Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Golden Living Center − Frankfurt (CCN: 18-5159),	)	Date: July 29, 2009
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-08-363
	)	Decision No. CR1981
Centers for Medicare & Medicaid Services.	)	
	)	

DECISION

Petitioner, Golden Living Center − Frankfurt (Petitioner or facility), is a long-term care facility located in Frankfurt, Kentucky, that participates in the Medicare program. Based primarily on the facility's treatment of one of its residents – who was admitted to the hospital "very clearly dehydrated" and suffering from acute renal failure − the Centers for Medicare and Medicaid Services (CMS) determined that the facility was not in substantial compliance with Medicare requirements, and that its deficiencies posed immediate jeopardy to resident health and safety. Petitioner here challenges those determinations.

I conclude that, from December 15, 2007, through March 2, 2008, the facility was not in substantial compliance with Medicare requirements, and that, from December 15, 2007, through January 28, 2008, its deficiencies posed immediate jeopardy to resident health and safety.

I. Background

The Social Security Act (Act) sets forth requirements for nursing facility participation in the Medicare program, and authorizes the Secretary of Health and Human Services to promulgate regulations implementing those statutory provisions. Act § 1819. The Secretary's regulations are found at 42 C.F.R. Part 483. To participate in the Medicare

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

The Secretary contracts with state survey agencies to conduct periodic surveys to determine whether skilled nursing facilities are in substantial compliance. Act § 1864(a); 42 C.F.R. § 488.20. The regulations require that each facility be surveyed once every 12 months, and more often, if necessary, to ensure that identified deficiencies are corrected. Act § 1819(g)(2)(A); 42 C.F.R. §§ 488.20(a), 488.308.

Here, following surveys completed January 4 and January 30, 2008, CMS determined that the facility was not in substantial compliance with the following Medicare participation requirements:

- 42 C.F.R. § 483.25 (quality of care)
- 42 C.F.R. § 483.25(j) (quality of care – hydration)
- 42 C.F.R. § 483.75(j) (administration – laboratory services)
- 42 C.F.R. § 483.75(o) (administration − quality assessment and assurance)
- 42 C.F.R. § 483.20(k)(3) (comprehensive care plans)

CMS also determined that the facility's deficiencies posed immediate jeopardy to resident health and safety. CMS subsequently determined that the immediate jeopardy abated effective January 29, 2008, and that the facility returned to substantial compliance on March 3, 2008. CMS Ex. 1; CMS Ex. 3, at 30-33; P. Exs. 1, 2, 37.

CMS has imposed against the facility a civil money penalty (CMP) of $3750 per day for the period of immediate jeopardy (45 days x $3750 = $168,750) and $100 per day for the period of substantial noncompliance that was not immediate jeopardy (34 days x $100 = $3400) (Total CMP: $172,150).

I held a hearing in Louisville, Kentucky, on February 18, 2009. Mr. Joseph L. Bianculli appeared on behalf of Petitioner, and Mr. Howard Lewis appeared on behalf of CMS. I have admitted into evidence CMS Exs. 1-19, and P. Exs. 1-43 (including P. Exs. 10A and 27A). Order (October 10, 2008); Tr. 3. The parties have filed initial briefs (CMS Br.; P. Br.), closing briefs (CMS Cl. Br.; P. Cl. Br.), and reply briefs (CMS Reply; P. Reply).

II. Issues

The issues before me are:

- Whether, from December 15, 2007, through March 2, 2008, the facility was in substantial compliance with Medicare participation requirements, specifically 42 C.F.R. §§ 483.25, 483.25(j), 483.75(j), 483.75(o) and 483.20(k)(3);

- If the facility was not in substantial compliance from December 15, 2007, through January 28, 2008, did its deficiencies then pose immediate jeopardy to resident health and safety?

Even though Petitioner's hearing request mentions, without further comment, that it "specifically challenges the amount and duration of the CMP," the reasonableness of the CMP is not before me. My pre-hearing order said that the party's pre-hearing brief "must contain any argument that a party intends to make" and warned that "I may exclude an argument and evidence that relates to such argument if a party fails to address it in its pre-hearing brief." Acknowledgment and Initial Pre-hearing Order, at 4 (April 4, 2008). Accordingly, CMS argued in its pre-hearing brief that the amount of the CMP was reasonable; however, Petitioner's subsequently-filed pre-hearing brief includes no argument as to the reasonableness of the CMP. During the October 9, 2008 pre-hearing conference (*see* 42 C.F.R. 498.47(a)), I pointed out that Petitioner had not challenged the amount of the penalty; my subsequent order listed the issues before me, and explicitly held that "except to argue its substantial compliance, Petitioner's pre-hearing brief does not challenge the reasonableness of the civil money penalty." Order (October 10, 2008). Petitioner did not subsequently object to that articulation of the issues, and the ruling is final. 42 C.F.R. § 498.50(b) (parties have 10 days to file objections to the pre-hearing order; after 10 days have elapsed, the ALJ settles the order). Therefore, the reasonableness of the CMP is not before me.[1]

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[1] Petitioner may have confused the issue of the CMP's duration with the issue of the CMP's reasonableness, claiming that "[t]he Court suggested at the hearing that Petitioner had waived any challenge to the duration of the CMP." P. Cl. Br. at 43, note 10. In fact, at the hearing I repeated what I had said during the pre-hearing conference and in my October 10, 2008 order: "[E]xcept to argue its substantial compliance, Petitioner's pre-hearing brief does not challenge the reasonableness of the civil money penalty." Tr. 2. Since the duration of the penalties is coterminous with the periods of substantial noncompliance and immediate jeopardy, the issues of duration are necessarily before me, as reflected in the above statement of the issues. ("Whether, *from December 15, 2007, through March 2, 2008*, the facility was in substantial compliance."; "If the facility was not in substantial compliance from *December 15, 2007, through January 28, 2008*, did its deficiencies then pose immediate jeopardy . . . ."). However the reasonableness of the amount is a separate issue, which Petitioner has waived.

III. Discussion

The deficiencies cited in this case center around care provided to Resident 1 (R1). R1 was a 66-year-old woman admitted to the facility on December 7, 2007, following a week-long stay at an acute care hospital. Among her many health issues, she had histories of coronary artery disease, congestive heart failure, massive cerebrovascular accident (stroke), seizure disorder and chronic kidney disease. She suffered from hypotension and gout. CMS Ex. 4, at 2-5, 11-12, 375; CMS Ex. 10, at 13-15; CMS Ex. 17, at 2 (Fink Decl. ¶ 7); P. Ex. 4; Tr. 10. Nevertheless, when admitted to the facility, her condition was stable. Tr. 23, 28-29. She had some modest impairment of her kidney function, but, as explained by CMS's expert witness, Dr. Jeffrey C. Fink,[2] lab results showed "acceptable renal function at the time and only mild renal impairment related to chronic kidney disease." CMS Ex. 17, at 3, 4, 6 (Fink Decl. ¶ ¶ 10, 11, 16); CMS Ex. 4, at 66; Tr. 8; P. Ex. 32, at 2 (Payton Decl.) (lab tests generally normal with slightly elevated BUN, which appeared to have been her baseline). R1 had a history of fluid imbalances and was assessed as at risk for dehydration; however, no evidence suggests that she was dehydrated or experiencing any other nutritional problems at the time of her admission. CMS Ex. 17, at 4 (Fink Decl. ¶ 12); CMS Ex. 10, at 23-29. Petitioner's expert witness, Dr. Michael Yao, Division Medical Director for Petitioner's parent company, agreed that "overall . . . she may have been in pretty good balance as far as her record of balance has been at that moment . . . . " Tr. 151. She was capable of feeding herself, and had no difficulty chewing or swallowing food or drink. CMS Ex. 9, at 36; CMS Ex. 10, at 25.

Thereafter, however, R1's condition deteriorated until − just 18 days after her admission − she was hospitalized with severe dehydration and dangerously high potassium levels. In CMS's view, facility staff contributed to her decline because (among other deficiencies) they: 1) failed to provide her with sufficient fluid intake to maintain proper hydration and health; 2) did not timely obtain necessary laboratory tests; 3) did not develop an individualized care plan, nor provide, pursuant to such plan, services meeting professional standards of quality; and 4) did not provide her the care and services she needed to attain or maintain her highest practicable physical well-being.[3]

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[2] Dr. Fink is an associate professor of Medicine and Epidemiology in the Division of Nephrology at the University of Maryland School of Medicine. CMS Ex. 15; CMS Ex. 17, at 1.

[3] I decline to rule on every deficiency cited, but discuss deficiencies that were persuasively established and are sufficient to support the remedies imposed. *Beechwood Sanitarium*, DAB No. 1824, at 19 (2002). No inference should be drawn as to the merits of the cited deficiency on which I have declined to comment.

A. Because its staff did not provide R1 with fluid intake adequate to maintain proper hydration and health, the facility was not in substantial compliance with 42 C.F.R. § 483.25(j).[4]

As part of the "quality of care" regulation (discussed below), the facility must "provide each resident with sufficient fluid intake to maintain proper hydration and health." 42 C.F.R. § 483.25(j). Where, as here, a resident is assessed as at risk for dehydration, I consider first what the facility did to mitigate that risk. Whether the facility provided the volume of fluids recommended by a resident's dietician may be a critical part of that consideration. *Woodland Village*, DAB No. 2053, at 10 (2006).

R1's care plan, dated December 7, 2007, indicates that she was at risk for dehydration. CMS Ex. 11, at 2; *see* P. Reply at 20 ("But no reasonable person could find on the current record that Petitioner's staff was *unaware* that the [r]esident was at risk for dehydration."). Although not mentioned in the plan or in her attending physician's assessment, she was apparently at risk for both dehydration and fluid overload, and, thus, her fluids should have been very closely monitored. Tr. 111.[5]

On December 11, 2007, the facility's registered dietician assessed R1 as requiring 2170 milliliters (mls) of fluid per day, and no one disputes that the dietician's assessment represents the most precise estimate of the resident's fluid needs. CMS Ex. 9, at 38. Nurse Practitioner Payton, who provided direct care to R1, testified that she would defer to the opinion of the dietician as to the amount of fluid a resident required. Tr. 136-37.

But the facility fell far short of providing R1 the level of fluids called for in her assessment. Review of the intake records offered by Petitioner shows that R1 did not consume anywhere near the amount she required, never consuming more than 960 ml,

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

[5] As discussed below, Dr. James Quarles, who was R1's attending physician and the facility's medical director, purportedly examined and assessed R1 on December 13, about a week following her admission. As his written report shows, he seems to have missed completely what Dr. Yao and Dr. Fink characterize as her most critical problem – difficulty maintaining adequate fluid balance. P. Ex. 5; *see* Tr. 161 (Per Dr. Yao: "[T]here isn't any mention of the difficulties in dealing with fluids that I would expect to have seen."). And, as discussed below, Advanced Registered Nurse Practitioner Susan Payton (who treated R1) came late to recognizing the severity of R1's fluid balance problems. P. Ex. 38, at 3, 6 (Payton Decl.).

and more often consuming as few as 240 ml. P. Ex. 20. Specifically, Petitioner presents R1's daily fluid intake as follows:

- 12/8 – 240 ml.
- 12/9 – 960 ml.
- 12/10 – 720 ml.
- 12/11 – 360 ml.
- 12/12 – 360 ml.
- 12/13 – nothing recorded.
- 12/14 – 480 ml.
- 12/15 – 240 ml.
- 12/16 – 240 ml.
- 12/17 – 240 ml.
- 12/18 – 480 ml.
- 12/19 – 620 ml.
- 12/20 – 480 ml.
- 12/21 – 240 ml.
- 12/22 – 360 ml.
- 12/23 – 600 ml.
- 12/24 – 720 ml.

P. Ex. 20; *see* P. Ex. 41 (Stonewall Decl.).[6] These dramatic figures, by themselves, could put the facility out of substantial compliance with section 483.25(j), particularly where, as here, no evidence suggests that the facility recognized or addressed the problem. *See Claiborne-Hughes Health Center*, DAB No. 2233, at 9 (2008) ("A facility's record of fluid intake, or lack thereof, can be relevant in determining whether a resident was provided with sufficient fluid intake to maintain proper hydration and health.").

[6] *But see* CMS Ex. 9, at 9, 10. The parties have offered discrepant versions of R1's intake. CMS offers a one-page document titled "Intake and Output Record," which shows that the facility staff only began recording R1's intake on December 17, contrary to facility protocol, under which they should have been recording intake at least as of a December 14 order to "push fluids." CMS Ex. 9, at 9. No one has explained the entries on the intake record, and it is difficult to determine what they mean, but, under any interpretation, the intake numbers recorded do not approach 2170 mls per day. CMS maintains that the facility only began to measure intake on December 17, days after Nurse Practitioner Payton ordered staff to "push fluids." But the above figures suggest that the facility measured intake from December 8 on – although not necessarily in the manner called for by the facility's written protocol. *See* CMS Ex. 12. Of course, that the facility apparently maintained inconsistent records of the resident's intake is itself deeply troubling.

Thereafter, R1's hydration needs became more acute. By December 12, Nurse Practitioner Payton detected abnormal lung sounds and a December 13, 2007 chest x-ray confirmed that R1 had pneumonia. CMS Ex. 7, at 15; CMS Ex. 8, at 3. In an order dated December 14, Nurse Practitioner Payton directed staff to "push fluids." CMS Ex. 7, at 16.

According to the facility's protocol, when ordered to "push fluids," staff were also required to monitor the resident's fluid intake and, where feasible, her output. Because R1 could not eliminate in a measuring device, the protocol apparently excused staff from measuring output. CMS Ex. 12. Nevertheless, the protocol dictated that staff measure her intake, record it at the end of each shift, and record the daily total. Presumably, nurses and/or R1's attending physician were supposed to review the daily totals and, if they showed that she was not ingesting sufficient fluids, they would reassess and/or adjust her care plan. Dr. Yao explained that measuring intake is very labor intensive, but agreed that requiring staff to do so is "a reasonable expectation." Tr. 151, 158.

Staff's monitoring appears to have been inconsistent. More important, however, the above numbers indicate that Nurse Practitioner Payton's "push fluids" order had no apparent effect on facility performance in keeping R1 hydrated. At no time before or after issuance of the December 14 order did R1's intake come close to her assessed need.

Petitioner does not dispute its own figures, but claims that "[t]his definitely is not a case where indifferent or careless nurses simply failed to administer sufficient fluids to an ill resident." P. Br. at 33. In fact, whether due to indifference, carelessness, incompetence, oversight, or some other reason, this is undeniably a case where staff failed to administer sufficient fluids to an ill resident. Staff were, or should have been, aware that R1 did not consume anywhere near the amount of fluid she required; yet, I see no evidence of any systematic effort to increase that fluid intake.

Indeed, the evidence suggests that those responsible for her care did not even recognize a serious problem. Licensed Practical Nurse (LPN) Evelyn Atha testified that, although trained "to be alert to hydration issues[,]" she did not recall R1 having "any problem of this sort. In fact, I recall that she drank a lot when I cared for her, that we always offered her fluids, and that she drank adequate amounts of fluid." P. Ex. 40. In contrast, a couple of the certified nurse assistants testified that they offered fluids (water, juice, soda) to R1, and encouraged her to drink, but she often refused. They also said that they reported her consumption to the nurses. P. Ex. 42, at 2 (Mahan Decl.); P. Ex. 43 (Brown Decl.). It does not appear that the facility took any particular action based on the CNAs' reports.

In her written declaration, Nurse Practitioner Payton expresses no concern for R1's low fluid intake. She says that she ordered staff to "push fluids" because R1 had an infection, suffered from chronic diarrhea, and frequently refused to eat or drink. But, when Nurse Practitioner Payton first saw R1 on December 12, she did not think she was dehydrated,

and "nothing subsequent to that time indicates that the [r]esident's hydration status changed significantly or required any specific intervention." P. Ex. 38, at 3, 6 (Payton Decl.).[7] I find this statement troubling because it appears to disregard multiple symptoms exhibited by R1 that are consistent with dehydration.

On the afternoon of December 15, R1 exhibited what staff characterized as "a slight change in mental status," in that she was "picking at the air" and "talking to the wall." CMS Ex. 8, at 4. These can be symptoms of dehydration. Tr. 124. At her son's insistence, she was taken to the emergency room. P. Ex. 38 (Payton Decl.). While there, lab tests showed that her potassium level was 6.0, which is considered extremely high (normal range is between 3.5 and 5.0-5.3).[8] She was diagnosed with hyperkalemia, and treated with Kayexalate, a medication commonly given to reduce potassium levels, even though it causes diarrhea. CMS Ex. 5, at 4, 24, 28; CMS Ex. 7, at 7; CMS Ex. 17, at 5 (Fink Decl. ¶ 14); Tr. 35. She returned to the facility and her potassium pills were withheld on the 16th and 17th, but resumed thereafter. CMS Ex. 9, at 44.

The December 15 lab tests also showed that R1's creatinine level was significantly higher than it had been when she was admitted to the facility, having climbed from 1.2 (adequate renal function) to 1.6 with an estimated GFR (glomerular filtration rate) of 34 ml/min. CMS Ex. 4, at 66; CMS Ex. 5, at 4. Dr. Fink explained that this change indicates worsening kidney function because of volume depletion and dehydration. The high level is a signal that kidney function is beginning to decline, so R1 needed to be watched even more closely. CMS Ex. 17, at 6 (Fink Decl. ¶ 16). Dr. Fink explained: potassium is an electrolyte, and the kidneys excrete electrolytes out of the body. If the kidneys are impaired, their ability to eliminate potassium and other electrolytes deteriorates. High potassium levels can cause cardiac arrhythmias. As dehydration and volume depletion worsen, acute renal dysfunction can become prolonged renal failure. CMS Ex. 17, at 6-7 (Fink Decl. ¶ 16).

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[7] I reject as unsupported Petitioner's after-the-fact, but repeated, suggestion that the facility's only alternative to providing R1 with a small fraction of her fluid needs would have been to administer intravenous fluids. No contemporaneous note or assessment mentions that Dr. Quarles or Nurse Practitioner Payton considered administering IV fluids or instituting any less intrusive intervention to increase R1's fluid intake.

[8] Nurse Practitioner Payton claims simply that R1's potassium levels "were a little high" (P. Ex. 38, at 4), which suggests that she did not appreciate the seriousness of the test result. The record does not reflect that Dr. Quarles had any opinion on the matter. *See* discussion, *infra*. This may explain why the facility resumed her potassium pills after only two days, and did not thereafter monitor her potassium levels.

Between December 15 and her hospital admission on December 25, R1 experienced 13 documented episodes of diarrhea. CMS Ex. 9, at 73-74. As Dr. Fink explained, diarrhea increases water and electrolyte loss. It can cause severe dehydration, volume depletion, shock and can even lead to death. CMS Ex. 17, at 7 (Fink Decl. ¶ 17). I agree with Dr. Fink that the facility should have recognized the risk. Moreover, R1's deterioration should have been observed during routine assessments. Signs of dehydration include drop in blood pressure, poor skin turgor, dry mucus membranes, and change in mental status. CMS Ex. 17, at 7 (Fink Decl.)

In addition, R1 lost a significant amount of weight. Upon admission, R1 weighed 191 pounds. Eleven days later, her weight had dropped to 183.7 pounds. CMS Ex. 9, at 37. Dr. Fink explained that the substantial rapid weight loss was likely due to dehydration. CMS Ex. 17, at 7-8 (Fink Decl. ¶ 18).

Nurses notes dated December 18 and December 22, 2007 describe R1 as "groggy" and "very drowsy." On December 22 she refused to eat. CMS Ex. 8, at 5. Staff took no action.

Her deterioration continued, and, by December 25, she was "slow to arouse," her speech difficult to understand. Staff notified Nurse Practitioner Payton who ordered her transferred to the hospital. CMS Ex. 8, at 6. At the hospital, she was described as "clearly very dehydrated." CMS Ex. 6, at 1. Her potassium level was 7.4. She was admitted to the hospital with acute renal failure, hyperkalemia, sepsis, pneumonia and acute dehydration. CMS Ex. 6, at 1-3; CMS Ex. 17, at 8; *see* Tr. 111, 113, 122, 128, 142 (Per Dr. Yao: R1 "had a degree of dehydration that did require rehydration."). Tr. 142.

Thus, facility staff did not follow dietician recommendations as to R1's fluid needs, did not respond to Nurse Practitioner Payton's order to "push fluids," and did not respond when R1 exhibited signs and symptoms of dehydration. They did not even alter her care after December 15 lab tests showed abnormal creatinine levels, which pointed to worsening kidney function, likely due to volume depletion and dehydration. The facility was not providing R1 sufficient fluid intake to maintain proper hydration and health, and was therefore not in substantial compliance with 42 C.F.R. § 483.25(j).

B. The facility was not in substantial compliance with 42 C.F.R. § 483.75(j) because it did not timely obtain necessary laboratory tests.

The facility must also provide or obtain laboratory services "to meet the needs of its residents[,]" and is responsible for the quality and timeliness of those services. Among other requirements, it must obtain the services only when ordered by the attending physician; it must promptly notify the attending physician of the laboratory test results;

and it must file the dated lab reports in the resident's clinical record. 42 C.F.R. § 483.75(j).[9]

On December 12, 2007, when Nurse Practitioner Payton detected R1's abnormal lung sounds, she ordered laboratory tests as well as the chest x-ray mentioned above. According to Nurse Practitioner Payton, the ordered tests "were very important for multiple issues." CMS Ex. 7, at 16; Tr. 118. But the facility did not implement that order. Several days later, a nurse apparently noticed that the tests had not been performed, and the facility finally did so on December 17, 2007. CMS Ex. 8, at 4, 5 (per December 16 nurse's note: "S. Payton ARNP wrote orders for labs to be drawn on 12/13/2007. . . . Called S. Payton to inform of no lab draw. New orders rec'd to do labs in AM.")[10]

Witnesses for both parties agreed that the delay in testing created serious problems. Too much potassium in the blood can cause extremely serious medical issues, possibly even death. CMS Ex. 17, at 5 (Fink Decl. ¶ 14). But, because no specific symptoms signify the condition, a lab test is the only means by which to discover high potassium levels. Tr. 47. As Dr. Fink explained, the lab tests provide crucial information and, had the labs been obtained as ordered on the 12th , the test results would have reflected an increasing potassium level, and R1's hyperkalemia could therefore have been treated before it reached dangerous levels. Tr. 46-47, 135; CMS Ex. 17, at 5-6 (Fink Decl. ¶ 15).

Petitioner mischaracterizes Dr. Fink's testimony when it suggests that Dr. Fink "conceded that the impact of this error – if any – was vitiated when the Resident actually received the lab test and treatment on December 15." P. Cl. Br. at 2. In fact, Dr. Fink simply agreed that the treatment administered in the hospital on the 15th halted and reversed the deterioration in R1's condition ("sets the clock differently . . . resets it back to zero."). Dr. Fink immediately followed up by opining that, had the labs been obtained as ordered on the 12th , the test results would have reflected an increasing potassium level, as well as her deteriorating renal function and "may have prevented the emergency room visit." CMS Ex. 17, at 5-6 (Fink Decl. ¶ 15), Tr. 46-47.

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[9] A physician may delegate tasks to a physician assistant, nurse practitioner, or clinical nurse specialist if certain criteria are met. 42 C.F.R. § 483.40(e).

[10] Petitioner claims that its "routine systems for catching errors worked as designed and intended to catch this error." P. Cl. Br. at 37. But no evidence suggests that the facility had such a system. In fact, Petitioner is not even able to explain how the error was found, much less describe any systematic approach. Rather, Petitioner speculates that the nurse may have discovered the error in response to Nurse Practitioner Payton's query about the test results, or she may have discovered the error when performing a chart audit.

Dr. Yao testified that he would have preferred "more than one lab" (Tr. 144-45) and that "if you order a lab, you should expect it to be done." Tr. 158, 167. He conceded that the care provided "was clearly not perfect" and "things could have been done better, including getting labs in a timely fashion," but opined that, inasmuch as the problem was detected and treated on December 15, "there wasn't a lasting harm initiated from that." Tr. 168-69. That the facility, through happenstance, may have avoided inflicting permanent harm is hardly the standard by which we judge either substantial compliance or immediate jeopardy.

For her part, Nurse Practitioner Payton characterized the delay in testing as "the downfall of this entire situation[,]" making it difficult for her to do her job, and I see no reason to question that opinion. P. Ex. 32, at 2; Tr. 119-20, 134.

Because the facility did not timely obtain very important laboratory tests, it was not in substantial compliance with 42 C.F.R. § 483.75(j).

C. The facility was not in substantial compliance with 42 C.F.R. § 483.20(k) because it did not develop for R1 an individualized care plan, nor provide services meeting professional standards of quality.

42 C.F.R. § 483.20(k)(1) and (3) mandate: 1) that the facility develop for each resident a comprehensive care plan with measurable objectives and timetables to meet the resident's medical, nursing, mental, and psychosocial needs as identified in the resident's comprehensive assessment; and 2) that the services provided or arranged by the facility pursuant to that plan meet professional standards of quality.

First, I agree with CMS that, because it failed to obtain timely lab tests for R1, the facility did not provide services meeting professional standards of quality. I also find that the facility fell short of meeting professional standards of quality because it did not provide R1 with fluids adequate to maintain proper hydration.

With respect to the requirement that the facility develop a comprehensive care plan for R1, Petitioner argues that R1 was not in the facility long enough to trigger the comprehensive care planning requirements. P. Reply, at 23. Petitioner is incorrect. The regulation requires development of a care plan within seven days after completion of the resident's comprehensive assessment. 42 C.F.R. § 483.20(2)(i). The comprehensive assessment is due within 14 days of admission. 42 C.F.R. § 483.20(b)(2)(i). Petitioner has submitted a "clinical assessment" dated December 7, 2007. P. Ex. 7; CMS Ex. 10, at 23-29. If this is the facility's comprehensive assessment, R1's care plan should have been completed no later than December 21, 2007. More likely, Petitioner considered this part of R1's comprehensive assessment and incorporated it into another document, dated December 14, 2007, that represents the comprehensive assessment. R1's care plan

therefore had to be developed no later than December 28, 2007, and, in fact, the facility developed a plan of sorts on that date. CMS Ex. 10.

At the time of her admission, the facility recognized that R1 was at risk for dehydration, and prepared a "care plan" that says simply "[no signs or symptoms of] dehydration [without] detection [and] intervention through next review." CMS Ex. 11, at 2; P. Ex. 8, at 1. Although an interim plan, it should have provided sufficient instructions to enable staff to care adequately for the resident, but it did not.

An amended plan was completed on December 28.[11] While more comprehensible than the earlier version, it offers little in the way of meaningful instructions to staff. The amended plan identifies R1's problem as "risk for dehydration /fluid imbalance related to [history] of CHF and pneumonia." But the interventions are generic: weigh monthly and as needed; labs as ordered – report abnormals; report signs and symptoms of dehydration; encourage fluids as tolerated; and "push fluids." CMS Ex. 11, at 5; P. Ex. 8, at 14. The plan does not reflect R1's assessment in that it says nothing about the quantity of fluids R1 required. It does not address staff's total lack of success in providing R1 anywhere near the volume of fluid she required.

Petitioner chides CMS for its purported failure to acknowledge that R1 had "significant nutritional problems, including persistent refusals to eat and drink (and that those issues further complicated management of her already complicated medical problems)." P. Reply, at 7. However, Petitioner points to no evidence suggesting that, following an appropriate assessment of R1's nutritional problems, an interdisciplinary team (that included her attending physician) developed a care plan with measurable objectives and timetables to address those "significant nutritional problems."

Nor does the plan address R1's dangerously high potassium levels; indeed, I see no evidence that the interdisciplinary team charged with planning R1's care ever considered the wisdom of resuming potassium pills after only two days respite, and without at least monitoring her potassium blood levels.

Thus, while Petitioner developed care plans for R1, they were inadequate. For this reason, and because it provided services that did not meet professional standards of quality, the facility was not in substantial compliance with 42 C.F.R. § 483.20(k).

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[11] The facility prepared this care plan in anticipation of R1's return to the facility following her hospitalization. However, when discharged from the hospital on January 4, 2008, R1 opted not to return to the facility. Nevertheless, as of December 28, the facility was required to develop a care plan for R1, and the fact that it was ultimately not implemented does not change the fact that the facility failed to develop an adequate plan.

D. The facility was not in substantial compliance with 42 C.F.R. § 483.25 because it did not provide R1 the care and services she needed to attain or maintain her highest practicable physical well-being.

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

I have already discussed the facility's failure to provide R1 with adequate fluid intake, and its failure to obtain timely laboratory tests that the resident required. These deficiencies, by themselves, establish that the facility was not providing necessary care.

The facility failed to provide necessary care and services in other significant respects. Following her December 15 emergency room visit, it did not give her the care and services she needed to prevent dangerously high potassium levels. As noted above, on December 15, R1's potassium was extremely high, at 6.0. As Dr. Fink noted, excessive potassium administration can cause complications in patients with R1's level of kidney function. CMS Ex. 17, at 4-5 (Fink Decl. ¶ 13), Tr. 33. Yet, except for the two days immediately following that emergency room visit (December 16 and 17), R1 was administered potassium pills from the time of her admission on December 7 until her hospital admission on December 25, 2007. CMS Ex. 9, at 44. And the record contains no apparent justification for continuing the medication. Dr. Fink points out that potassium is commonly prescribed with the diuretic Lasix, which R1 had been taking immediately prior to her first hospitalization. CMS Ex. 17, at 4 (Fink Decl. ¶ 13); CMS Ex. 4, at 40. Lasix frequently causes potassium excretion by the kidneys. But the Lasix was discontinued by December 2, so she was no longer receiving it at the time of her admission to the facility. Yet, no one at the facility re-evaluated the wisdom of continuing the potassium. Nor did the facility make any effort to monitor her potassium blood levels. Someone – the attending physician, nurse practitioner, or consultant pharmacist − should have reviewed the decision to continue the medication. Tr. 34. If the medication were ultimately deemed appropriate, periodic laboratory tests would at least have alerted R1's treaters to any dangerous increase in her potassium level. As Dr. Yao noted, daily labs may not be the standard of care for a skilled nursing facility, but "there are times when a resident will go through a rough patch where you may have to get labs for a few days." Tr. 158.

Petitioner claims that R1's attending physician and Nurse Practitioner Payton "consistently walked a tightrope" to avoid the equally serious complications of dehydration, on the one hand, and fluid overload on the other . . . ." P. Reply, at 19. But the record does not support this proposition. In fact, the evidence shows exactly the opposite. I have already discussed Nurse Practitioner Payton's admission that she did

not, at the time she assessed R1 or any time thereafter, observe any problem with R1's hydration status nor see any need to intervene. P. Ex. 38, at 3, 6. And, as the discussion above shows, R1's treatment records support the conclusion that, except for her generally disregarded orders for lab tests and to "push fluids," Nurse Practitioner Payton did not intervene in order to maintain an adequate fluid balance for R1.

For his part, Dr. Quarles, R1's nominal attending physician and the facility's medical director, overlooked entirely any potential complications. His assessment listed a history of medical problems, but his "review of systems" was essentially negative, and, his physical examination describes R1 as "in general a well-appearing [white female] in no apparent distress;" her coronary artery disease is stable; her gout is stable; her hypertension controlled. He concludes the assessment with "once she is strong enough to go back home, she may be discharged." P. Ex. 5. Petitioner's own expert was critical of Dr. Quarles' assessment. Dr. Yao pointed out that the resident's attending physician is ultimately responsible for the resident's care, and noted that the assessment included no "mention of the difficulties in dealing with fluids that I would expect to have seen on this, and that I did see in the [hospital] discharge summary." Tr. 161.

Dr. Yao also rejected the suggestion that the facility is not accountable for the inadequacies of care attributable to an attending physician. He testified, accurately, that, as both R1's attending physician and the facility's medical director, Dr. Quarles' obligations under the regulations were two-fold:

> [I]f somebody is deemed not to be getting the kind of care that they should be getting from their attending physician, the medical director's responsibilities are two-fold. The medical director may have to intervene in terms of additional care, okaying a transfer, calling in orders. . . . But also a medical director does have to look at the system and say, gee, should this attending physician be on staff and . . . are there things that we can do in our facility that can decrease the risk of this happening again?

Tr. 165; *see also* Tr. 160, 164-65.[12]

Finally, Petitioner makes much of R1's fragility and complicated health issues. But, for this very reason, she required especially careful assessment and monitoring, and the facility had a heightened duty to provide her the care she needed. Tr. 163-164. Drs. Fink and Yao agreed that the facility needed to be extra diligent when monitoring R1's

[12] Although he did not cite to the specific regulations, Dr. Yao was referring to 42 C.F.R. § 483.75(i), which makes the medical director responsible for implementing resident care policies and coordinating medical care within the facility, and § 483.40, which governs physician services within the facility.

hydration. Tr. 149. Because identifying when such a patient is fluid overloaded or depleted or insufficient in her volume status can be confusing, such individuals "require day-to-day observation and assessment to properly manage them. . . ." Tr. 22.

Moreover, the problem here was not that the facility fell short of providing a complicated level of care; rather, the facility failed to provide even an ordinary level of care. Staff did not give this woman (who was fully capable of eating and drinking on her own) anywhere near the level of fluid she required; they delayed obtaining a necessary lab test; they did not develop an individualized care plan; no one considered why they should continue to administer potassium to someone who no longer took a potassium-depleting medication, and who had experienced dangerously high potassium levels; and, her attending physician did not even appear to recognize her most serious problems. R1's care may have been "challenging," but the facility did not even provide a level of care sufficient to address the problems of a resident without any significant complications.

For all of these reasons, I find that the facility was not providing R1 the care and services she needed to attain or maintain her highest practicable physical well-being and was therefore not in substantial compliance with 42 C.F.R. § 483.25.

E. CMS's finding of immediate jeopardy is not clearly erroneous.

I next consider whether CMS's immediate jeopardy finding was "clearly erroneous."

Immediate jeopardy exists if the facility's noncompliance has caused or is likely to cause "serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301. CMS's determination as to the level of a facility's noncompliance (which would include an immediate jeopardy finding) must be upheld unless it is "clearly erroneous." 42 C.F.R. § 498.60(c). The Board has observed repeatedly that the "clearly erroneous" standard imposes on facilities a "heavy burden" to show no immediate jeopardy, and has sustained determinations of immediate jeopardy where CMS presented evidence "from which '[o]ne could reasonably conclude' that immediate jeopardy exists." *Barbourville Nursing Home*, DAB No. 1962, at 11 (2005) (citing *Florence Park Care Center*, DAB No. 1931, at 27-28 (2004)) (citing *Koester Pavilion*, DAB No. 1750 (2000)); *Daughters of Miriam*, DAB No. 2067, at 7, 9 (2007).

I reject Petitioner's suggestion that R1's difficulties were simply the result of her underlying ailments, and not attributable to the care she received. Under any standard, the facility's deficiencies posed immediate jeopardy, because they caused or were likely to cause serious harm. Specifically:

- A seriously ill resident, identified as at risk for dehydration, received only a small fraction of the fluids she required. Not surprisingly, she ended up in the hospital with severe dehydration. I consider severe dehydration to be serious harm, and I

find that the facility's failure to keep her adequately hydrated likely caused that harm. In any event, not meeting the identified hydration needs of someone at risk for dehydration is likely to cause serious harm;

- The facility's failure to obtain timely the ordered lab tests for this resident meant that her rising potassium levels and deteriorating renal function went undetected for at least two days – and could have gone undetected for up to four days, but for her family's insistence that she be sent to the emergency room;

- Even after R1 had been diagnosed with dangerously high potassium levels, neither her attending physician, nurse practitioner, nor the facility's consulting pharmacist reviewed the decision to continue her potassium medication;

- Even after R1 had been diagnosed with dangerously high potassium levels, the facility did not monitor her potassium levels, and she ended up hospitalized with an even higher potassium level of 7.4, which subjected her to additional complications.

Based on these instances of actual and potential harm, I find that CMS's immediate jeopardy determination is not clearly erroneous.

F. CMS's determinations as to the duration of the noncompliance and immediate jeopardy are consistent with statutory and regulatory requirements.

Substantial compliance means not only that the specific cited instances of substandard care were corrected, and that no other instances have occurred, but also that the facility has implemented a plan of correction designed to assure that no such incidents occur in the future. The burden is on the *facility* to prove that it has resumed complying with program requirements, not on CMS to prove that deficiencies continued to exist after they were discovered. *Asbury Center at Johnson City*, DAB No. 1815, at 19-20 (2002). A facility's return to substantial compliance usually must be established through a resurvey. *Cross Creek Care Center*, DAB No. 1665 (1998); *Hermina Traeye Memorial Nursing Home*, DAB No. 1810, at 12 (citing 42 C.F.R. § 488.454(a) and (e)).

Petitioner complains about the duration of the period of noncompliance and the period of immediate jeopardy, claiming that all of its purported noncompliance occurred on or before December 15, and that any risk of harm to R1 ended on that day. P. Cl. Br. at 43-44. I find this assertion wholly unsupported and perplexing.

Even though CMS imposes its CMP as of December 15, the care provided R1 was deficient from the date of her admission. And, as the above discussion shows, her care did not improve following her December 15 emergency room visit. She continued to

receive only a fraction of the fluids she needed. P. Ex. 20. Knowing about her significant problems with potassium, the facility continued, without further assessment, to administer potassium to her. Prior to December 15, the facility had in place a deficient care plan, and the plan it drafted on December 28 was also deficient.

Moreover, although the cited deficiencies affected R1 most dramatically, they represented systemic problems relating to assessment, care planning, hydration, and obtaining sufficient, timely lab tests. For example, facility staff did not recognize symptoms of dehydration; they were not insuring that each resident receive the volume of fluid recommended in his/her dietary assessment. To correct, facility nurses assessed each resident for symptoms of dehydration. They initiated intake and output monitoring for the facility's at-risk residents to determine whether their fluid recommendations were being met. They advised the attending physicians of those instances in which a resident displayed symptoms of dehydration and/or was not receiving adequate fluids. Staff were trained to recognize symptoms of dehydration. Similar actions were taken to address the other deficiencies.

The facility told CMS the dates it completed these corrections. For the most part, it finished identifying the at-risk residents and completed the staff's in-service training by the end of January 2008. The facility set March 3 as the date it completed all of its corrections, and CMS apparently accepted the facility's dates. CMS Ex. 1.

Because Petitioner has not established that an effective plan of correction was implemented any earlier than that determined by CMS, I sustain CMS's determinations as to the duration of the periods of substantial noncompliance and immediate jeopardy.

IV. Conclusion

For the reasons discussed above, I find that, from December 15, 2007, through March 2, 2008, the facility was not in substantial compliance with Medicare requirements, specifically, 42 C.F.R. §§ 483.25, 483.25(j), 483.75(j), and 483.20(k)(3). From December 15, 2007, through January 28, 2008, its deficiencies posed immediate jeopardy to resident health and safety.

/s/
Carolyn Cozad Hughes
Administrative Law Judge