Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Universal Health Care - King
(CCN: 34-5449),

Petitioner

v.

Centers for Medicare and Medicaid Services.

Docket No. C-10-209

Decision No. CR2278

Date: November 5, 2010

DECISION

I sustain the determination of the Centers for Medicare and Medicaid Services (CMS) to impose remedies against Petitioner, Universal Health Care-King, consisting of civil money penalties of $3,050 per day for each day of a period that began on March 21, 2009 and that continued through September 27, 2009.

I also sustain the imposition of civil money penalties against Petitioner in the amount of $150 per day for each day of a period that began on September 28, 2009 and that continued through November 2, 2009.

I. Background

Petitioner is a skilled nursing facility in King, North Carolina. 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. Regulations at 42 C.F.R. Part 498 govern its hearing rights in this case.

The state survey agency performed a complaint investigation survey of Petitioner on September 26, 2009 (September Survey), and Petitioner was found to be deficient in several respects. The findings of noncompliance included findings that Petitioner failed to comply substantially with the requirements of: 42 C.F.R. § 483.25(l), which requires that residents' drug regimens be free of unnecessary drugs and defines such drugs to include drugs that are given in excessive doses or without adequate monitoring; and 42 C.F.R. § 483.75(j)(1), which requires a skilled nursing facility to provide or obtain laboratory services that are timely and that meet quality requirements. These noncompliance findings were determined to be so egregious as to place Petitioner's residents in immediate jeopardy. The term "immediate jeopardy" means noncompliance that causes, or is likely to cause, serious injury, harm, impairment, or death to one or more residents of a facility. 42 C.F.R. § 488.301.

Petitioner was resurveyed on October 13 – 15, 2009 (October Survey). At this survey, it was determined that Petitioner had abated its immediate jeopardy level noncompliance effective September 28, 2009. Additional non-immediate jeopardy level deficiencies were found at the October Survey. CMS notified Petitioner on December 14, 2009 that based on the November 30, 2009 revisit survey, Petitioner came back into substantial compliance as of November 3, 2009.

Petitioner requested a hearing, and the case was assigned to me for a hearing and a decision. The parties exchanged proposed exhibits and pre-hearing briefs. Then, they agreed that the case could be decided based on their written submissions. The parties filed final briefs.

CMS filed exhibits that it identified as CMS Ex. 1 – CMS Ex. 10. Petitioner filed exhibits that it identified as P. Ex. 1 – P. Ex. 31. I receive these exhibits into evidence.

II. Issues, Findings of Fact, and Conclusions of Law

A. Issues

The issues are whether:

1. Petitioner failed to comply with Medicare participation requirements.

2. CMS's determination of immediate jeopardy level noncompliance is clearly erroneous.

3. CMS's remedy determinations are reasonable in duration and amount.

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(l) and 483.75(j)(1).

The evidence overwhelmingly supports my conclusion that Petitioner did not adequately monitor the administration of a drug, Coumadin, to one of its residents, an individual who is identified as Resident # 1. The staff failed to test the resident for possibly dangerous effects of Coumadin, failed to report to the resident's physician a test result that showed the resident to have a dangerously slow blood clotting time, and failed to address the resident's Coumadin use in her care plan. These failures contravened the requirements of 42 C.F.R. § 483.25(l), because they enabled Resident # 1 to receive excessive and potentially life-threatening doses of Coumadin. They contravened the requirements of 42 C.F.R. § 483.75(j)(1), because Petitioner failed to obtain laboratory results for the resident that met her medical needs.

Coumadin is an extremely powerful anticoagulant drug that is administered to individuals to prevent them from developing dangerous blood clots. CMS Ex. 10 at 1. It is a medication that poses significant risks to those patients who receive it. It has a very narrow therapeutic range, and Coumadin recipients run the risk of developing life-threatening uncontrollable bleeding. *Id.* Administration of Coumadin must be monitored carefully because of the risks related to unanticipated effects of the drug. Moreover, Coumadin may have unpredictable effects on those who receive it. Every individual responds uniquely to the drug. *Id.* Its anticoagulant effects may vary from individual to individual as a result of factors that include the individual's age, diet, health, and other medications that the individual is taking. *Id.* at 1-2.

Coumadin's effect on an individual is monitored by a blood test known as the International Normalized Ratio (INR). CMS Ex. 10 at 2. The test measures the amount of time that it takes blood to clot. A therapeutic range for Coumadin is generally considered to be an INR of 2-3. A lower INR indicates a subtherapeutic effect of Coumadin. An INR of 4.0 or higher indicates that the risk of uncontrolled bleeding exceeds the therapeutic benefits of Coumadin. *Id.*

It is necessary that a skilled nursing facility have a system in place to ensure that residents who receive Coumadin are properly monitored. CMS Ex. 10 at 2. The system must ensure that: (1) INRs are performed as prescribed, and their results are reported timely to the residents' physicians; and (2) those residents who receive Coumadin have care plans that address the drug's risks to these residents.

Review of the care provided by Petitioner's staff to Resident # 1 establishes that the resident's response to Coumadin was labile. At times, her INR readings were outside of the therapeutic range, either too low, or frequently, dangerously high. Despite that, and despite the fact that the resident's physician had ordered daily INR testing, Petitioner's staff failed to perform INR tests on this resident on multiple occasions. Between February 10 and March 21, 2009, Petitioner's staff failed on five days to perform INR testing on Resident # 1. On at least one occasion, the staff failed to notify the physician of a dangerously high INR reading. Thus, Petitioner's staff left Resident # 1 vulnerable to uncontrolled bleeding.

Resident # 1 was an elderly individual who suffered from multiple medical problems. In early February 2009, the resident developed a deep vein thrombosis – a blood clot – in her right leg. CMS Ex. 1 at 6; CMS Ex. 10 at 3. On February 10, 2009, her physician ordered that the resident be given 10 mg of Coumadin daily along with another anticoagulant, Lovenox. CMS Ex. 7 at 2; CMS Ex. 10 at 3. On that same date the physician ordered daily INR testing of the resident. CMS Ex. 7 at 2.

Petitioner's staff failed to perform INR testing on February 11, 12, and 13, 2009, notwithstanding the physician's order for daily testing. CMS Ex. 1 at 6. On February 14, 2009 staff did perform INR testing, and the results were critically high at 6.68. *Id.* at 6-7. The physician ordered that administration of Coumadin be discontinued temporarily. On February 24, 2009, another INR result showed that the resident had a dangerously high reading of 7.27. *Id.* at 7-8. There is no evidence that the physician was notified of this reading. However, on February 26, 2009, the physician – evidently after having been notified about another very high INR result – ordered for a second time that administration of Coumadin and Lovenox be discontinued. CMS Ex. 7 at 5. Daily INRs were again ordered by the physician. *Id.*

On February 28, 2009, the physician ordered that administration of Coumadin be restarted, albeit at a reduced dose, and once again ordered daily INR testing. CMS Ex. 7 at 7. The physician then added a prescription for another anticoagulant, Arixtra, because the resident's INR readings were subtherapeutic. Arixtra was discontinued after a March 10 INR showed a dangerously high reading. CMS Ex. 7 at 8.

On March 3, 2009, for reasons that are not explained, Petitioner' staff failed to give the resident her prescribed daily dose of Coumadin. CMS Ex. 1 at 10. On March 2, 4, and 5, the resident's INR readings were subtherapeutic. However, Petitioner's staff did not notify the resident's physician of these abnormal results until March 5, 2009. *Id.*

Petitioner's staff failed to perform an INR test on March 14 despite the fact that the physician had ordered daily INR readings. CMS Ex. 1 at 13; CMS Ex. 7 at 8. On March 16, the physician ordered that an INR reading be made on March 21, 2009. CMS Ex. 1 at

14. However, Petitioner's staff failed to perform this test. The staff continued to administer Coumadin to the resident through March 23, 2009. *Id.*

On March 24, 2009, Resident # 1 showed bruising in the vicinity of her breast and armpit. CMS Ex. 8 at 2-3. The resident's physician ordered that she be sent to the emergency room. CMS Ex. 7 at 11. At the hospital, severe swelling and bruising were noted, and the resident's INR was recorded at a dangerously high level of 8.1. CMS Ex. 5 at 3, 6. The resident was treated for a toxic reaction to Coumadin, but she died on March 25, 2009. CMS Ex. 5 at 4. The cause of the resident's death was given as Coumadin poisoning and internal bleeding. CMS Ex. 8 at 1.

The multiple failures by Petitioner's staff to conduct physician ordered INR testing of Resident # 1 and the staff's failures on two occasions to report out-of-range test results to the resident's physician put the resident at risk for very serious consequences. CMS Ex. 10 at 5. This resident, given her varying reactions to Coumadin, needed extremely careful monitoring to avoid the possibilities that the Coumadin would not produce therapeutic results or that it would cause a toxic reaction. *Id.* at 4. Petitioner's staff failed to provide careful monitoring. The evidence establishes, moreover, that this failure was the consequence of a lack of planning on the staff's part and, at bottom, reflected an insensitivity on the staff's part to the risks that Resident # 1 faced. As I have discussed, it is necessary that a skilled nursing facility have a system in place to assure that residents who receive Coumadin are properly monitored. A critical element of such a system is careful care planning for each resident who receives Coumadin. But, Resident # 1 did not have a care plan that addressed her clotting problems and anticoagulant therapy. *Id.* at 5.

Petitioner has not challenged the facts that I discuss above. Instead, it focuses on the failure by its staff to perform INR testing on March 21, 2009, as if that failure is the *only* error that the staff committed in providing care to Resident # 1. Petitioner's Pre-Hearing Brief at 3. Thus, Petitioner seeks to minimize the significance of its noncompliance. However, and Petitioner's contention notwithstanding, the noncompliance demonstrated by the care Petitioner's staff gave to the resident is far more pervasive than Petitioner acknowledges. This is not a case of a single judgment error by the staff but one of a systemic failure by the staff to understand the risks and dangers associated with Coumadin administration. There were multiple failures – five in all – by Petitioner's staff to perform physician ordered INR testing on the resident. These failures transpired over a period of more than a month. Petitioner's staff never care planned for the resident's anticoagulant therapy, and they failed to notify the resident's treating physician of both low and dangerously high INRs.

Petitioner argues additionally that CMS failed to make a prima facie case of noncompliance with the requirements of 42 C.F.R. § 483.75(j)(1). Petitioner's argument is that the regulation – which requires a skilled nursing facility to provide or obtain

laboratory services to meet the needs of its residents and to ensure the quality and timeliness of such services – is inapplicable to the facts. It contends that staff errors related to performing INR testing have nothing to do with the operations of the laboratory to which those tests were sent for readings. Petitioner's Pre-Hearing Brief at 5-6.

Petitioner reads the regulation too narrowly. An INR test is a laboratory service in the sense that the result is read and interpreted by a laboratory. But, Petitioner is responsible for initiating that service by performing or ordering the test. A failure by the staff to perform or order INR testing as directed by a physician is a failure to assure timely laboratory services because the test itself is an essential element of those services, and it is performed directly by Petitioner's staff or ordered by them.

2. Petitioner did not challenge the noncompliance findings that were made at the October Survey, and these findings are administratively final.

Three findings of substantial noncompliance were made at the October Survey. These were failures to comply with the requirements of 42 C.F.R. §§ 483.25, 483.25(f)(2), and 483.35(i). P. Ex. 31. Petitioner challenged none of these findings, and they are, therefore, administratively final. CMS is authorized to impose remedies based on these noncompliance findings.

3. Petitioner did not prove to be clearly erroneous the findings of immediate jeopardy level noncompliance that were made at the September Survey.

There is ample evidence that Petitioner put residents at risk for serious injury, harm, impairment, or death. A high likelihood of such outcomes was present even if Petitioner's failure to monitor effectively Resident # 1's use of Coumadin did not directly cause her death.

As I have discussed, it is critically important to plan the care of, and to monitor closely, residents of a skilled nursing facility who are taking Coumadin. Coumadin is a highly dangerous drug, which can cause catastrophic damage to an individual from uncontrolled bleeding if not closely and carefully monitored. The evidence in this case establishes that not only was there a series of failures to monitor Resident # 1 but that these failures prove a systemic weakness in the way Petitioner monitored residents who received Coumadin. Petitioner did not plan for Resident # 1's care and, clearly, had no systems in place that would detect errors in monitoring its residents who received Coumadin. The fact that there were five failures to monitor Resident # 1 over a period of about a month, all undetected despite explicit orders by a physician that the resident be monitored daily, is proof of this systemic failure.

Petitioner has not offered evidence to prove that CMS's finding of immediate jeopardy was clearly erroneous. Rather, it argues that the finding of *duration* of immediate jeopardy is wrong. I discuss this argument at Finding 4.

4. Petitioner's immediate jeopardy level noncompliance persisted from March 21 through September 27, 2009.

Petitioner's principal argument is that it corrected all immediate jeopardy level noncompliance by no later than April 7, 2009. Consequently, it asserts, CMS is without authority to impose immediate jeopardy level remedies against Petitioner after April 7.

Petitioner premises this argument on its assertion that its own staff discovered the error in failing to perform INR testing of Resident # 1 on March 21, 2009. It asserts that a licensed professional nurse discovered this error on March 23, 2009. Petitioner's Pre-Hearing Brief at 6. It contends that it immediately undertook a series of corrective actions – entirely on its own initiative – to address the error to assure that it would not occur again. *Id.* The measures that Petitioner asserts it took included:

- Investigating the cause of the March 21 error, which, according to Petitioner, revealed that the failure to perform the test was due to a transcription error by a nurse.

- Bedside re-inservicing of direct care staff on laboratory protocol and procedures.

- Evaluating existing laboratory procedures and protocol, leading to the conclusion that they were appropriate and sufficient.

- Developing a new form, an "Anticoagulate Therapy" form, for use by staff to monitor the due dates for INR testing of residents. The form listed residents on Coumadin, when each resident's monitoring tests were due to be performed, and when follow up was due. Staff were instructed that, in the event of a missed test, they were to notify immediately the resident's physician and Petitioner's director of nursing and to perform the test.

- Formal inservicing of pertinent direct care, management, and administrative staff on the use of the new form, which was completed by April 7, 2009.

- Implementing an ongoing monitoring process in order to oversee the effectiveness of the laboratory protocol. This was implemented on April 7. The process requires that the facility's assistant director of nursing review copies of lab orders and to compare them with facility records establishing what laboratory tests are to be performed. The process was intended to result in the creation of labels to be

> entered into the facility's lab book and to serve as a method of comparison to assure that requisitions for laboratory tests were properly drawn.

Petitioner's Pre-Hearing Brief at 6-8.

I do not find Petitioner's argument to be persuasive. Petitioner's self-instituted corrective actions focused on assuring that staff members and laboratory personnel performed those tests that are ordered by a resident's physician. It is clear that these actions are based on the staff's failure to conduct INR testing of Resident # 1 on March 21, 2009. These measures address an element of Petitioner's noncompliance. But, they do not address the totality of the noncompliance, and, for that reason, they are inadequate proof that Petitioner self-corrected its deficiencies by April 7, 2009.

The noncompliance that I discuss at Finding 1 certainly involves failure – on multiple occasions – to perform INR testing as Resident # 1's physician directed. But, it involves much more than that. There was a failure on the part of Petitioner and its staff to comprehend the risks that Coumadin posed for Resident # 1 and for other residents as well. This incomprehension is demonstrated not just by missed INR tests, but by the failure to plan comprehensively the care of Resident # 1 and other residents who received Coumadin so as to address the risks and dangers posed by the drug and by the failure of Petitioner's staff to consult immediately with Resident #1's physician about out of therapeutic range test results (INRs that were low as well as high). It is demonstrated also by the failure of Petitioner's supervisory staff to notice the errors that rank and file care givers were committing in providing care to Resident # 1 until after March 21, 2009.

Petitioner did not address these problems comprehensively, until it developed a plan of correction in response to the September Survey findings of noncompliance. CMS Ex. 1. The plan of correction, which stated completion dates as late as September 28, 2009, included the following items not previously implemented by Petitioner:

- Petitioner's director of nursing personally audited each care plan for those residents who were being treated with Coumadin as of September 24, 2009, and each of these care plans was revised to include signs and/or symptoms of bleeding related to Coumadin therapy. *Id.* at 1.

- A temporary care plan for Coumadin was developed on September 25, 2009 and placed in the record of each resident who received Coumadin. A copy of the plan was also posted at Petitioner's nurses' station. *Id.* at 2.

- The director of nurses and the assistant director of nurses were assigned the responsibility of personally auditing the medical record of the next 20 residents admitted to the facility who were receiving Coumadin to assure that a Coumadin care plan was written for each of these residents. The results of those audits were

to be reviewed at Petitioner's quality assurance meetings, once monthly for four months, and quarterly thereafter. *Id.*

- On September 24, 2009, Petitioner put in place a revised anticoagulant therapy form for each resident who received Coumadin, Lovenox, or Heparin, and which listed the specific dosage of anticoagulant medication that a resident was receiving and the next date when INR or similar testing was to be performed. Petitioner placed these forms in a binder that was to be kept at the nurses' station. *Id.* at 8.

- Petitioner trained its staff ("in-serviced") on September 24 and 25, 2009, regarding use of the new anticoagulant therapy form. *Id.*

- On September 28, 2009 Petitioner in-serviced its staff on "stat" laboratory tests (tests that are ordered for an immediate response) and on laboratory tests that are sent to other designated facilities. *Id.* at 12.

- Petitioner assigned the task of auditing the anticoagulant therapy forms daily to Petitioner's director of nursing and assistant director of nursing and determined to counsel each nurse who fails to follow facility protocol. *Id.* at 13.

Thus, Petitioner did not implement comprehensive corrective actions addressing the deficiencies that I discuss at Finding 1 until September 28, 2009. For that reason, CMS's determination that Petitioner did not eliminate its immediate jeopardy level noncompliance until September 27, 2009 is reasonable.

Petitioner offered the declaration of Darlyne Menscer, M.D., to support its contention that it self-corrected its noncompliance by April 4, 2009. P. Ex. 24. I find Dr. Menscer's testimony not to be persuasive. She asserts that:

> The additions to the lab procedures in September 2009 after the survey were superfluous and not necessary to comply with the standard of care.

P. Ex. 24 at 3. I infer that Dr. Menscer is referring to Petitioner's plan of correction. Dr. Menscer offers no explanation why the corrective actions undertaken by Petitioner in that plan were superfluous. Furthermore, in discussing Petitioner's corrective actions, Dr. Menscer focuses on the failure to perform INR testing on Resident # 1 on March 21, 2009, as if that failure was the *only* error committed by Petitioner and its staff in providing care for the resident and for all of its residents who were receiving Coumadin. *Id.* at 2-3. At Finding 1, I explain why the failure to perform INR testing on March 21 is but one of a series of errors and not just an isolated mistake by an employee. I also explain that the deficiencies manifested by Petitioner are broader in scope than simple mistakes in performing testing but establish a broad failure by Petitioner and its staff to comprehend and to address problems and risks associated with administering Coumadin.

Dr. Menscer acknowledges none of this in her declaration. The narrowness of her focus undercuts her credibility.

Petitioner also relies on the declaration of William Simonson, PharmD, to support its assertion that it corrected all of its deficiencies by April 4, 2009. P. Ex. 23. I find Dr. Simonson's testimony to be unpersuasive for reasons similar to those that render Dr. Menscer's testimony less than persuasive. As with Dr. Menscer, Dr. Simonson focuses on the March 21, 2009 failure by Petitioner to conduct INR testing of Resident # 1. P. Ex. 23 at 3. He expands on this somewhat by asserting that:

> To the extent that the pre-March 21 missed labs now allegedly form the basis of the immediate jeopardy, I note that these labs all pre-date the March 21 missed lab.

P. Ex. 23 at 5. Dr. Simonson's conclusion is that the corrective actions that Petitioner undertook in April 2009 ensured that, not only would the error of March 21 have been prevented, but all previous errors consisting of failures to do INR testing would have been prevented as well.

But, and as I have discussed, failure to perform INR testing per physicians' orders is only one element of Petitioner's noncompliance. Making sure that the staff performed lab testing as ordered certainly addressed a problem. But, that correction did not address other problems, such as the failure of the staff to plan for the care of residents receiving anticoagulants or the failure of the staff to recognize that out of therapeutic range INR test results required physician consultation. Those problems were not addressed by Petitioner, until it filed its corrective action plan in September 2009.

The date when CMS credited Petitioner with having corrected its immediate jeopardy level noncompliance – September 27, 2009 – was the earliest date that CMS reasonably could have found correction to have occurred, given the deficiencies and the corrective action implemented by Petitioner. State surveyors had no information from Petitioner prior to September 27 showing a comprehensive approach to rectifying the immediate jeopardy level noncompliance. Petitioner only addressed the totality of its noncompliance with its corrective action plan that listed September 28, 2009 as one of its anticipated completion dates.

The September 27 compliance date was determined during the October Survey, which was completed on October 15, 2009. The surveyors, in effect, gave credit to Petitioner for its assertions that it had implemented all of its corrections by September 28, 2009. As a matter of law, CMS could have found a later date of correction than September 27. It could have determined the date of correction as late as the October Survey completion date of October 15. The deficiencies that are at issue in this case are deficiencies of the type that require surveyor observation of staff performance before compliance can be

certified. *See Omni Manor Nursing Home*, DAB CR2213 (August 2010). Thus, CMS gave Petitioner the benefit of the doubt in determining that it had corrected its immediate jeopardy level noncompliance on a date that was two weeks earlier than the completion of the October Survey.

5. CMS's civil money penalty determinations are reasonable.

a. Civil money penalties of $3,050 per day for each day of the period that began on March 21, 2009 and that continued through September 27, 2009 are reasonable as a matter of law.

CMS determined to impose civil money penalties of $3,050 per day against Petitioner for each day of the period that began on March 21, 2009 and that ran through September 27, 2009. I have found Petitioner manifested immediate jeopardy level noncompliance throughout this period. The penalties that CMS determined to impose to redress Petitioner's immediate jeopardy level noncompliance are reasonable as a matter of law. $3,050 per day is the minimum amount that may be imposed to remedy an immediate jeopardy level deficiency. 42 C.F.R. § 488.438(a)(1)(i).

b. Civil money penalties of $150 per day for each day of the period that began on September 28, 2009 and that continued through November 2, 2009 are reasonable.

It is unclear whether CMS determined that Petitioner's immediate jeopardy level deficiencies were abated completely as of September 27, 2009, or whether Petitioner continued to be noncompliant, albeit at a level that is less than immediate jeopardy, for dates after September 27. The report of the October Survey does not address this question. Therefore, I make no finding that remedies may be imposed after September 27, 2009, at a level that is less than immediate jeopardy, to redress those deficiencies that were identified in the September survey report.

The State survey agency and CMS found additional deficiencies at the October Survey, and it is evident from the report of that survey that the surveyors concluded that Petitioner's noncompliance predated October 15. For example, one of the deficiencies that the surveyors found in October was a failure by Petitioner to comply with the requirements of 42 C.F.R. § 483.25(f)(2). P. Ex. 31 at 6-9. The regulation requires a facility to ensure that a resident whose assessment did not reveal a mental or psychosocial adjustment difficulty does not develop a pattern of psychological problems, unless the resident's clinical condition demonstrates that such a pattern is unavoidable. The surveyors found that Petitioner failed to assess the needs of one of its residents, identified as Resident # 8, for potential psychological problems. That noncompliance originated weeks or months prior to the October Survey. The survey report makes it plain that the

resident began to manifest such problems months prior to the October survey. For example, the resident had lost 13 pounds in the previous 30 days and 26 pounds in the previous 180 days. *Id.* at 7.

Petitioner did not challenge the findings of noncompliance that were made at the October Survey. It has, therefore, effectively conceded that CMS may impose civil money penalties of $150 per day to remedy the noncompliance that was found at the October Survey. Imposing those penalties beginning with September 28, 2009 is reasonable given that noncompliance identified at the October Survey originated weeks or months prior to that survey.

/s/
Steven T. Kessel
Administrative Law Judge