any deficiency evidenced by the failure to consult cannot be characterized as serious because the resident allegedly suffered no harm from the lapse.

I disagree with both of these arguments. First, the staff's failure to consult in the case of Resident # 56 supports other evidence of a systemic failure by Petitioner's staff to comprehend its responsibility to consult immediately with treating physicians when residents experienced significant medical changes in their conditions. It is part of a broad pattern of failures to consult when consultation was mandatory.

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[8] Petitioner did not call the nurse practitioner as a witness so there is no testimony from her that describes whether and when she was consulted.

Second, Petitioner's assertion that deficient conduct should be excused because a resident allegedly sustained no harm from that conduct is simply wrong as a matter of law. Actual harm certainly can be relevant to deciding whether a facility was deficient but it is not a necessary element of a finding of noncompliance. The issue here is whether noncompliant conduct created a potential for harm. The evidence in this case amply supports my conclusion that the potential for harm existed in abundance.

b. Petitioner failed to provide or arrange services that met professional standards of quality.

A skilled nursing facility is obligated by 42 C.F.R. § 483.20(k)(2) to provide care and services that meet professional standards of quality. There is no ambiguity to this regulation. It imposes on all skilled nursing facilities the duty to provide care commensurate with those standards of care that are recognized and widely practiced by the nursing profession.

The evidence that I discuss at Part a. of this Finding establishes plainly that Petitioner failed to provide or arrange services that met professional standards of quality in providing care to its diabetic residents and also to Resident # 56. The failures of the nursing staff consisted of at least the following:

- Failure to comply with Petitioner's written diabetes protocol;
- Failure to comply with physicians' orders; and
- Failure to consult with treating physicians about potentially life-threatening medical crises experienced by residents of the facility and the treatments that the staff initiated to address these crises.

These were egregious failures to comply with professionally recognized standards of care. Nursing standards of practice absolutely require compliance with a facility's standard protocols and with physicians' orders. CMS Ex. 47, at 4-5. And, they require consultation with physicians in every instance where a resident is exposed to potentially life-threatening complications of a medical condition as was the case here. CMS Ex. 50, at 3-4.

Petitioner asserts that CMS offered "no evidence at all regarding generally accepted – or generally available – published standards [of care]." Petitioner's post-hearing brief at 60. Petitioner seems to premise this statement on an assertion that standards of care, in order to be generally accepted, must be contained in published professionally utilized textbooks, journals, or other similar documents. It argues that CMS's case against Petitioner fails because CMS did not offer as exhibits the published documents which explicate applicable standards of care.

I find this argument to be without merit. CMS relied on the professional opinions of two of the surveyors, both nurses, who conducted the November survey and of a physician whose field of expertise includes geriatric care. CMS Ex. 47; CMS Ex. 48; CMS Ex. 50. The opinions of these experts are well-founded. Their knowledge, based on years of experience and professional training is, in my opinion, equal to anything that CMS might have found in a medical or nursing text. Petitioner's counsel cross-examined each of these witnesses at length and nothing was said by them during their cross-examination that undercut their credibility.

Petitioner also asserts that the standards enunciated by CMS's witnesses are "ad hoc, unpublished, and unknowable." Petitioner's post-hearing brief at 61. I disagree with Petitioner's characterization of these standards. The credible testimony of CMS's witnesses satisfies me that these standards – far from being obscure or ad hoc – are basic to the nursing profession. Indeed, I note that Petitioner's own witnesses never directly challenged the standards enunciated by CMS's experts. No witness whose testimony was offered by Petitioner averred, for example, that it is acceptable nursing practice for a nurse to disregard a physician's written order. Nor did any of them suggest that a nurse should be free to ignore a facility's express protocol for dealing with a particular medical event.

c. Petitioner failed to provide its residents with the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the residents' comprehensive assessment and plan of care.

The duty that is imposed on a skilled nursing facility by 42 C.F.R. § 483.25 is to provide each resident with services that are in accordance with the resident's comprehensive plan of care and which operate towards achieving the objective of enabling the resident to attain the highest possible level of physical, mental, and psychosocial well-being.

CMS argues, essentially, that the evidence which I have described at Part a. of this Finding establishes defects in Petitioner's nursing care that were so fundamental and widespread that residents could not be assured of receiving the care and treatment that was necessitated by their medical conditions. CMS's post-hearing brief at 26. More specifically, it points to the complete failure of Petitioner's staff to comply with the facility's diabetes protocol as an example of how the staff systematically failed to provide mandated care to residents.

I find CMS's arguments to be persuasive. The evidence in this case establishes overwhelmingly that Petitioner's nursing staff disregarded wholesale the express protocols and orders that had been issued to govern the care of diabetic residents. It establishes also that the staff failed to understand, even in the gravest of medical circumstances – as with the cases of Residents #s 18, 27, 40, and 56 – the need to operate under the control and supervision of physicians, and not as independent contractors.

Petitioner argues that CMS presented "no evidence at all to address the Section 483.25 element that some resident actually failed to achieve his or her highest practicable level of function." Petitioner's post-hearing brief at 60. But, "actual failure" to achieve a level of function is not a measure of a facility's compliance under the regulation. The issue is whether a facility offers the requisite services – which would include complying with physician orders or internal facility care protocols – not whether, in any case, the services provided caused the resident to achieve some measurable result.

d. Petitioner failed to ensure that its residents were free from significant medication errors.

On more than one occasion Petitioner gave residents medications in dosages that had not been prescribed. Staff misfeasance in medication administration posed grave, even life-threatening risks for residents at Petitioner's facility.

The evidence offered by CMS centers around administration of medications to two residents, Resident # 18, whose care I have discussed at Part a. of this Finding, and Resident # 48. I find that it provides compelling support for my conclusion that Petitioner failed to ensure that its residents were free from significant medication errors. I find also that Petitioner did not rebut this evidence.

CMS introduced compelling evidence of a serious error by Petitioner's staff in administering insulin to Resident # 18. This resident was readmitted to Petitioner's facility from a hospital on October 19, 2007. During her hospitalization the resident received insulin according to the following schedule: 20 units every morning at breakfast, and 10 units every evening at dinnertime. CMS Ex. 12, at 25; Tr. at 85. The insulin dosages were stated on a patient transfer form that was supplied to Petitioner's facility by the hospital when the resident was transferred there. *Id.* There is no evidence that any physician at the hospital or the resident's personal physician ordered that the resident be given insulin in doses other than that which the resident had been receiving while hospitalized.

However, and in an obvious misreading of the resident's hospital record, Petitioner's staff wrote an admission order for the resident on the date of her transfer which ordered administration of insulin in the following amounts: 55 units in the morning and 40 units in the evening. CMS Ex. 12, at 27. The error was due to a misreading of the hospital

transfer form by Petitioner's nursing staff. The form lists the resident's *home medications taken prior to admission to the hospital* as including insulin in amounts of 55 units in the morning and 40 in the evening. CMS Ex. 12, at 21. The nurse who transcribed the insulin dosage failed to comprehend that a superseding and much lower dose had been administered to the resident while she was hospitalized and that this lower dose had not been countermanded or rescinded by later orders.

The transcription error and the subsequent administration of overdoses of insulin to Resident # 18 had adverse effects. On the several days following the resident's readmission to the facility the resident had repeated hypoglycemic episodes culminating with the October 27, 2007 episode that caused her to experience convulsions. These episodes occurred on October 20 (blood sugar of 39 mg/dl at 8:00 a.m.), October 21 (blood sugar of 50 mg/dl at 1:00 a.m.), October 24 (blood sugar of 59 mg/dl at 11:00 a.m.), October 26 (blood sugar of 47 mg/dl at 8:00 p.m.) and twice on October 27 (blood sugar of 50 mg/dl at 7:00 a.m. and 20 mg/dl at 7:15 p.m.). CMS Ex. 12, at 12, 14, 16.[9]

Petitioner argues in its defense that its staff actually reasonably concluded that the dosages of insulin that they gave to Resident # 18 were correct and that there was no transcription error or significant medication error. I am not persuaded by this argument.

As support for its argument Petitioner cites to a hospital history, physical examination report, and discharge summary that was signed by Dr. Susan Briley, the resident's treating physician while she was hospitalized. P. Ex. 10. Petitioner asserts that this document was not transcribed until November 11, 2007 and therefore, could not have been used by Petitioner's nurses in transcribing the resident's admission orders on October 19, 2007.

This assertion is an obvious red herring. CMS never contended that Petitioner's nursing staff relied on Dr. Briley's report to determine appropriate insulin dosages. The evidence relied on by CMS consists of a patient transfer form that was completed on October 19, 2007, the date of the resident's discharge from the hospital (CMS Ex. 12, at 21-25) and which I infer was faxed to Petitioner's staff on that date. *Id.* at 21. This was the document that was mis-transcribed.

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[9] Had Petitioner's staff consulted with the resident's treating physician on any one of these instances – as was required by Petitioner's diabetes protocol and Petitioner's medical director's explicit order – the physician and the staff might have realized that the resident was receiving an insulin overdose. At the very least, the physician might have considered adjusting the resident's insulin dosage to account for her hypoglycemia.

Petitioner also argues that the patient transfer form required Dr. Briley to check which medications that the resident had been taking – at home or in the hospital – which she wanted the resident to continue taking while residing at Petitioner's facility. *See* CMS Ex. 12. Petitioner argues that Dr. Briley did so as part of the hospital's discharge process. According to Petitioner, check marks next to the insulin dosages under the "Home Meds Prior to Admission" heading clearly told Petitioner's staff that Dr. Briley wanted Petitioner to continue administering insulin in the doses of 55 units in the morning and 40 at night. Petitioner's post-hearing brief at 30; *see* CMS Ex. 12, at 21.[10]

But, this argument collapses the instant one looks at the exhibit. It is true that someone (Dr. Briley was not called as a witness so it is simply speculation to contend it was her) put check marks next to the dosages of insulin listed under the home medications heading. But, someone also put check marks next to the much smaller dosages listed further on in the patient transfer form. *Id.* at 25. Following Petitioner's logic, that would evidently mean that Dr. Briley wanted Petitioner to administer 55 units *plus* an additional 20 units of insulin to Resident # 18 in the morning and 40 units *plus* an additional 10 units of insulin to the resident in the evening. That obviously makes no sense.

The logical reading of the resident's hospital transfer form was that the resident's insulin dosages had been reduced while in the hospital. It was also entirely logical to read the record to mean that no increase of insulin dosages had been ordered after discharge inasmuch as nothing in the hospital record supplied to the facility on October 19, 2007 directs that dosages be increased.

Moreover, even if there had been some ambiguity in the hospital record, that did not give the staff the authority to make an uninformed conclusion as to which dosage was the prescribed amount. At the least, the nursing staff should have consulted with Dr. Briley about the insulin dosage she intended to be administered to Resident # 18.

The evidence presented by CMS concerning the care given to Resident # 48 establishes an equally compelling case of a significant medication error. The resident was readmitted to Petitioner's facility on August 2, 2007, with an order for the medication Tegretol. The hospital discharge orders specified that the medication, which had been administered in a dosage of 200 mg, twice daily, be reduced to 200 mg, once per day. CMS Ex. 33, at 5. Notwithstanding, Petitioner's nursing staff erroneously recorded the

[10] It is utter speculation for Petitioner to assert that its staff relied on check marks or other handwritten notations on the hospital transfer form. None of Petitioner's staff testified and so, there is no evidence to show what staff may have thought about check marks when copying the incorrect insulin dosages from the hospital transfer form.

prescribed dosage of Tegretol as 200 mg administered twice daily. CMS Ex. 33, at 8. The staff repeated this error in September. CMS Ex. 47, at 8; CMS Ex. 48, at 15. Resident # 48 thus received 400 mg of Tegretol daily − double his prescribed dose − from August 2 through September 13, 2007.

Overdoses of Tegretol can cause serious and even lethal damage. CMS Ex. 50, at 5. Potential complications include neutropenia (an abnormally low number of white blood cells, which can expose a patient to life-threatening bacterial infection), and impaired liver and cardiac function. *Id.*

Petitioner admits that its staff gave Resident # 48 a prolonged dosage of Tegretol that was double the prescribed amount. Petitioner denies that the error was significant. According to Petitioner, the overdose would not have exposed the resident to any risk of harm much less serious harm or death. Petitioner's post-hearing brief at 49. Petitioner asserts that a dose of 400 mg per day – which was the amount that Resident # 18 was receiving instead of the 200 mg per day which had been prescribed for him – is actually a low dose of the medication. A therapeutic dose of the medication can range up to 800 to 1200 mg. per day, according to Petitioner. Moreover, Petitioner contends, blood tests of the resident showed no actual harm because the 400 mg per day of Tegretol that the resident had been receiving in fact produced a sub-therapeutic level of the medication in the resident's blood. Thus, Petitioner argues that even if Resident # 48 received an overdose of Tegretol, it was well within the margin of error and posed no danger. *Id.* However, the issue here is not whether Resident # 48 was actually harmed by the overdose of Tegretol. Nor is Petitioner's case helped by the fact that the dosage the resident received turned out, in retrospect, to not be a threat to his health.

Petitioner's argument is essentially a post hoc excuse for administering the Tegretol overdose to Resident # 48. Obviously, the resident's physician had a reason for limiting the medication to 200 mg per day and not 400 mg as was given by Petitioner's staff. And, as was testified to credibly by Dr. Schmitt, there was a potential for adverse consequences from an overdose even if those consequences did not occur.

The inaccurate transcription of prescriptions and the subsequent overdosing of not one but two residents at Petitioner's facility establish a pattern of sloppiness by Petitioner's nursing staff. There was an evident failure by the staff to exercise necessary diligence to make sure that prescriptions were transcribed accurately and that the correct dosages of medication were given to residents. That pattern posed a great risk for residents. Even if the error in the case of Resident # 48 might not actually have posed jeopardy for the resident, it supports a finding that, overall, Petitioner's staff was administering medications to its residents in a decidedly careless and unsafe way. The potential for harm from this weakness in Petitioner's operations was substantial.

e. Petitioner was not administered in a manner that enabled it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being for each of its residents.

CMS's argument that Petitioner failed to comply with the requirements of 42 C.F.R. § 483.75 is based on the findings of noncompliance that I make at Parts a.-d. of this Finding. Essentially, CMS reasons that the widespread and pervasive deficiencies that were present at Petitioner's facility provided proof that Petitioner was not managed in an effective or efficient manner. Petitioner offered neither evidence nor argument to rebut CMS's assertions of management failure.

I find CMS's logic to be compelling. The systemic failure of Petitioner's nursing staff to comply with physicians' orders and with Petitioner's internal protocol can and should be laid at the feet of Petitioner's management. It was Petitioner's management that bore ultimate responsibility for assuring that its internal policies – as expressed in its protocols – and physicians' orders were effectively carried out. The wholesale failure of Petitioner's nursing staff to do so shows a disregard for this responsibility.

2. Petitioner did not prove CMS's determination of immediate jeopardy level noncompliance to be clearly erroneous.

An immediate jeopardy level deficiency is one in which a facility's noncompliance causes or is likely to cause serious injury, harm, impairment, or death to a resident or residents. 42 C.F.R. § 488.301. The evidence in this case overwhelmingly demonstrates that Petitioner's noncompliance caused residents of its facility to be in immediate jeopardy. There was a high probability that residents would suffer serious injury, harm, or death, from:

- The nursing staff's wholesale disregard of Petitioner's diabetes protocol and of explicit physicians orders;

- The staff's failure to consult with residents' physicians in circumstances that clearly constituted medical emergencies;

- The egregious errors that the staff made in transcribing medication orders and administering medication to residents; and

- The failure of Petitioner's management to assure that facility protocols and physicians orders were executed by the nursing staff.

The failure of Petitioner's nursing staff to consult with residents' treating physicians about the hypoglycemic crises sustained by residents #s 18, 27, and 40 certainly put these

residents at a high likelihood of suffering serious harm including seizures, coma, or death. CMS Ex. 50, at 5. The failure to consult in the case of Resident # 56, when the resident experienced an incidence of bradycardia coupled with very elevated serum potassium levels, exposed this resident to a likelihood of serious harm at the least. *Id.* at 6.

These examples are part of a much broader pattern of resident-endangering noncompliance which I have discussed at length in this decision. The operations at Petitioner's facility were essentially anarchic, with nursing staff acting without apparent guidance from anyone when they dealt with residents' medical crises.

Petitioner did not offer evidence that proved CMS's immediate jeopardy determination to be clearly erroneous. Petitioner contends that the surveyors' and CMS's medical expert's opinion as to the probabilities of harm or worse resulting from its noncompliance may be laid to "somewhat overheated rhetoric about the likely, or even potential, impact of . . . errors. . . ." Petitioner's post-hearing brief at 63. In the main, however, it argues that it complied with Medicare participation requirements and that the premise for finding immediate jeopardy is wrong.

I do not find the conclusions of CMS's experts to be overheated. The testimony that these witnesses offered is persuasive. CMS Ex. 47; CMS Ex. 48; CMS Ex. 50. Nothing said by these witnesses during their cross-examination impeached their credibility.

Petitioner also contends that there could not have been immediate jeopardy at its facility because none of the residents whose specific care I have discussed in this decision suffered lasting harm from the care that Petitioner's staff rendered. This argument is without merit because proof of actual harm is not a prerequisite to finding immediate jeopardy. That residents did not suffer lasting injury or die from the actions or inactions of Petitioner's staff was fortuitous, but that does not detract from my finding that the likelihood of serious injury or worse was very high in those specific instances that I have discussed.

3. Civil money penalties of $6,550 per day are reasonable remedies for Petitioner's noncompliance.

The permissible range for civil money penalties that are imposed to remedy immediate jeopardy level deficiencies is from $3,050 to $10,000 for each day of noncompliance. 42 C.F.R. § 488.438(a)(1)(i). There are regulatory criteria which must be applied to decide where within this range a penalty amount should fall. These criteria include: the seriousness of a facility's noncompliance; its compliance history; its culpability; and its financial condition. 42 C.F.R. §§ 488.438(f)(1) – (4); 488.404 (incorporated by reference into 42 C.F.R. § 488.438(f)(3)).

CMS determined to impose civil money penalties of $6,550 per day for each day of a period that began on June 25 and which continued through November 27, 2007. The penalty amount falls within the middle of the permissible range for immediate jeopardy level noncompliance. The duration of penalties is based on CMS's determination of the beginning and end dates of the immediate jeopardy level noncompliance at Petitioner's facility.

CMS's remedy determination is reasonable both in terms of duration and amount. Petitioner has offered no evidence directly challenging the determination of duration. It has not contended that, if there was immediate jeopardy noncompliance, it began later than or ended earlier than the dates determined by CMS. Consequently, I sustain CMS's duration determination.[11]

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

Petitioner does not aver that its financial condition precludes it from paying the penalties. Instead, it once again challenges the evidence addressing the noncompliance and its seriousness. That is evidence which I have discussed at length in this decision and which I will not revisit here. It asserts that it is unfair to impose so large a civil money penalty amount given that CMS, in the end, elected to pursue only five of the many deficiencies that were cited in the November survey report. It argues that "retroactive" civil money penalties have no remedial value and that they should not be imposed against it. And, it contends that the total civil money penalty amount, more than $1,000,000 in this case, is unreasonable.

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[11] Petitioner complains that the beginning date of noncompliance determined by CMS was arbitrarily set based on the first date that Resident # 27 had a hypoglycemic episode. Petitioner's post-hearing brief at 68, n.20. I do not find that date to be arbitrary inasmuch as the evidence plainly establishes immediate jeopardy level noncompliance as of that date.

There is nothing unfair about basing the remedy in this case on the five deficiencies that I have addressed in this decision. The remedy is amply supported by evidence establishing the egregiousness of these deficiencies. Indeed, I would have sustained penalties of $6,550 per day against Petitioner based on the presence of any of these deficiencies, given their seriousness and the probability of harm or worse that they created.

The total amount of the penalties is simply a reflection of the duration of Petitioner's noncompliance and it is plainly authorized by the Act and regulations. Act § 1819(h)(2)(B)(ii); 42 C.F.R. § 488.438(a)(1)(i). I do not find it to be punitive because it fairly reflects the seriousness of Petitioner's noncompliance.

Nor do I understand Petitioner's assertion that the penalties are unreasonably "retroactive." All civil money penalties are retroactive when they address noncompliance that predates a survey, as was the case here. That is perfectly consistent with what Congress envisioned in adopting section 1819 of the Act.

/s/
Steven T. Kessel
Administrative Law Judge