Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Greenbrier Nursing and Rehabilitation Center,
(CCN: 04-5381),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-09-440

Decision No. CR2100

Date: March 29, 2010

DECISION

I sustain the determination of the Centers for Medicare & Medicaid Services (CMS) to impose remedies against Petitioner, Greenbrier Nursing and Rehabilitation Center, consisting of:

- civil money penalties of $5,550 per day for each day of a period that began on January 11, 2009 and which ran through February 2, 2009; and

- civil money penalties of $600 a day for each day of a period that began on February 3, 2009 and which ran through March 1, 2009.

I. Background

Petitioner is a skilled nursing home doing business in the State of Arkansas. It participates in the Medicare program. Its participation in that program is governed by sections 1819 and 1866 of the Social Security Act (Act) and by implementing regulations at 42 C.F.R. Parts 483 and 488. Its right to a hearing in this case is governed by regulations at 42 C.F.R. Part 498.

CMS determined to impose the above-described remedies against Petitioner after Petitioner was found not to be complying substantially with Medicare participation requirements at a survey of its facility that was completed on February 4, 2009 (February survey).[1] Petitioner requested a hearing and the case was assigned to me for a hearing and a decision.

The parties completed pre-hearing exchanges that included filing pre-hearing briefs plus all of their proposed evidence including the written direct testimony of each proposed witness. CMS moved for summary disposition, Petitioner opposed the motion, and I denied it. Then, the parties agreed that the case could be tried based on their written pre-hearing exchanges without an in-person hearing. Each party then filed a final brief with me.

CMS filed 14 proposed exhibits with its pre-hearing exchange which it identified as CMS Ex. 1 – CMS Ex. 14. Petitioner filed eight proposed exhibits with its pre-hearing exchange which it identified as P. Ex. 1 – P. Ex. 8. I receive into evidence CMS Ex. 1 – CMS Ex. 14 and P. Ex. 1 – P. Ex. 8.

II. Issues, findings of fact and conclusions of law

A. Issues

The February survey report identifies three findings of alleged noncompliance by Petitioner. These include findings that Petitioner failed to comply with the requirements of: 42 C.F.R. §§ 483.25; 483.25(j); and 483.60(c). CMS Ex. 2 at 1-14. CMS asserts that Petitioner's alleged non-compliance with the requirements of 42 C.F.R. § 483.25 was so egregious as to comprise immediate jeopardy for Petitioner's residents. An "immediate jeopardy" level deficiency is one that causes, or is likely to cause, serious injury, harm, impairment, or death to a resident or residents of a facility. 42 C.F.R. § 488.301. CMS assigned a scope and severity to the remaining two deficiencies that is less than the immediate jeopardy level of noncompliance.

[1] Originally, CMS determined to impose a per-instance civil money penalty of $7,000 against Petitioner. Subsequently, it revised the penalties so that they consist of the daily penalties that I describe in the opening paragraph of this decision, except that CMS imposed the immediate jeopardy level penalty for a period that ran through February 3, 2009. I explain below why the immediate jeopardy level penalty runs only through February 2, 2009.

Petitioner challenges only the alleged immediate jeopardy level noncompliance with the requirements of 42 C.F.R. § 483.25. Consequently, the two non-immediate jeopardy level deficiencies are administratively final. They become relevant to my analysis of the imposed remedies and I discuss them below where it is appropriate to do so.

The issues in this case are whether:

1. Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.25;

2. CMS's determination of immediate jeopardy was clearly erroneous; and

3. CMS's remedy determinations are reasonable.[2]

B. Findings of fact and conclusions of law

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

1. Petitioner failed to comply substantially with the requirements of 42 C.F.R. § 483.25.

The regulation that is implicated in this case requires a facility to provide each of its residents with the necessary care and services in order for that 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. CMS alleges that Petitioner failed to satisfy the requirements of this regulation in providing care to several of its residents who were receiving the anti-coagulant medication Coumadin.

Coumadin (warfarin) is a medication that anticoagulates the blood, antagonizing blood proteins to slow the rate of clotting. CMS Ex. 12 at 3. The medication is beneficial in treating diseases in which the propensity for blood clotting is increased, such as atrial fibrillation, in which clots can form in an individual's heart, break off and float through the blood stream, and lodge in the brain, causing strokes. *Id.*

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[2] Petitioner raises an additional issue, that being whether the Departmental Appeals Board's assignment to Petitioner of the ultimate burden of persuasion is lawful. *See Hillman Rehabilitation Center v. United States*, DAB No. 1611 (1997). I do not address that issue here for two reasons. First, I have no authority to do so. Second, the issue is moot because I find to be overwhelming the evidence supporting CMS's noncompliance finding and remedy determinations.

There are major risks associated with the use of Coumadin. CMS Ex. 12 at 3. Principally, Coumadin increases the risk that the patient may bleed. *Id.* The risk of bleeding increases with the intensity of therapy. *Id.*

Tests have been developed which measure a patient's blood clotting time. These tests are known as international normalized ratio (INR) and Prothrombin Time (PT). CMS Ex. 12 at 3-4. Generally, an INR of 1.0 is considered to show a normal blood clotting time and increases above 1.0 show an enhanced risk for bleeding. *Id.* An INR of between 2.0 and 3.0 is considered to be an acceptable risk for bleeding in a patient who is receiving Coumadin when measured against the benefits that the patient may obtain from Coumadin therapy. *Id.* at 4.

Coumadin's effects on an individual patient may vary based on the patient's medical condition, his or her diet, or the medications he or she is taking. The INR for a patient receiving Coumadin is thus unstable and the risk for bleeding may become exacerbated even if the dose of Coumadin that the patient receives is unchanged over time. INR or PT testing must be done regularly for a patient who is receiving Coumadin in order to assure that the patient's blood clotting time is not outside of acceptable parameters. CMS Ex. 12 at 4.

The professionally recognized standard of care for monitoring a patient who is receiving a stable dose of Coumadin is to monitor that patient (conduct INR and PT testing) at least once every four weeks. *Id*. In addition, a patient who is receiving Coumadin should be monitored physically for signs and symptoms of bleeding such as easy bruising and visible bleeding. *Id.* In a skilled nursing facility such as Petitioner's facility these duties fall on the professional nursing staff:

> In a long term care facility, it is the nurses' role to administer . . . [Coumadin], ensure that the INR is obtained according to the physicians' orders and that the results are communicated to the physicians. In addition, it is their role to report any observations of possible bleeding associated with treatment in a prompt fashion to the physician. The physician is responsible for ordering INR testing, but if this is not done, there are several levels of oversight to ensure that it is done. First the nurses would be expected to know that the INR testing should be done so that they enquire about an order if it is not, secondly medications are reviewed and orders renewed no less frequently than every 30 days by the physicians, and the consultant pharmacist usually reviews the medication regimen every month, providing suggestions and oversight.

Id.

The heart of CMS's allegations relate to a resident who is identified in the report of the February survey as Resident # 5. The resident's medical problems include cerebrovascular accident (CVA) and atrial fibrillation. CMS Ex. 7 at 30, 33, and 46-47. Throughout her stay at Petitioner's facility up until the February survey, Resident # 5 received Coumadin, which had been prescribed to her by her physician, Petitioner's medical director. CMS Ex. 7.

CMS asserts that, in at least four respects, Petitioner failed to provide Resident # 5 with necessary care and services. First, CMS argues that Petitioner's staff failed to provide requisite INR and PT testing to Resident # 5 for a period lasting nearly three months. Second, according to CMS, Petitioner's staff failed to comprehend the signs of Coumadin toxicity that were manifested by the resident. Third, the staff failed to take into account in managing the resident's care that the resident was receiving antibiotics, Levaquin and Bactrim, which could heighten the anti-clotting effects of Coumadin. Finally, CMS asserts that Petitioner's pharmacy consultant failed to discharge a responsibility to evaluate the resident's use of Coumadin in conjunction with the resident's antibiotic regime and to make appropriate recommendations. The consequence of these errors, according to CMS, was that Resident # 5 developed a toxic reaction to Coumadin, one so severe that it required hospitalization on an emergency basis in order to treat the resident's bleeding and anemia.

I find that the weight of the evidence amply supports CMS's assertions. I find it to be evident that Petitioner's staff was remiss in that they failed to test Resident # 5's blood clotting time in order to assure that it remained within a therapeutic range. The staff also overlooked developments that could have enhanced the effects of the Coumadin that the resident received. And, they failed to react to the signs manifested by the resident – bruising – that should have put them on notice that the resident's blood clotting times were dangerously reduced.

As I have discussed, the professionally recognized standard of care requires a facility's staff to test the clotting time of a resident who is receiving Coumadin at least monthly. In this case, however, the staff simply failed to do so. INR and PT testing were done on Resident # 5 on October 29, 2008. CMS Ex. 7 at 79; CMS Ex. 9 at 7. No further INR or PT testing was performed on Resident # 5 from that date until she was hospitalized on January 19, 2009. CMS Ex. 7 at 158-59.

Petitioner concedes that its staff failed to do INR and PT testing during the period between October 29, 2008 and January 19, 2009. It argues that its staff was merely carrying out the wishes of the resident's treating physician, who, according to Petitioner, never ordered that the resident's INR and PT testing be done monthly. Petitioner's Final

Brief at 3. According to Petitioner, the resident's treating physician – who is also Petitioner's medical director – refused to implement standing orders to have patients tested routinely for clotting time, but preferred, instead, to have testing done on an as needed and case-by-case basis. *Id.*

I find Petitioner's argument to be without merit. Petitioner's argument notwithstanding, the credible evidence in this case proves that the physician ordered monthly INR and PT testing be done. The resident's care plan, which was prepared with the medical director's input, directs monthly INR and PT testing as follows:

> LAB PER PHY: MONIT PT/INR AT LEAST MONTHLY

CMS Ex. 7 at 35, 43. That directive is supplemented with an undated handwritten note which states "per phy," and which I infer means that the resident's physician ordered monthly INR and PT testing. *Id.*

Petitioner argues that the expression "per phy" means that the staff should look to the medical director for specific orders about when to perform testing. Petitioner would have me infer that the absence of a particularized and date specific order that a test be done meant that the physician did not want the test to be performed. Petitioner's Post-Hearing Brief at 3. I find that to be a strained and implausible interpretation of the resident's plan of care. The care plan is not at all ambiguous, it ordered monthly INR and PT testing and the reasonable interpretation of the expression "per phy" is that such testing was ordered by Resident # 5's physician.

Moreover, there are no documents in the treatment record of Resident # 5 that suggest that anything other than monthly INR and PT testing was ordered for the resident. There is nothing in the resident's treatment record which rescinds the order for monthly testing in the care plan. The physician's evaluation and progress notes say nothing about discontinuing monthly INR and PT testing. *Id.* at 34. There are no physician orders of record ordering that monthly testing be discontinued.

Petitioner argues also that its medical director asserted to the surveyors who performed the February survey that he had no standing orders that INR and PT testing be performed. From that, Petitioner would have me conclude that the physician did not want testing to be performed on Resident # 5 at least monthly. Petitioner's Post-Hearing Brief at 3, 6-7.

However, and contrary to Petitioner's assertion, the medical director affirmed that under most circumstances a resident who receives Coumadin should have his or her blood clotting times monitored one time per month "if no other issues are going on." CMS Ex. 4 at 39. That is an acknowledgment of what I have found, a failure to test the resident at least monthly is a violation of professionally recognized standards of care governing Coumadin administration. CMS Ex. 12 at 4.

Petitioner's staff's failure to observe and react to signs of Coumadin toxicity manifested by Resident # 5 was as egregious as the staff's failure to assure that the resident's blood clotting times be tested regularly. On December 27, 2008 a nurse noted that the resident had small darkened areas on her left thigh – obvious bruises – which the resident said had occurred when she bumped her legs. CMS Ex. 7 at 121. On January 11, 2009 a nurse observed extensive bruising under the resident's right armpit. *Id.* at 123. The nurse described the bruise covering an area of approximately five inches on the resident's shoulder blade and seven inches on the underside of her arm. *Id.* As with the previous incident, the resident reported that the bruising had been caused by trauma when her hand slipped on the hand rails of her safety riser commode. *Id.* The resident continued to complain of pain in her right arm in the days following this event. *Id.* at 124. On January 19, 2009, the resident scratched a scab on her left forearm arm and she began to bleed. *Id.* at 125. This event was followed by changes in the resident's vital signs and her hospitalization shortly thereafter. *Id.*

In essence, the evidence establishes that Petitioner's staff noted the bruising and bleeding that was manifested by Resident # 5, but failed to address these signs as possible evidence of Coumadin toxicity. The bruising was a red flag that the staff failed to comprehend, compounding the error of their failure to assure that the resident's clotting times were tested regularly. Petitioner's staff clearly was diligent in noting the bruising and related problems that Resident # 5 developed. And, the staff realized that Coumadin consumption could be causing the resident to bruise easily. CMS Ex. 7 at 121. But, the staff failed utterly to connect these facts and conclusions with the possibility that the resident might be showing signs of Coumadin toxicity. There is nothing in the resident's treatment record showing that the bruising and related problems caused the staff to reassess the resident's condition or to consider interventions that were specifically aimed at possible Coumadin toxicity.[3] That is a violation of the professionally recognized standard of care that I describe above. At the least, the resident's episodes of bruising and other problems should have caused Petitioner's staff to review the resident's record to determine whether her blood clotting times were being monitored appropriately.

Petitioner acknowledges that there is no documented proof that a physician was notified of each episode of bruising that is identified in the resident's records. Petitioner's post-hearing brief at 7. But, according to Petitioner, "CMS has failed to show that such notification is the standard of care." *Id.* I find this argument to be a red herring. This is

[3] CMS states in its final brief that Petitioner's staff consulted with the resident's physician, evidently in connection with the bruising observed on December 27, 2008, "regarding the need for monitoring the PT/INR," citing CMS Ex. 7 at 121. However, and notwithstanding that statement, I fail to see any reference in the nursing notes showing that there was a consultation on or shortly after December 27, 2008 in which the staff discussed with the physician the need for monitoring the resident's PT and INR test results.

not a case in which CMS alleges that Petitioner failed to consult with the resident's treating physician about significant changes in the resident's medical condition. *See* 42 C.F.R. § 483.10(b)(11). The gravamen of CMS's allegation – which I find to be substantiated by the weight of the evidence – is that Petitioner's staff failed to recognize and apply the relevant standards of care for treating a patient who is receiving Coumadin. Here, the failure by Petitioner's staff was a failure to assess the resident for possible Coumadin toxicity despite the fact that the resident was manifesting signs that any reasonable trained health care professional should have recognized as ominous.

The weight of the evidence establishes also that Petitioner's staff failed to consider the possibly dangerous interactions between the resident's consumption of Coumadin and her consumption of the antibiotics Levaquin and Bactrim. Antibiotics have the potential to heighten the effects of Coumadin and, therefore, to increase the risk of Coumadin toxicity and bleeding. CMS Ex. 12 at 2. Bactrim was prescribed to Resident # 5 on January 18, 2009 and was to be administered to her for a period of 10 days. CMS Ex. 7 at 67, 124. Levaquin was prescribed to the resident beginning on October 16, 2008. *Id.* at 53. But, Petitioner's staff took no special precautions to guard against the possible adverse effects of either medication administered in conjunction with Coumadin. There is nothing in the record to show that the staff considered, for example, INR and PT testing, to assure that the Bactrim and/or Levaquin did not cause the resident's clotting times to be increased dangerously.

Petitioner argues that its staff's failure to take cognizance of the potential dangers of administering Coumadin in combination with Levaquin and Bactrim to Resident # 5 are non-issues. It notes that the administration of Levaquin to the resident ended on October 20, 2008, that PT and INR testing were performed on the resident subsequently (October 29, 2008) and at that time that the resident's physician and Petitioner's staff addressed issues concerning elevated clotting times. As for administration of Bactrim, Petitioner asserts that the resident first began receiving this antibiotic on January 18, 2009, the day before she was admitted to the hospital. Thus, according to Petitioner, there was simply nothing for the staff to do with regard to a potentially dangerous interaction between this medication and Coumadin. Petitioner's Post-Hearing Brief at 8.

What Petitioner fails to acknowledge is that its staff had a duty to anticipate problems resulting from the administration of both Levaquin and Bactrim to the resident, not simply to react to those problems as they may have developed. Neither the order to administer Levaquin nor the subsequent order to administer Bactrim to the resident prompted the staff to assess and plan for the possible risks to the resident. The INR and PT testing that was done of Resident # 5 in late October 2008, was unrelated to any risks anticipated by the staff concerning the administration of Levaquin to the resident. There was no change in the resident's care plan concerning the risks of Coumadin-antibiotic interactions as the consequence of her prescription for Bactrim.

Finally, the weight of the evidence strongly supports a conclusion that Petitioner's consulting pharmacist failed to provide any review or assessment to the staff concerning the administration of Coumadin to Resident # 5. The pharmacist reviewed the resident's drug regimen in October, November, and December 2008. CMS Ex. 7 at 147-49. These reviews are silent about the risks associated with taking Coumadin either by itself or in combination with other medications and fail to mention the absence of any PT/INR testing after October 2008.

The consequences for Resident # 5 of Petitioner's failure to provide appropriate oversight of her use of Coumadin were potentially catastrophic. When the resident was admitted to the hospital on January 19, 2009, she was manifesting a decreased level of consciousness. CMS Ex. 7 at 125. Her hemoglobin and hematocrit (measures of anemia or possible bleeding) were 5.6 and 16.8, respectively. *Id.* at 158-59. The normal range for these two tests are 11.5-16.0 for hemoglobin and 35.0-47.0 for hematocrit. *Id.* In other words, the resident was extremely anemic on her admission. It is likely that her anemia was caused by Coumadin toxicity. CMS Ex. 12 at 6; CMS Ex. 7 at 160-61. She required both blood transfusion therapy and the administration of Vitamin K, a substance used to counteract the effects of Coumadin.

CMS argues, and I agree, that Petitioner's mishandling of Resident # 5's use of Coumadin had adverse implications for four additional residents who were receiving Coumadin therapy. CMS Ex. 2 at 8; CMS Ex. 8 at 26-27. Petitioner had no system in place for assuring that any of these residents would be monitored comprehensively for possible Coumadin toxicity.

2. CMS's determination of immediate jeopardy level noncompliance is not clearly erroneous.

There is ample evidence to support CMS's determination that Petitioner's noncompliance with the requirements of 42 C.F.R. § 483.25 was immediate jeopardy level noncompliance. The failure to monitor Resident # 5's use of Coumadin coupled with the other deficient practices that I have discussed created a high likelihood of severe harm or worse. This resident was in the process of bleeding to death when she was hospitalized on January 19, 2009. The anemia that the resident experienced might not have occurred or might have been detected sooner had the staff monitored her Coumadin use on a regular basis, had it reacted appropriately to the bruising and signs of bleeding that the resident manifested, or had it taken other steps to anticipate and plan for the risks of Coumadin.

It is not possible to say definitively that the anemia that the resident experienced was caused by the staff's multiple failures. But, neither is it necessary for me to reach that conclusion to sustain an immediate jeopardy level deficiency finding. It suffices for me to conclude, as I do here, that the facility was in no position to protect Resident # 5 or its

other residents who received Coumadin from experiencing possible Coumadin toxicity. Without appropriate protective systems in place, these residents' reactions to the medication were unmonitored and the residents were unprotected. That caused a likelihood of severe injury, harm, impairment, or death for all of them.

Petitioner argues that the finding of immediate jeopardy in this case is clearly erroneous. According to Petitioner, "CMS has failed to demonstrate, however, that Resident 5 would not have developed Coumadin toxicity had she received monthly PT/INR testing." Petitioner's Final Brief at 11. But, as I have discussed, such a finding is unnecessary. Here, it is sufficient to say that residents, including Resident # 5, were left unprotected against the possible adverse effects of Coumadin and that created a likelihood of severe adverse consequences. That conclusion is certainly not clearly erroneous.

3. CMS's remedy determinations are reasonable.

This case involves two civil money penalty determinations: penalties of $5,500 per day for each day of the period beginning on January 11 and running through February 3, 2009; and penalties of $600 a day for each day of the period beginning on February 4, 2009 and running through March 1, 2009. I find these penalty determinations to be reasonable in both amount and duration except that I find that Petitioner's immediate jeopardy level noncompliance ended on February 2, 2009. Therefore, imposition of an immediate jeopardy level penalty for February 3 is impermissible.

a. Civil money penalties of $5,500 per day are reasonable for each day of a January 11 – February 2, 2009 period.

Civil money penalties that are imposed 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). There are regulatory criteria for deciding where within the range a penalty should fall. These criteria may include the seriousness of a facility's noncompliance, its compliance history, its culpability, and its financial condition. 42 C.F.R. §§ 488.438(f)(1) – (4); 488.404 (incorporated by reference into 42 C.F.R. § 488.438(f)(3)).

The record amply supports a $5,500 per day immediate jeopardy level penalty. The seriousness of Petitioner's noncompliance and its culpability is sufficient to justify the penalty amount. In this case, the facility failed egregiously to comply with professionally recognized standards of care. The disregard of those standards was gross negligence on Petitioner's part. The effect of that disregard was to put residents at jeopardy and, in all probability, to cause consequences that may have resulted in Resident # 5 being hospitalized. As I have discussed, it is not possible to say that Petitioner's disregard of

standards of care caused the resident to experience Coumadin toxicity. But, it is clear that Petitioner, by failing to comply with professionally recognized standards of care, failed to provide the resident and others similarly situated with even basic protection against toxicity.

Petitioner has offered no argument to show why the amount of the immediate jeopardy level penalty is unreasonable. It has offered no evidence to show that its financial condition would preclude it from paying the penalties. Petitioner argues that imposing a per day civil money penalty for what it characterizes as "past immediate jeopardy" – noncompliance that occurs prior to the survey – is unfair. Petitioner's Final Brief at 12. But, the Act and the regulations precisely permit that remedy. There is nothing in the Act that requires penalties to be prospective only. Regulations specifically provide that:

> The per day civil money penalty may start accruing as early as the date that the facility was first out of compliance . . . .

42 C.F.R. § 488.440(a)(1). Here, CMS determined that the first day of Petitioner's noncompliance was January 11, 2009, and Petitioner has offered no evidence to establish that determination to be incorrect. Indeed, Petitioner's noncompliance actually began much earlier than January 11, 2009, because its staff ceased providing INR and PT testing for Resident # 5 after October 2008.

Petitioner also argues that it should not be liable for an immediate jeopardy level civil money penalty for February 3, 2009, the final date when CMS determined that there was immediate jeopardy level noncompliance. I agree with Petitioner that there is no basis to impose an immediate jeopardy level penalty for February 3. As CMS acknowledges, the period of Petitioner's immediate jeopardy level noncompliance ended on February 2, 2009 because Petitioner abated immediate jeopardy on that date. CMS's Final Brief at 14; CMS Ex. 2 at 7; P. Ex. 8 at 1.

b. Civil money penalties of $600 per day are reasonable for each day of a February 3 – March 11, 2009 period.

Civil money penalties that are imposed to remedy non-immediate jeopardy level deficiencies must fall within a range of from $50 - $3,000 per day. 42 C.F.R. § 488.438(a)(1)(ii). The same criteria apply for determining the amount of a penalty falling within the non-immediate jeopardy range (seriousness, culpability, compliance history, financial condition) as apply to determining the amount of a penalty falling within the immediate jeopardy range. 42 C.F.R. §§ 488.438(f)(1) – (4); 488.404 (incorporated by reference into 42 C.F.R. § 488.438(f)(3)).

CMS determined that, although Petitioner abated its immediate jeopardy level noncompliance on February 2, 2009, noncompliance at the non-immediate jeopardy level continued through March 11, 2009. It determined to impose a $600 per day civil money penalty against Petitioner for each day of the period running through March 11.

The non-immediate jeopardy level noncompliance included continued noncompliance with the requirements of 42 C.F.R. § 483.25. There was additional noncompliance cited by CMS which I have determined that Petitioner has not challenged and that is Petitioner's failure to comply with the requirements of 42 C.F.R. §§ 483.25(j); and 483.60(c).

Petitioner argues that it came fully into compliance with the requirements of 42 C.F.R. § 483.25 on February 2, 2009 and that, consequently, CMS may not base any additional remedy determinations on alleged continued noncompliance with this regulation. As proof of its alleged resumption of compliance, Petitioner offers evidence that it put into place a new system for monitoring laboratory results on February 3, 2009. Petitioner's Final Brief at 9; P. Ex. 4.

I do not find that Petitioner attained full compliance with the requirements of 42 C.F.R. § 483.25 with its implementation of a new system for monitoring laboratory results. This step – while necessary – did not address all of Petitioner's noncompliance with the regulation. Petitioner did not provide assurances that it had addressed with its pharmacy consultant the consultant's failure to evaluate the possible effects of Coumadin administered in combination with other medications. Moreover, and as Petitioner admits, it had not completed in-service training of its entire professional staff by February 3, 2009. Petitioner's Final Brief at 9. As of that date it had not completed in-service training of non-routine, temporary, or PRN (as needed) staff. Yet, and as Petitioner implicitly concedes, some of these individuals could be involved in evaluating and assessing residents who are receiving Coumadin. Indeed, that is precisely why Petitioner continued its in-service training *after* February 3.

Petitioner argues that the additional two non-immediate jeopardy level deficiencies cannot be a basis for the imposition of any remedies against it. It contends that these additional deficiencies were never cited by CMS as a basis for imposing remedies and that, consequently, it would be a denial of due process to impose penalties based on them. Petitioner's Final Brief at 13-14.

I disagree. CMS provided Petitioner with more than adequate notice that it intended to impose remedies based, in part, on the two non-immediate jeopardy level deficiencies that Petitioner did not contest. The initial notice letter that CMS sent to Petitioner on

February 23, 2009 explicitly refers to all of the deficiencies that were found at the February survey – and not just Petitioner's noncompliance with 42 C.F.R. § 483.25 – as a basis for imposing remedies. CMS Ex. 1 at 1. It cites all three deficiencies and then states that remedies would be imposed:

> Because of your failure to substantially comply with Medicare/Medicaid participation *requirements*. . . .

Id. (emphasis added). Moreover, CMS cited all three deficiencies in its opening brief as a basis for imposing non-immediate jeopardy level penalties. CMS's Pre-Hearing Brief at 11. Petitioner thus had a full month's notice of CMS's arguments, even assuming it had not understood the implications of the February 23, 2009 notice letter, and could have prepared a defense to them based on what CMS had contended.

Petitioner has offered no argument that the $600 daily penalty amount is unreasonable if based on continued non-immediate jeopardy level noncompliance. I sustain the non-immediate jeopardy level penalty amount for that reason, and also because the non-immediate jeopardy level deficiencies were, in and of themselves, adequate to support the penalty amount.

The two additional deficiencies asserted by CMS and not challenged by Petitioner were relatively serious and they, plus Petitioner's continued noncompliance with the requirements of 42 C.F.R. § 483.25, are sufficient to support a daily penalty amount of $600. Indeed, just the two additional deficiencies, standing alone, would be adequate to support a $600 daily penalty. Petitioner failed to comply with the requirements of 42 C.F.R. § 483.25(j) because it failed to assure that several of its residents were adequately hydrated. CMS Ex. 2 at 8-11. That failure had at least the potential for causing serious problems for residents of Petitioner's facility. For example, the care plan for Resident # 5 noted a risk of dehydration and directed that water be available to the resident at all times. However, on February 2 and February 4, 2009, the resident was observed to be in her room without water within reach. *Id.*

Petitioner failed to comply with the requirements of 42 C.F.R. § 483.60(c), because it failed to ensure that its consultant pharmacist review and assess the medications regimes of residents who were receiving Coumadin. This deficiency stands independent of the noncompliance with 42 C.F.R. § 483.25, which I have discussed at length, above.

/s/
Steven T. Kessel
Administrative Law Judge