Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Virginia Highlands Health Rehab
(CCN: 52-5653),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-09-506

Decision No. CR2083

Date: March 4, 2010

DECISION

I grant summary disposition in favor of the Centers for Medicare & Medicaid Services (CMS) sustaining its determination to impose civil money penalties against Petitioner, Virginia Highlands Health and Rehabilitation Center, totaling $247,550.[1]

I. Background

Petitioner is a skilled nursing facility located in Germantown, Wisconsin. It participates in the Medicare program. Its participation in Medicare is governed by sections 1818 and 1866 of the Social Security Act and by implementing regulations at 42 C.F.R. Parts 483 and 488. Its hearing rights in this case are governed by regulations at 42 C.F.R. Part 498.

[1] The civil money penalties consist of penalties of $10,000 per day for each day of a period that began on March 2, 2009 and which continued through March 23, 2009, and of $950 per day for each day of a period that began on March 24, 2009 and which continued through April 21, 2009. I discuss these penalty amounts and duration in detail below.

CMS determined to impose against Petitioner the civil money penalties that I describe in this decision's opening paragraph based on noncompliance findings that were made at a survey conducted at Petitioner's facility on March 24, 2009.[2] The noncompliance findings included findings that Petitioner manifested immediate jeopardy level deficiencies.

Petitioner requested a hearing and the case was assigned to me for a hearing and a decision. I issued a pre-hearing order which directed the parties to file pre-hearing briefs and to exchange all of their proposed evidence including the written direct testimony of each proposed witness. CMS exchanged a total of 127 proposed exhibits which it identified as CMS Ex. 1 – CMS Ex. 127. Petitioner exchanged a total of 22 proposed exhibits which it identified as P. Ex. 1 – P. Ex. 22. I receive all of the parties proposed exhibits, including the written direct testimony of their witnesses, into the record of this case.

CMS then moved for summary disposition. Petitioner opposed the motion.

II. Issues, findings of fact and conclusions of law

A. Issues

The issues in this case are whether the undisputed material facts establish that:

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

2. CMS's finding of immediate jeopardy is not clearly erroneous; and

3. CMS's remedy determinations, as to penalty amount and duration, are reasonable.

B. Findings of fact and conclusions of law

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

[2] The penalty amounts in this case also take into consideration previous episodes of noncompliance by Petitioner with Medicare participation requirements.

1. The undisputed material facts establish that Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.25(j).

Lying at the heart of this case are CMS's allegations that Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.25(j). This regulation requires a skilled nursing facility to provide each of its residents "with sufficient fluid intake to maintain proper hydration and health."

There is no dispute as to what is meant by sufficient fluid intake. Petitioner's own policies define "sufficient fluid" as "the amount of fluid needed to prevent dehydration." CMS Ex. 76, at 1. Dehydration occurs whenever a resident's fluids output greatly exceeds that resident's intake of fluids. *Id.* Dehydration is a serious condition that can cause a resident to experience grave consequences, including death, if not prevented or properly treated. CMS Ex. 123, at 2; CMS Ex. 124, at 2.

a. Resident # 26

CMS's allegations of noncompliance with the hydration regulation focus to a large extent on the care that Petitioner and its staff provided to a resident who is identified as Resident # 26. It is undisputed that, on February 23, 2009, this resident was transported from Petitioner's facility to a local hospital. CMS Ex. 43. On admission the resident was diagnosed to be suffering from, among other things, renal insufficiency, a C-difficile infection, and volume depletion. *Id.* at 6. The resident was observed to be suffering from "skin tenting", a manifestation of decreased skin turgor, and a sign of dehydration. *Id.* at 12. In light of these findings the hospital emergency room physician ordered that Resident #26 be administered intravenous fluids and more than 1.3 gallons of fluids were given to the resident. *Id.* at 11-15, 27. Treatment was unavailing and the resident died within 12 hours of his admission. CMS Ex. 44.

The undisputed facts establish also that Resident # 26 was admitted to Petitioner's facility on January 13, 2009, a little more than a month prior to the date of his death. Petitioner's staff assessed the resident to be at risk for dehydration. CMS Ex. 30; CMS Ex. 34, at 7; CMS Ex. 35, at 2. The assessment of a dehydration risk was based in part on the fact that the resident was taking Lasix, a diuretic medication. CMS Ex. 34, at 2; CMS Ex. 35, at 2. Petitioner's hydration management guidelines note that diuretic medications are a risk factor for dehydration. CMS Ex. 76, at 4.

At about the time of the resident's admission Petitioner's dietician determined that the resident needed to consume 2000 cc of fluid daily in order to avoid becoming dehydrated. CMS Ex. 36. At some point in January 2009, Petitioner's staff developed a care plan for the resident which required the staff to: check the resident's skin turgor each shift, place fluids at the resident's bedside within the resident's reach; provide eight ounces of fluids at each medication pass; provide eight ounces of extra fluids for the resident at each

meal; notify the resident's physician of a change in the resident's status; and monitor the resident's laboratory values. CMS Ex. 35, at 2. However, the care plan did not direct the staff to monitor the resident's intake and output of fluids.

It is also undisputed that, at the time of his admission, Resident # 26 was receiving 20 mg. of the diuretic Lasix once each day. On January 24, 2009, the resident's physician ordered that the resident's Lasix dosage be quadrupled to 40 mg., twice daily. CMS Ex. 38, at 12,13. This increase in the resident's diuretic medication did not prompt Petitioner's staff to reassess his fluid intake needs nor did they develop a new care plan for the resident that took into account the increased dosage of Lasix.

Furthermore, there is no dispute that, on February 11, 2009, Resident # 26 developed diarrhea. P. Ex. 17, at 2. Diarrhea may be a cause of dehydration. That is recognized in Petitioner's own internal guidelines. CMS Ex. 76, at 3. Fluid intake by a resident that might, under normal circumstances, be considered adequate and may be insufficient to prevent dehydration if that resident is experiencing diarrhea. ***Id.***

Petitioner's staff made a notation on the resident's care plan that his diarrhea was an additional risk factor for dehydration. CMS Ex. 35, at 2. The undisputed facts are that the resident's diarrhea persisted from the time of its development until his admission to the hospital on February 23, 2009. CMS Ex. 37, at 4-5; CMS Ex. 39, at 8-10; CMS Ex. 40, at 18-30; CMS Ex. 43. But, the staff did not modify the resident's care plan to account for the resident's diarrhea despite the persistence of this dangerous condition. No increased monitoring of the resident was planned nor did Petitioner's dietician increase the resident's daily fluid requirements to compensate for his diarrhea.

The undisputed facts relied on by CMS thus establish the following:

- Resident # 26 was known to Petitioner's staff from the moment of his admission to be at risk for dehydration.

- The staff implemented a care plan to address the resident's dehydration risk. However, this care plan, which included an estimated necessary fluid intake by the resident of 2000 cc per day, was based only on the resident's condition *at the time of his admission to the facility*.

- The plan put into effect by Petitioner's staff failed to put into place any objective mechanism to monitor the intake or output of fluids by the resident. Thus, the staff could not determine objectively whether the resident's output of fluids exceeded his intake.

- During the resident's stay at the facility the risk that the resident might become dehydrated was greatly exacerbated by virtue of the increase in his prescribed diuretic medication and his development of persistent diarrhea.

- Despite these additional or enhanced dehydration risk factors the staff failed to revise the resident's care plan or to implement additional interventions to account for them. The staff knew that the resident's use of a diuretic at the time of his admission to the facility posed a risk for dehydration but they made no reassessment of that risk and planned no new interventions even though the resident's dosage of the diuretic was subsequently increased fourfold. The staff knew, and recorded, that the resident had diarrhea but conducted no reassessment of the resident based on that development and implemented no new measures to protect him.

These undisputed facts are more than enough to establish noncompliance with the requirements of 42 C.F.R. § 483.25(j) and a failure by Petitioner and its staff to protect Resident # 26 against becoming dehydrated. Petitioner's staff appears to have been aware of the heightened dehydration risks encountered by Resident # 26. But, the facts offered by CMS show that, notwithstanding this knowledge, the staff did nothing to enhance the protection that they were offering the resident in order to offset the increased risks to that individual. They did not assess the resident to determine whether he needed to increase his fluid consumption. They did not attempt to increase the amount of fluid that he consumed. They did not increase their surveillance of the resident. And, they did not attempt to determine objectively whether the resident was becoming dehydrated as a result of putting out more fluid than he was consuming. This last failing is especially significant because, without measuring the resident's fluid output, Petitioner's staff had no way of knowing whether the amount of fluids that they were giving to him each day was sufficient to protect against dehydration.

And, clearly, the resident was severely dehydrated upon his admission to the hospital on February 23, 2009. One might argue about the cause of the resident's dehydration but there is no dispute that this resident was suffering from massive fluid depletion. That is established by the undisputed fact that the hospital physician found it necessary to administer more than 1.3 gallons of fluids to the resident upon his admission. It is also made evident by the resident's appearance on admission, including observation that he manifested tenting of his skin, an obvious sign of advanced dehydration.

The facts offered by CMS would establish noncompliance with the hydration regulation in providing care for Resident # 26 even if the resident had not become dehydrated. Petitioner's staff's failure to assess and respond to risk factors for dehydration that the resident encountered after his admission and after the staff had developed its initial care plan is sufficient in and of itself to establish noncompliance.

In order to provide proper hydration to a resident a facility must assess the resident's condition and must adjust whatever protective measures it adopts to account for changes that may occur. Here, there were obvious developments in the condition of Resident # 26 that put Petitioner and its staff on notice that the measures that they adopted when the resident was admitted to the facility to keep the resident hydrated might well be obsolete. These new developments – clearly enhanced risk factors in the case of this resident – included the fourfold increase in the dosage of the resident's diuretic medicine and his development of persistent diarrhea. Petitioner's staff failed to take any meaningful measures to react to these changes in the resident's condition.

Petitioner makes several arguments and assertions concerning the care it provided to Resident # 26. All of them, however, are based on a central premise. That is Petitioner's contention that a facility cannot be found to have contravened 42 C.F.R. § 483.25(j) absent a showing that staff failures to hydrate adequately residents caused those residents to become dehydrated. In essence, Petitioner contends that noncompliance with the hydration regulation occurs only when residents are, by objective measures, not adequately hydrated.

Taken to its logical conclusion Petitioner's argument means that even a facility that provides *no* measures to assure that its at risk residents are adequately hydrated would be in compliance with the hydration regulation if, by chance, all of its residents were adequately hydrated. Petitioner's argument also means, essentially, that the measures that a facility takes or fails to take on behalf of its residents' hydration needs are irrelevant to determining whether that facility is in compliance with the hydration regulation. All that matters, under Petitioner's theory, is whether residents are adequately hydrated however they obtain fluids.

The governing regulation provides no support for this argument. The regulation, on its face, requires that a facility provide adequate hydration to its residents. But, assuring adequate hydration is not a matter of chance or random luck. In order for a facility to comply with the regulation it must assess its residents' needs, it must plan to care for those needs, and it must implement the care plans that it develops. Furthermore, a facility is obligated to continually reassess its residents' needs and to adjust their care plans, if necessary, as the residents' conditions change.

The hydration regulation is a subsection of 42 C.F.R. § 483.25. The general preamble to the regulation's subsections states:

> Each resident 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 comprehensive assessment and plan of care.*

42 C.F.R. § 483.25 (emphasis added). The requirement of assessment and care planning is therefore incorporated into every one of the regulation's subsections including 42 C.F.R. § 483.25(j). A facility that fails adequately to assess its residents' hydration needs or to plan their care pursuant to the assessment, is noncompliant even as is the facility that fails to implement a care plan.

Petitioner contends, relying on an affidavit by Dirk Steinart, M.D., Petitioner's medical director, that the resident's decline, his dehydration, and ultimately, his death, was caused by a medical condition – sepsis – and not by any noncompliance by Petitioner or its staff. Petitioner's response to CMS's motion for summary judgment (Response) at 7; P. Ex. 17, at 3-6. For the purposes of this decision I accept this assertion as true. However, it is irrelevant. Petitioner is not excused from compliance with the hydration regulation by the fact that the resident may have experienced or even died from sepsis. As I discuss above, Resident # 26 manifested risk factors resulting from his consumption of diuretic medication and his chronic diarrhea which Petitioner was required to address but which it did not address. The fact that the resident may also have developed sepsis provides no justification for Petitioner's failure to address these factors.

Dr. Steinart also asserts that whatever dehydration the resident experienced was not caused by acts or omissions by Petitioner's staff. P. Ex. 17, at 4-5. According to Dr. Steinart, when seen at the hospital the resident's sodium and potassium levels were within normal limits, his urine output was adequate, his creatinine levels were not such as to indicate dehydration resulting from an extended period of dehydration, and his overall laboratory results were not consistent with someone suffering from a severe or extended fluid intake deficit. I accept all of these assertions of fact as true. However, they are irrelevant as is Dr. Steinart's conclusion that the cause of the resident's death was sepsis and not a generalized failure by Petitioner's staff to hydrate Resident # 26 adequately.

A finding of noncompliance in this case does not depend on a finding that Petitioner's omissions caused Resident # 26 to experience an adverse outcome. The deficiency rests on the failure by Petitioner and its staff to address the increased risks manifested by the resident *whether or not the resident experienced an adverse outcome*. That Petitioner's noncompliance may not have been the proximate cause of the resident's sepsis-related dehydration may have been fortuitous but it is no defense. As I discuss above, Petitioner's staff should have known that quadrupling the quantity of diuretic medicine given to Resident # 26 risked dehydrating him. And, they certainly knew that the resident was at a greatly enhanced risk of dehydration as a consequence of his persistent diarrhea over a period of about 10 days. But, notwithstanding what the staff knew or should have known, they failed to assess the dimensions of the risks encountered by the resident and they failed to make changes in the resident's care in order to address those risks. They did not increase the resident's fluid consumption nor did they monitor the resident in a way that would have detected the signs of dehydration, including dehydration from a cause such as sepsis.

Dr. Steinart also asserts that he evaluated Resident # 26 when he saw the resident on January 15, January 24, January 29, February 5, and February 12, 2009 and that the resident manifested no signs of dehydration on these occasions. P. Ex. 17, at 3. Again, I accept these assertions as true. But, assuming them to be true, they beg the question of Petitioner's duty to address the risks of dehydration that Resident # 26 faced. Furthermore, Dr. Steinart does not contend that he evaluated the resident after February 12, 2009 and the resident manifested persistent diarrhea beginning on February 11 and continuing through his admission to the hospital on February 23, 2009. Thus, the resident manifested diarrhea – and attendant risk factors for dehydration – during a period when he was not personally assessed by Dr. Steinart.

Petitioner also offers the affidavits of Christy Bozich and Laurel Sormrude, L.P.N., to support its assertion that there are material facts in dispute concerning the hydration care given to Resident # 26. Ms. Bozich, who is a social worker and not a nurse, avers that the staff was aware of the resident's diarrhea and noted it on his care plan as a significant change in his condition. P. Ex. 21, at 7. However, according to Ms. Bozich, the facility Action Team (evidently, the staff group whose responsibilities included assuring that residents received appropriate hydration):

> Never discussed . . . [Resident # 26's] fluid intake because there were never any concerns regarding . . . [the resident's] fluid intake.

P. Ex. 21, at 8. That assertion, assuming its truth, raises no disputed issue of fact in this case. The question here is not whether staff had "concerns" about the resident's hydration but whether they *should have had* concerns given the resident's increased dosage of diuretic medication and his persistent diarrhea. I have made it plain that those two factors were danger signs that the staff should have identified and addressed with an updated assessment and, if necessary, new interventions. Moreover, the amount of fluid that the resident consumed is not, by itself, a measure of whether the facility assured that he was hydrated adequately. Petitioner's own guidelines assert that dehydration is a condition in which *output* of fluids greatly exceeds *input*. CMS Ex. 76, at 1. Intake is only one side of the equation that one must address in protecting a resident against dehydration. In this case, the resident encountered risk factors that potentially greatly increased his output of fluids. The staff's deficiency lay in their failure to take those factors into consideration.

I find Ms. Sormrude's assertions, as expressed in her affidavit, to be similarly irrelevant to the issue of whether Petitioner properly managed Resident # 26's hydration. P. Ex. 22. Ms. Sormrude avers that she had no concern about the resident's level of fluid intake. *Id.* at 4. She asserts the conclusion that the resident was provided sufficient fluid by Petitioner's staff to maintain proper hydration and to maintain his health. *Id.* And, she discusses in some detail the efforts by staff to offer the resident fluids at mealtimes and during medication passes. What is missing from her affidavit is any discussion of how

Petitioner's staff tracked the resident's output of fluids. Nor does Ms. Sormrude suggest that the staff considered whether the fluids that they originally determined to give to Resident # 26 remained adequate given his increased consumption of diuretic medication and his persistent diarrhea.

As I discuss above, giving fluids to a resident is only part of the equation that must be addressed in order to assure that a resident is hydrated adequately. Adequate hydration cannot be assured unless there is a reasonable balance between what a resident takes in and what he excretes. Nothing in Ms. Sormrude's affidavit explains how Petitioner's staff – in light of the increased dehydration risk factors faced by Resident # 26 – addressed how Petitioner would account for these factors. Nor does Ms. Sormrude explain how Petitioner assured that a balance was maintained between the fluids that Petitioner gave the resident and his output.

The only reasonable inference that I can draw from the facts offered by CMS and Petitioner is that Petitioner did not address the increased risk factors faced by Resident # 26. To reiterate, there is no evidence whatsoever showing that Petitioner's staff assessed the resident for the risk factors posed by his increased dose of diuretic medication or by his persistent diarrhea. The failure by Petitioner's staff to address, systematically or objectively, those increased risk factors was a deficiency because it meant that Petitioner was in no position to assure that Resident # 26 was hydrated adequately.

Petitioner argues that a failure to monitor a resident's intake and output of fluids – and, in particular, its failure to monitor Resident # 26's intake and output – is not in and of itself a deficiency. I agree with Petitioner to the extent that I conclude that there is no language in 42 C.F.R. § 483.25(j) that explicitly directs a skilled nursing facility to monitor each resident's fluid intake and output. However, a facility cannot possibly assure that an at-risk resident, such as Resident # 26, is protected adequately against dehydration unless it has some way of determining that the resident's consumption of fluids equals or exceeds that which he is excreting.

Petitioner had no system in place that would assure that Resident #26's consumption of fluids equaled or exceeded that which he excreted. Petitioner argues repeatedly that it gave the resident adequate quantities of fluid. But, this conclusion is not supported by the undisputed material facts. The undisputed facts establish that Petitioner and its staff had no way of knowing whether they were giving the resident adequate quantities of fluid. It is an undisputed fact that the staff made an assessment of the quantity of fluid that the resident needed to consume based on his condition as of the time of his admission to the facility and never revisited that issue of how much the resident needed to consume despite the fact that the resident encountered greatly increased risks of dehydration during his stay at Petitioner's facility. It is also an undisputed fact that Petitioner's staff never developed any specific interventions to address the resident's increased risk of

dehydration. And, finally, it is an undisputed fact that Petitioner had absolutely no objective mechanisms in place to assure that the resident's output did not greatly exceed his intake.

b. Other residents

CMS offers facts – which I find to be undisputed – which establish that Petitioner neglected to address the hydration needs of residents other than Resident # 26. The shortcomings in care with respect to these other residents are very similar to those manifested by Petitioner's care of Resident # 26. The undisputed facts show that each of these residents experienced hydration risk factors during his or her stay at Petitioner's facility that were not assessed or addressed systematically by Petitioner's staff.

Petitioner has not offered evidence to call into dispute any of the facts relied on by CMS. Instead, Petitioner makes essentially the same argument with respect to these other residents that it makes concerning its care of Resident # 26. According to Petitioner:

> CMS presents no actual instance of insufficient fluid intake or dehydration for any of these residents. CMS does not offer a single lab report, a single clinical symptom, or identify a single instance of actual dehydration. All CMS offers is that there is a *theoretical* risk for these residents to have experienced dehydration.

Response at 11 (emphasis in original). Petitioner couples this assertion with facts that are intended to show that ample fluids were provided to all of the remaining residents whose care is at issue.

This argument fails here for the same reason that it fails with respect to Resident # 26. As it argues with respect to the care it gave to Resident # 26, Petitioner essentially asserts a kind of "no harm, no foul" theory which would absolve it so long as its residents did not become objectively dehydrated. Petitioner's argument again ignores the regulatory requirement that a facility's staff assess residents' hydration risks and plan their care accordingly.

The risks to these residents that are established by the undisputed material facts offered by CMS are not theoretical but are real. The development of those risks and hazards imposed on Petitioner's staff imposes the obligation to assess the risks and to plan for them. It is not sufficient to assert, as Petitioner argues, that its staff always offered ample fluids to its residents because the undisputed facts establish that Petitioner failed entirely to address its residents' hydration needs in a comprehensive way that would take into account the possibility – due to enhanced risk factors – that residents would become dehydrated in spite of the quantity of fluids that the staff offered to them. For purposes of this decision I accept as true the contentions of Petitioner and its witnesses that all of its

residents were offered ample fluids by the staff. But, that assertion begs the question of Petitioner's compliance. Petitioner literally had nothing in place that would have addressed whether these residents' intake of fluids balanced their output. Thus, Petitioner's staff had no way of knowing objectively whether these residents were, in fact, adequately hydrated.

i. Resident # 12

The undisputed facts offered by CMS establish that this resident had a care plan for fluid deficit dated February 2009 that listed vomiting, diarrhea, and diuretic medications as risk factors for dehydration. CMS Ex. 56. On February 24, 2009, Petitioner's dietician observed that the resident's appetite had decreased. She estimated the resident's daily fluid intake need as 1800 cc. CMS Ex. 57, at 2. A review of the resident's condition conducted by staff on March 6, 2009 concluded that the resident's risk for fluid deficit had increased because the resident had a urinary tract infection. CMS Ex. 55, at 1. On March 13, 2009, the resident's physician ordered that the resident's fluid intake be increased. CMS Ex. 58.

However, and notwithstanding all of these findings that Resident # 12 was at increased risk of dehydration and needed additional fluids, Petitioner's staff never modified the resident's fluid deficit care plan. Nor did the facility staff direct an increase in the amount of fluids given to the resident in response either to the March 6 review or the physician's order. Thus, the undisputed material facts establish a failure by Petitioner to plan and implement appropriate interventions to assure that Resident # 12 received additional fluids in the face of increased dehydration risk factors.

ii. Resident # 27

The undisputed facts offered by CMS establish that in December 2008 Petitioner's staff estimated that this resident needed to consume 1700 cc of fluid per day. CMS Ex. 47. Subsequently, this resident experienced loss of appetite, she lost weight, she developed diarrhea, and she complained of occasional vomiting. CMS Ex. 48, at 1. Her diarrhea continued in January and February 2009. She continued to manifest diarrhea and to lose weight in March 2009. *Id.* at 2-4. However, Petitioner did not adjust the resident's estimated fluid intake or make any changes to the resident's hydration care plan subsequent to December 2008 despite these changes in her condition and the development of a new and obvious risk factor for dehydration (persistent diarrhea).

iii. Resident # 7

The undisputed facts establish that Resident # 7 manifested several risk factors for dehydration. The resident experienced dysphagia, weight loss, hypotension and severe skin break down. He was on a diet of thickened liquids and he was receiving

psychotropic medications. CMS Ex. 6; CMS Ex. 7, at 9-10; CMS Ex. 17, at 17; CMS Ex. 18; CMS Ex. 124, at 3; P. Ex. 9, at 2. In September 2008 Petitioner's staff estimated that the resident required 2000 cc of fluid per day. However, subsequently, this resident developed multiple pressure sores, including one that was assessed as a Stage 4 ulcer. CMS Ex. 19; CMS Ex. 21. I take notice that pressure ulcers can be a cause of fluid loss. However, Petitioner did not modify the resident's care plan to take into account increased risk factors. And, although it was tracking the resident's fluid intake, it did not track his output. CMS Ex. 62; *see* CMS Ex. 63. Consequently, Petitioner's staff was in no position to evaluate objectively whether the resident's output exceeded his intake.

iv. Resident # 28

The undisputed facts show that this resident manifested several risk factors for dehydration. Resident # 28 suffered from dementia, end-stage congestive heart failure, a urinary tract infection, a C. difficile infection, and diarrhea. CMS Ex. 65 – CMS Ex. 69. The resident also experienced weight loss. Petitioner's staff developed a care plan for dehydration and fluid deficit. CMS Ex. 68, at 1-2. However, the staff made no estimate of the amount of fluids the resident needed to consume. *Id.*; CMS Ex. 69, at 2. Petitioner's staff could not have known objectively whether the resident was being hydrated adequately because it made no evaluation of what the resident needed to consume in order to be hydrated adequately.

v. Resident # 29

The undisputed facts are that this resident was on a regime that restricted her intake of fluids. CMS Ex. 1, at 123. The resident risked becoming dehydrated if the restriction proved to be too great. That made it imperative that Petitioner track the resident's consumption of fluids. However, Petitioner's staff failed to do so comprehensively or diligently. Between March 16 and March 22, 2009 the staff tracked some, but not all, of the resident's fluid intake. CMS Ex. 78, at 2. On other dates (March 6, and March 8-15, 2009) the staff tracked some, but not all, of the resident's fluid intake. CMS Ex. 79.

2. The undisputed material facts establish that CMS's determination of immediate jeopardy level noncompliance with 42 C.F.R. § 483.25(j) is not clearly erroneous.

Immediate jeopardy is defined to mean noncompliance that:

> has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident.

42 C.F.R. § 488.301. A determination of immediate jeopardy by CMS must be sustained absent evidence proving it to be clearly erroneous. In a case where summary disposition is sought, as with this one, I must sustain CMS's determination of immediate jeopardy where there are no facts from which I might reasonably infer that the determination is clearly erroneous.

There are no such facts here. The undisputed material facts show that residents of Petitioner's facility were placed at grave risk for dehydration. The undisputed facts establish a likelihood of serious injury, harm, impairment, or death, in the cases of these residents even if these residents did not become dehydrated as a result of misfeasance by Petitioner.

The undisputed facts relating to Resident # 26 are illustrative. The resident was at risk for organ failure and death as a consequence of dehydration.

> Especially in the elderly, insufficient hydration can lead to hypotension (low blood pressure) and death. It could also cause renal failure. Hydration is essential to bodily functions because our bodies are approximately 50 to 70 percent water. Dehydration depletes cells' fluid and can cause trauma and, ultimately, irreversible cell damage, organ failure, and death.

CMS Ex. 124, at 2.

Petitioner's staff knew that there were extreme risks factors present in his case (the increase in the prescribed dose of diuretic medication and the resident's persistent diarrhea) and yet, they failed to put into place measures that were clearly necessary to protect the resident from becoming dehydrated. They did not reassess him when the new risk factors became evident, they did not consider the possibility that his fluid intake might need to be adjusted to compensate for the presence of heightened risk, and they did nothing to assure that there were objective measurements that would have tracked the resident's ratio of intake vs. output of fluids. By any objective measure, this resident was, consequently, in a position where he was likely to become dehydrated.

The failure of Petitioner's supervision of Resident # 26 was made manifest when the resident presented at the hospital on February 23, 2009. The resident was, on that date, severely dehydrated, so much so that the hospital medical professionals infused him with more than 1.3 gallons of fluids. Yet, Petitioner had nothing in place that would have forewarned the staff that the resident was becoming so dehydrated. Even if sepsis – and not persistent inadequate fluid administration – was the proximate cause of the resident's dehydration the staff should have detected the signs of a grave and extremely dangerous condition, but they failed to do so.

Petitioner asserts that there are disputed issues of fact concerning CMS's determination of immediate jeopardy. However, it has pointed to nothing that is materially in dispute. Rather, Petitioner characterizes CMS's assertion that there was a likelihood of harm to the residents, including Resident # 26, as being merely speculative and asserts that there are:

> [V]arying degrees of dehydration which would result in varying degrees of potential harm, many of which would never rise to the level of . . . immediate jeopardy.

Response at 13-14.

I do not find CMS's argument that dehydration may lead to organ failure or death to be at all speculative. It is grounded on expert testimony that Petitioner has not rebutted with any facts. CMS Ex. 124, at 2.

3. The undisputed material facts establish CMS's civil money penalty determinations to be reasonable in duration and amount.

CMS determined that Petitioner failed to comply substantially with several participation requirements in addition to the noncompliance with 42 C.F.R. § 483.25(j). I find it unnecessary that I address these additional findings in this decision because Petitioner's noncompliance with 42 C.F.R. § 483.25(j), when considered in context with Petitioner's past egregious noncompliance with participation requirements, is sufficient to justify both the duration and the amounts of the civil money penalties that CMS determined to impose.[3]

a. CMS's determinations as to duration of noncompliance are supported by the undisputed material facts.

CMS determined that Petitioner's immediate jeopardy level noncompliance with the hydration regulation began on February 11, 2009 and continued unabated at that level

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[3] The alleged additional noncompliance included an alleged immediate jeopardy level failure to comply with the requirements of section 483.25(c)(2) (treatment of pressure sores), and eight alleged non-immediate jeopardy level deficiencies at 42 C.F.R. §§ 483.10(b)(11)(i) (consultation with treating physician); 483.25 (quality of care); 483.25(h)(1) (maintaining a resident environment free from accident hazards); 483.13(c)(3) (investigation of abuse); 483.20(d), (k) (review and revision of plans of care); 483.20(g) (resident assessment); 483.35(i)(2) (sanitation); and 483.75(*l*)(1) (clinical records). CMS did not move for summary disposition regarding the alleged immediate jeopardy level noncompliance with 42 C.F.R. § 483.25(c)(2) but moved for summary judgment as to the eight alleged non-immediate jeopardy level deficiencies.

until March 24, 2009. It found noncompliance at the non-immediate jeopardy level, including noncompliance with 42 C.F.R. § 483.25(j), continued through April 21, 2009.

CMS's determinations of duration are presumptively correct. A facility may rebut a duration determination only by proving affirmatively that it became noncompliant on a date that is later than that which CMS determined to be the date when noncompliance began and/or that it corrected the noncompliance on a date that is earlier than that which CMS determined to be the date when compliance was attained. In deciding a motion for summary disposition I ask: has Petitioner adduced any facts which, if true, would rebut the presumption of duration?

I find that Petitioner has not done so. Petitioner asserts in its Response that "(t)here are material questions of fact whether the . . . duration of the [civil money penalties are] reasonable." Response at 14. However, it has not offered any facts that call into question CMS's duration determinations. It has offered no affirmative proof to show that it abated the immediate jeopardy level noncompliance with 42 C.F.R. § 483.25(j) on any date that is earlier than March 24, 2009. Nor has it offered affirmative proof to show that its immediate jeopardy level noncompliance began later than February 11. Petitioner offered no affirmative evidence to show that its non-immediate jeopardy level noncompliance ended earlier than April 21.

b. CMS's determinations as to penalty amounts are supported by the undisputed material facts.

At issue in this case are two civil money penalty amounts: $10,000 per day for each day of Petitioner's immediate jeopardy level noncompliance; and $950 per day for each day of Petitioner's non-immediate jeopardy level noncompliance. Civil money penalties that are intended to remedy immediate jeopardy level deficiencies must fall within a range of from $3,050 to $10,000 per day. 42 C.F.R. § 488.438(a)(1)(i). Civil money penalties that are intended to remedy non-immediate jeopardy level deficiencies must fall within a range of from $50 to $3,000 per day. 42 C.F.R. § 488.438(a)(1)(ii).

There are regulatory factors which may be considered in deciding whether a penalty amount within one of the two ranges is reasonable. These factors include: the seriousness of a facility's noncompliance; its compliance history; 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)). The undisputed material facts in this case strongly support CMS's determinations, both as to immediate jeopardy, and as to non-immediate jeopardy penalty amounts. Petitioner has offered no facts that would call into dispute the facts relied on by CMS.

I address first the immediate jeopardy level civil money penalty amount of $10,000 per day. This is the highest possible daily penalty amount and, as Petitioner correctly notes, is generally reserved for the most egregious noncompliance.[4] I find such to be reasonable here because Petitioner's noncompliance was egregious and because Petitioner has a history of serious noncompliance with Medicare participation requirements.[5]

The failure by Petitioner's staff to assess and plan for the hydration needs of its residents was especially egregious because several of the residents including, but not only, Resident # 26, manifested changes in their clinical conditions that the staff knew about but which they failed to address. These residents were in grave danger of life threatening consequences. Petitioner's staff failed to recognize and address appropriately that danger.

This is not a simple case of failure to review residents' conditions periodically or to revise care plans on a scheduled basis. To the contrary, several of Petitioner's residents manifested highly dangerous changes in their conditions which Petitioner's staff knew about and, yet, the staff failed even to consider meaningful measures to protect these residents. Thus, Resident # 26's care plan was never reevaluated or revised even though he developed two conditions that threatened his state of hydration, his safety, and his life.

Not only did the staff fail to react appropriately to the discovery of hydration risk factors but they were clueless as to how to react. Petitioner's own hydration management guidelines define dehydration as a circumstance where output of fluids far exceeds fluid intake. CMS Ex. 76, at 1. These guidelines effectively told Petitioner's staff that they could not manage the care of residents who were at risk for dehydration unless they could assure that these residents were not excreting more fluid than they consumed. That is, in fact, the essential minimum element of proper hydration care. Yet, in the case of the residents whose care I address in this decision Petitioner's staff did not develop any mechanisms for assuring that output did not exceed intake. And, in some instances, they not only failed to track output but they failed to track intake as well.

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[4] However, I reject Petitioner's suggestion that penalties of $10,000 per day should be reserved for "fraudulent or criminal behavior." *See* Response at 15. Petitioner has offered no legal support for this suggestion.

[5] CMS also urges that I consider the alleged non-immediate jeopardy level deficiencies as a reason for imposing a maximum $10,000 per day immediate jeopardy level penalty amount. I need not address the impact of these alleged non-immediate jeopardy level deficiencies because I conclude that the egregiousness of Petitioner's noncompliance coupled with its history of serious noncompliance is sufficient, in and of itself, to justify the $10,000 per day penalty amount.

Petitioner's noncompliance is made more egregious by its poor compliance history. The undisputed facts establish that Petitioner has a history of immediate jeopardy level noncompliance. In 2007, Petitioner paid civil money penalties totaling more than $12,500 to remedy an immediate-jeopardy level deficiency. CMS Ex. 127. They establish also that, in 2008, Petitioner paid civil money penalties of more than $151,000 to remedy another immediate jeopardy level deficiency. *Id.* What is evident from this history is that the imposition of civil money penalties against Petitioner, even very substantial civil money penalties, has not been sufficient to deter Petitioner from committing egregious noncompliance. In light of this fact, a maximum penalty amount is not only reasonable, it is necessary.

Petitioner argues that CMS's remedy determination was premised on findings of not one, but two immediate jeopardy level noncompliance findings. It contends that, axiomatically, a maximum penalty may not be imposed if there is only a single finding of an immediate jeopardy level deficiency. I disagree. The regulations make it clear that a penalty of up to $10,000 per day may be imposed to remedy even a single finding of immediate jeopardy level noncompliance. 42 C.F.R. § 488.438(a)(1)(i). The single finding of immediate jeopardy for which I grant summary disposition is more than enough in this case to justify the maximum penalty amount, given the egregiousness of the noncompliance and Petitioner's compliance history.

Petitioner also complains that CMS failed to take into account Petitioner's financial condition in determining the penalty amounts. CMS is not required to prove a negative. The regulations afford a facility the opportunity to prove that it lacks the wherewithal to pay a civil money penalty. But, the regulations impose no burden on CMS to investigate a facility's financial condition before determining to impose a penalty. Petitioner could have come forward with evidence – to the extent that it exists – proving it lacked the ability to pay the penalties in this case. In fact, it has offered nothing addressing that possible issue.

I turn next to the $950 per day civil money penalty that CMS imposed to remedy Petitioner's continuing non-immediate jeopardy level noncompliance. Petitioner has offered neither argument nor facts to challenge CMS's determination. Consequently, I sustain it. I add, however, that $950 per day is not unreasonable in light of Petitioner's compliance history and the inherent seriousness of any failure by a facility – even at the non-immediate jeopardy level – to protect its residents against dehydration.

/s/
Steven T. Kessel
Administrative Law Judge