Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Agape Rehabilitation of Rock Hill,
(CCN: 42-5159),

Petitioner

v.

Centers for Medicare and Medicaid Services.

Docket No. C-10-40

Decision No. CR2335

Date: March 9, 2011

DECISION

Petitioner, Agape Rehabilitation of Rock Hill (Petitioner or facility), is a long-term care facility, located in Rock Hill, South Carolina, that participates in the Medicare program. The parties agree that, from July 16 through August 23, 2009, the facility was not in substantial compliance with Medicare program requirements and that the Centers for Medicare and Medicaid Services (CMS) may therefore impose penalties against it.

CMS also determined that the facility's practices in managing its residents' anti-coagulant medications were deficient and posed immediate jeopardy to resident health and safety. It has imposed against the facility civil money penalties (CMPs) of $5,200 per day for 20 days of immediate jeopardy and $250 per day for 19 days of substantial noncompliance that was not immediate jeopardy. Petitioner challenges five of the deficiencies cited, as well as the immediate jeopardy determination and the amount of the CMPs.

For the reasons set forth below, I find that the facility was not in substantial compliance with Medicare program requirements; its deficiencies posed immediate jeopardy to resident health and safety; and the penalties imposed are 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 to promulgate regulations implementing those 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.

The Secretary contracts with state survey agencies to conduct periodic surveys to determine whether skilled nursing facilities are in substantial compliance. Act § 1864(a); 42 C.F.R. § 488.20. The regulations require that each facility be surveyed once every twelve 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, following a recertification survey completed July 31, 2009, CMS determined that the facility was not in substantial compliance with multiple Medicare participation requirements, specifically:

- 42 C.F.R. § 483.10(c)(6) (Tag F160 – conveyance upon death) 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. § 483.10(c)(7) (Tag F161 – assurance of financial security) at a D level of scope and severity;

- 42 C.F.R. § 483.13(a) (Tag F221 – physical restraints) 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. § 483.13(c)(1)(ii)-(iii), (c)(2)-(4) (Tag F225 – staff treatment of residents) at a D level of scope and severity;

- 42 C.F.R. § 483.20(k)(3)(i) (Tag F281 – comprehensive care plans) 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 (Tag F309 – quality of care) at a K level of scope and severity (pattern of noncompliance that poses immediate jeopardy to resident health and safety);

- 42 C.F.R. § 483.25(h) (Tag F323 – accidents and supervision) at a G level of scope and severity (isolated instance of noncompliance that causes actual harm);

- 42 C.F.R. § 483.25(m)(2) (Tag F333 – medication errors) at an E level of scope and severity;

- 42 C.F.R. § 483.35(e) (Tag F367 – therapeutic diets) at a D level of scope and severity;

- 42 C.F.R. § 483.60(c) (Tag F428 – drug regimen review) at a D level of scope and severity;

- 42 C.F.R. § 483.75(e)(5)-(7) (Tag F496 – nurse aide training) at a D level of scope and severity;

- 42 C.F.R. § 483.75(j)(2)(i) (Tag F504 – laboratory services) at a D level of scope and severity;

- 42 C.F.R. § 483.75(j)(2)(ii) (Tag F505 – laboratory services) at a J level of scope and severity; and

- 42 C.F.R. § 483.75(o)(1) (Tag F520 – quality assessment and assurance) at an E level of scope and severity.

CMS also determined that three of these deficiencies (42 C.F.R. §§ 483.20(k)(3)(i), 483.25, and 483.75(j)(ii)) posed immediate jeopardy to resident health and safety. CMS Exhibits (Exs.) 2, 3.[1]

CMS subsequently determined that the facility's deficiencies no longer posed immediate jeopardy as of August 5, 2009, and that the facility returned to substantial compliance on August 24, 2009. CMS Exs. 5, 54.

CMS has imposed against the facility a CMP of $ 5,200 per day for 20 days of immediate jeopardy (July 16 through August 4, 2009), and $250 per day for 19 days of substantial noncompliance that was not immediate jeopardy (August 5 through 23, 2009), for a total CMP of $ 108,750. CMS Exs. 3, 5, 54.

Petitioner timely requested a hearing to challenge five of the cited deficiencies: 42 C.F.R. § 483.13(c)(1)(ii)-(iii) (Tag F225 – staff treatment of residents); 42 C.F.R.

[1] In error, CMS asserted that it cited deficiencies under 42 C.F.R. §§ 483.15(e)(1) – Tag F246 and 483.60(a) – Tag F425. CMS Closing Brief at 4. No such deficiencies were cited, as CMS ultimately conceded. CMS Ex. 2; CMS Reply at 2. In its closing brief, CMS also misstates the scope and severity for two of the deficiencies cited. Deficiencies were cited at scope and severity level D (not E) for 42 C.F.R. §§ 483.60(c) and 483.75(j)(2)(i). CMS Ex. 2 at 42, 46.

§ 483.20(k)(3)(i) (Tag F 281 – comprehensive care plans); 42 C.F.R. § 483.25 (Tag F309 – quality of care); 42 C.F.R. § 483.25(h) (Tag F323 – accidents and supervision); and 42 C.F.R. § 483.75(j)(2)(ii) (Tag F505 – laboratory services). Petitioner also challenged CMS's determinations as to the scope and severity of the cited deficiencies, their duration, and the remedies imposed. Hearing Request (October 13, 2009); CMS Ex. 56.

The parties agree that this matter may be decided based on the written record, without need for an in-person hearing. *See* Order Following Prehearing Conference at 3 (May 28, 2010); P. Cl. Br. at 2; 42 C.F.R. § 498.66.

I admit into evidence CMS Exs. 1-62. I decline to admit CMS Exs. 63-65. My initial order directed CMS to submit its proposed exhibits and other documents on or before February 22, 2010. Acknowledgment and Initial Prehearing Order ¶ 1 (October 19, 2009). CMS complied and timely submitted CMS Exs. 1-62. By motion dated June 24, 2010, CMS asked to amend its exhibit list to add CMS Exs. 63, 64, and 65. CMS Proposed Exhibits 63 and 64 are records relating to Residents 38 and 40. CMS Proposed Exhibit 65 is a scholarly article from the American College of Chest Physicians, which describes clinical practice guidelines relating to anticoagulation therapy.

On July 29, 2010, after the deadline for responding had passed, Petitioner objected to the admission of these documents. By regulation, as well as my initial order, a party has 20 days in which to respond to a motion. 42 C.F.R. § 498.17(b); Acknowledgment and Initial Prehearing Order ¶ 22 (October 19, 2009). Petitioner has therefore waived its objections. On the other hand, CMS provides no good cause for its failure to submit the documents timely. *See* CMS Cl. Br. at 22 n.9 (claiming that the documents relating to R38 and R40 were "inadvertently omitted"). I am not inclined to admit documents submitted four months after their filing deadline without any legitimate justification offered for the delay. I therefore decline to admit CMS Exs. 63-65. I also admit P. Exs. 1-35. *See* Order Following Prehearing Conference (May 28, 2010) at 2-3.[2]

[2] There have been additional complications with the exhibits. With its initial submission, Petitioner omitted page 2 of P. Ex. 24. It subsequently submitted the page, and I include it with the documents admitted. Portions of other exhibits (CMS Ex. 23 at 2; CMS Ex. 25 at 1, 7; CMS Ex. 33 at 2; CMS Ex. 34; CMS Ex. 49; P. Ex. 30; and P. Ex. 31) were difficult to read or had been cut off in copying. By motion dated July 29, 2010, Petitioner asked to substitute a more legible copy of P. Ex. 31 at 1-13. Petitioner was unable to obtain a legible copy of P. Ex. 30, a medication package insert, and asked to substitute an alternative insert from a different manufacturer. I grant Petitioner's motion to substitute. With respect to CMS's exhibits, CMS apparently obtained most of those documents (except CMS Ex. 25 at 1, 7, where the cut-off portion seems minimal) from Petitioner and could not provide better copies. Petitioner, however, had original copies of them and submitted P. Exs. 34 and 35, copies of the problematic pages from CMS Exs. 34 and 33, respectively, asking that they be admitted. In the absence of objections, I admit these documents. CMS also submitted a more legible copy of CMS Ex. 49, which I substitute.

The parties have filed initial briefs (CMS Br.; P. Br.), closing briefs (CMS Cl. Br; P. Cl. Br.), and replies (CMS Reply, P. Reply).

II. Issues

Petitioner did not appeal nine of the deficiencies cited at scope and severity levels that constitute substantial noncompliance, so the facility's substantial noncompliance is not an issue. The facility was not in substantial compliance with Medicare program requirements.

The issues before me are:

1. Whether, from July 16 – August 23, 2009, the facility was in substantial compliance with the following Medicare participation requirements:

   42 C.F.R. § 483.13(c)(1)(ii)-(iii) and (c)(2)-(4)(staff treatment of residents);

   42 C.F.R. § 483.20(k)(3)(i) (comprehensive care plans);

   42 C.F.R. § 483.25 (quality of care);

   42 C.F.R. § 483.25(h) (accident prevention); and

   42 C.F.R. § 483.75(j)(2)(ii) (laboratory services).

2. If, from July 16 - August 4, 2009, the facility was not in substantial compliance with 42 C.F.R. §§ 483.20(k)(3)(i), 483.25, 483.25(h), and 483.75(j)(2)(ii), did those deficiencies pose immediate jeopardy to resident health and safety; and

3. If the facility was not in substantial compliance, were the penalties imposed – $5,200 per day for 20 days of immediate jeopardy, and $250 per day for 19 days of substantial noncompliance that was not immediate jeopardy (total $108,750) – reasonable?

Except for the finding of immediate jeopardy, I have no authority to review CMS's scope and severity findings. 42 C.F.R. § 498.3(b)(14); 42 C.F.R. § 498.3(d)(10).

Petitioner also raises some Constitutional claims, which I have no authority to review.

III. Discussion

A. The facility was not in substantial compliance with Medicare requirements governing quality of care, comprehensive care plans, and laboratory services – 42 C.F.R. §§ 483.25, 483.20(k)(3)(i), and 483.75(j)(2)(ii) – because its procedures for immediately notifying the attending physician (or nurse practitioner) of a resident's critical laboratory test results were not followed.[3]

Program requirements. Under the Act and "quality of care" regulation, each resident must receive and the facility must provide 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 Ctr.*, DAB No. 1902 at 16-17 (2003); *Woodstock Care Ctr.*, DAB No. 1726 at 25-30 (2000).

The services provided or arranged by the facility must meet professional standards of quality. 42 C.F.R. § 483.20(k)(3)(i).

With respect to laboratory services specifically, the facility must provide or obtain laboratory services to meet the needs of its residents and is responsible for the quality and timeliness of the services. 42 C.F.R. § 483.75(j)(1). The facility must promptly notify the attending physician of laboratory findings. 42 C.F.R. § 483.75(j)(2)(ii).

Anticoagulant medications. In this case, CMS cited significant deficiencies involving the facility's practices with respect to anticoagulant drugs, particularly Coumadin (Warfarin).

Anticoagulant 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. CMS Exs. 38, 39; P. Ex. 30. Unfortunately, bleeding is a major complication associated with anticoagulants. P. Ex. 33 at 6. For individuals administered these drugs, blood levels must be monitored carefully to assure that they are within a safe and therapeutic range. CMS Ex. 39 at 2. If the levels are too high, the resident risks bleeding complications; if the levels are too low, stroke could result. *See* CMS Ex. 32 at 13; CMS Ex. 39, at 1; P. Ex. 13 at 16 (Jones Decl. ¶ 3). The need for careful monitoring is even more pronounced when the resident is prescribed additional medications, because Coumadin interacts with many other drugs in dangerous, even fatal, ways. P. Ex. 13 at 14 (Jones Decl.); P. Ex. 30 at 5-6.

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

A specific test, referred to as PT/INR (prothrombin time/international normalized ratio) evaluates the ability of blood to clot properly. P. Ex. 30 at 4. 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 to 1.3; for people on Coumadin, desirable ranges may be 2.0 to 3.0. CMS Ex. 39 at 4. However, many factors – such as patient age, diet, manner of administration – can affect the test results, so the physician generally determines an acceptable range for each individual patient, based on the individual's PT/INR. CMS Ex. 39 at 2; P. Ex. 13 at 14; P. Ex. 30 at 7. *See* CMS Ex. 39 at 2 (reiterating that "[i]t cannot be emphasized too strongly that treatment of each patient is a highly individualized matter"). According to the manufacturer, an INR above 4.0 exposes the patient to a higher risk of bleeding without providing any additional therapeutic benefit. CMS Ex. 39 at 4. In a black box warning, the manufacturer cautions that Coumadin can cause major or fatal bleeding, which is more likely to occur during the starting period of the medication. Risk factors for bleeding include an INR greater than 4, and the patient's age (65 or older). CMS Ex. 39 at 1.

In treating deep vein thrombosis, physicians commonly prescribe subcutaneous Lovenox (Enoxaparin) in addition to Coumadin, until the patient's blood levels reach a therapeutic level. So, when the patient's INR reaches 2.0 to 3.0, the Lovenox is discontinued. P. Ex. 31 at 3; CMS Ex. 38 at 7.

Facility policies and procedures. Here, the facility contracted with Meridian Laboratory to provide the bulk of its laboratory services. P. Ex. 8. Under the terms of their written agreement, Meridian was to send a phlebotomist to the facility on Tuesdays and Thursdays to perform routine blood draws. P. Ex. 8 at 5. Meridian agreed to inform the facility of critical lab values by telephone upon completion of the test. P. Ex. 8 at 4; P. Ex. 2 at 3 (Henderson Decl. ¶ 21); CMS Ex. 35. Meridian also agreed to provide routine lab results within 24 hours. P. Ex. 8 at 4.

According to the facility's administrator, Danielle Henderson, non-critical lab results were "typically faxed" to the office of the facility's nurse manager at some time in the afternoon. P. Ex. 2 at 3 (Henderson Decl. ¶¶ 19, 22); CMS Ex. 35.

The facility required its staff to notify *immediately* the facility's nurse practitioner or the resident's attending physician of any critical lab result. P. Ex. 9 (Brown Decl. ¶5); CMS Ex. 35. According to Elizabeth Ann Brown, the facility's nurse practitioner, when informed of a critical lab result, she would "immediately" pull the resident's record, review the result, review the records, visit the resident, and change medication orders as necessary. P. Ex. 9 (Brown Decl. ¶ 6).

The facility's standing orders for Coumadin required staff to decrease dosages (by 0.5 milligrams (mg.) for one week) when INR values were between 3.1 and 4.5, and to contact the physician when INR values exceeded 4.5. If INR values fell below 1.5, staff

were to increase the dosage by 1 mg.; for values from 1.5 to 2.0, they were to increase the dose by 0.5 mg. CMS Ex. 32 at 15; CMS Ex. 40.

CMS does not fault any of these procedures for ensuring the safety of facility residents receiving anticoagulants. *See* P. Ex. 13. However, in July 2009, those procedures were not followed, and staff continued to administer full doses of anticoagulant medications to a resident whose test results registered a dangerously high INR.

Resident 41 (R41). R41 was an 87-year-old woman admitted to the facility on July 14, 2009, "for short term rehab" after surgery (open reduction and internal fixation) to repair a right hip fracture. She had a history of breast cancer, depression, and vitamin B12 deficiency. CMS Ex. 19 at 9. She was also diagnosed with deep vein thrombosis. CMS Ex. 19 at 9-10. Among other medications, she was prescribed two anticoagulants, Coumadin (5 mg daily by mouth at 6:00 p.m.) and Lovenox (60 mg, subcutaneously, twice daily at 9:00 a.m. and 9:00 p.m.). CMS Ex. 19 at 20.

Her physician also ordered PT/INR testing to commence on July 16, 2009 (a Thursday) and weekly thereafter, on Tuesdays. CMS Ex. 19 at 20.

On July 16, R41's INR measured a critically-high 9.96. CMS Ex. 19 at 3. According to Meridian's report, the lab completed the testing at 1:32 p.m. that day and called the results in to "Susan Rice" at 1:33 p.m. The document also shows that the report was faxed to the facility on July 16 at 10:18 p.m. CMS Ex. 19 at 3.

No one named "Susan Rice" worked at the facility. However, Licensed Practical Nurse (LPN) Susan *Brice* was assigned to care for R41. CMS Ex. 19 at 15, 31, 35, 37. CMS argues that Meridian called the lab results in to her. Petitioner denies receiving any such call, pointing to records of the incoming calls received by the facility between 1:18 p.m. and 1:38 p.m. on July 16. P. Ex. 34; CMS Ex. 34.

CMS, on the other hand, points to the lab report itself, which indicates that laboratory staff made the call and identifies by name (with only a minor and understandable error) a specific facility employee to whom the message was given. CMS Ex. 19 at 3. Surveyor notes indicate that a lab supervisor assured the surveyors that a lab employee made the call, pointing out that lab employees would not know the names of facility staff but are required to document the name of the person taking the call. CMS Ex. 19 at 41. How would lab staff have known the name of R41's nurse if they had not made the call? Even the error in the name seems to support CMS's position, since this is the type of error commonly made when an unfamiliar name is given over the telephone.

Moreover, in her declaration, LPN Brice does not address specifically whether Meridian called her with the critical lab results on July 16. Instead, she explains her responses to surveyor questions about the lab results. According to LPN Brice, she initially told the surveyor that she remembered receiving a call on July 21, but "could not recall the lab on

July 16." But she also inconsistently admits that she told the surveyor that she notified the nurse practitioner of the lab results on the 16th and the 21st. P. Ex. 28 (Brice Decl. ¶¶ 5, 7); *see* CMS Ex. 19 at 5. She did not document on either day receiving a call from the lab or notifying the physician /nurse practitioner of the lab results, so the absence of such a note among the July 16 nurses' notes has no particular significance. CMS Ex. 19 at 32.[4]

By themselves, CMS's arguments are compelling, but whether these arguments are sufficient to overcome the facility's telephone records is certainly debatable. In any event, I need not resolve the question, because federal regulations hold the facility as responsible for the actions of its contractors as it is for the actions of its employees. 42 C.F.R. § 483.20(k)(3)(i) (requiring that services arranged by the facility meet professional standards of quality); 42 C.F.R. § 483.75(j)(1) (making the facility responsible for the quality and timeliness of its laboratory services).

R41's physician should unquestionably have been informed of the critical lab results no later than the afternoon of July 16. The parties agree that no one conveyed the results to either the nurse practitioner or to R41's attending physician until some time the following day.[5] In the meantime, staff administered a full dose of Coumadin at 6:00 p.m. on July 16. They administered Lovenox to R41 at 9:00 p.m. on July 16, and 9:00 a.m. on July 17. CMS Ex. 19 at 24.

It appears that the physician first learned of the critical test results on July 17, although the record does not indicate when and by whom the information was conveyed. According to Nurse Practitioner Brown, she was not notified of R41's July 16 lab results until "some time on July 17." P. Ex. 9 (Brown Decl. ¶ 7). Other than saying she received a copy of the faxed critical lab results "at some time" on July 17, Nurse Practitioner Brown is vague as to exactly when and how she learned of the results and what actions she took, claiming generally that she took her usual steps. Administrator Henderson notes that the lab report was faxed to a locked office on Thursday night, so no one would have picked it up until the following day, but she does not say when it was

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[4] I find a disturbing absence of documentation in the facility's records. The record includes virtually no evidence that staff documented any consultations with physicians about significant lab results.

[5] Although not cited by CMS, regulations also require staff to consult immediately a resident's physician when there is a significant change in the resident's physical, mental, or psychosocial status (*i.e.*, a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications); or a need to alter treatment significantly (*i.e.*, a need to discontinue an existing form of treatment due to adverse consequences or to commence a new form of treatment). 42 C.F.R. § 483.10(b)(11). No one disputes that R41's critical test results evidenced a need to alter treatment significantly.

picked up. Nor does she indicate how the physician or nurse practitioner learned of R41's critical INR level. P. Ex. 2 at 4 (Henderson Decl. ¶ 23).

I infer that someone eventually advised the physician, because physician telephone orders dated July 17 instruct staff to hold the Coumadin for three days and "resume [at] 4.5," discontinue the Lovenox, and repeat the PT/INR on Tuesday, July 21. CMS Ex. 19 at 17. The orders do not indicate what time they were given.

On July 21, 2009, the lab test was repeated, and R41's INR measured at an even-higher level – greater than 10 (>10). CMS Ex. 19 at 4. Meridian's documents indicate that the lab called the results in to "Susan Rice" at 10:52 a.m., and the document shows that it was faxed to the facility. CMS Ex. 19 at 4, 11.

A physician's telephone order, taken at 1:00 p.m. on July 21, says to hold the Coumadin until further notice, administer Mephyton (Vitamin K) "now," and to repeat the PT/INR test on July 23, 2009. CMS Ex. 19 at 17, 38. Nursing notes for that day refer to the instruction to hold the Coumadin. CMS Ex. 19 at 38. A second telephone order, also dated July 21, says to discontinue Vitamin K, which probably explains why the medication was not given. CMS Ex. 19 at 18.[6]

On July 23, a different laboratory, Piedmont Medical Center Laboratory, tested R41's blood. Her INR was still >10. CMS Ex. 19 at 12. Physician's telephone orders dated July 23, July 24, July 26, and July 27 instruct staff to hold the Coumadin and repeat the PT/INR. CMS Ex. 19 at 18-19. By July 28, R41's INR was down to 6.34, which is still abnormally high. CMS Ex. 19 at 13.

Based on these facts, I find that the facility was not in substantial compliance with 42 C.F.R. §§ 483.25, 483.20(k)(3)(i), and 483.75(j)(2)(ii). Staff did not follow the facility's own protocol, which created the potential for more than minimal harm.

Although he minimizes the potential harm posed by a one-day delay in adjusting Coumadin dosages, the facility's medical director, James Lee Jewell, M.D., does not extend that opinion to situations involving critical INR levels. He begins his opinion with the exception, opining that a short delay would cause no harm "if the PT/INR is not at a critical level" and in the absence of abnormal bleeding. P. Ex. 24 (Jewell Decl. ¶ 9). Crystal F. Todd, the facility's pharmacist agrees: *"So long as a resident's PT/INR is not*

[6] In its closing brief, CMS complains, for the first time, that Mephyton was not administered to R41, even though, at 1:00 p.m., the physician ordered it given "now." CMS Cl. Br. at 13. The surveyors cited no deficiency in this regard, and I agree with Petitioner that a closing brief is simply too late to raise this new allegation. In any event, although I am troubled by the facility's insufficient documentation as to exactly what happened with these orders, I would not fault staff for failing to follow an order that had been rescinded.

at a critical level, a dosage difference of .5 or 1 mg. of Coumadin would not cause the potential for more than minimal harm." P. Ex. 5 at 2 (Todd Decl. ¶ 9) (emphasis added).

Another of Petitioner's witnesses, Kelly W. Jones., Pharm.D., notes that Coumadin is a very complicated medication, so facilities should have in place a standard protocol for managing its residents who are administered the drug.

> It is very important to realize that a systematic approach to monitoring INR's for [Coumadin] is important and in my opinion saves lives rather than placing residents at undue risk.

P. Ex. 13 at 15 (Jones Decl. ¶ 1). The facility had such an approach in place. As described above, it required the lab to inform facility staff of any critical lab values "upon completion of the test," and required facility staff to notify immediately a resident's attending physician of that result. Thus, if the facility's procedures were followed, a resident's attending physician would know about critical test results almost immediately. Standing orders also required nursing staff to decrease Coumadin dosages when INR values fell between 3.1and 4.5, and to contact the physician when levels exceeded 4.5. CMS Ex. 32 at 15; CMS Ex. 40.

I may reasonably rely on these policies as evidence of the facility's "own judgment as to what must be done to attain or maintain it residents' highest practicable physical, mental and psychosocial well-being, as required by section 483.25." *Senior Rehab and Skilled Nursing Ctr.*, DAB No. 2300 (2010), *aff'd*, *Senior Rehab and Skilled Nursing Ctr. v. HHS*, No. 10-60241 (2011) (*quoting Sheridan Health Care Ctr.*, DAB No. 2178 at 15 (2008)).

But on July 16 the facility policies were not followed, and, as a result, staff administered three additional doses of anticoagulant medications to a resident who already had a critically high INR, placing the resident at undue risk for hemorrhage or other serious bleeding. *See* CMS Ex. 38 at 12; CMS Ex. 39 at 1. The facility therefore failed to provide R41 the care and services she needed to attain her highest practicable physical well-being and was not in substantial compliance with 42 C.F.R. § 483.25. Nor did the facility promptly notify the attending physician of the laboratory findings, as required by 42 C.F.R. § 483.75(j)(2)(ii). Because the standard of care (as reflected in the facility's own policies) calls for prompt physician notification, these services did not meet professional standards of quality, as required by 42 C.F.R. § 483.20(k)(3)(i).

The facility presented testimony from a nurse consultant, Karon Goldsmith, who opines that Meridian was at fault for any delay in notification, because Meridian did not timely report the test results to the facility. P. Ex. 14 at 8 (Goldsmith Decl.). But, as noted above, it does not help the facility to blame laboratory staff, because services provided *or arranged* by the facility must meet professional standards of quality, and, by regulation,

the facility is responsible for the quality and *timeliness* of its laboratory services. 42 C.F.R. §§ 483.20(k)(3)(i), 483.75(j)(1).[7]

Moreover, when facility staff picked up the fax on July 17, they knew, or should have known, that either: 1) the lab timely notified LPN Brice of the critical test results, and she failed to notify the attending physician/nurse practitioner; or 2) laboratory staff failed to notify the facility of the lab results and falsified a document to indicate that they had done so. Either of these options demonstrates a significant break-down in the facility's procedures for reporting critical lab results. But, until after the survey, it does not appear that anyone at the facility was particularly concerned about the problem; no one questioned LPN Brice, contacted Meridian or made any other effort to determine what went wrong. Such inaction suggests a lack of concern about whether facility procedures were followed.

Dr. Jones's testimony reflects a similar lack of concern. After extolling the virtues of the facility's policies and procedures, he summarily dismisses, as insignificant, the facility's failure to follow them in this case. According to Dr. Jones, "even the best of systems and their application can fail us" because "[e]ven well constructed systems . . . are subject to human error." P. Ex. 13 at 15 (Jones Decl. ¶ 1). The Departmental Appeals Board (Board) has long recognized that virtually all deficiencies are, at bottom, attributable to human error and that the regulations include no "human error" exception. *Barn Hill Care Ctr.*, DAB No. 1848 at 18 (2002).

Moreover, to accept Dr. Jones's opinion, I would have to agree that, under the standard of care, a facility may, from time to time, wait more than 19 hours before informing a resident's attending physician of her critical PT/INR test results and may also, without consulting the physician, continue to administer powerful anticoagulant drugs to a resident at high-risk for bleeding based on her age (over 65) and INR values (significantly greater than 4). I do not agree. I find that the facility's failure to follow its own procedures for immediately notifying the attending physician (or nurse practitioner) of R41's critical lab results put it out of substantial compliance with Medicare program requirements.

[7] Moreover, had facility staff been able to recover the faxed report on the night of July 16, R41 could have avoided at least one dose of the Lovenox. The facility itself is plainly responsible for the location of its fax machine and for having instructed the lab to fax its test results to a machine that was accessible to nursing staff only when the nurse manager was there. As the following discussion shows, the facility's reliance on one specific nurse to recover the faxed lab reports seriously impaired its ability to consult timely attending physicians about necessary treatment changes.

B. The facility was not in substantial compliance with 42 C.F.R. § 483.25, because it repeatedly disregarded standing orders to adjust dosages of Coumadin, delayed advising physicians of significant lab test results, and delayed implementing physicians' orders to change the dosages of the anticoagulant medication.

CMS points to multiple instances in which facility staff: 1) disregarded standing orders to adjust dosages of Coumadin; 2) delayed informing the attending physician of a significant lab test result; and/or 3) did not timely respond to a physician's order to change the dosage of anticoagulant medications. Petitioner apparently does not dispute that the delays occurred, but argues that "any cited delay in carrying out orders or the very limited instances of a lack of documentation in the administration of anticoagulant therapy does not place residents at risk for *serious injury or harm*." P. Cl. Br. at 19 (emphasis added).

I discuss below CMS's immediate jeopardy determination. Here, in determining whether these findings constitute substantial noncompliance, however, I apply a different standard – whether the facility practice posed the potential for "more than minimal" (not "serious") harm. 42 C.F.R. § 488.301.

Resident 19 (R19). R19 was a 92-year-old woman admitted to the facility on April 13, 2009. CMS Ex. 15 at 1. She had a history of pulmonary embolism and diagnoses of deep vein thrombosis, chronic obstructive pulmonary disease, dementia, anemia, and osteoporosis. CMS Ex. 15 at 1. Prior to May 12, she was receiving 2.0 mg. of Coumadin daily; however, according to lab results reported at 1:35 p.m. that day, her PT/INR measured 22.4/1.95. CMS Ex. 15 at 12. Based on the facility's standing orders, staff should have increased her Coumadin dosage by 0.5 mg. CMS Ex. 40. An undated hand-written notation on the lab report, which appears to have been signed by her physician, calls for a 0.5 mg. increase.[8] The record includes no other written order, nor does it indicate when this order was given. CMS Ex. 15 at 12. Staff did not increase R19's Coumadin on May 12, but began administering the increased dose (2.5 mg.) at 6:00 p.m. on May 13. CMS Ex. 15 at 32.

Staff continued administering that dosage until May 21, when it was increased to 3.0 mg. CMS Ex. 15 at 32. At 12:56 p.m. on May 26, 2009, Meridian reported that R19's PT/INR was 16/1.42. CMS Ex. 15 at 10. Based on the standing order, staff should have increased her Coumadin by 1.0 mg. CMS Ex. 40. They again disregarded the order and continued to administer 3.0 mg. The record does not indicate when or how the physician was notified of the lab result, but an undated handwritten note on the lab report, apparently signed by the physician, says to increase the dosage by 1 mg. CMS Ex. 15 at 10. A telephone order written at 8:00 a.m. on May 27 calls for Coumadin 4.0 mg. daily. CMS Ex. 15 at 22. Staff still failed to increase the Coumadin, administering 3.0 mg. at

[8] *See, e.g.*, P. Ex. 16 at 22 for a sample of the physician's written signature.

6:00 p.m. on May 27. Almost twenty-four hours later, at 5:00 p.m. on May 28, staff finally followed both the standing order and the telephone order. CMS Ex. 15 at 32. This delay is especially puzzling since staff wrote on the face of the Medication Administration Record (MAR) that the 3.0 mg. Coumadin order was discontinued on May 27. *Id*.

On June 9, 2009, R19's blood was drawn at 9:50 a.m. and test results "approved" at 11:38 a.m. Her PT/INR was 45/3.78. CMS Ex. 15 at 15. Once more, staff did not follow the standing order, which directed them to decrease the Coumadin dosage by 0.5 mg. Nothing in the record indicates when or how the physician learned of the test results, but a telephone order dated June 10 at 8:00 a.m. notes the test results and orders the Coumadin decreased to 3.5 mg. CMS Ex. 15 at 19. Staff decreased the Coumadin at 6:00 p.m. on June 11, more than two days after the test results were known (and when the standing order should have been implemented) and more than one day after the physician specifically ordered the change. CMS Ex. 15 at 31.

On June 23, R19's test results were 16.2/1.44, which Meridian reported to the facility at 1:03 p.m. An undated, unsigned, hand-written notation on the report says "current 3.5 mg.[;] increase by 1.0 mg.[;] new dose 4.5 mg." In the corner of the document, it appears that the physician initialed to indicate that he had reviewed the report. Again the initials are not dated. CMS Ex. 15 at 23. Again, according to the facility's standing order, staff should have increased the Coumadin dosage by 1 mg. CMS Ex. 40. But at 6:00 p.m. on June 23, staff administered 3.5 mg. of Coumadin to the resident. CMS Ex. 15 at 31. In a telephone order received at 12:20 p.m. the following day, R19's physician increased the dosage to 4.5 mg. (CMS Ex. 15 at 17), and that evening, June 24, staff administered the correct dosage. CMS Ex. 15 at 26.

On July 7, 2009, R19's PT/INR was 69.2/5.69. CMS Ex. 15 at 14. In a progress note also dated July 7, Nurse Practitioner Brown notes the elevated INR and writes "will hold Coumadin and resume at reduced dose – repeat INR [in] 7 days. Follow closely." P. Ex. 16 at 19.[9] She does not indicate how long the hold should be, but a telephone order dated July 7 directs staff to "hold Coumadin" for twenty-four hours. CMS Ex. 15 at 16. Yet, contrary to this order, the MAR directs staff to hold the Coumadin for *two* days, and shows that staff did not administer the drug on either July 7 or 8. CMS Ex. 15 at 24. They administered the medication on July 9 and 10, but, without explanation, administered no Coumadin on either July 11 or July 12, resuming it on July 13. CMS Ex. 15 at 24. A doctor's progress note, dated July 9, says "meds reviewed" but does not indicate any changes in the order for Coumadin. P. Ex. 16 at 22.

[9] Curiously, a doctor's progress note is also dated July 7, but it does not mention the resident's INR or any orders for Coumadin. P. Ex. 16 at 23.

In a progress note dated July 13, 2009, Nurse Practitioner Brown says that R19 is "bleeding from the side of her mouth." P. Ex. 16 at 16.[10] Upon examination, she notes "old dried blood from lips" but "no evidence bleeding from mouth or tongue." P. Ex. 16 at 16. She does not mention Coumadin. In a July 15 follow-up, Nurse Practitioner Brown notes R19's PT/INR as 22/1.92 on July 14. She directs staff to decrease Coumadin from 4 mg. to 3.5 mg. and to recheck in a week, which is puzzling because the physician's standing order says to *increase* the dose by 0.5 mg. when the INR value is between 1.5 and 2.0. P. Ex. 16 at 11; CMS Ex. 40.[11]

The test was repeated on July 21, 2009, and R19's PT/INR results were 82.4/6.72, which the lab characterized as "critical." According to the lab report, the laboratory staff called those results in to "Susan Rice" at 10:52 a.m. and reported again to the facility at 12:02 p.m. (presumably by fax). CMS Ex. 15 at 5. A hand-written notation on the report says "hold [for] 2 days[,] then 4 mg." The physician initialed the report, and his initials are dated July 22. CMS Ex. 15 at 5. In her July 21 progress note, Nurse Practitioner Brown notes the test results and directs staff to hold the Coumadin for two days, then resume at a reduced dose. She says to repeat the INR on July 28, and to watch for bleeding. P. Ex. 16 at 13. But, without explanation, staff held the medication for *three* days – July 21, July 22, and July 23. CMS Ex. 15 at 24.[12] Nurses' notes for these days do not mention the lab tests or Coumadin. P. Ex. 16 at 4.

Resident 20 (R20). R20 was an 88-year-old man admitted to the facility on May 13, 2009, for rehabilitation following hip surgery. CMS Ex. 16 at 1; P. Ex. 17 at 33. He had a long list of diagnoses, including coronary artery disease with a history of myocardial

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[10] The progress reports from Nurse Practitioner Brown are very confusing because of the manner in which Petitioner submitted them. Not only has Petitioner submitted them in no particular order, but in some instances, page 2 does not immediately follow page one of the report. I have sorted them out as follows : July 7 progress report – P. Ex. 16 at 18-19 (with a duplicate at 20-21); July 13 progress report – P. Ex. 16 at 16-17; July 15 progress report – P. Ex. 16 at 8, 11; July 16 progress report – P. Ex. 16 at 14-15; July 21 progress report – P. Ex. 16 at 12-13; July 24 progress report – P. Ex. 16 at 10, 9.

[11] There may have been valid reasons for this deviation from the standing order, but nothing in the record suggests that anyone even referred to that order, much less explained why it should not be followed in this instance.

[12] The MAR suggests that staff confused the directions to hold the medication. Under the order for "Coumadin 4.5 mg.," they indicate "hold" for two days – July 21 and 22. But under the subsequent order "Coumadin 4 mg.," they repeat "hold [for] two days," and count July 22 and 23 as the two days for which they held that order. The physician had ordered them to hold the Coumadin for two days total (July 21 and 22), then resume at the lower dose (4.0 mg.) on July 23.

infarction, atrial fibrillation, and diabetes. He had suffered a post-operative bleed. CMS Ex. 16 at 1; P. Ex. 17 at 33. At the time of his admission, he was prescribed 5 mg. of Coumadin daily. CMS Ex. 16 at 3. According to the surveyor notes (which Petitioner does not challenge), on May 19, 2009, his PT/INR results were 41.7/3.52, and those results were apparently available at 4:11 p.m. CMS Ex. 16 at 3. Staff did not follow the facility's standing order to decrease the Coumadin dosage by 0.5 mg. for two days but continued to administer the full 5.0 mg. In a written order, dated May 20, R20's physician directed staff to decrease the dosage by 0.5 mg., to 4.5 mg. Staff did not lower R20's Coumadin dose until the next day, May 21, two days after the facility received the abnormal test results. CMS Ex. 16 at 3.

On May 26, at 10:38 a.m., R20's PT/INR measured 21.6/1.89. Staff did not follow the standing order but gave R20 4.5 mg. of Coumadin that day. On May 27, R20's physician ordered a 0.5 mg. increase in Coumadin, but, again, staff did not follow that order until the following day, May 28. CMS Ex. 16 at 3.

A progress note written by Nurse Practitioner Paula Smith on June 1, 2009, indicates that the resident was then suffering from cellulitis of a wound on his left foot, as well as painful muscle spasms in his thighs. She also reported that he had fallen three days earlier and suffered a skin tear on his right forearm. She did not mention his Coumadin. P. Ex. 17 at 33-35.

On June 2, 2009, at 12:21 p.m., R20's PT/INR tests results were 19/1.67. Again, no one paid any attention to the standing order. A day later, his physician increased his Coumadin dosage by 0.5 mg., but the facility did not implement that order until June 4. CMS Ex. 16 at 3.

Resident 1 (R1). R1 was an 87-year-old woman admitted to the facility on May 11, 2009. She had a long list of diagnoses, including cerebral artery occlusion, atrial fibrillation, aortic valve disorder, and history of a cerebral vascular accident. She had a long list of prescribed medications, including Coumadin. CMS Ex. 10 at 1, 2. On May 12, 2009, Meridian reported PT/INR results of 17.4/1.54. CMS Ex. 10 at 6. Consistent with the facility's standing order, at 4:00 p.m. that day, her physician ordered her Coumadin increased from 2.5 mg. to 3.0 mg. CMS Ex. 10 at 7. Yet, staff did not comply with that order until 6:00 p.m. on May 13. CMS Ex. 10 at 12.

Mid-day on May 26, Meridian reported PT/INR levels of 23/1.99.[13] CMS Ex. 10 at 10. Again, according to the facility's standing orders for Coumadin, staff were supposed to increase the dose (then at 2.5 mg.) by 0.5 mg. CMS Ex. 40. They disregarded the standing order and administered 2.5 mg. at 6:00 p.m. that day. CMS Ex. 10 at 12. An undated hand-written note on the face of Meridian's report, apparently initialed by R1's physician, says to increase the dosage by 0.5 mg. CMS Ex. 10 at 10. In a telephone

[13] Citing the report, CMS says that Meridian reported these results at 1:35 p.m., but the report sets the time at 12:56 p.m. CMS Ex. 10 at 10.

order, written at 8:00 a.m. on May 27, R1's physician discontinued Coumadin at 2.5 mg. and ordered Coumadin at 3.0 mg. daily. CMS Ex. 10, at 11. At 6:00 p.m. on May 27, staff increased the dosage to 3.0. CMS Ex. 10 at 12.

On June 9, at 12:02 p.m., Meridian reported PT/INR results of 39.9/3.37. CMS Ex. 10 at 15. An undated, unsigned hand-written note says "on 3.5 mg.[,] decrease to 3.0[,] repeat in 1 week." CMS Ex. 10 at 15. According to the facility's standing order, staff were to decrease the dosage by 0.5 mg. CMS Ex. 40. But R1's MAR shows that staff administered 3.5 mg. on June 9 *and* on June 10. CMS Ex. 10 at 21. In a telephone order, written at 8:00 a.m. on June 10, R1's physician discontinued Coumadin at 3.5 mg. and ordered Coumadin at 3.0 mg. CMS Ex. 10 at 16. Staff finally decreased her dosage on June 11. CMS Ex. 10 at 21. So staff once more disregarded the standing order and delayed implementing the physician's telephone order.

On June 16, R1's PT/INR measured 21.9/1.91. CMS Ex. 10 at 17. An undated, unsigned handwritten note says "on 3 mg. [change] to 3.5 mg.," which would have been consistent with the standing order. CMS Ex. 10 at 17; CMS Ex. 40. The facility received a telephone order at 3:31 p.m. on June 16 to change the 3 mg. dosage to 3.5 mg. CMS Ex. 10 at 18. Nevertheless, at 6:00 p.m. that day, staff administered 3.0 mg. They increased the dosage the following day, June 17. CMS Ex. 10 at 21.

On June 23, 2009, R1's PT/INR values were 15.1/1.34. CMS Ex. 10 at 19. Another undated note on the lab report says to increase by 1.0 (again consistent with the standing order). An undated signature indicates that the physician reviewed the lab report at some point. On June 23, a physician's telephone order directs staff to increase the dosage by 1.0 mg., from 3.5 mg. to 4.5 mg. daily. CMS Ex. 10 at 20. Yet, staff administered 3.5 mg. Coumadin on June 23, and began the new dosage on June 24. CMS Ex. 10 at 21, 24.

Resident 39 (R39). R39 was a 96-year-old woman admitted to the facility in 2005, whose diagnoses included dementia, atrial fibrillation, congestive heart failure, and angioneurotic edema. CMS Ex. 18 at 1; P. Ex. 22 at 7-10. On May 26, 2009, Meridian reported her PT/INR results as 41.4/3.5. CMS Ex. 18 at 18. On the face of the report, an undated hand-written note, initialed by the physician, says "on 6 [decrease] by 0.5." CMS Ex. 18 at 18. An 8:00 a.m. telephone order, dated May 27, instructs staff to decrease the Coumadin to 5.5 mg. CMS Ex. 18 at 19. But on May 26 and 27, staff gave R39 6.0 mg. of Coumadin. They did not decrease the dosage until May 28. CMS Ex. 18 at 20.

On June 3, Meridian reported PT/INR test results of 16.5/1.46. On the face of Meridian's report is another hand-written note, initialed by the physician, which says "on 5.5 [; increase] by 5.5." CMS Ex. 18 at 14. This is an obvious error. Under no circumstances could the physician have intended a 5.5 mg. increase in Coumadin. Also perplexing is a physician's telephone order form dated June 3 at 8:00 a.m. that includes the same test results (16.5/1.46) and instructs staff to increase Coumadin from 5.5 to 6.5 mg. daily. CMS Ex. 18 at 15. This must be another error, since the test referred to in the

order was not performed until the afternoon of June 3. In any event, under the standing order, staff should have increased the dosage by 1 mg. CMS Ex. 40. The MAR shows that staff discontinued the 5.5 mg. dosage on June 3, but did not administer the 6.5 mg. dosage until June 4, failing to give her any Coumadin on June 3. CMS Ex. 18 at 16-17.

On June 9, Meridian reported PT/INR levels of 15.2/1.35. CMS Ex. 18 at 9. Staff did not follow the standing order to increase the dosage. At 8:00 a.m. on June 10, R39's physician ordered a 1 mg. increase in the Coumadin dosage, from 6.5 mg. to 7.5 mg. daily. CMS Ex. 18 at 10. But once more, staff failed to increase the dosage until June 11. CMS Ex. 18 at 11.

On July 14, Meridian reported PT/INR levels as 70.2/5.77, a critical level. According to the report, Meridian called the facility and reported the result to Estrella Cohn. An undated, hand-written note on the face of the report says "on 8.5 mg. hold x 2 days then start Coumadin 8.0 mg." CMS Ex. 18 at 4. A physician's telephone order dated July 14 repeats that staff should hold Coumadin for two days, then start at 8 mg. per day. CMS Ex. 18 at 5. According to a July 15 progress note written by Nurse Practitioner Brown, R39's Coumadin would be held for two days and then decreased from 8.5 mg. to 8.0. mg. daily. P. Ex. 22 at 6. But the resident's MAR shows that staff held the Coumadin for *three* days, July 13, 14, and 15. CMS Ex. 18 at 6. Why they held it on July 13 is a mystery, since the facility had not yet learned of the critical test results.

Resident 42 (R42). Finally, CMS cites two instances in which staff delayed making ordered changes to R42's Coumadin dosages. R42 was an 81-year-old woman with multiple diagnoses, including congestive heart failure, coronary artery disease, deep vein thrombosis, diabetes, atrial fibrillation and hypertension. She had undergone a coronary artery bypass graft. CMS Ex. 20 at 1; P. Ex. 23 at 35, 38-40. On June 2, 2009, Meridian reported her PT/INR values at 18.1/1.59. An undated handwritten note on the face of the report says "on 1 mg. [increase] 0.5 mg." and the attending physician's undated initials indicate that he reviewed the document. CMS Ex. 20 at 4. According to the facility's standing order, the dose should have been increased by 0.5 mg. CMS Ex. 40. A June 3, 8:00 a.m. telephone order increases the dosage to 1.5 mg. daily. CMS Ex. 20 at 5. Staff did not make the change until June 4. CMS Ex. 20 at 6.

On June 16, R42's PT/INR values were 21.5/1.88, which, according to the standing order, called for a 0.5 increase in dosage. Another undated handwritten note, initialed by the physician, indicates that her dosage should be increased from 2 mg. to 2.5 mg. CMS Ex. 20 at 8; CMS Ex. 40. A June 16, 3:32 p.m. telephone order includes the same instructions. CMS Ex. 20 at 9. Yet, staff did not increase R42's Coumadin dosage until the following day, June 17. In fact, the MAR indicates that, rather than increasing the dosage on June 16, as ordered, staff gave her no Coumadin at all that day. CMS Ex. 20 at 10.

No one seriously questions that, under the standard of care, changes in Coumadin dosages should be implemented as soon as the new lab values are known, and that

medication orders (including standing orders) should be implemented on the day they are received or per the physician's instructions. CMS Ex. 10 at 32; CMS Ex. 26 at 1; P. Ex. 24 (Jewell Decl. ¶ 9) (stating "it is ideal if the dosage is changed on the day the PT/INR is drawn"). Staff should not delay implementing valid orders. Yet, with alarming regularity, facility staff disregarded entirely the facility's standing orders and responded to abnormal lab values only after they received the attending physician's telephone order. Staff then regularly delayed implementing that order. As a result, up to two days could elapse before they adjusted a resident's Coumadin dosage.

Dr. Jones suggests that the facility's practice in this regard was part of a deliberate and consistent policy in which "[a]ll residents get labs drawn on one day and interpretation and action on the next day." Dr. Jones opines that such a system is preferable to "an inconsistent or haphazard method of lab draws, interpretations, and recommendations," which "puts the patients at greater risk of harm." P. Ex. 13 at 16 (Jones Decl. ¶ 4). Whether any long term care facility may, as a matter of policy, deliberately delay administration of its physician orders (standing or individualized) to achieve consistency is highly questionable.[14] But here, no evidence supports Dr. Jones' assumption that these delays reflected the institution's protocol for managing anti-coagulant therapy. To the contrary, the evidence establishes that the facility had no consistent and effective procedure in place. Sometimes staff adjusted a resident's medication on the day of the testing; sometimes they adjusted it a day later; and sometimes they adjusted it two days later. The facility has offered no consistent or satisfactory explanation for the delays, a failure that suggests precisely the situation Dr. Jones characterizes as putting residents "at greater risk of harm."

According to CMS, the LPN assigned to pick up the faxed lab reports offered a partial explanation for the delays. She told the surveyors that they occurred because she was at times not at the facility when the lab faxes arrived. She was the only one who picked up the reports, so no one would get the information unless and until she returned to work. CMS Ex. 15 at 34. Petitioner does not challenge this assertion, which does not explain all of the delays (*e.g.*, delays following receipt of the physician's order), but is consistent with Administrator Henderson's testimony that reports faxed to the nurse manager's locked office would not be picked up until the nurse reported for duty. P. Ex. 2 at 4 (Henderson Decl. ¶ 23).

In their declarations, Administrator Henderson and Director of Nursing (DON) Natasha Wells opine that delays in changing dosages of medication may have been "due to the timing of obtaining the new dosage from the pharmacy." P. Ex. 2 at 5 (Henderson Decl.

[14] Dr. Jones also claims that such systemic delays are "very common in many private practice settings" including his own. P. Ex. 13 at 16 (Jones Decl. ¶ 4). But his is a "family medicine" practice, which presumably involves a population that is significantly less vulnerable than the aged and infirm residents of a nursing home. P. Ex. 13 at 14.

¶ 30); P. Ex. 3 at 3 (Wells Decl. ¶ 17).[15] Even if true, that explanation hardly helps the facility. Given the number of residents dependent on Coumadin, the facility should have in place a reliable method for obtaining promptly the ordered dosages. Moreover, a problem obtaining the drug does not explain the instances in which staff administered too much Coumadin. *See* CMS Ex. 19 at 16, 24; CMS Ex. 15 at 19, 31; CMS Ex. 16 at 3; CMS Ex. 10 at 15, 16, 21; CMS Ex. 18 at 18, 20.

The above discussion shows that the facility did not have in place an effective system to assure the facility's prompt response to abnormal PT/INR values. Equally disturbing, and unexplained, were the numbers of instances in which staff incorrectly implemented the physician's order – they held the medication for two days instead of one (CMS Ex. 15 at 24); they twice held the medication for three days instead of two (CMS Ex. 15 at 24; CMS Ex. 18 at 6); and they twice failed to administer any medications when they should have *increased* the resident's dosage (CMS Ex. 18 at 16-17; CMS Ex. 20 at 10).

These failures meant that staff often administered the wrong dosage of anticoagulant medications. A facility is not providing the care necessary to assure a resident's highest practicable well-being if it administers drugs in dosages that are different from the one currently ordered by the resident's attending physician. On this basis, the facility was not in substantial compliance with the quality of care regulation, 42 C.F.R. § 483.25.[16]

C. The facility was not in substantial compliance with 42 C.F.R. § 483.25(h), because staff did not take reasonable steps to prevent foreseeable accidents; they did not consistently follow care plan instructions for preventing accidents and did not adjust interventions that proved ineffective.[17]

Program requirements. So that a resident can attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with his/her comprehensive

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[15] One of the nurses, however, told the surveyors that "[i]f the dosage is adjusted [and] it is late in the day, Coumadin is available in the E-Boxes. 1 of each unit." CMS Ex. 26 at 1.

[16] Because I find that the deficiencies relating to the facility's administration of anti-coagulant drugs more than justifies CMS's findings of substantial noncompliance and immediate jeopardy under 42 C.F.R. § 483.25, as well as the penalties imposed, I need not address the adequacy of its hospice services to Residents 9, 12, and 14. *See Claiborne-Hughes Health Ctr.*, No. 09-3239 at 11 (6th Cir. 2010); *Carrington Place of Muscatine*, DAB No. 2321 at 20-21 (2010).

[17] Again, I do not address whether the facility's failure to protect R4 from accidents also constituted neglect, putting the facility out of substantial compliance with 42 C.F.R. § 483.13(c), because the deficiency findings I have sustained, as well as the un-appealed deficiencies, more than justify the penalties imposed.

assessment and plan of care, the "quality of care" regulation mandates that the facility "ensure" that each resident's environment remains as free of accident hazards as possible. 42 C.F.R. § 483.25(h)(1). It must "take reasonable steps to ensure that a resident receives supervision and assistance devices designed to meet his assessed needs and to mitigate foreseeable risks of harm from accidents." *Guardian Health Care Ctr.*, DAB No. 1943 at 17 (2004) (*citing* 42 C.F.R. § 483.25(h)(2)); *Briarwood Nursing Ctr.*, DAB No. 2115 at 5 (2007). The facility must anticipate what accidents might befall a resident and take steps to prevent them. 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. *Briarwood*, DAB No. 2115 at 5; *Windsor Health Care Ctr.*, DAB No. 1902, at 5 (2003); *see Burton Health Care Ctr.*, DAB No. 2051 at 9 (2006) (holding that determining whether supervision/assistive devices are adequate for a particular resident "depends on the resident's ability to protect himself from harm").

Resident 4 (R4). The deficiencies cited under 42 C.F.R. § 483.25(h) center around R4. R4 was a 92-year-old man, admitted to the facility on January 29, 2009, with diagnoses of stroke, osteoarthritis, dementia, depression, and remote subdural hematomas. CMS Ex. 11 at 1. He had a history of a left hip fracture caused by a fall. CMS Ex. 11 at 25. Notwithstanding that history, a series of fall risk assessments, dated January 29 through February 19, indicate that he did not then present a high risk for falls. CMS Ex. 11 at 50.

Nevertheless, his care plan described him as at high risk for falls because of his diminished cognition and poor safety awareness. CMS Ex. 11 at 15. The plan set as a goal that he would "exhibit no [signs or symptoms] of injury related to falls without intervention through (an unspecified) review date." Under the "approaches" column, staff are told to: 1) keep his call light within reach, encourage him to use it, and respond promptly to his requests for assistance; 2) "anticipate and meet needs"; 3) coordinate with appropriate staff to ensure a safe environment with floors free from spills and clutter, call light in place, bed in low position at night, side rails as ordered, handrails on walls, and personal items within reach; 4) physical therapy to evaluate and treat as ordered; 5) "evaluate for" and supply adaptive equipment or devices "as needed," and reevaluate "as needed for continued appropriateness and to ensure least restrictive device or restraint"; 6) provide activities that minimize the potential for falls; and 7) ensure that he is wearing appropriate footwear when ambulating or up in his wheelchair. CMS Ex. 4 at 15.

At the time of his admission, staff completed a restraint assessment for a wheelchair seatbelt, which his physician apparently ordered at that time. He also had orders for a low bed with tumble mat. CMS Ex. 11 at 3, 9, 12-13, 25, 52.

On February 9, 2009, R4 was "found on the floor" lying on his left side. His bed rails were up. To prevent recurrence, the report indicates that a bed alarm will be applied to

the resident while in bed and that staff would keep the bed rails up. CMS Ex. 11 at 38. [18] The record contains no evidence that a bed alarm was ordered or installed until months (and numerous falls) later.

An incident/accident report, dated February 19, 2009, indicates that, notwithstanding the February 9 instructions to "keep the bed rails up," no bed rails were ordered and none were used. According to the report's narrative, R4 "slid down from sit to stand" and "let go of hand rails." He was taken by ambulance to the hospital. To prevent recurrence, the report instructs staff to "monitor resident while using sit to stand" and calls for additional training for the nurse aides involved in the incident. CMS Ex. 11 at 39.

Another incident/accident report says that on April 28, 2009, a nurse aide was passing R4's room when she noted him sitting on the floor of his bathroom in front of the commode. His wheelchair was outside the bathroom door. To prevent recurrence, the report says that staff would keep the resident in viewing sight when not accompanied by staff or family, and would make sure that his safety belt is secure. CMS Ex. 11 at 45. A note describing the incident was added to his care plan, with the approach that staff "ensure safety belt secure." CMS Ex. 11 at 70.

A note dated April 29, 2009, which may refer to the April 28 incident, says that he "was found" on his bathroom floor by a nurse aide who happened to be passing by his room. The nurse aide assigned to care for him admitted that she had not securely applied the resident's safety belt. She also noted that the resident is able to remove the safety belt whenever the belt was loose. He had taken himself to the bathroom and attempted to get on the commode without assistance. CMS Ex. 11 at 16.

By April 29, R4's assessments indicated that he was at high risk for falls. An undated addendum to the assessments says that he is in the facility's "falling star" program, has a low bed with mat, wheelchair seatbelt, and rear "anti-tippers" to his wheelchair, and a bed alarm. CMS Ex. 11 at 51. Inasmuch as his physician did not order a bed alarm until May 13, I assume the addendum post-dates May 13. On April 29, however, R4's care plan was apparently amended to address the "potential for complications related to use of physical restraint," his wheelchair safety belt. The plan directs staff to follow the facility protocol for assessing restraint use and release. Staff are also instructed to "offer opportunities for restraint-free time and physical activity daily." CMS Ex. 11 at 69.

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[18] Side rails are potentially dangerous restraints, and their usefulness should be carefully assessed. *See, e.g., Laurelwood Care Ctr.*, DAB 2229 at 9 (2009). I see neither an assessment nor a physician's order for side rails in R4's record. Staff appears to have used them inconsistently. *Compare* CMS Ex. 11 at 38 *with* CMS Ex. 11 at 39, 40. CMS, however, has not pursued the issue with respect to the facility's use of side rails. *But see* CMS Ex. 2 at 38; CMS Br. at 14 (noting CMS expresses concern about the facility's restraint assessment for R4's seat belt).

On May 12, 2009, R4 was found on the floor of his room with a cut to his forehead, bleeding profusely. He was sent to the emergency room for stitches. Again, the steps to prevent recurrence are "seat belt needs to be put on a little tighter," and to apply anti-tippers to the rear of the wheelchair to prevent the criss-cross seat belt from releasing. CMS Ex. 11 at 46, 65. A note added to his care plan on that day said "remind staff to place safety belt on [wheelchair at] all times, including meals and activities." It also notes that a bed alarm *is to be added on May 13*, and calls for rear "anti-tippers" to the wheelchair to prevent the criss-cross seat belt from becoming undone. CMS Ex. 11 at 70.

His order sheet indicates that an order for a bed alarm was finally added on May 13. CMS Ex. 11 at 9.

On May 20, 2009, a housekeeper passing R4's room noticed that his wheelchair was tipped forward, and his legs were underneath the chair. His seatbelt was in place. Notes to prevent recurrence say: medication evaluation and have the resident at activity, if possible, or at the nurses' desk or in the TV area when not in bed. It also mentions anti-tippers. CMS Ex. 11 at 47, 61, 63. The following day a nurse noted that his forehead was bruised above the right eyebrow, which she attributed to the recent fall. CMS Ex. 11 at 61. According to his care plan, a medical evaluation was done for agitation. CMS Ex. 11 at 70.

On June 15, 2009, R4 tipped over his wheelchair while in the dining room. According to the incident report, the nurse aide, who was a new employee, had released the seatbelt, apparently in the presence of other staff. CMS Ex. 11 at 22; P. Ex. 6 (Fitzpatrick Decl. ¶ 4); P. Ex. 7 (Blackman Decl. ¶ 4); P. Ex. 3 at 2 (Wells Decl. ¶ 10). The nurse aide's superiors then counseled her that the "resident's restraint not to be released" and instructed her "to ask other coworkers and check [patient care plan] for seatbelt orders." CMS Ex. 11 at 22-23, 70, 73.[19]

An incident report dated June 30, 2009, says that the resident got out of bed while having breakfast. He fell on the floor and hit the right side of his forehead and suffered a skin tear to his right arm. According to this report, bed rails were ordered and in place at the time of the accident. To prevent recurrence, the report says that R4 needs to be out of bed in his wheelchair with the safety belt attached during all meals. CMS Ex. 11 at 42, 56, 70.

On July 11, 2009, the nurse "was called to" R4's room. He was lying on the floor with his wheelchair behind him. According to the report, the lap belt was not hooked to the back of the wheelchair, although a nurse's note inconsistently says that the lap belt "was hooked on" the wheelchair. According to the report, the "current interventions" included wheelchair seatbelt at all times, bed alarm, rear and forward anti-tippers, and a medical

[19] In telling the nurse aide that the restraint was "not to be released," facility staff apparently did not consider that the physician order also (appropriately) called for "release per protocol for repositioning." CMS Ex. 11 at 9.

evaluation. To prevent recurrence, the report says to steer him to common areas when he is up in his wheelchair and to apply dycem (a non-slip material) to the wheelchair to reduce sliding back and forth. CMS Ex. 11 at 41, 58, 71.

On July 14, 2009, the resident's bed alarm sounded, alerting Nurse Aide T. Roberts that the resident was on the floor beside a floor mattress. The report indicates that bed rails were ordered and were up. To prevent recurrence, staff were to keep the bed alarm in place, have a low bed and floor mattress in place, and to monitor the resident frequently. CMS Ex. 11 at 40, 59.

According to CMS, notwithstanding the multiple instances in which R4's seat belt was improperly applied, facility management declined to investigate or retrain the nurse aides, explaining to the surveyors that the nurse aides had already been trained in restraints during their orientation to the facility. CMS Ex. 11 at 3. Petitioner has repeated that claim here. According to DON Wells, "[u]pon new employee orientation, all [nurse aides] are trained in the appropriate use of restraints and, as part of that training, the [nurse aide] is subject to competency checks." P. Ex. 3 at 2 (Wells Decl. ¶ 9). She also claims, remarkably, that "[b]ecause no problems had been identified at the [f]acility concerning the proper use of restraints, no additional inservice was needed." P. Ex. 3 at 3 (Wells Decl. ¶ 13).

I find this position remarkable, inasmuch as the facility's own records document R4's repeated falls and some injuries as a result of staff's failures to secure his seat belt. In one instance, he fell because a nurse aide deliberately released the belt, in contravention of his care plan instructions. These incidents should have alerted the facility that its employees were not adequately supervising him.

Even though Petitioner repeatedly attributed R4's falls to its staff's failure to secure his seat belt adequately, it argues here that it should not be held accountable for those failings because the resident himself made the task so difficult. According to Administrator Henderson, he "continuously leaned side to side and far forward, stretching the restraint nearly to its limits, thereby loosening it to the point that it came out of position . . . ." P. Cl. Br. at 33; P. Ex. 2 at 2 (Henderson Decl. ¶ 8). But this argument only strengthens CMS's case. The facility recognized that R4 was capable of thwarting their plan, yet it neither identified that behavior as a problem nor addressed it in the resident's plan of care. Instead, the facility continued reminding staff to tighten the belt, even though staff plainly did not or could not comply in a way that would keep the resident safe.

Moreover, not all of R4's falls were caused by an improperly attached seat belt. He also fell from his bed. To meet his assessed need and mitigate the risk of harm from accidents, the facility staff called for a bed alarm following his February 9 fall. Yet the alarm was not ordered or in place until May 13, more than three months later. After his April 28 fall, staff were instructed to "have [him] in viewing sight." CMS Ex. 11 at 45. I see no evidence of any systematic effort to assure that level of supervision. In fact, as subsequent falls show, he was not supervised as required.

Thus, the facility did not take reasonable steps to provide the level of supervision and the assistive devices that R4 needed to meet his assessed needs and to mitigate foreseeable risks of harm from accidents. The facility was therefore not in substantial compliance with 42 C.F.R. § 483.25(h).

D. CMS's determination that the facility's deficiencies posed immediate jeopardy to resident health and safety is not clearly erroneous.

Immediate jeopardy exists if a 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 would include an immediate jeopardy finding) must be upheld unless it is "clearly erroneous." 42 C.F.R. § 498.60(c). The 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." *Florence Park Care Ctr.*, DAB No. 1931 at 27-28 (2004) (*citing Koester Pavilion*, DAB No. 1750 (2000)); *Daughters of Miriam Ctr.*, DAB No. 2067 at 7, 9 (2007).

Here, everyone agrees that Coumadin is a complicated medication and that the consequences of its mismanagement can be dire. P. Ex. 13 at 14-15 (Jones Decl. ¶ 1). The manufacturer's black box warning underscores that Coumadin can cause major or fatal bleeding, which is more likely to occur in the elderly, and in those with an INR greater than 4. CMS Ex. 39 at 1. In this case, R41's INR value was more than double that black box value. Yet, staff failed to consult her physician and continued to administer to her anticoagulant medications, thus increasing her risk.

Petitioner minimizes the risk by pointing out that she was not actively bleeding at the time. While fortuitous, the immediate jeopardy standard does not require actual harm, and, given her blood level, R41 was just a fall or bruise away from a true medical emergency. This alone satisfies the standard for immediate jeopardy.

While Dr. Jones minimized the risk posed by continuing to administer higher doses of Coumadin to residents with high INRs (defined as greater than 5), he also claimed that an INR of less than 2 presents a real danger to someone in need of anticoagulant therapy. P. Ex. 13 at 16 (Jones Decl. ¶ 3a.) ("You are ten times more likely to have a stroke (which is what we are trying to prevent with [Coumadin]) with an INR less than 2 versus the patient having a bleed from a high INR of >5.").[20] The record contains multiple instances

[20] In reaching his conclusion, Dr. Jones relied on a treatise on anticoagulant therapy in patients with mechanical heart valves. He did not demonstrate that conclusions drawn from a study of that population would apply to these nursing home residents.

in which staff delayed increasing the dosages to residents with INR values below 2. At least twice the staff not only delayed increasing the dosages, they neglected to administer any of the ordered Coumadin. CMS Ex. 18 at 14, 16-17; CMS Ex. 20 at 8, 10.

The facility's over-arching problem was that staff ignored the physician's standing orders, routinely delayed notifying the physician of abnormal test results, and then delayed implementing the physician's orders to change dosages. The facility simply did not have in place a reliable system for timely adjusting dosages of Coumadin based on lab values or for timely implementing physician orders. I am not aware of any responsible authority that permits a facility such delays. The facility's systemic failure to follow physician orders at the time they were given created a potentially dangerous situation for all of its residents in need of anticoagulant medications.

CMS's immediate jeopardy determination is therefore not clearly erroneous.

E. The penalties imposed are reasonable.

I next consider whether the CMPs are reasonable by applying 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. The factors in 42 C.F.R. § 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.

In reaching a decision on the reasonableness of the CMP, I consider whether the evidence supports a finding that the amount of the CMP is at a level reasonably related to an effort to produce corrective action by a facility with the kind of deficiencies found, and in light of the above factors. I am neither bound to defer to CMS's factual assertions, nor free to make a wholly independent choice of remedies without regard for CMS's discretion. *Barn Hill Care Ctr.*, DAB No. 1848, at 21 (2002); *Cmty. Nursing Home*, DAB No. 1807, at 22 *et seq*. (2002); *Emerald Oaks*, DAB No. 1800, at 9-10 (2001); *CarePlex of Silver Spring*, DAB No. 1683, at 8 (1999).

CMS has imposed penalties of $5,200 per day, which is at the low-to-mid penalty range for situations of immediate jeopardy ($3,050-$10,000), and $250, which is at the low end of the penalty range for per-day CMPs ($50-$3,000). 42 C.F.R. §§ 488.408(d), 488.438(a)(1).

Nevertheless, there seems no dispute that, for an individual in need of anticoagulant therapy, an INR below 2 puts him/her at serious risk.

The facility had a history of substantial noncompliance. During its prior annual surveys, deficiencies were cited under tags F309 (quality of care) and F323 (accidents and supervision). CMS Ex. 6.

Petitioner has not argued that its financial condition affects its ability to pay the penalty.

With respect to the remaining factors, I consider *all* of the facility's deficiencies, including those that Petitioner does not contest. The sheer number of deficiencies cited (14), as well as their scope and severity (one at level K, two at level J, one at level G, and three at level E) justifies penalties well above the minimum.

Here, the facility simply did not have in place systems that would protect an especially vulnerable population. I find the facility is particularly culpable because it not only failed to act promptly in response to R41's critical lab values, but then, knowing that its procedures for reporting lab values had failed, it took no action to correct.

I also consider the facility culpable because it did not protect R4. Knowing that he was vulnerable, and that his behaviors increased his risk of serious injury, facility staff failed to address the problem, demonstrating disregard for his safety.

Based on all of the significant deficiencies cited, I do not find the penalties imposed unreasonable.

IV. Conclusion

For the reasons discussed above, I find that the facility was not in substantial compliance with the Medicare requirements, its deficiencies posed immediate jeopardy to resident health and safety, and I affirm as reasonable the penalties imposed.

/s/
Carolyn Cozad Hughes
Administrative Law Judge