Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Quality Care Health Center,
(CCN: 44-5154),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-09-448

Decision No. CR2101

Date: April 1, 2010

DECISION AND ORDER OF REMAND

I find no basis to impose immediate jeopardy level civil money penalties against Petitioner, Quality Care Health Center.

However, there remain additional issues, which neither party developed sufficiently for me to hear and decide. That is whether Petitioner failed to comply substantially, at the non-immediate jeopardy level of noncompliance, with the requirements of 42 C.F.R. § 483.10(b)(11)(i)(B) and whether a remedy should be imposed for any noncompliance that may have occurred. I find that the Centers for Medicare & Medicaid Services (CMS) failed to make a determination addressing the issue of remedy, and the parties did not address either the issue of noncompliance or remedy adequately in their briefs and evidentiary submissions. For those reasons, I remand this case back to CMS in order that CMS may make a determination.

I. Background

Petitioner is a skilled nursing facility located in the State of Tennessee. It participates in the Medicare program. Its participation in that program is governed by sections 1819 and 1866 of the Social Security Act and by implementing regulations at 42 C.F.R. Parts 483 and 488.

On March 11, 2009 (March 11 Survey), Petitioner was surveyed in order to determine whether it was complying with Medicare participation requirements. The surveyors found that Petitioner failed to comply with numerous Medicare participation requirements. They concluded that six of these alleged deficiencies were so egregious as to comprise immediate jeopardy for residents of Petitioner's facility. 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. 42 C.F.R. § 488.301.

CMS concurred with the surveyors' findings. It determined to impose remedies consisting of civil money penalties of: $3,050 per day for each day of a period that began on December 13, 2008 and which ran through March 25, 2009; and $250 per day for each day of a period that began on March 26, 2009 and which ran through March 30, 2009.

Petitioner requested a hearing, and the case was assigned to me for a hearing and a decision. I ordered the parties to file pre-hearing exchanges, including their proposed exhibits and briefs. Acknowledgment and Initial Pre-Hearing Order, May 18, 2009 (initial pre-hearing order). The parties completed their exchanges, and Petitioner then moved for summary disposition.[1] CMS opposed the motion, and I denied it. The parties then agreed that this case could be decided based on their pre-hearing exchanges and without an in-person hearing.

CMS filed a total of 38 proposed exhibits that it identified as CMS Ex. 1 – CMS Ex. 38. Petitioner filed 10 proposed exhibits that it identified as P. Ex. 1 – P. Ex. 10. I receive all of these exhibits into the record.

[1] In fact, CMS counsel failed to comply with my initial pre-hearing order. Her initial submission did not contain the written direct testimony of witnesses notwithstanding my explicit instruction that all testimony be filed in writing. I granted her a week within which to comply, and counsel then filed the written direct testimony of a surveyor.

I note that CMS, in its Brief in Lieu of Hearing (CMS's Final Brief), states that it attached a document, identified as Attachment 1, to the brief. CMS's Final Brief at 18. This document is described by counsel for CMS as a publication from the United States Department of Health and Human Services, Agency for Healthcare Research and Quality, which addresses risk factors attending the use of the medication Coumadin that might require physician consultation when clinical signs corresponding to those risk factors become evident. *Id.* at 18.

However, no such attachment was appended to CMS's final brief. Moreover, had CMS submitted it, I would have almost certainly excluded it from evidence, because the document – based on counsel's description – contains opinion evidence that would arguably be relevant to the issues that I hear and decide in this case. Counsel for CMS should have filed the document with her pre-hearing exchange. Or, counsel could have moved to show good cause for filing it late. But, simply attaching such a document to a final brief and asking that it be considered is not compliant with my initial pre-hearing order that set deadlines for submissions of evidence.

II. Issue, findings of fact and conclusions of law

A. Issue

The single issue that I decide is whether Petitioner failed to comply substantially with any of the six participation requirements that the surveyors who conducted the March 11 Survey cited as having been contravened by Petitioner at the immediate jeopardy level of noncompliance. CMS Ex. 1 at 1-16; 18-27; 48-56.

I do not address the multiple non-immediate jeopardy level deficiencies that were cited in the March 11 Survey separately from the alleged immediate jeopardy level deficiencies. I do not do so because CMS addressed none of them, either in its pre-hearing brief or in its final brief. My initial pre-hearing order instructed each party explicitly to address each issue that it intended to prove. CMS's failure to address the alleged non-immediate jeopardy noncompliance in light of that is tantamount to abandonment of that alleged noncompliance.[2]

---

[2] In its pre-hearing brief CMS said, with respect to the alleged non-immediate jeopardy deficiencies that:

> Evidence related to remaining non immediate jeopardy tags as cited within the text of the March, 2009 2567 [survey report] will be presented via documents as listed in the enclosed witness list and via the written and oral testimony of surveyors listed on the enclosed witness list.

(continued…)

However, there is an additional finding of non-immediate jeopardy level noncompliance, which CMS discussed in passing in its pre-hearing brief although not subsequently. That is whether Petitioner failed to comply substantially, at the non-immediate jeopardy level of noncompliance, with the requirements of 42 C.F.R. § 483.10(b)(11)(i)(B). CMS's allegations of noncompliance with this regulation address three residents, identified in the report of the March 11 Survey as Residents #s 8, 15, and 19. Allegations concerning Resident # 8, which I discuss in detail below, have to do with the asserted failure of Petitioner's staff to consult with an on-call physician concerning an episode of bleeding that the resident experienced. CMS alleges that this asserted noncompliance is at the immediate jeopardy level of noncompliance. Allegations concerning the other two residents, Residents #s 15 and 19, have to do with the residents' loss of weight over a period of months and the staff's alleged failure to consult with the residents' physicians about these allegedly significant changes in the residents' conditions. These allegations are at the non-immediate jeopardy level of noncompliance. CMS Ex. 1 at 1.[3]

The parties briefed the allegations of immediate jeopardy level noncompliance concerning Resident # 8. They barely addressed those allegations made about Residents #s 15 and 19. CMS devoted a scant page of its opening brief to discussing these residents and the care that they received. CMS's Pre-Hearing Brief at 5-6.[4] It never again discussed the care that Petitioner gave to these residents, except to state in its final brief

---

[2] (…continued)

CMS's Pre-Hearing Brief at 8. That laconic assertion is utterly inconsistent with what I ordered in my initial pre-hearing order. Furthermore, counsel for CMS either knows or should know better because she has made such statements in other cases and, on those occasions, I have struck CMS's allegations for the same reason that I strike them here.

[3] The report of the March 11 Survey explicitly distinguishes between alleged immediate jeopardy level noncompliance with respect to Resident # 8 and alleged non-immediate jeopardy level noncompliance with respect to Residents #s 15 and 19. The report states:

> the facility failed to notify the physician of one resident # 8, who was receiving anticoagulation therapy of bleeding in the mouth, *placing resident # 8 in immediate jeopardy*; failed to notify the physician of significant weight loss for two residents #15, #19, *resulting in harm to resident #15, and resident #19.*

CMS Ex. 1 at 1 (emphasis added).

[4] In her opening brief, counsel represented that she would provide testimony concerning the care that Petitioner gave to Residents #s 15 and 19 but, in fact, she failed to offer any testimony pertaining to these two residents.

that it relied on "evidence submitted on the record" pertaining to the two residents without stating what that evidence is or what it means. CMS's Final Brief at 16.[5] At no time did CMS address the issue of whether a separate, non-immediate jeopardy level civil money penalty would be merited for Petitioner's alleged non-immediate jeopardy level noncompliance concerning the two residents. It did not address duration of noncompliance and, of course, it provided me with no guidance as to how to decide penalty amount.

For its part, Petitioner assumed, correctly, that the findings concerning the two residents were irrelevant to CMS's allegations of immediate jeopardy level noncompliance. But, it then made a logical leap by concluding that the allegations concerning these two residents were simply irrelevant to the case. For that reason, apparently, Petitioner did not offer evidence or argument concerning the merits of CMS's findings regarding the two residents (although it did challenge them in its hearing request).

There remains an open question of whether non-immediate jeopardy level noncompliance with the regulation might justify the imposition of a remedy against Petitioner. I conclude that CMS did not abandon the non-immediate jeopardy level allegations about the care Petitioner gave to Residents #s 15 and 19, because it addressed them in its pre-hearing brief, albeit in cursory form.

The record is, at this juncture, undeveloped as to the care given to the two residents. I conclude that it would be unfair to Petitioner if I were to decide the merits of CMS's allegations inasmuch as Petitioner may have been misled into believing that it had did not have to develop evidence concerning the care it gave to Residents #s 15 and 19 by CMS's failure to address the care given to these residents as a separate, non-immediate jeopardy

level deficiency. It would also be inappropriate to decide the merits as pertains to the two residents, because CMS has provided me with no guidance as to what it would seek as a

---

[5] In its brief in opposition to Petitioner's motion for summary judgment, CMS stated that it:

> Clearly asserted in the . . . [March 11 Survey report], which is the proper notice document in this enforcement action, that Residents 15 and 19 were considered to be in immediate jeopardy. . . .

CMS's Brief in Opposition to Petitioner's Summary Judgment Motion at 2. This is an incorrect assertion. As I discuss, the March 11 Survey explicitly distinguishes between Petitioner's alleged immediate jeopardy level noncompliance with respect to Resident # 8 and its alleged non-immediate jeopardy level noncompliance with respect to Residents #s 15 and 19. CMS did not repeat its assertion in its final brief.

remedy were I to sustain a finding of non-immediate jeopardy noncompliance with the physician consultation requirement.

I remand to CMS the question of whether it wishes to make a remedy determination based on the non-immediate jeopardy level findings pertaining to the two residents that were cited as evidence of non-immediate jeopardy level noncompliance with 42 C.F.R. § 483.10(b)(11)(i)(B).[6] If CMS makes such a determination then, of course, Petitioner would have a right to request a hearing in order to challenge both the underlying findings and the amount and duration of any civil money penalty that CMS may determine to impose.

B. Findings of fact and conclusions of law

I make the following findings of fact and conclusions of law (Findings).

1. Petitioner complied with the requirements of 42 C.F.R. § 483.10(b)(11)(i)(B).

The regulation that is at issue states in relevant part that a facility must immediately consult with a resident's physician when there is:

> A significant change in the resident's physical, mental, or psychosocial status (i.e., a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications).

42 C.F.R. § 483.10(b)(11)(i)(B).

Resident # 8 has resided at Petitioner's facility since January 2005. The resident has a number of medical problems including Alzheimer's disease, hypertension, and chronic atrial fibrillation. She receives Coumadin, a medication that is typically prescribed to increase blood clotting time. I take notice that Coumadin often is prescribed to individuals who experience atrial fibrillation in order to protect those individuals from developing blood clots that might cause strokes.

[6] I am deciding all other issues that are before me and my decision as to those issues, and also as to whether remand of the issue of non-immediate jeopardy level noncompliance with the requirements of 42 C.F.R. § 483.10(b)(11)(i)(B), may be appealed.

Petitioner's staff was aware that there are risks – principally bleeding and loss of blood – associated with the consumption of Coumadin. CMS Ex. 16 at 16.[7] In obvious recognition of these risks, Petitioner's professional staff was instructed to: monitor the resident's blood clotting times as ordered; keep an antidote (Vitamin K) available for the resident; use a soft bristled toothbrush to brush the resident's teeth; handle the resident with extreme caution due to the resident's risk of sustaining bruises; assess the resident regularly for blood in urine and stools, bleeding gums, tarry stools, easy bruising, petechiae, nosebleeds, melena, and hematemesis (blood in vomit); and call the resident's physician as needed. CMS Ex. 16 at 16.

Petitioner's staff tested the resident's blood clotting times at relative regular intervals using tests known as Prothrombin Time (PT) and international normalized ratio (INR) to measure clotting times. CMS Ex. 16 at 59-62. The test results for this resident showed clotting times that were within therapeutic ranges. *Id.* There were no test results showing abnormally prolonged clotting times that would have put Petitioner's staff on notice that the resident was at a greater risk for developing bleeding than any individual who receives Coumadin and who is experiencing therapeutic effects of the medication. In other words, the medication prolonged the resident's clotting time but, according to test results, not abnormally so.

CMS asserts that Petitioner's deficient care to Resident # 8 commenced early in the morning of December 13, 2008. At 1:00 a.m. on that date, a nurse was advised by certified nursing assistants (CNAs) that there was a blood tinged spot on the left side of the resident's gown above the resident's shoulder. CMS Ex. 16 at 32. The nurse assessed the resident and saw dried blood on the resident's lips. *Id.* She obtained a medical device known as a toothete to clean the resident's mouth and discovered a "large" blood clot about the size of a quarter. *Id.*; P. Ex. 4 at 1. After cleaning the resident's mouth, the nurse observed no additional bleeding. P. Ex. 7 at 1. The nurse checked the resident's body for signs of bleeding or bruising and there were none observed. *Id.*

---

[7] CMS elected not to offer any expert testimony, nor has it referred to any professionally accepted standards of care, concerning the risks associated with the administration of Coumadin. The testimony of CMS's sole witness, Sarah Hardy, R.N., does not describe the risks that are inherent with taking Coumadin nor does it describe the routine precautions that a facility must take in order to monitor such a patient. *See* CMS Ex. 38. As I discuss above, counsel for CMS asserted that she had included an attachment with its final brief that discusses these risks. However, she failed to provide it and I would have excluded it as being filed late and without good cause had it been provided. Consequently, my conclusion in this case that Coumadin administration carries risks is based solely on that which Petitioner's own staff recognized and discussed in the resident's plan of care. CMS Ex. 16 at 16.

The nurse determined that the resident required additional monitoring. CMS Ex. 16 at 32. She instructed the CNAs to watch the resident closely during the night so that if additional bleeding occurred it could be assessed quickly. P. Ex. 7 at 1.

At 3:00 on the morning of December 13, 2008, the nurse again cleaned Resident # 8's mouth. She found and removed another large blood clot. CMS Ex. 16 at 31. The nurse then called and consulted with an on-call physician. *Id.*; P. Ex. 4. The physician inquired about: the size of the blood clot that had been removed; whether the resident was bleeding actively; whether there was blood in the resident's urine or stools; and the resident's vital signs. P. Ex. 4 at 1. He and the nurse speculated that the resident's oral bleeding might be the consequence of dental problems. *Id.* The physician ordered continued monitoring of the resident in light of his consultation with Petitioner's nurse and his knowledge of the resident's history. *Id.* However, he also told the nurse that the resident should be sent to an emergency room if more blood was discovered. *Id.*; P. Ex. 7 at 2.

At 7:00 on the morning of December 13, Petitioner's assistant director of nursing (ADON) came on duty. P. Ex. 7 at 2. After consulting with the nurse, the ADON decided that it would be prudent to send Resident # 8 to the emergency room. P. Ex. 6 at 1. This decision was motivated in part by the ADON's concern that INR test results to measure the resident's blood clotting time might be unduly delayed because December 13, 2008 was a Saturday. *Id.* The resident was then sent to the hospital where it was discovered that she was suffering from Coumadin toxicity.

CMS argues that these facts are prima facie proof that Petitioner failed immediately to consult with a physician about a significant change in Resident # 8's condition. It contends that the blood clot and dried blood that were observed at 1:00 on the morning of December 13 constituted a significant change, and that failure immediately to consult with the resident's physician at 1:00 a.m. was a violation of the consultation requirement.

I find CMS's assertion to be unpersuasive for two reasons. First, CMS failed to offer prima facie evidence that the signs of bleeding observed at 1:00 a.m. on December 13 constituted a significant change in the resident's condition necessitating consultation. Second, the preponderance of the evidence shows that Petitioner's staff reacted appropriately to the signs exhibited by the resident on December 13.

CMS has offered no evidence to show exactly when or under what circumstances bleeding – such as that demonstrated by Resident # 8 – would necessitate physician consultation. It is unquestionable that bleeding by an individual who is receiving Coumadin *may be* a sign of Coumadin toxicity and Petitioner's staff clearly was aware of that. CMS Ex. 16 at 16. But what is unclear, and CMS has provided no evidence that provides clarification, is *at what point* does bleeding by a resident who is receiving Coumadin become so significant as to necessitate consultation. CMS seems to be

arguing that any bleeding, no matter how slight, triggers the consultation requirement. But, if that is CMS's position, it has offered no evidence, either in the form of expert testimony or as a recognized treatise on the risk factors associated with taking Coumadin, that would support that argument.

What is known about Resident # 8 is that at 1:00 a.m. on December 13, 2008, the staff observed signs of bleeding that had ceased. There was no fresh blood in the resident's mouth at that time, nor was there fresh blood elsewhere. There was no sign of active bleeding at 1:00 a.m., and the staff could have reasonably assumed that whatever bleeding had occurred prior to 1:00 a.m. was a transitory event that had been resolved. It does not strike me as being unreasonable that the staff would determine to continue to monitor the resident at that point without consulting with the treating physician. My conclusion is consistent with the opinion expressed by the resident's personal physician. P. Ex. 2 at 2.

Nor were Petitioner's staff's actions on December 13, 2008 inconsistent with the resident's plan of care. The plan of care directed Petitioner's staff to monitor the resident for, among other things, bleeding gums, and blood in the resident's urine and stools and to: "Call M.D. as needed." CMS Ex. 16 at 16. The care plan thus gave a certain amount of discretion to determine when consultation was required. There was nothing in the plan, for example, that mandated consultation at the first sign of bleeding. *Id.* I am not suggesting that the plan of care excused the staff from carrying out their professional responsibilities to consult in the presence of a significant change in the resident's condition. But, the plan did not define for the staff what would constitute a significant change and it certainly imposed on them no duties that were greater than that which is required by regulation.

CMS argues also that the staff's failure to consult with the on-call physician at 1:00 a.m. on December 13 was inconsistent with Petitioner's anticoagulant policy, "which required physician notification with symptoms similar to Resident 8's." CMS's Final Brief at 9. CMS has cited to no exhibit that contains this alleged anticoagulant policy, and I am at a loss to explain or comprehend what CMS is alluding to. The sole citation that CMS gives for its assertion is the affidavit of the surveyor who conducted the March 11 Survey. *See* CMS Ex. 38 at 3. But, in fact, the surveyor merely states that such a policy exists without giving any foundation for her assertion and without reciting the policy's contents. I do not find this assertion to be credible absent some concrete evidence as to the existence of the alleged policy and, more particularly, as to its contents.

The staff's determination to consult with an on-call physician at 3:00 a.m. on December 13 appears to have been a prudent reaction to further developments that suggested a potentially significant change in the resident's condition. The presence of a second blood

clot in the resident's mouth at 3:00 a.m. was evidence that the resident's bleeding had not ceased. At 3:00 a.m., the staff reacted entirely appropriately by having a detailed telephone consultation with the on-call physician and by following his orders. P. Ex. 4 at 1.

2. Petitioner complied with the requirements of 42 C.F.R. §§ 483.20 and 483.20(b).

The regulation that is at issue here provides generally that a skilled nursing facility must conduct initially and periodically a comprehensive, accurate, standardized, and reproducible assessment of each resident's functional capacity. Subsection (b) states that the comprehensive assessment must use a resident assessment instrument (RAI) as is specified by a relevant State government. At subpart (1), it itemizes the various elements that must be included in the comprehensive assessment, in effect defining what is meant by a "comprehensive assessment" within the context of the regulation. Subpart (2) of subsection (b) sets forth the time frames when comprehensive assessments must be made and updated.

The gravamen of CMS's allegations concerning Petitioner's alleged noncompliance with this regulation is that Petitioner's staff failed to assess Resident # 8 *on the morning of December 13, 2008* during the sequence of events that I describe at Finding 1 of this decision. CMS alleges that Petitioner's staff failed to:

- document the resident's vital signs or make a physical assessment of the resident at 1:00 a.m. on the 13th when blood was first observed on the resident's garment and a blood clot was discovered in the resident's mouth;

- conduct any assessment of the resident between 1:00 and 3:00 on the morning of the 13th; and

- conduct any assessments of the resident between 3:00 a.m. and 7:00 a.m. on the 13th.

I find CMS's allegations to be unpersuasive for two reasons. First, whatever Petitioner's obligations may have been to Resident # 8 on the morning of December 13, 2008, those obligations – and any failure by Petitioner to fulfill them – cannot be characterized as noncompliance with the requirements of 42 C.F.R. §§ 483.20 and 483.20(b). Second, and notwithstanding CMS's assertions, Petitioner assessed Resident # 8 reasonably in order to keep abreast of her condition and to keep the on-call physician informed of the problems she might be experiencing.

The regulation relied on by CMS requires a facility to perform periodic and comprehensive assessments of a resident's condition. It is a regulation that is designed to assure that a skilled nursing facility perform thorough periodic assessments as part of a comprehensive care planning process. However, the formalized and comprehensive assessments envisioned by the regulation are not at all at issue here. Here, the question is not whether the facility complied with the comprehensive assessment requirements but whether the facility performed another type of assessment not discussed by the regulation, an on-the-spot assessment to determine whether immediate and previously unplanned action needed to be taken in order to protect the resident from sustaining harm.

The actions (or inactions) of Petitioner's staff on the morning of December 13, 2008 simply do not fall within the reach of the comprehensive assessment regulation. Whatever the merits of what the staff did on that morning, these actions cannot be evaluated in terms of a possible violation of 42 C.F.R. § 483.20. For that reason alone, I find no noncompliance with the regulation.[8]

What is really at issue here is whether the nursing staff appropriately assessed Resident # 8 in a potentially emergency situation in order to determine what immediate action needed to be taken on the resident's behalf. The assessments that the staff needed to perform on the morning of December 13, 2008 were simply not the kind of comprehensive assessments discussed in the regulation. These assessments, to the extent that they occurred, would have been ad hoc assessments of the resident's condition to determine: whether to consult with the on-call physician; and what to tell that physician.

The preponderance of the evidence supports a conclusion that the staff made the necessary on-the-spot assessments. Contrary to CMS's contentions, the staff did assess the resident for the purpose of deciding whether, and how, to communicate with the on-call physician. They observed the clinical signs of bleeding and blood clots, made measurements, evaluated the possible cause or causes of the bleeding and blood clots, measured vital signs, and communicated to the on-call physician that information and their opinion as to the possible cause of the resident's problem.

At 1:00 a.m., the nurse who saw Resident # 8 recorded the presence of dried blood on the resident's lips, the blood tinged spot on the resident's garment, and the presence of a large blood clot in the resident's mouth. CMS Ex. 31 at 16. Those observations caused the nurse to conclude that continued monitoring of the resident was necessary. *Id.* The

[8] The regulation provides, at 42 C.F.R. § 483.20(b)(2)(ii), that a facility must conduct a comprehensive assessment of a resident, as is defined at 42 C.F.R. § 483.20(b)(1), within 14 calendar days after the facility determines, or should have determined, that there has been a significant change in the resident's physical or mental condition. CMS did not allege that Petitioner failed to conduct a comprehensive assessment within the 14-day time frame and, so, I do not address that possible issue here.

assessment that the nurse made at that time – that the resident needed to be monitored in light of the observed signs of past bleeding – appears to have been prudent. Finding 1. CMS has offered no evidence to explain why doing more than that at 1:00 a.m. on the 13th would have been necessary. As I discuss above, CMS has not provided any evidence establishing a standard of nursing care that would have required the staff to do more for the resident at 1:00 a.m. given what the staff observed.

For example, CMS criticizes Petitioner's staff for not recording the resident's vital signs at 1:00 a.m. However, CMS has offered no evidence showing that professionally recognized standards of care would require that the resident's vital signs be recorded at that moment. Asserting that Petitioner's staff failed to record vital signs at 1:00 a.m. – in the absence of proof that such would have been required by the circumstances – is simply a naked allegation of noncompliance that is unsupported.

Of course, at 3:00 a.m. on the 13th of December, Petitioner's staff did much more. At that time, the staff recorded the resident's vital signs and communicated them directly to the on-call physician. CMS Ex. 16 at 31. That was prompted by the fact that a second blood clot had been discovered in the resident's mouth. The staff interpreted the development of a second clot as something that was potentially significant and concluded that merely monitoring the resident without physician consultation was inadequate. The nurse described the clot that had been observed and gave the physician her assessment that there was no active bleeding. She also assessed the resident's stools and urine as being negative for signs of blood. P. Ex. 4 at 1. There ensued a discussion between the nurse and the on-call physician about the possible cause of the blood clot, and the nurse opined that it might be due to the resident's periodontal disease. *Id.* Thus, the nurse assessed the possible cause of the resident's problem along with obtaining and reporting objective information about the resident's condition.

CMS also criticizes Petitioner's staff for doing no additional assessments of the resident between 3:00 a.m. and 7:00 a.m. on the morning of December 13. This contention fails to take into account the fact that the resident was being monitored closely during this period pursuant to the instructions given by the on-call physician. During that time frame, the resident experienced two episodes of urinary incontinence. These episodes were assessed as being negative for blood in the resident's urine.

Finally, CMS asserts that the staff failed to record additional vital signs for the resident between 3:00 a.m. and 7:00 a.m. on December 13. During this period, the staff was operating under the orders of the on-call physician, and he did not order that vital signs be taken. CMS has not offered any evidence establishing a professionally recognized standard of care that would require vital signs be taken between 3:00 a.m. and 7:00 a.m. on December 13. I note that the vital signs that were taken at 3:00 a.m. showed the resident to be stable. CMS Ex. 16 at 31; P. Ex. 4 at 1. The reasonable inference that I

draw from that is that the on-call physician did not consider it necessary that vital signs be recorded again during the ensuing four hours.

3. Petitioner complied with the requirements of 42 C.F.R. § 483.20(k)(3)(ii).

The regulation that is at issue here states that services provided or arranged by a skilled nursing facility for a resident must be provided by qualified persons in accordance with that resident's written plan of care. CMS alleges that Petitioner failed to implement the plan of care that it had developed for Resident # 8. Essentially, CMS asserts that Petitioner failed to assess the resident for "blood in urine, stool, bleeding gums, tarry stools, easy bruising, petechiae, nosebleed, melena, hematemesis" and failed to "Call MD as needed," consistent with the requirements of the resident's plan of care. CMS Ex. 16 at 16.

I disagree with this assertion. The preponderance of the evidence establishes that Petitioner complied with the plan of care that it had developed for Resident # 8. First, and as I discuss at Finding 2, Petitioner's staff did assess the resident for bleeding and blood in her stools and urine. Second, they called the on-call physician "as needed," that is, when the staff reasonably determined that the resident was manifesting signs that necessitated physician consultation.

CMS seems to interpret the plan of care as requiring physician consultation whenever the resident manifested even the least sign of bleeding. But, the plan does not say that. It does not direct the staff to call the resident's physician at the least sign of bleeding. Rather, it gives some discretion to the staff to call when the staff determines that a call is necessary. Obviously, the staff would be expected to exercise their judgment in that regard consistent with professionally recognized standards of care. But, and as I discuss at Finding 1, CMS offered no prima facie evidence to show that Petitioner's staff failed to comply with professionally recognized standards of care in determining when to consult with the on-call physician about Resident # 8.

4. Petitioner complied with the requirements of 42 C.F.R. § 483.25.

The regulation in question states that each resident of a facility must receive, and the facility must provide, the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the resident's comprehensive assessment and plan of care.

CMS's allegations that Petitioner failed to comply with this requirement are a restatement of the allegations that it made concerning Petitioner's alleged failure to consult with the on-call physician concerning Resident # 8's bleeding on the morning of December 13,

2008. CMS Ex. 1 at 22-27. I have addressed these allegations in detail above, at Finding # 1, and I find it unnecessary to revisit them, and my analysis, here.

5. Petitioner complied with the requirements of 42 C.F.R. § 483.75(i).

The relevant regulation specifies that a skilled nursing facility must designate a physician to serve as its medical director. It specifies additionally that the medical director is responsible for the implementation of resident care policies and the coordination of medical care in the facility.

CMS argues that Petitioner failed to ensure that its medical director was actively involved in assuring that standards of practice were followed in providing care for residents. CMS Ex. 1 at 48. This assertion is premised on an interview that the surveyor who conducted the March 11 Survey had with Morris Ferguson, M.D., Petitioner's medical director. According to the surveyor:

> I was particularly alarmed by the following statement by the Medical Director during our interview: "I am not responsible for the physicians here; the residents have their own doctors who are responsible for their medical care, and I am not responsible for the medical care of these residents." . . . In addition, the Medical Director stated that he did not think it was his responsibility to make any determinations on the quality of care that residents' received from their own physicians, as he "didn't feel right telling the (doctors) they weren't doing a good job . . . I won't do it."

CMS Ex. 38 at 6. Additionally, according to the surveyor, Petitioner's medical director confirmed that he had not been informed about Resident # 8's unexplained bleeding on December 13, 2008, nor about any of the events that followed including the resident's subsequent hospitalization. According to the surveyor, the medical director stated that it was not necessary for the facility to inform him of the incident. CMS Ex. 38 at 6-7.

There is no question that 42 C.F.R. § 483.75(i) requires a skilled nursing facility's medical director to oversee the care that is provided to the residents by their personal physicians. But oversight is not tantamount to supervision. The regulation does not require a medical director to supervise personally the care that a resident's physician renders in each instance nor does it require a medical director personally to review each instance of care in order to unearth problems. And, while it is certain that a medical director must exercise overall responsibility for the activities of a skilled nursing facility, there is nothing in the regulation governing the medical director's duties that specifically requires the facility staff to notify him or her about every incident that occurs at the facility. What the medical director clearly needs to know about, in order to discharge his or her duties effectively, are events or incidents that might appear to depart from

professionally recognized standards of care. Those events – not events that are consistent with standards of care – are the events that require corrective action or rectification.[9]

There is no evidence showing that Dr. Ferguson failed to discharge his responsibilities, either in the case of Resident # 8 or in providing general oversight. I have found that the care that Petitioner's staff gave to Resident # 8 on the evening of December 13, 2008 was consistent with accepted standards of care. This is not a situation where the staff exercised questionable or faulty judgment or where a physician acted inappropriately in dealing with his or her patient. Consequently, there was no particular reason why Dr. Ferguson needed to be informed specifically about the events of that evening.

Furthermore, CMS and the surveyor have quoted Dr. Ferguson out of context. From the surveyor's written notes it appears that Dr. Ferguson's assertion that he is not responsible for the actions of the residents' personal physicians means only that he is not responsible for supervising these physicians *directly* as they provide care to residents. CMS Ex. 16 at 6. In his interview, Dr. Ferguson separated his lack of direct supervisory authority from the broader oversight role conferred by 42 C.F.R. § 483.75(i). The surveyor reported Dr. Ferguson to have acknowledged that role by attributing the following comment to him:

> I oversee care of . . . [patients]. If I think someone is not doing a good job, I could send them a letter. *Id.*

Dr. Ferguson amplified on this comment in his written direct testimony:

> If there were a situation where a treating or an on-call physician did not respond timely or appropriately, I expect to be notified of that. The comments that I made to the surveyors that I did not need to be notified about . . . [Resident # 8] are based on my belief that the nursing staff and physicians handled the situation appropriately. To the extent these comments were construed to mean I believe I have no responsibility when a situation is not handled appropriately, that is a mischaracterization.
>
> P. Ex. 3 at 2.

Dr. Ferguson also testified that it was a mischaracterization to suggest that he was unwilling to tell doctors that they needed to improve their care in certain situations. *Id.*

---

[9] CMS did not allege that there was a systemic failure at Petitioner's facility to keep the medical director abreast of problems that might warrant his intervention. Nor did it assert that Petitioner lacked systems that would communicate such problems to the medical director.

6. Petitioner complied with the requirements of 42 C.F.R. § 483.75(o).

A skilled nursing facility must maintain a quality assessment and assurance committee consisting of its director of nursing services, a physician that is designated by the facility, and at least three other staff members. 42 C.F.R. § 483.75(o)(1). That committee must meet at least quarterly to identify issues with respect to which quality assessment and assurance activities are necessary. 42 C.F.R. § 483.75(o)(2)(i). The committee will develop and implement appropriate plans of action to correct identified quality deficiencies. 42 C.F.R. § 483.75(o)(2)(ii).

I find no failure by Petitioner's quality assurance committee to carry out its regulatory responsibilities. The preponderance of the evidence proves that Petitioner established a quality assurance committee in compliance with regulatory requirements. Indeed, CMS does not contend that Petitioner failed to do so. The preponderance of the evidence establishes also that Petitioner operated its quality assurance committee in a way that accomplished the regulation's objective of developing and implementing appropriate plans of action to correct identified quality deficiencies.

CMS contends that Petitioner failed to comply with regulatory requirements because it had no system in place for reporting to its quality assessment committee episodes, such as the episode involving Resident # 8 on the morning of December 13, 2008. This allegation is based on an interview between the surveyor and Petitioner's quality assurance manager. The surveyor averred that the:

> Quality Assurance Manager confirmed that the facility's . . . [director of nursing] and . . . [assistant director of nursing] conducted monthly Quality Assurance audits of medical records of all residents like Resident 8, who received anticoagulant therapy, to ensure that labs were being obtained as ordered and that medication changes were made as prescribed by physicians' orders. However, the audits did not review incidents where residents had experienced complications (i.e. unexplained bleeding) as a result of anticoagulant therapy, and any negative outcomes (i.e. hospitalization, further treatment) that had resulted. In fact, the Quality Assurance Manager was not aware of the incident involving Resident 8.
>
> CMS Ex. 38 at 7-8.

The attributed statement is hearsay and of dubious credibility for that reason. Furthermore, CMS did not cite to any record of this interview in either its pre-hearing or final brief, and I am, therefore, unaware of any document that actually records these attributed statements other than the surveyor's declaration.[10]

But, even assuming these statements were accurately reported, they were fully rebutted by the testimony of Pat Hudgins, LPN, Petitioner's assistant director of nursing. Ms. Hudgins testified that she serves on Petitioner's quality assurance committee. She specifically rebutted the statements that the surveyor reported:

> The [quality assurance] committee also reviews unusual incidents at the facility where there is some question as to whether the incident was handled appropriately. The December 13, 2008 situation with . . . [Resident # 8] was reported to me as the ADON, and I am a member of the Quality Assurance Committee. There was a series of caregivers who each evaluated the December 13, 2008 situation . . . If any member of our team had not reported appropriately up the chain of command or if any member of our team had not responded appropriately when this situation was reported to them, I would have triggered this for QA Committee review. The matter did not warrant a QA investigation because our protocol was followed and proper care was given to Resident # 8.
>
> P. Ex. 6 at 1-2.

I note, furthermore, that CMS's allegations appear to rest on the unstated assumption that a facility's quality assurance committee must investigate all negative outcomes in cases of resident care. That is not required by the governing regulation either explicitly or implicitly. The regulation requires investigation of any instance of care of suspect quality whether or not the outcome is negative. But, it does not require a facility to assume that an adverse outcome in a particular case is negative and to investigate each such episode as if there were a quality of care issue associated with it.

/s/
Steven T. Kessel
Administrative Law Judge

[10] In its final brief, CMS cites to CMS Ex. 28 as support for the surveyor's assertions concerning her interview with Petitioner's quality assurance manager. CMS's Final Brief at 15. CMS Ex. 28 is not an interview report. Rather, it is a document entitled "Resident Level Quality Measure/Indicator Report: Chronic Care Sample." CMS Ex. 28. CMS has not explained its significance to the case, but it clearly is not corroborating evidence of statements that were attributed to the quality assurance manager.