Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Transitional Health Services of Fremont (CCN: 23-5176),	)	Date: August 25, 2008
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-07-730
	)	Decision No. CR1833
Centers for Medicare & Medicaid Services.	)	
	)	

DECISION

Petitioner, Transitional Health Services of Fremont (Petitioner or facility), is a long term care facility located in Fremont, Michigan, that is certified to participate in the Medicare program as a provider of services. Here, Petitioner appeals CMS's determinations that, from July 20 through November 15, 2007, it was not in substantial compliance with Medicare requirements, and that on July 20, 2007, its deficiencies posed immediate jeopardy to resident health and safety. For this alleged noncompliance, CMS has imposed civil money penalties (CMPs) of $5500 per day for the one day of immediate jeopardy, plus $250 per day for 55 days (July 21 through September 13, 2007), and $400 per day for 63 days (September 14 through November 15, 2007) of substantial noncompliance that was not immediate jeopardy (total CMP: $44,450).

For the reasons set forth below, I find that from July 20 through November 15, 2007, the facility was not in substantial compliance with Medicare requirements, and that on July 20, 2007, its deficiencies posed immediate jeopardy to resident health and safety. I find the CMPs reasonable.

I. Background

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

Medicare program, a nursing facility must maintain substantial compliance with program requirements. To be in substantial compliance, a facility's deficiencies may pose no greater risk to resident health and safety than "the potential for causing minimal harm." 42 C.F.R. § 488.301. Immediate jeopardy exists if the facility's noncompliance has caused or is likely to cause "serious injury, harm, impairment or death to a resident." 42 C.F.R. § 488.301. CMS's determination as to the level of a facility's noncompliance – which includes its immediate jeopardy finding – must be upheld unless it is "clearly erroneous." 42 C.F.R. § 498.60(c).

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

Here, the facility seems to have a troubled compliance history. On June 1, 2007, surveyors from the Michigan Department of Community Health (State Agency) went to the facility to investigate a complaint and found, among other problems, a pattern of sexual and physical abuse which the facility had neither investigated nor reported. CMS Ex. 1.

Thereafter, a July 19, 2007 Life Safety Code (LSC) Survey found substantial noncompliance with LSC requirements.

From July 17 – 20, 2007, surveyors returned to conduct the facility's annual recertification and licensure survey. The State Agency again concluded that the facility was not in substantial compliance with federal requirements for nursing homes participating in the Medicare program. Specifically, it did not meet the following federal requirements:

- 42 C.F.R. § 483.15(h)(2) (Tag F253 – housekeeping/maintenance) at an "E" level of scope and severity (pattern of noncompliance that causes no actual harm with the potential for more than minimal harm);

- 42 C.F.R. § 483.25 (Tag F309 – quality of care) at a "J" level of scope and severity (isolated instance of noncompliance that poses immediate jeopardy to resident health and safety);

- 42 C.F.R. § 483.25(c) (Tag F314 – pressure sores) at a "G" level of scope and severity (isolated instance of noncompliance that causes actual harm that is not immediate jeopardy);

- 42 C.F.R. § 483.25(h)(2) (Tag F324 – accidents) at an "E" level of scope and severity;

- 42 C.F.R. § 483.25(i)(1) (Tag F325 – nutrition) at a "D" level of scope and severity (isolated instance of noncompliance that causes no actual harm with the potential for more than minimal harm);

- 42 C.F.R. § 483.25(l) (Tag F329 – unnecessary drugs) at an "E" level of scope and severity;

- 42 C.F.R. § 483.60(a) and (b) (Tag F425 – pharmacy services) at a "D" level of scope and severity; and

- 42 C.F.R. § 483.60(b), (d), and (e) (Tag F431 – pharmacy services) at a "D" level of scope and severity.

CMS Ex. 3.

On September 14, 2007, the surveyors revisited the facility, and determined that its substantial noncompliance continued, citing G level deficiencies under 42 C.F.R. § 483.25 (quality of care – accidents and pressure sores). CMS Ex. 4.

CMS agrees with the State Agency conclusions and, among other remedies, has imposed CMPs of $5500 for one day of immediate jeopardy (July 20, 2007) and $250 per day for the 55 days (July 21 through September 13), and $400 per day for the 63 days (September 14 through November 15, 2007) of substantial noncompliance that is not immediate jeopardy. ($5550 + $13,750 + $25,200 = $44,450 total CMP). CMS Exs. 8, 11.

CMS later determined that the facility had achieved substantial compliance as of November 16, 2007. CMS Ex. 11.

Petitioner here appeals the July 20 and September 14 survey findings. *See* Hearing Request; Order, at 1 (March 25, 2008). It does not contest the June 1 complaint investigation findings nor the July 19 LSC findings, so the CMS determinations with respect to those surveys are final and binding. 42 C.F.R. § 498.20(b).[1]

[1] Although the record is a bit murky, it appears that, following an August 23, 2007 LSC re-visit survey, the State Agency determined that the facility had corrected its LSC deficiencies as of August 15. CMS Exs. 2, 9; CMS Op. Br. at 3. CMS accurately points out that, based on this undisputed noncompliance, it was therefore authorized to impose penalties until August 15, without regard to the subsequent, disputed survey findings.

Responding to my order of October 5, 2007, the parties filed their opening briefs (CMS Op. Br. and P. Op. Br.) and submissions. CMS offered 83 exhibits, but, during a March 20, 2008 prehearing conference, withdrew CMS Exhibits (Exs.) 12 and 13. In the absence of any objection, I have admitted into the record CMS Exs. 1-11 and 14-83. Petitioner offered 18 exhibits into evidence. CMS objected to portions of P. Exs. 1, 11, and 18, which include unsworn statements from various individuals. While the documents in question may be entitled to little weight, I found that they were neither irrelevant nor immaterial, and admitted them. Order, at 2 (March 25, 2008); 42 C.F.R. § 498.60(b)(1).

Among its submissions, Petitioner included a list of proposed witnesses, but it failed to submit any written declarations, as explicitly required by my initial prehearing order. Acknowledgment and Initial Prehearing Order ¶ 4 ("A party *must* exchange as a proposed exhibit the complete written direct testimony of any proposed witness." Emphasis added). I therefore ruled that I would not allow Petitioner's witnesses to testify at the in-person hearing. Order, at 2 (March 25, 2008); *see* Acknowledgment and Initial Prehearing Order ¶ 11 ("I may impose sanctions pursuant to section 1128A(c)(4) of the . . . Act for a party's failure to comply with any order including this order.") (October 5, 2007); *see Kenton Healthcare, LLC*, DAB No. 2186, at 29 (2008) (Where witness failed to appear for cross-examination, it was reasonable and within the ALJ's discretion to strike the witness's written direct testimony rather than re-convening the hearing at a later date); *Lutheran Home at Trinity Oaks*, DAB No. 2111, at 25, n.15 (2007) (ALJ may strike testimony based on party's failure to comply with prehearing order). I subsequently denied both Petitioner's motion to file its declarations as late-filed exhibits and its request for reconsideration, finding that Petitioner had not shown good cause for late filing. Order, at 2 (March 25, 2008); Ruling (April 3, 2008).[2]

By letter dated April 29, 2008, Petitioner declined to cross-examine any of CMS's witnesses, so the scheduled hearing was cancelled. *See*, Order Cancelling Hearing and Setting Briefing Schedule (April 30, 2008). The parties then filed closing briefs (CMS Cl. Br. and P. Cl. Br.).

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[2] A purpose of the pre-hearing order is to obtain early and full disclosure by both parties, leading to the expeditious (and correct) resolution of the case. Here, not only did Petitioner fail to submit any written declarations as ordered, its initial brief cites to no evidence in support of its arguments. Only in its closing brief does Petitioner actually cite to any evidence in the record. The prehearing order also explicitly states that "a prehearing brief *must* contain any argument that a party intends to make . . . . I may exclude an argument and evidence that relates to such argument if the party fails to address it in its prehearing brief." Acknowledgment and Prehearing Order ¶ 7 (October 5, 2007). CMS might legitimately have moved for the exclusion of arguments and citations to evidence that were mentioned for the first time in Petitioner's closing brief. *Compare*, *e.g.*, P. Op. Br. at 4-5 *with* P. Cl. Br. at 5-10.

II. Issues

- Whether, from July 20 through November 15, 2007, the facility was in substantial compliance with Medicare requirements;

- If the facility was not in substantial compliance on July 20, 2007, did its deficiencies then pose immediate jeopardy to resident health and safety; and

- Except to argue that it was in compliance so no penalties should have been imposed, Petitioner has not raised any arguments concerning the reasonableness of the CMPs. I nevertheless conclude that the CMPs are reasonable.

III. Discussion

A. From July 20, 2007, through November 15, 2007, the facility was not in substantial compliance with the program participation requirement set forth at 42 C.F.R. § 483.25.[3]

1. The facility abdicated its responsibility to monitor the safety and effectiveness of its residents' anti-coagulant medications.

Under the Act and "quality of care" regulation, each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the resident's comprehensive assessment and plan of care. Act, § 1819(b); 42 C.F.R. § 483.25. The regulation imposes on facilities an affirmative duty designed to achieve favorable outcomes "to the highest practicable degree." *Windsor Health Care Center*, DAB No. 1902, at 16-17 (2003); *Woodstock Care Center,* DAB No. 1726, at 25-30.

Three facility residents, identified as R15, R18, and R19, were receiving the anti-coagulant drug, Coumadin, at the time of the July survey. Anti-coagulant drugs help to inhibit the formation of blood clots, and are often prescribed to individuals who have experienced inappropriate blood clotting, such as those who have had heart attacks, strokes, or deep vein thrombosis. Dosages are individualized based on the patient's

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

PT/INR (prothrombin time/international normalized ration) response to the drug.[4] CMS Ex. 59; CMS Ex. 14, at 2 (Kralka Decl. ¶ 9); CMS Ex. 22, at 1-2 (Miller Decl. ¶ 7).

Coumadin blood levels must be monitored carefully to assure that they are within a safe and therapeutic range. If the levels are too high, the resident risks bleeding complications; if the levels are too low, stroke could result. CMS Ex. 14, at 2 (Kralka Decl. ¶ 11). This need for careful monitoring is even more pronounced when the resident is prescribed additional medications since Coumadin interacts with many other drugs in dangerous, even fatal, ways. Antibiotics are particularly problematic because they can increase Coumadin's anti-coagulant effect. Thus, even greater care must be taken when antibiotics are administered to an elderly patient on Coumadin. CMS Ex. 77, at 6.

The question here is what, if any, responsibility did the facility have to ensure that its residents' blood levels were monitored appropriately.

CMS is highly critical of the facility's performance in this regard. The facility apparently had no written policy in place that addressed assessing or monitoring residents who were taking Coumadin. In practice, it seems that the facility itself took little, if any, responsibility for monitoring the PT/INR of its residents – even those who were at exceptionally high risk of bleeding complications. According to CMS, the facility's inattention contributed to two residents' hospitalizations for Coumadin toxicity. CMS Op. Br. at 7.

Resident 15 (R15). In February 2007, **R15** was a sixty-nine year old man with a history of atrial fibrillation, for which he was prescribed Coumadin. P. Ex. 3, at 13. His care plan identified him as at risk for bleeding and "abnormal labs" secondary to anticoagulant therapy, and called for "labs as ordered" and "INR between 2.0 – 3.0 or per physician's parameters." CMS Ex. 47, at 9.

A document titled "lab tracking log" indicates that, prior to February 18, R15's INR target values were set at 1.8 – 3.0. On January 19, 2007, his INR test results were below that target, at 1.6. CMS Ex. 47, at 14.

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[4] PT/INR tests evaluate the ability of blood to clot properly. The INR is the ratio of an individual's prothrombin time to a control (i.e., normal) sample. The higher the INR, the greater the chance of bleeding. A very low INR suggests the risk of a blood clot. Normal ranges for a healthy person are 0.9 – 1.3; for people on Coumadin, desirable ranges may be 2.0 to 3.0. However, many factors – such as patient age, gender, test method – can affect the test results, so the physician generally determines an acceptable range for each individual patient. *See* CMS Ex. 14, at 2 (Kralka Decl. ¶ 9).

A physician telephone order, dated January 26, 2007, mentions the 1.6 INR, which the physician, Dr. Robert Gunnell, apparently found acceptable since he ordered no change in the Coumadin dosage. CMS Ex. 47, at 25. Dr. Gunnell ordered the INR rechecked in two weeks, on February 9. CMS Ex. 47, at 26.

Thereafter, however, on February 4, 2007, Dr. Gunnell ordered a two-week course of the antibiotic, Flagyl, to treat a clostridium infection, and R15 was given his first dose at noon that day. CMS Ex. 47, at 12, 21, 26, 38; P. Ex. 3, at 9.[5] The following day, the pharmacy sent a written warning that the antibiotic medication could lead to significant drug interaction with Coumadin; specifically, it could increase INR. The pharmacist recommended "Monitor INR Day 3 and following antibiotic course." P. Ex. 3, at 10. Apparently, the times of highest risk for a drug interaction are when the drug is initiated and when it is discontinued. P. Ex. 3, at 5.

CMS asserts that the facility did not communicate the pharmacist's warning to R15's physician. Apparently the pharmacy forwarded a copy to him because Dr. Gunnell appears to have signed and dated the document. Although difficult to read, Dr. Gunnell's signature appears to be dated "2/7/07." The form asks the physician to respond with instructions, but the physician did not. CMS Ex. 20, at 2 (McKay Decl. ¶ 10).

CMS is correct that facility staff had no evidence that Dr. Gunnell knew about the pharmacy warnings. He made no changes in R15's orders. His treatment notes do not mention any concerns about a possible drug interaction. CMS Ex. 47, at 9, 12, 22. For its part, the facility made no changes to R15's care plan to reflect the heightened risk. CMS Ex. 47, at 9, 22.

R15 underwent the previously ordered PT/INR check on February 9, but, notwithstanding the pharmacist's warning, his next PT/INR check was not scheduled for another four weeks. CMS Ex. 47, at 22, 26. His INR on February 9 was 2.3. CMS Ex. 47, at 14.

On the evening of February 9, a facility nurse reports "scant amount" of rectal bleeding with his bowel movement, but it was "controlled easily" and she attributed it to hemorrhoids. CMS Ex. 47, at 22. The physician was apparently not notified.

By 7:00 a.m. on February 10, however, R15 had had two additional bouts of rectal bleeding, described as bright red and dark red. The facility sent him to the emergency

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[5] The record is not altogether clear on this, but it appears that R15 had earlier been prescribed antibiotics for a foot infection. An undated physician note speculates that his colitis "may be due to antibiotic therapy" and that "he will remain on antibiotics for the time being" while waiting for the results of a C-difficile culture, which presumably was the culture that detected his clostridium infection. CMS Ex. 47, at 11. This earlier program of antibiotic therapy is not the subject of the deficiencies cited here.

room where his PT/INR was too high to measure ("extremely high, above 100"). P. Ex. 3, at 16; CMS Ex. 47, at 6, 22. In a February 10, 2007 report, the hospital physician, Dr. Wyssem Ramdani wrote:

> It is a well known fact that Flagyl interacts with Coumadin and would increase the Coumadin level, of course, make the Coumadin toxicity very likely. This is probably . . . the cause of his high INR at this time, which the patient has ongoing lower gastrointestinal bleed.

CMS Ex. 47, at 6-7; P. Ex. 3, at 16-17. R15 was diagnosed with Coumadin toxicity, was hospitalized for three days, and required blood transfusions. CMS Ex. 47, at 10, 22,

Contrary to Petitioner's assertion, CMS does not fault Dr. Gunnell for ordering both Flagyl and Coumadin. P. Op. Br. at 4-5; CMS Ex. 3, at 6-16; CMS Cl. Br. at 9. Rather, CMS faults the facility because it did not intervene when, by all appearances, Dr. Gunnel was not aware of or had ignored the pharmacy warnings and, without explanation, failed to order the PT/INR monitoring during and immediately following R15's antibiotic treatment. At a minimum, the facility should have consulted Dr. Gunnell to ensure that he had received and understood the pharmacy warning and had made an informed decision not to monitor R15's blood levels as recommended.

In an undated, unauthenticated statement, Dr. Gunnell claims that he was, in fact, complying with the pharmacy recommendation. He writes:

> On recommendation of the consulting pharmacy service (who had identified the risk of drug interaction) P.T. and P.T. INR levels were obtained four days after combination therapy had been started.

P. Ex. 3, at 1. But Dr. Gunnell's claim is not substantiated by the documentary evidence. R15's PT/INR was measured on the *sixth* day,[6] not the recommended third day of the course of antibiotics, and this measurement was plainly unrelated to any recommendation from the pharmacy. Dr. Gunnell had ordered the test back in January, well before R15 began taking Flagyl. Further, the pharmacy also recommended an additional test upon completion of the course of antibiotics, which would have been on or about February 17. On February 9, Dr. Gunnell ordered R15's next PT/INR "in 4 weeks." CMS Ex. 47, at 26.

[6] R15 received his first dose of Flagyl on February 4, which was therefore "Day 1." He was tested on February 9 – Day 6 of the two-week course of antibiotic treatment.

Petitioner makes much of the fact that R15's blood was within acceptable limits on February 9, the day before R15 presented to the emergency room, and argues, based on the physician statement (but with no reference to any underlying medical evidence), that R15's bleed was not due to Coumadin toxicity, but to a lesion. P. Cl. Br. at 6 *et seq*.

These assertions miss the point. When it started administering Flagyl to R15, the facility knew, or should have known, that he was at increased risk, and that his existing plan for monitoring INR levels was likely inadequate. To attain or maintain "the highest practicable physical . . . well-being" he would require more frequent testing. When the physician neither commented nor acted, the facility, at a minimum, was obligated to inquire.

Finally, the medical evidence establishing a connection between R15's INR and his hospitalization seems pretty overwhelming. But even if R15 had not suffered Coumadin toxicity or other bleeding problems related to his medication, the facility's inattention to his needs certainly put him at significant risk for such problems, and therefore violated the quality of care regulation.

Resident 19 (R19). **R19** was an 80-year-old woman taking Coumadin because of atrial fibrillation. She also suffered from renal failure and was on dialysis. CMS Ex. 37, at 1-2, 16; CMS Ex. 14, at 2 (Kralka Decl. ¶ 8). Her care plan identified as a problem the risk for bleeding and "abnormal labs" secondary to anticoagulant use. It listed an INR range of 2.0 – 3.0, and, among other interventions, called for monitoring and reporting abnormal bleeding and increased platelet count, and "labs as ordered per Davita." CMS Ex. 37, at 5.[7]

In fact, the facility seems to have assumed virtually no responsibility for monitoring R19's blood levels. Instead, it relied completely on the dialysis center to perform the monitoring. Although the facility has not provided any evidence that it had any written procedures, the system was apparently supposed to work as follows: R19's blood would be drawn at the dialysis center on Mondays and Wednesdays and the samples sent to an out-of-state laboratory for testing. Two days after the blood draw, the lab sent the test results back to the dialysis center. The dialysis center then called the test results into the facility, which recorded them on to the resident's lab tracking log. It did not send copies of the lab reports, however. CMS Ex. 14, at 2 (Kralka Decl. ¶ 12);[8] CMS Ex. 37, at 6.

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[7] "Davita" apparently refers to R19's dialysis center, although it is also the name of the laboratory that tested her blood. *See* CMS Ex. 38; P. Cl. Br. at 8.

[8] The facility obtained copies of the lab reports, CMS Ex. 38, during the survey. CMS Ex. 14, at 2 (Kralka Decl. ¶ 12).

Larry Miller, RPh, CMS's pharmacist/surveyor, testified that same-day reporting of PT/INR test results is the standard, acceptable practice, and that a two-day delay is not acceptable. CMS Ex. 22, at 2 (Miller Decl. ¶ 7); *accord*, CMS Ex. 14, at 2 (Kralka Decl. ¶ 12).

On April 18, 2007, R19's physician prescribed for her a week-long course of the antibiotic Keflex to treat a carbuncle on her neck. CMS Ex. 37, at 8, 9, 11. Like Flagyl, Keflex is a medication known to increase Coumadin's anti-coagulant effect. CMS Ex. 77, at 2, 6; CMS Ex. 68, at 3. No evidence suggests that anyone at the facility even noted that the antibiotic put her at increased risk.

At 6:00 p.m. on April 24, the nurse reported that R19 had been having large, loose stools with "[large amount] of blood present [with] mucous." CMS Ex. 37, at 14. At 10:30 the following morning, a nurse called R19's physician's office reporting the blood, and requesting an order for hemoccult and C-difficile testing. At 12:30 p.m. she called again to report a large bright red stool with dime-sized clots, and received an order to perform an INR test immediately. Blood was drawn and sent to the lab, which, at 2:30 p.m. reported an INR of 6.46. CMS Ex. 37, at 14, 20.[9] She was taken to the emergency room, and diagnosed with a gastrointestinal bleed and coagulopathy secondary to Coumadin. She was hospitalized, administered Vitamin K and two units of blood plasma. CMS Ex. 37, at 16-19.

Petitioner nevertheless argues no deficient practice. "These matters were within the control of the resident's physician and the dialysis center, not [the facility]." P. Op. Br. at 5. Without any doubt, the resident's physician and dialysis center are responsible for monitoring their patients, but that does not eliminate the facility's independent responsibility under the regulation to monitor R19's blood levels so that she could maintain "the highest practicable physical . . . well-being."

The facility is, of course, free to contract with an outside entity to perform this function, so long as it makes certain that those services are adequate. 42 C.F.R. § 483.75(h)(2). Here, the facility's awkward and problematic "system" did not ensure accurate and timely monitoring of R19's blood levels. As the following chart shows, comparing the actual test reports to the facility's lab tracking log belies any claim that the facility received and maintained a complete and accurate accounting of R19's INR test results. Some data is missing; in some cases the lab reports do not coincide with the tracking log. Indeed, for more than three weeks prior to her gastrointestinal bleed, the facility had not been tracking her INR values at all, apparently because the nurse responsible for documentation was on vacation. CMS Ex. 3, at 21.

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[9] Petitioner alludes to its small-town location to justify the delays in obtaining INR test results. P. Cl. Br. at 8. In fact, the test is relatively simple and inexpensive, and the facility was obviously capable of performing it and obtaining timely results.

Date Blood Drawn	INR per lab report	INR per Lab Tracking Log[10]
2/14/07	2.4 (CMS Ex. 38, at 1)	not recorded
2/21/07	1.7 (CMS Ex. 38, at 4)	1.7
3/07/07	2.3 (CMS Ex. 38, at 6)	not recorded
3/14/07	1.5 (CMS Ex. 38, at 7)	1.5 (dated 3/16/07)[11]
3/21/07	2.8 (CMS Ex. 38, at 9)	not recorded
3/28/07	**>10** (CMS Ex. 38, at 11)[12]	**2.98** (dated 3/30/07)
4/04/07	**4.2** (CMS Ex. 38, at 12)	**4.72** (dated 4/2/07)
4/11/07	2.3 (CMS Ex. 38, at 36)	not recorded
4/18/07	3.2 (CMS Ex. 38, at 13)	not recorded
4/25/07	7.7 (CMS Ex. 38, at 15)	**6.46**[13]
5/09/07	1.9 (CMS Ex. 38, at 17)	not recorded
5/16/07	1.8 (CMS Ex. 38, at 18)	not recorded
5/23/07	1.7 (CMS Ex. 38, at 20)	not recorded
5/30/07	1.5 (CMS Ex. 38, at 22)	not recorded
6/06/07	1.6 (CMS Ex. 38, at 24)	1.6 (dated 6/8/07)
6/13/07	2.4 (CMS Ex. 38, at 25)	not recorded
6/27/07	3.4 (CMS Ex. 38, at 28)	3.4 (dated 6/29/07)
7/02/07	3.9 (CMS Ex. 38, at 29)	3.9 (dated 7/4/07)
7/11/07	1.7 (CMS Ex. 38, at 30)	1.7 (dated 7/13/07)

[10] CMS Ex. 37, at 6.

[11] Blood was drawn on Monday and Wednesday and the results received on Wednesday and Friday. It seems that the facility usually recorded the date it received the test results, not the date the blood was drawn. *But compare* CMS Ex. 38, at 4 *with* CMS Ex. 37, at 6 (2/21/07 log entry reflects date of blood draw). So the tracking log does not even reliably reflect the dates on which the resident's blood registered the listed INR levels.

[12] No explanation has been offered for the discrepancy between this lab report and the tracking log entry. The lab report notes that the accuracy of its results had been confirmed, and directed the clinician to correlate the results with the patient's clinical condition. However, the record suggests that the facility was not even aware of this extreme result, since it was not recorded in the tracking log, and no nurses notes or other indication of the facility's response is in the record.

[13] This reflects the test taken at the facility following R19's symptoms of a gastrointestinal bleed. The record contains no evidence that the facility received from the dialysis center a report of R19's April 25 test result of 7.7. Based on the facility's procedures, it likely would not have learned about this dangerously high INR until April 27.

Resident 18 (R18). **R18** was a 54-year-old woman, admitted to the facility on June 14, 2007, who suffered from end stage renal disease and deep vein thrombosis for which she was prescribed Coumadin. CMS Ex. 44, at 1. Her transfer order from Mercy General Hospital calls for checking her PT/INR "stat [immediately] 6/25 then [every] week." CMS Ex. 44, at 6.

R18's care plan identified her as at risk for bleeding and abnormal labs secondary to Coumadin use. Among the interventions listed are "labs as ordered" but no INR range is listed. CMS Ex. 44, at 26. Her medication orders, dated June 14, 2007, say "Davita to check PT/INR weekly." CMS Ex. 44, at 7. A physician order dated July 3, 2007 calls for daily Coumadin, and says, "Davita to do labs [and] dosing." P. Ex. 2, at 5. I assume by "dosing" he meant that Davita would determine the dosages to be administered; facility staff actually administered the daily Coumadin to R18.

As discussed above, the facility had no reliable system in place for monitoring R18's test results. It assumed that dialysis center staff would take care of it, and made virtually no efforts to monitor the dialysis center's performance in that regard. Test reports were not forwarded to the facility; as with R19, the facility only obtained them from the dialysis center at the time of the survey. CMS Ex. 16, at 2 (Lindsay Decl. ¶ 10). And it appears that, contrary to the orders in place, R18's PT/INR was measured only twice – on July 2, and July 13. CMS Ex. 44, at 11, 12.

Petitioner maintains that the dialysis center "obtained all necessary tests and the resident had normal PT/INR results." P. Op. Br. at 5. In fact, the evidence presented demonstrates that the dialysis center did not obtain all the necessary tests. According to the orders, R18 was supposed to have been tested on June 25, and weekly thereafter. Missing are tests from June 25, July 9, and/or July 20. A separate physician order, dated July 19, calls for a PT/INR. P. Ex. 2, at 6. But there is no evidence of a blood draw in response to this order until July 27. P. Ex. 2, at 1.

I reject Petitioner's suggestion that the July 3 physician order (P. Ex. 2, at 5) eliminated the order for weekly testing. The July 3 order changed the Coumadin dosage from 3 mg per day (CMS Ex. 44, at 8) to "alternating 3 mg [and] 6 mg" dosages. The order for weekly testing remained unchanged, as shown by the physician's order sheet for the period from July 1 through 31, 2007, which the surveyors photocopied at the time of the survey. Had the physician's order changed the frequency of testing, the order sheet would have reflected the change. CMS Ex. 44, at 7. *See*, *e.g.*, P. Ex. 1, at 5, 6 ; P. Ex. 3, at 147-150 (reflecting handwritten changes on the printed order sheets).

I note also that accepting Petitioner's interpretation of the July 3 order results in the unacceptable alternative that the facility had absolutely no idea as to the ordered frequency of the PT/INR testing for this resident.

Further, contrary to Petitioner's claim, R18 *never* had a normal test result recorded. Her INR range was supposedly 2.0 – 3.0, and her test results were consistently below that range (1.32, 1.76, 1.85), except on July 27, when it was a dangerously high 5.81. P. Ex. 2, at 1.

2. The facility did not take reasonable steps to ensure that its residents received supervision and assistance devices to mitigate foreseeable risks of harm from accidents.

The quality of care regulation also specifically requires the facility to "take reasonable steps to ensure that a resident receives supervision and assistance devices designed to meet his or her assessed needs and to mitigate foreseeable risks of harm from accidents." 42 C.F.R. § 483.25(h)(2); *Windsor Health Care Center,* DAB No. 1902, at 5 (2003); *Asbury Center at Johnson City,* DAB No. 1815, at 12 (2002); *Koester Pavilion,* DAB No. 1750, at 25- 6 (2000); *Woodstock,* DAB No. 1726, at 25. The regulation directs the facility to anticipate what accidents might befall a resident and to take steps – increased supervision or the use of assistance devices – to prevent them. *Guardian Health Care Center*, DAB No. 1943, at 18 (2004).

> A facility is permitted the flexibility to choose the methods it uses to prevent accidents, but the chosen methods must constitute an "adequate" level of supervision under all the circumstances.

Windsor at 5.

July Survey. During the July survey, the surveyors cited multiple instances of inadequate supervision and failures to follow care plans that resulted in accidents.

R5 was an 82-year-old man, admitted to the facility in 2001, whose diagnoses included acute renal failure, coronary artery disease, congestive heart failure, depression, and dementia. CMS Ex. 48, at 1. According to a February 8, 2007 risk identification form, he was at risk for falls. CMS Ex. 48, at 22; CMS Ex. 18, at 2 (Maze Decl. ¶¶ 7, 8). Among other interventions, his care plan called for a two-person assist with toileting and transfers; his bed was to be kept in the lowest position, with a mat on the floor next to it; and he was to have pressure alarms on his bed and wheelchair. CMS Ex. 48, at 22; CMS Ex. 18, at 2 (Maze Decl. ¶ 8).

Undisputed evidence establishes that facility staff did not consistently follow the care plan, and, between March 1 and June 1, 2007, R5 fell six times.[14]

- On March 1, 2007, at 11:45 p.m., R5 was found "sitting on floor on blue mat" of his room, apparently uninjured. According to a nurses note, he had tried to get out of bed when his "body pillow slipped out [and resident] had an easy way to remove self." CMS Ex. 48, at 5. The facility's incident reports provide few additional details, except to say that neither environment nor equipment were factors. In future, according to the reports, bolsters would be applied to his bed to prevent him from sliding out. CMS Ex. 48, at 24. Neither the nurses notes nor the incident reports mention whether a bed alarm had been in place nor whether it had sounded.

- On March 9, 2007, at 9:30 p.m., he was again found on the floor, uninjured, after getting out of bed to get himself some water. CMS Ex. 48, at 9, 26-29. Nurses notes indicate that his bed was in the lowest position as called for in the care plan, but, again, neither the notes nor the incident reports mention anything about a bed alarm.

- On March 14, 2007, at midnight, he was again found, uninjured, on the floor after getting out of bed for a drink of water. His alarm was sounding. CMS Ex. 48, at 11, 18, 30, 31-33. A hand-written note says, "I don't know what more to do for this man to keep him safe, other than move him to room 301." CMS Ex. 48, at 31.

- On March 17, at 1:30 p.m., he apparently pulled himself out of bed, and was found sitting by the side of his bed, the alarm sounding. However, his bed was not in its lowest position, as required by his care plan, and the required bolsters were not in place. CMS Ex. 48, at 12, 18, 35-39. The investigation worksheet cites as error the staff's failures to put the bed in its lowest position and to put bolsters in place. CMS Ex. 48, at 37. In her written statement, the nurse aide says that she had just laid R5 down with "all alarms on him" and was still in the room. CMS Ex. 48, at 39. She does not mention whether the alarms sounded, and there seems to have been no follow-up investigation to determine whether they had been properly applied. If, in fact, the nurse aide was in the room when the alarm sounded, her inability to intervene to prevent the fall is baffling and required investigation.

- On March 24, at 1:10 a.m., R5 was again found on the floor next to his bed, uninjured except for a reddened wrist caused by his call light's having been wrapped around it. CMS Ex. 48, at 15, 19, 40-43. A note explains that the

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[14] On February 26, 2007, R5 was found face down on the floor in front of his wheel chair with his personal alarm sounding. He sustained a hematoma to the forehead. CMS Ex. 48, at 17. CMS does not cite this incident.

pressure alarm had slipped, so it apparently had not sounded. CMS Ex. 48, at 18. The investigative report indicates that R5 would be moved to room 301, and "remove strips and secure pressure alarm to bed under resident's shoulders." CMS Ex. 48, at 19, 43.

- On May 31, at 4:30 p.m., R5 was found on the floor between his bed and the wall. The bed had apparently not been locked in place because the locks were broken, and, when it moved, he rolled out. CMS Ex. 48, at 44-47. According to one report, his bed was in the low position with a pressure alarm in place, but the reports do not say whether the alarm sounded. CMS Ex. 48, at 21, 45.

These incidents establish that the facility was not providing R5 the supervision and assistance devices necessary to prevent accidents. Interventions set forth in the care plan were not consistently followed. That staff repeatedly were unable to reach the resident in time to prevent a fall after the alarm sounded shows inadequate supervision. As early as March 14, staff recognized that no one responding to an alarm could reach him in time, yet, he was not moved to a more accessible location until 10 days – and two falls – later.

I am also troubled by the facility's consistently inadequate investigative reports. The reports say that R5 "was found" on the floor, but provide no indication of how long he had been there nor what happened after he fell. They often fail to indicate whether an alarm was in place and functioning at the time of the fall. *See* CMS Ex. 18, at 2 (Maze Decl. ¶¶ 9, 10); *Century Care of Crystal Coast*, DAB No. 2076, at 21 (2007), *aff'd Century Care of Crystal Coast v. Leavitt*, No. 07-1491 (4th Cir. 2008) (By not investigating, the facility loses an opportunity to analyze and correct its problems).

Resident 17 (R17). **R17** was admitted to the facility on July 13, 2007, with a diagnosis of metastatic prostate cancer, and, at that time, the facility identified him as at risk for falls. CMS Ex. 49, at 5, 9. Among other interventions, his care plan called for a pressure alarm for his bed. CMS Ex. 49, at 5, 6. At 11:45 on the night of his admission, he was found on the floor of his room, with a laceration and swelling to his left ear. CMS Ex. 49, at 10-15. The alarm had not sounded because it was not attached to his bed ("people just didn't do it"); it was sitting on the dresser. CMS Ex. 49, at 3, 11; CMS Ex. 18, at 2 (Maze Decl. ¶ 12).

Resident 8 (R8). **R8** was an 86-year-old woman, admitted to the facility in August 2006. She suffered from renal failure, osteoporosis, glaucoma, depression, and Alzheimers disease. CMS Ex. 35, at 1. She was at risk for falls, and, among other interventions, her care plan required pressure alarms for her wheel chair and for her bed. CMS Ex. 35, at 5, 6. According to CMS, her medical record documented six falls between May 4 and July 17, 2007, but the facility investigated only four of these falls. CMS Ex. 35, at 4.

- At 8:25 p.m. on May 4, 2007, R8 fell out of bed, and suffered a knot on the back of her head. Two nurse aides heard the alarm go off, but said that they were unable to assist her because they were caring for another resident who required a 2-person assist. A third nurse aide was on her break. CMS Ex. 35, at 15-19. That no one was available to assist a resident who was in jeopardy shows inadequate supervision.

- At 10:30 p.m. on May 18, 2007, R8 rolled out of bed and sustained a skin tear on her left elbow. CMS Ex. 35, at 20. The investigative report offers no additional information, so the record is silent as to whether anyone witnessed the accident or an alarm sounded. CMS Ex. 35, at 21-23.

- At 7:30 p.m. on July 12, R8 was found on the floor of the dining room, uninjured. CMS Ex. 35, at 24. Surveyor notes indicate that the dining room is about 25 feet from her own room. CMS Ex. 35, at 4. The investigative report is silent as to the circumstances surrounding her fall. According to surveyor notes, her alarm did not sound, although I see no reference to any alarm in the facility documents. CMS Ex. 35, at 4, 25.

- On July 17, 2007, at 8:00 p.m., R8 fell from her Broda chair,[15] sustaining a bruised left elbow. CMS Ex. 35, at 26-31. Staff had failed to unlock the chair's brakes after she completed an activity, which apparently caused her to fall when she attempted to propel herself. CMS Ex. 35, at 27.

Surveyor notes refer to two additional incidents, for which the facility had no incident reports. On May 7, 2007, at 8:25 p.m., R8 fell out of bed and hit the back of her head. The alarm sounded. On June 12, 1007, at "9:30," the alarm sounded and R8 was found beside her bed. CMS Ex. 35, at 4. Although the record contains no facility documentation as to the purported incident of May 7, the facility's "risk identification review" confirms that on June 12, the resident sustained a fall (although it places the time at 7:15 p.m.). Petitioner does not explain what, if anything, happened at that time, except to say generally that "incident reports were done for each fall." P. Op. Br. at 7. Inasmuch as Petitioner has not produced an incident report for the June fall, I can reasonably infer that, contrary to state law, acceptable standards of practice, and its own policies, the facility did not prepare and/or maintain an incident/accident report of the fall. CMS Ex. 69. Failure to investigate an accident can itself be evidence of inadequate supervision. *Lake Park Nursing and Rehabilitation Center*, DAB No. 2035, at 11 (2006); *see also Century Care of Crystal Coast*, DAB No. 2076, at 21 (2007), *aff'd Century Care of Crystal Coast v. Leavitt*, No. 07-1491 (4th Cir. 2008).

[15] A Broda chair is an adjustable chair that sits on casters, which makes it easier to propel.

Resident 9 (R9). **R9** was admitted to the facility in March 2007, and was 85 years old at the time of the survey. She suffered from arteriosclerotic heart disease, dementia, and memory loss. She had a history of elopement. CMS Ex. 36, at 1, 3. She was at risk for falls, and her care plan called for a pressure alarm in her wheel chair and on her bed. CMS Ex. 36, at 5, 7. She also wore a wanderguard ankle bracelet. CMS Ex. 36, at 7.

- On May 15, 2007, at 7:10 a.m., an agency nurse found R9 on the floor at the bathroom door of her room, having apparently hit her head. No alarm had sounded. CMS Ex. 36, at 9, 15. The alarm had not been "hooked." CMS Ex. 36, at 16.

- On May 17, at 1:45 p.m., a nurses note indicates that the nurse heard the alarm sounding, and found the resident sitting on the floor near her bed. She was not injured. CMS Ex. 36, at 10.

- On June 9, R9 attempted unsuccessfully to elope. Then, on June 11, 2007, she successfully exited the facility. Fortunately, a nurse on break happened to be sitting outside when R9 "came flying out the door, heading down [the] path." CMS Ex. 36, at 11. But the nurses note does not mention whether an alarm went off and I see no evidence of an investigative report. Indeed, the facility provides no evidence that it investigated the incident at all, nor that it took steps to ensure that R9 not elope. Petitioner argues that R9 did not elope because she was so quickly returned to the facility. P. Op. Br. at 7. That an employee happened to be in the area when she exited the facility was fortuitous, but her ability to exit, apparently undetected by the staff who were supposed to be responsible, further suggests that she was not properly supervised.

- At 5:30 a.m. on June 14, the bed alarm sounded, and staff found R9 sitting on the floor, "trying to scoot self over to [the bathroom]." CMS Ex. 36, at 12.

- On June 24, at 4:00 a.m., the alarm sounded and staff found R9 sitting on the floor next to her bed. CMS Ex. 36, at 13.

Thus, the evidence again shows multiple instances in which staff were unable to reach a resident they knew to be in potential jeopardy; staff failed to follow a vulnerable resident's care plan; and staff inadequately investigated incidents.

September survey. When the surveyors returned to the facility in September 2007, they concluded that staff were still not providing adequate supervision and assistance devices to prevent accidents, citing incidents involving **R39**.

R39 was a 54-year-old man who was admitted to the facility on August 1, 2007, suffering from Charcot-Marie-Tooth disease. CMS Ex. 57, at 1, 9. Charcot-Marie-Tooth disease is

a neurological disorder that affects the peripheral nerves. Weakness in the foot and lower leg muscles causes "foot drop" and a high-stepped gait, which can result in frequent tripping and falls. CMS Ex. 58. R39 wore leg braces, and was assessed as a fall risk. CMS Ex. 57, at 15, 17, 18. His care plan required a two-person assist for transfers. CMS Ex. 57, at 17, 18.

- According to a nurses note, on August 11, 2007, R39 was "being assisted" in the bathroom when his brace "gave way," causing his knee to buckle and scrape against the wall. He suffered a scratch. CMS Ex. 57, at 11. The facility offers no evidence that it investigated this incident. The note does not mention whether he was assisted by two staff members, as required by his care plan.

- According to an August 29 nurses note, the nurse was called to the resident's room by a nurse aide, and found R39 sitting on the bathroom floor. He had fallen and suffered abrasions to his left knee and right toe. CMS Ex. 57, at 12. An incident report indicates that he was transferring to the toilet; he was barefoot, when he should have been wearing non-skid footwear; he was assisted by only one CNA, instead of the two called for by his care plan; and the CNA did not use a gait belt, as required by the standard of care and the facility policies. CMS Ex. 57, at 19-24; CMS Ex. 79 ("It is standard care to use a gait belt on all residents while transferring . . . . It is also standard of care to make sure every resident has non-skid footwear of some sort during transfers.")

Thus, the evidence establishes that, at the time of the September survey, staff still were not providing adequate supervision and assistance devices to prevent accidents. They were not consistently following the resident care plans; they were not adequately investigating and reporting incidents. Substantial evidence thus establishes that the facility's noncompliance with the quality of care regulation, 42 C.F.R. § 483.25(h), continued.

I recognize that CMS has cited numerous other deficiencies, including failure to ensure that residents receive nutrition adequate to his/her needs (42 C.F.R. § 483.25(i)(1)); failure to ensure that residents' drug regimes are free from unnecessary drugs (42 C.F.R. § 483.25(l)(1)); failure to provide adequate pharmaceutical services (42 C.F.R. § 483.60); failure to maintain a sanitary, orderly, and comfortable environment (42 C.F.R. § 483.15(h)(2)); and failure to prevent/promote healing of pressure sores (42 C.F.R. § 483.25(c)). In the interests of administrative economy, I decline to address these additional deficiencies since, as discussed below, I conclude that the quality-of-care deficiencies that I have addressed more than justify the relatively low penalties imposed. *See Grace Healthcare of Benton*, DAB No. 2189, at 5 (2008).

B. Petitioner's inadequate system for monitoring the PT/INR levels of its high risk residents posed immediate jeopardy to their health and safety.

I next consider whether CMS's immediate jeopardy finding was "clearly erroneous." 42 C.F.R. § 498.60(c)(2). Immediate jeopardy exists if the facility's noncompliance has caused *or is likely to cause* "serious injury, harm, impairment or death to a resident." 42 C.F.R. § 488.301. CMS's determination as to the level of a facility's noncompliance – which includes its immediate jeopardy finding – must be upheld unless it is "clearly erroneous." 42 C.F.R. § 498.60(c). The Departmental Appeals Board has observed repeatedly that the "clearly erroneous" standard imposes on facilities a "heavy burden" to show no immediate jeopardy, and has sustained determinations of immediate jeopardy where CMS presented evidence "from which '[o]ne could reasonably conclude' that immediate jeopardy exists." *Barbourville Nursing Home*, DAB No. 1962, at 11 (2005); *Florence Park Care Center*, DAB No. 1931, at 27-28 (2004) *citing Koester Pavilion*, DAB No. 1750 (2000).

Here, strong evidence links R15's and R19's gastrointestinal bleeds to the facility's inadequate monitoring of their PT/INR levels. But I need not make that connection in order to sustain CMS's immediate jeopardy finding. So long as the facility's noncompliance "is likely to cause serious injury, harm [or] impairment," its deficiencies pose immediate jeopardy. Here, facility residents were at high risk for complications related to their medications. Their health and safety required careful PT/INR monitoring. Yet the facility had no reliable systems in place to ensure that monitoring. Indeed, the facility did not even recognize that it had any responsibilities in this regard. Where the facility assumed virtually no responsibility for assuring the accurate and timely monitoring of its vulnerable residents' blood levels, CMS's determination that such practices pose immediate jeopardy to resident safety was not clearly erroneous.

C. The penalties imposed are reasonable.[16]

Because the facility was not in substantial compliance with program requirements, CMS has the authority to impose a remedy, and I have no authority to review CMS's choice of remedies, in this case, per day CMPs. 42 C.F.R. § 488.438(e)(2); 42 C.F.R. § 498.3(b)(13); *see also* 42 C.F.R. § 488.408(g)(2).

For the one day of immediate jeopardy, CMS has imposed a penalty of $5500, which is in the low to mid range for situations that pose immediate jeopardy ($3050 to $10,000). 42

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[16] Although at the conclusion of its closing brief Petitioner insisted that it has preserved as an issue the reasonableness of the penalties imposed, it has presented no actual arguments on the matter, except to say that the deficiency findings were unfounded. P. Cl. Br. at 15, n.3. I nevertheless address the issue here.

C.F.R. § 488.438(a)(1). For the 55 days of substantial noncompliance immediately following the July survey, its penalty, $250 per day, is in the low end of the penalty range for situations of substantial noncompliance that does not pose immediate jeopardy ($50-$3000). When, at the time of the September survey, the facility had not brought itself into substantial compliance, CMS increased the penalty to $400 per day, but that amount is still at the low end of the range.

To determine the reasonableness of the penalty, I apply the factors listed in 42 C.F.R. § 488.438(f): 1) the facility's history of noncompliance; 2) the facility's financial condition; 3) factors specified in 42 C.F.R. § 488.404; and 4) the facility's degree of culpability, which includes neglect, indifference, or disregard for resident care, comfort, or safety. The absence of culpability is not a mitigating factor. 42 C.F.R. § 488.438(f). The factors in section 488.404 include: 1) the scope and severity of the deficiency; 2) the relationship of the deficiency to other deficiencies resulting in noncompliance; and 3) the facility's prior history of noncompliance in general and specifically with reference to the cited deficiencies.

It is well-settled that, in reaching a decision on the reasonableness of the CMP, I may not consider CMS's internal decision-making processes. Instead, I consider whether the record evidence concerning the relevant regulatory factors supports the finding that the amount of the CMP is at a level "reasonably related to an effort to produce corrective action by a provider with the kind of deficiencies found and in light of the other factors involved" (facility history, financial condition, culpability). *Barn Hill Care Center*, DAB No. 1848, at 21 (2002); *Community Nursing Home*, DAB No. 1807, at 22 *et seq*. (2002); *Emerald Oaks*, DAB No. 1800, at 9 (2001); *CarePlex of Silver Spring*, DAB No. 1683, at 8 (1999).

The facility's dreadful compliance history suggests that it is the kind of facility for which substantial penalties are necessary in order to induce compliance. As noted above, the facility was not in substantial compliance with LSC requirements at the time of its July 2007 LSC survey. The June 2007 complaint investigation showed that it was not in substantial compliance with regulations governing abuse (42 C.F.R. § 483.13(b)), staff treatment of residents (42 C.F.R. § 483.13(c)), comprehensive care plans (42 C.F.R. § 483.20(k)), and, as here, quality of care (42 C.F.R. § 483.25). Except for the care planning, all of its deficiencies were cited at scope and severity level E (pattern of noncompliance with the potential for more than minimal harm). CMS Ex. 1.

And, as CMS points out, the facility has not been in substantial compliance during any annual survey since before 2003. Its deficiencies have included quality of care violations (October 2005 and September 2006 surveys), failure to prevent accidents (October 2005 and September 2006 surveys), and failure to prevent/heal pressure sores (October 2006). Additional complaint investigations conducted in April 2005 and November 2005 found the complaints substantiated. CMS Ex. 80.

Without even considering the other factors, this history justifies raising the penalty well above the minimal amounts.

But none of the other factors augers in favor of lowering the CMPs. Petitioner has not alleged that its financial condition affects its ability to pay the penalty. The facility is culpable for its almost complete abdication of any responsibility for monitoring the INR levels of its vulnerable residents. The number and circumstances of incidents suggest that the facility's failure to ensure adequate supervision to prevent accidents was related to systematic failures in planning, investigating, staffing, and training, that seriously undermined its ability to protect its residents from harm. The facility is culpable for these failures.

Finally, increasing the penalty following the September survey findings is reasonable. The facility had been afforded ample opportunity to correct its deficiencies and had not done so, which shows that the lower CMP amount was insufficient to produce corrective action.

IV. Conclusion

Thus, because the facility did not monitor the safety and effectiveness of its vulnerable residents' anti-coagulant medications and because it did not adequately supervise its residents, placing them at significant risk of suffering an accident and potentially serious injury, it was not in substantial compliance with 42 C.F.R. §§ 483.25 and 483.25(h)(2) from July 20 through November 15, 2007. On July 20, 2007, its deficiencies posed immediate jeopardy to resident health and safety. I find reasonable the $5500 per day CMP for one day of immediate jeopardy. I also find reasonable the $250 per day penalty for the period July 21 through September 13, 2007, and the $400 per day penalty for the period September 14 through November 15, 2007.

/s/
Carolyn Cozad Hughes
Administrative Law Judge