Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Claiborne and Hughes Health Center, (CCN: 44-5157)	)	Date: November 09, 2007
	)	
Petitioner,	)	
	)	
- v. -	)	Docket Nos. C-07-31 C-07-111
	)	Decision No. CR1687
Centers for Medicare & Medicaid Services.	)	
	)	

DECISION

I sustain the determination of the Centers for Medicare & Medicaid Services (CMS) to impose remedies against Petitioner, Claiborne and Hughes Health Care Center, consisting of the following:

- Civil money penalties of $3,050 per day for each day of a period beginning on July 18, 2006 and continuing through September 4, 2006; and

- Civil money penalties of $100 per day for each day of a period beginning on September 5, 2006 and continuing through September 17, 2006.

- Denial of payment for new admissions for each day of a period that began on August 20, 2006 and continuing through September 17, 2006.

I. Background

Petitioner is a skilled nursing facility that is located in Franklin, Tennessee. Petitioner participates in the Medicare program. Its participation in Medicare is governed by sections 1819 and 1866 of the Social Security Act and by implementing regulations at 42 C.F.R. Parts 483 and 488. Additionally, its right to a hearing in these cases, and the hearing process, are governed by regulations at 42 C.F.R. Part 498.

Surveys of Petitioner's facility for compliance with Medicare participation requirements were completed on August 14, 2006 (August survey) and on September 6, 2006 (September survey). Based on these surveys CMS determined that Petitioner was not complying with Medicare participation requirements and determined to impose the above-described remedies against Petitioner. Petitioner requested hearings from CMS's determinations and its hearing requests were docketed separately as Civil Remedies Docket No. C-07-31 (the challenge to the August survey results and remedy determination) and Civil Remedies Docket No. C-07-111 (the challenge to the September survey results and remedy determination). The cases were assigned to me for hearings and decisions.

In each case I directed the parties to file a pre-hearing exchange consisting of their proposed exhibits, including the written direct testimony of their proposed witnesses, and briefs. Each party completed its exchange in each case. In Docket No. C-07-31, CMS filed a brief and proposed exhibits which it identified as CMS Ex. 1 - CMS Ex. 22. In Docket No. C-07-111, CMS filed a brief and proposed exhibits which it identified as CMS Ex. 1 - CMS Ex. 29. In Docket No. C-07-31, Petitioner filed a brief and proposed exhibits which it identified as P. Ex. 1 - P. Ex. 29. In Docket No. C-07-111, Petitioner filed a brief and proposed exhibits which it identified as P. Ex. 1 - P. Ex. 17.

I consolidated these cases and scheduled them for an in-person hearing. Prior to the hearing the parties advised me that they agreed that the cases could be heard and decided based on their written submissions. I then cancelled the hearing but afforded each party the opportunity to file an additional brief. Each party filed an additional brief in the consolidated cases.

I receive into evidence all of the parties' proposed exhibits. In order to avoid confusion where I cite to an exhibit in my decision I cite both to the exhibit number and to a docket number prefix. For example, I cite to "07-31 CMS Ex. 1" when I cite to CMS Ex. 1 in Docket No. C-07-31.

II. Issues, findings of fact and conclusions of law

A. Issues

The issues in these consolidated cases are whether:

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

2. If so, whether CMS's remedy determinations are reasonable.

B. Findings of fact and conclusions of law

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

Each of the two survey reports alleges that Petitioner was noncompliant with Medicare requirements in multiple respects. The August survey report avers that Petitioner failed to comply substantially with seven distinct Medicare participation requirements and that Petitioner's failure to comply with each of these requirements was so egregious as to comprise immediate jeopardy for Petitioner's residents.[1] 07-31 CMS Ex. 1. The September survey report alleges that Petitioner failed to comply substantially with three Medicare participation requirements albeit not at the immediate jeopardy level of noncompliance. 07-111 CMS Ex. 1.

It is not necessary for me to address all of the findings of noncompliance that were made at the two surveys in order for me to sustain CMS's remedy determinations. The $3,050 daily civil money penalties that CMS determined to impose based on the findings of noncompliance made at the August survey are, as I discuss below, the minimum daily amount that CMS may impose to remedy an immediate jeopardy level deficiency. Consequently, the presence of only one immediate jeopardy level deficiency is sufficient to sustain the penalty amount. The $100 daily civil money penalties that CMS determined to impose based on the findings of noncompliance made at the September survey are very close to the minimum permissible remedy amount for a non-immediate jeopardy level deficiency and comprise only three percent of the maximum permissible

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[1] The term "immediate jeopardy" is defined at 42 C.F.R. § 488.301 to mean:

> a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident.

amount. For reasons that I discuss below, a finding of a single deficiency at the September survey is sufficient to sustain that penalty amount. And, as I discuss below, CMS has discretion to impose denial of payment for new admissions for each day that Petitioner failed to comply substantially with a Medicare participation requirement.

In this decision I address a single immediate jeopardy level deficiency that was found at the August survey, a failure by Petitioner's staff to notify a resident's family and consult with that resident's treating physician about a significant change in a resident's condition as is required by 42 C.F.R. § 483.10(b)(11). And, I address a single non-immediate jeopardy level deficiency that was found at the September survey, similarly, a failure by Petitioner's staff to consult with a resident's treating physician about a significant change in a resident's condition. Petitioner's failure to comply with this requirement, both at the immediate jeopardy level of noncompliance, and at the non-immediate jeopardy level, is ample support for CMS's remedy determinations in these two cases.[2]

1. As of the August survey Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.10(b)(11).

The regulation at issue requires that a facility immediately notify a resident's family and consult with that resident's physician about:

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

CMS premises its allegation of immediate jeopardy level noncompliance by Petitioner with this requirement on the care that Petitioner's staff provided to a resident who is identified in the August survey report as Resident #4. 07-31 CMS Ex. 1, at 1 - 4.[3] It is undisputed that this resident was a very sick individual. He was admitted to Petitioner's facility in September 2004 with diagnoses that included diabetes, dementia, and depression. *Id.*, at 2. Petitioner's staff determined that the resident was at risk for malnutrition, dehydration, and weight loss. 07-31 CMS Ex. 4, at 62. Reflecting that

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[2] I do not suggest that Petitioner was either compliant or non-compliant with the other participation requirements for which Petitioner was cited as being non-compliant in the August and September surveys. I make no findings about the other allegations of noncompliance because it is unnecessary that I do so.

[3] The August survey report also alleges a compliance failure with respect to another resident who is identified as Resident #11. However, CMS does not allege that Petitioner's noncompliance in providing care for this resident was at the immediate jeopardy level and, so, I do not address CMS's allegations concerning Resident #11.

assessment, the care plan that Petitioner's staff developed for the resident included several interventions designed to assure that the resident received adequate nutrition and fluids. *Id.* Among other things the staff was supposed to maintain daily records documenting the resident's consumption of food and fluids. *Id.*, at 64.

These concerns and the interventions listed in the care plan notwithstanding the Resident's appetite and consumption of food diminished sharply by mid-June 2006. In June and July 2006, when the staff documented what the resident consumed, it documented that the resident was eating less than the full portions that had been prescribed to him. In June, the resident consistently only ate a fraction of the food offered to him at dinner. 07-31 CMS Ex. 4, at 12. In July, the pattern of reduced consumption continued. *Id.*, at 13.

Even though the staff was instructed to document the resident's food intake it failed to do so consistently. In June 2006, Petitioner's staff failed to document 23 out of 90 meals offered to the resident. CMS Ex. 4, at 12. In July, the staff failed to document 11 of 56 meals. *Id.*, at 13. Thus, over the period that corresponded with the resident's weight loss, staff failed to document what the resident consumed during about 1/5 of his meals. As a consequence of the staff's failure to document food consumption it is impossible to state with certainty exactly how much the resident consumed after mid-June 2006. It is, however, evident, that his food consumption diminished sharply.

As of January 1, 2006, the resident's weight was 126.3 pounds. *Id.*, at 8. On June 13, 2006, the resident's weight was recorded at 135 pounds. But, beginning with that date the resident rapidly lost weight. Petitioner's staff failed to record the resident's weight during the period between June 13 and July 18, but the staff weighed him on July 18 and on that date his weight was recorded at 116.5 pounds, an 18.5 pound loss over a five-week period. 07-31 CMS Ex. 1, at 2; 07-31 CMS Ex. 4, at 8. On July 19, 2006, the resident was hospitalized. There, his weight was recorded at 110 pounds. 07-31 CMS Ex. 7, at 14. The resident died within days.

There is nothing in the resident's treatment record to show that Petitioner's staff notified the resident's family at any time during the period from mid-June to mid-July 2006 of the resident's anorexia or weight loss.[4] Nor is there evidence to show that the staff alerted the

[4] Indeed, in a conversation with a surveyor, a member of the resident's family reported that she noticed the resident's weight loss about two weeks before the resident's hospitalization on July 19, 2006 and brought it to the staff's attention. According to this family member, the staff person to whom she spoke told her that the resident was fine. 07-31 CMS Ex. 4, at 3.

resident's physician and consulted with him at any time prior to July 13, 2006 concerning the decline that began in June. The resident's treatment record is devoid of any record of such communication. *See* 07-31 CMS Ex. 4.

The evidence offered by CMS supports a finding that the resident's anorexia and weight loss beginning in mid-June 2006 constituted a significant – in fact, a life threatening – change in his condition.[5] As a general matter malnutrition is a life-threatening problem for frail and debilitated individuals. Without adequate nutrition the various systems of an individual's body will fail and, eventually, that person will die. 07-31 CMS Ex. 14, at 4. A malnourished individual, especially one who is frail and beset with other illnesses, is at an increased risk for developing infection. *Id.* Without adequate nutrition and hydration there is a significantly increased likelihood that a nursing home resident will succumb to infection. *Id*., at 4 - 5.

Not only is adequate nutrition important as an element of care for a nursing home population, it was especially important for the well-being of Resident #4. As I have discussed, the resident's appetite and need to retain weight was a major problem identified by Petitioner's staff in its care plan for Resident #4. Consequently, a decline in food consumption or apparent weight loss by this resident was a significant change, measured not only by the medically mandated need to keep nursing home residents well nourished but by the staff's expressed concerns for *this resident's* condition and his vulnerabilities. This resident's reduced consumption of food put Petitioner's staff on notice that something was seriously wrong and it should have prompted the staff immediately to notify the resident's family and to consult with his physician about the change. Adequate consumption of both food and liquids was essential to protecting Resident #4 from the risk of infection. 07-31 CMS Ex. 14, at 9.

The evidence offered by CMS establishes a strong basis for concluding that Petitioner failed to comply with the requirements of 42 C.F.R. § 483.10(b)(11) by failing to notify the resident's family and to consult with the resident's physician immediately about the significant change in the resident's condition established by his loss of appetite and diminished consumption of food beginning in mid-June 2006. This was a change in the resident's condition that was a red flag that a competent staff should have observed and to which it should have reacted immediately.

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[5] CMS's prima facie evidence relating to the nutritional needs of elderly and sick individuals consists of the testimony of Larry Johnson, M.D., a professor of geriatric medicine at the University of Arkansas. 07-31 CMS Ex. 14. I find Dr. Johnson to be well-qualified to testify as to the subject and his testimony is persuasive. Petitioner attacked the credibility of Dr. Johnson. Below, I explain why I am not persuaded by Petitioner's attack.

Petitioner offered neither argument nor evidence that rebuts CMS's prima facie case. In sum, Petitioner's arguments and contentions are as follows:

> • The report of the August survey is unreliable and provides no basis for finding it to be deficient because it contains statements that are "inaccurate, misleading and taken out of context." Petitioner's brief in lieu of hearing at 7.
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> • The facts cited in the August survey report concerning the care that Petitioner's staff provided to Resident #4 do not describe a significant change in the resident's condition. Petitioner's brief in lieu of hearing at 12.
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> • Furthermore, when notification was required, Petitioner timely notified the resident's physician and family members as appropriate. Petitioner's brief in lieu of hearing at 12.
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> • Petitioner's staff cared for Resident #4 as best as it could given the resident's condition. Petitioner's brief in lieu of hearing at 19.

In support of its assertion that the August survey report is unreliable Petitioner focuses on several alleged inaccuracies or misinterpretations in the report. But, none of the alleged errors address the allegations made concerning Petitioner's failure to meet regulatory notification and consultation requirements while providing care to Resident #4. Petitioner has not specifically challenged any of the surveyors' fact findings concerning the care that its staff gave to the resident. For these reasons I conclude that Petitioner has not materially impeached the credibility or accuracy of the August survey report as concerns the failure of Petitioner to comply with notification and consultation requirements.

The heart of Petitioner's argument about its failure to notify and consult is that it was not required to do so because Resident #4's anorexia and weight loss did not constitute a significant change in the resident's condition. Petitioner characterizes the resident's anorexia and weight loss as "mere decline in intake" related to the resident's "final state of decline." Petitioner's brief in lieu of hearing at 13. Essentially, Petitioner asserts that the resident was dying, that his anorexia and weight loss was a natural and not significant consequence of the process of dying, and therefore, there was no need for the staff to notify the resident's family or to consult with his physician about this natural process.

However, there is no "dying resident" exception to the requirement that a facility immediately notify a resident's family and consult with that resident's physician about a significant change in a resident's condition. The regulation imposes on a facility the obligation to do everything reasonably possible to assist and to aid a resident. The

regulation does not permit a facility to write a resident off as a lost cause absent consultation with a resident's physician and notification of the resident's family. Nor does the regulation allow a facility simply to warehouse a resident and accept reimbursement for that resident's care.[6]

Petitioner's staff had no way of knowing in June and July 2006 whether the resident's anorexia and weight loss was a sign that his death was inevitable because there is no evidence that the staff made such an assessment in consultation with the resident's physician. As part of its case, Petitioner offered the entire treatment record of Resident #4. 07-31 P. Ex. 8. The exhibit totals 778 pages. Yet, Petitioner did not cite to a single entry in that enormous document showing an assessment by Petitioner's staff of Resident #4's anorexia or weight loss in the period between June 13 and July 18, 2006.

Nor do I agree with Petitioner's characterization of what happened to Resident # 4 as being a "mere decline in intake." Petitioner's own staff had identified the resident as being at risk for malnutrition. It was for that reason that it prepared a care plan that specifically addressed that problem and which ordered interventions that were designed to protect the resident. The staff therefore knew that a decline in food consumption by Resident #4 was not a "mere" event. Based on its own assessment of the resident that change was significant.

Petitioner offered no evidence to rebut CMS's proof that, as a general medical matter, a decline in food consumption by any resident who is at risk for malnutrition comprises a significant change in that resident's condition. 07-31 CMS Ex. 14, at 4. However, according to Petitioner, Dr. Johnson's testimony, which sets forth the applicable standards of care, is not credible because he has never set foot in Petitioner's facility, did not treat Resident # 4, and was supplied by CMS with allegedly incomplete records. I do not find these attacks on Dr. Johnson's credibility to be persuasive. Dr. Johnson is plainly well

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[6] Petitioner also seems to suggest, at times, that its staff was absolved of responsibility for Resident #4 because the resident's physician recommended that the resident be fed via a feeding tube and the resident's family declined this treatment. *See* 07-31 P. Ex. 24, at 2, 3, 4. The resident's guardians may have had the right to act on his behalf to decline recommended care. But, that did not absolve Petitioner or its staff from taking other measures on the resident's behalf described in his plan of care nor did it relieve the staff of responsibility to notify the resident's family and consult with the resident's treating physician about the resident's anorexia and loss of weight.

qualified to opine about the standards of care for elderly individuals who are at risk for malnutrition. Petitioner has not shown how the fact that Dr. Johnson did not care directly for the resident impeaches his credibility. Nor has it shown how Dr. Johnson's testimony was made less than credible by the records CMS supplied to him.

I am not persuaded by Petitioner's argument that Resident #4's treating physician was consulted appropriately about the resident's anorexia and weight loss.[7] Petitioner points to nothing in the resident's treatment record establishing any discussion between Petitioner's staff and the resident's treating physician concerning the resident's anorexia and weight loss on dates between the middle of June and July 13, 2006. On that latter date the physician saw the resident and observed his condition. 07-31 P. Ex. 24, at 3. But, even that visit does not appear to have been prompted by a call from Petitioner's staff alerting the physician to the resident's condition. *See Id*.

Resident #4's treating physician averred in an affidavit that he was "aware of the resident's declining condition, including his nutritional status and poor appetite." 07-31 P. Ex. 24, at 4. But, the physician's awareness of the resident's overall condition does not relieve Petitioner or its staff from the obligation to consult with the physician about the decline that began in mid-June 2006. In a nursing home a resident's physician is not constantly at the resident's bedside. At best, a physician's visits to his or her patient in a nursing home are episodic. In between those visits the physician depends on the nursing staff to keep him or her apprised continuously of any changes in the patient's condition that require physician attention. Here, there was an evident and ominous change in the resident's condition beginning in mid-June 2006. Yet, there is nothing to show any communication between Petitioner's staff and the resident's physician about that change at any time prior to July 13, 2006.

As part of its argument that the staff consulted with the resident's physician Petitioner appears to argue that there were no meaningful changes in the resident's condition prior to July 18, 2006 when the staff recorded an 18.5 pound decline in the resident's weight from June. But, the reality is that staff should have been alerted to the resident's decline long before it weighed him on July 18. The resident's weight loss did not occur over night. It logically was the consequence of a decline in food intake. Petitioner's staff, up

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[7] Petitioner offered no affirmative evidence to establish that it notified the resident's family about the resident's anorexia and weight loss at any time prior to July 18, 2006. Petitioner notified the family about the resident's change in condition on that date after it weighed him and recorded the 18.5 pound weight loss. 07-31 P. Ex. 26. As I discuss above, the resident's treatment record runs to nearly 800 pages. Petitioner pointed to nothing in that document establishing notification of the family prior to July 18.

until mid-June 2006, had been successful in maintaining and even increasing the resident's weight. 07-31 CMS Ex. 1, at 2. Something obviously happened after the resident was weighed on June 13, 2006 that caused this resident to lose weight over the next five weeks. Had the staff been observant, had it faithfully charted the resident's food intake, it would have been able to identify whatever changes were occurring and to consult with the resident's physician.

Petitioner argues that the resident's weight loss was not necessarily due to a decline in food consumption and may have been very precipitous. Petitioner's brief in lieu of hearing at 18. The basis for this argument is that the resident's weight was recorded at the hospital as 110 pounds on July 19, 2006, after the resident had been transferred there. According to Petitioner the additional rapid weight loss shows that the resident's body was not losing weight because he was being improperly fed but because his body was "just shutting down due to his finally reaching the final stages of his life." *Id.* I am unpersuaded by this argument. First, it is not possible to know whether the scales at the hospital and Petitioner's facility were calibrated to measure identical weights identically. Thus, there is no way that I can conclude that the weight loss recorded at the hospital reflects an actual additional loss of weight by the resident. Second, the unrebutted expert testimony of Dr. Johnson persuades me that malnutrition was the most logical cause of the resident's weight loss between June 13 and July 18, 2006. 07-31 CMS Ex. 14, at 9.

I am unpersuaded by Petitioner's assertion that it did the best that it could to provide care for Resident #4. As I have discussed in detail, the *minimum* that Petitioner should have done for this resident included notifying the resident's family and consulting with the resident's physician about any significant change in the resident's condition. Petitioner plainly failed to satisfy this requirement. Moreover, it is evident from the record that Petitioner failed even to comply with its own plan of care for the resident. That plan required, among other things, that Petitioner's staff closely monitor the resident's food intake. That requirement was based on an assessment that the resident was at great risk for malnutrition. The staff failed manifestly to comply with that directive.

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

It is Petitioner's burden to prove clearly erroneous a determination by CMS that a deficiency puts residents at immediate jeopardy. 42 C.F.R. § 498.60(c)(2). Here, Petitioner failed to offer any evidence challenging CMS's immediate jeopardy determination.

Petitioner's argument as to immediate jeopardy is that there was no likelihood of serious injury, harm, or death to Resident #4 because the resident's decline was the inevitable consequence of his condition. Consequently, according to Petitioner, there was nothing that Petitioner did that put the resident at greater risk than was caused by his condition. Petitioner's brief in lieu of hearing at 20.

I find this argument to be unpersuasive. It is not possible to say now whether more timely intervention by Petitioner's staff, including consulting the resident's physician early in the process of the resident's anorexia and weight loss, would have prolonged the resident's life. What is clear, however, is that as a general matter failure by a facility to be attentive to its residents' nutritional needs, including consulting with residents' physicians about anorexia and weight loss, will put frail and debilitated residents at great risk for injury, harm, or death. The overwhelming evidence in this case is that Petitioner's staff was inattentive to the needs of Resident #4. And, it is reasonable that I infer from this inattentiveness that Petitioner's staff lacked a basic understanding of its responsibilities to provide care for residents who, like Resident #4, were at risk of injury, harm, or death from malnutrition. CMS's determination that this lack of understanding and the concomitant failure by Petitioner's staff to provide required care to Resident #4 put residents at immediate jeopardy is not clearly erroneous.

3. Petitioner did not prove that it corrected its immediate jeopardy level noncompliance before September 5, 2006.

CMS determined that Petitioner's immediate jeopardy level noncompliance persisted through September 4, 2006. Petitioner disputes that determination, arguing that immediate jeopardy, if it existed at all, ended on July 20, 2006, the date that Resident #4 died.

A facility that is out of compliance with Medicare participation requirements is presumed to remain noncompliant until CMS certifies that the facility has corrected its deficiencies. That presumption is rebuttable, but it is the facility's burden to prove that it attained compliance at a date earlier than the compliance date that is certified by CMS.

The death of Resident #4 is no proof that Petitioner eliminated immediate jeopardy earlier than September 5, 2006. The failure by the staff to consult with the resident's physician and to notify the resident's family about his decline is not a failure that is limited solely to the care provided to the resident. As I discuss above, at Finding 2, it evidences a broader problem at the facility, a failure by the staff to understand their obligations to attend to nutritionally endangered residents and to consult with these residents' physicians at the

first sign of anorexia or decline. The death of Resident #4 didn't cure the problem at Petitioner's facility. That problem persisted after the resident's death until Petitioner undertook satisfactory corrective action to make sure that its staff understood their obligations in future cases. Petitioner did not prove that this corrective action was completed before September 5, 2006.

4. As of the September survey Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.10(b)(11).

CMS alleges that, as of the September survey, Petitioner remained out of compliance with the physician consultation requirements of 42 C.F.R. § 483.10(b)(11). CMS bases its allegation of noncompliance on the care that Petitioner gave to a resident who is identified as Resident #1 in the report of the September survey. 07-111 CMS Ex. 1, at 1 - 3.

The resident was diagnosed with a seizure disorder and had been observed by Petitioner's staff to exhibit seizure activity. 07-111 CMS Ex. 1, at 2. The resident had a prescription for anti-seizure medications consisting of Depakote and Dilantin. On August 18, 2006, the resident's physician ordered that the resident's Depakote and Dilantin levels be measured every week.

Laboratory tests of the resident's Depakote levels taken on August 25, 2006 and again on September 5, 2006 reported on both occasions that the resident's Depakote levels were below the normal therapeutic range for the medication. On August 25, the resident's Depakote level was reported at 29.0 (the normal therapeutic range being between 50 and 100) and on September 5, the resident's Depakote level was reported at 44. However, there was nothing in the resident's record to establish that the resident's physician had been advised of these two test results. When interviewed the resident's physician stated that he would have wanted to know whether the resident's Depakote levels were below the normal therapeutic range for the medication. 07-111 CMS Ex. 1 at 2 - 3.

There is a high prevalence of seizures (epilepsy) among older individuals. 07-111 CMS Ex. 18, at 4. The psychosocial effects of seizures in old age can profoundly affect quality of life. *Id.* A failure to control seizures in an elderly person can put that individual at risk for serious harm. Seizures may increase the risk of falling and associated injuries including head trauma and broken bones. 07-111 CMS Ex. 16, at 1 - 2; *see* 07-111 CMS Ex. 25, at 2.

The evidence offered by CMS establishes a prima facie case that Petitioner failed to comply with the regulation's physician consultation requirements. It shows that Resident #1 was not only at risk for seizures but that the resident's physician wanted to be kept informed of her anti-seizure medication levels in order that he could properly treat her. A

sub-therapeutic medication level in an individual such as Resident #1 is significant because it exposes that individual to the enhanced risk of suffering potentially injurious seizures. Consequently, a resident's blood medication levels that are outside of a therapeutic range constitutes a significant medical development necessitating consultation with that resident's treating physician. Failure to consult with the resident's physician about non-therapeutic blood levels, in light of the fact that the physician had ordered that blood levels be taken weekly, constituted a failure to comply with the governing regulation.

Petitioner does not deny that its staff failed to consult with Resident #1's treating physician about the resident's August 25 and September 5, 2006 Depakote levels. But, it argues that there was no significant change in Resident #1's condition necessitating consultation with the resident's physician. In making this argument Petitioner focuses entirely on the September 5 test result showing the resident's Depakote level on that date to be 44. Petitioner argues that this result was not so far out of range as to be considered "abnormal" especially given the resident's age and many impairments. It offers a statement from the resident's treating physician, Robert Hollister, M.D., to support this argument. He asserts that:

> While still below the "normal" range, this [Depakote level of 44] was the highest level . . . [the resident] had experienced in over four months, and as there were no seizures or adverse effects corresponding to that blood level being manifested at the time, this did not constitute a significant change, and certainly not a deterioration in Resident #1's health, that would require my immediate notification.

07-111 P. Ex. 5, at 5.

The problem with Petitioner's argument is that it focuses only on the September 5 test result. Even if Dr. Hollister's characterization of the resident's September 5 Depakote level as being near normal is correct, that says nothing about the failure by Petitioner's staff to consult with Dr. Hollister about the resident's Depakote level of 29.0 recorded on August 25, 2006. That earlier level was sub-therapeutic by any measure and Petitioner has offered no justification for its staff's failure to consult with Dr. Hollister about it.

In fact, the staff's error was particularly egregious in light of the fact that, just one week prior to August 25, Dr. Hollister had ordered that the resident's Depakote levels be checked weekly. Obviously, Dr. Hollister was concerned about the resident's tendency to

display a sub-therapeutic Depakote level and so he directed Petitioner's staff to monitor them closely. Checking the resident's Depakote level weekly would be a meaningless exercise if the results – particularly sub-therapeutic results – are not communicated immediately to the resident's treating physician.[8]

5. Petitioner did not prove that it corrected its noncompliance before September 18, 2006.

CMS determined that Petitioner attained compliance with all participation requirements, including the requirement described at 42 C.F.R. § 483.10(b)(11), on September 18, 2006. Petitioner has not offered affirmative evidence to show that it corrected its noncompliance prior to that date. Consequently, I sustain CMS's determination as to duration of noncompliance.

6. CMS's remedy determinations are reasonable.

a. Civil money penalties of $3,050 per day are reasonable as a matter of law.

The $3,050 daily civil money penalties that CMS determined to impose to remedy Petitioner's noncompliance during the July 18 - September 4, 2006 period are at the minimum daily civil money penalty amount that may be imposed as a remedy for an immediate jeopardy level deficiency. 42 C.F.R. § 488.438(a)(1)(i). In this case the $3,050 daily penalties are reasonable as a matter of law because Petitioner manifested an immediate jeopardy level deficiency throughout the period for which CMS determined to impose them.

b. Civil money penalties of $100 per day are reasonable.

CMS is authorized to impose civil money penalties ranging from $50 to $3,000 per day to remedy a deficiency that is substantial but not at the immediate jeopardy level. 42 C.F.R. § 488.438(a)(1)(ii). The criteria for deciding where within that range a penalty amount should be are stated at 42 C.F.R. §§ 488.438(f)(1) - (4) and 488.404 (incorporated by reference into 42 C.F.R. § 488.438(f)(3)). These criteria include: the seriousness of a deficiency, the relationship of one deficiency to another, a facility's compliance history, its culpability, and its financial condition.

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[8] The validity of the physician's concern is evidenced by the fact that the resident had a seizure on September 2, 2006.

Neither party to this case offered argument concerning whether the $100 daily penalty amount that CMS determined to impose during the September 5 - 17, 2006 as a remedy for Petitioner's non-immediate jeopardy noncompliance was reasonable. That may be due to the fact that the penalty amount is minimal, comprising only three percent of the possible maximum daily penalty that CMS may impose for a non-immediate jeopardy level deficiency.

I find the penalty amount to be reasonable based on the evidence in this case considered in light of the applicable regulatory factors. The non-immediate jeopardy level deficiency that I discuss above, at Finding 4, was relatively serious. The potential for harm to Resident #1 resulting from a sub-therapeutic anti-seizure medication level is apparent, consisting of at least the possibility that she might be injured by a fall sustained during a seizure. Obviously, the resident's physician was aware of that potential because he ordered her anti-seizure medication levels to be monitored weekly. Petitioner's failure to report sub-therapeutic levels to the resident's physician put the resident at risk for seizures and injuries.

Also, the penalty amount is reasonable in light of the facility's compliance history. The identical non-compliance – failure to consult with a resident's physician about a significant change in that resident's condition – was manifested by Petitioner at both the August and September surveys.

c. CMS has discretion to deny Petitioner payment for new admissions during the period that began on August 20 and which continued through September 17, 2006.

CMS may impose the remedy of denial of payments for new admissions for each day that a facility is not complying substantially with Medicare participation requirements. 42 C.F.R. § 488.417(a). As a matter of law CMS has discretion to deny payment to Petitioner for new admissions for each day of a period that began on August 20 and which continued through September 17, 2006 because Petitioner was not complying substantially with Medicare participation requirements on each day of that period.

Aside from denying that it was out of compliance during the period Petitioner asserts, for the following reasons, that the remedy of denial of payment for new admissions should not be imposed for dates beginning September 6, 2006:

- In a letter dated September 11, 2006, the State of Tennessee told Petitioner that it had attained substantial compliance as of September 6, 2006 and that, consequently, the remedy of "suspension of admission of new residents to the facility" was lifted. 07-111 P. Ex. 1.

• In a subsequent letter dated September 18, 2006, the State of Tennessee told Petitioner that it had been found out of compliance at the September survey and that, consequently, remedies including continued denial of payment for new admissions were being imposed. 07-111 P. Ex. 2.

• Petitioner relied to its detriment on the September 11 letter in that it began admitting new residents. Consequently, it should not be denied payment for these admissions.

But, Petitioner's argument notwithstanding, the determination to impose denial of payment for new admissions ultimately rests within CMS's discretion. CMS is not bound by State determinations and, moreover, I have no authority to question CMS's exercise of discretion. Here, the imposition of the remedy through September 17, 2006 was justified by Petitioner's noncompliance through that date and its imposition is a matter entirely within the discretion of CMS.

/s/
Steven T. Kessel
Administrative Law Judge