Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Colorado Department of Human Services,
Colorado State Veterans Home at Fitzsimons
(CCN: 06-5380)

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-14-132

Decision No. CR4662

Date: July 21, 2016

DECISION

Petitioner, Colorado State Veterans Home at Fitzsimons, is a long-term care facility located in Aurora, Colorado, that participates in the Medicare program. Some of its employees complained to state regulators that serious glitches in the facility's new electronic health information system jeopardized their ability to administer medications as ordered. Responding to these complaints, state surveyors investigated and, on August 8, 2013, completed a complaint survey. Based on the results, the Centers for Medicare & Medicaid Services (CMS) determined that the facility was not in substantial compliance with Medicare program requirements governing medication errors and facility administration and that its deficiencies posed immediate jeopardy to resident health and safety. CMS imposed an $8,750 per instance civil money penalty (CMP) for the "medication errors" deficiency. Petitioner appeals, and CMS moves for summary judgment, which Petitioner opposes.

As discussed below, the undisputed evidence establishes that the facility was not in substantial compliance with program requirements governing medication errors, and the modest penalty imposed is reasonable. I therefore grant CMS's motion.

Background

The Social Security Act (Act) sets forth requirements for nursing facilities to participate 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 survey skilled nursing facilities in order to determine whether they are in substantial compliance. Act § 1864(a); 42 C.F.R. § 488.20. Each facility must be surveyed annually, with no more than fifteen months elapsing between surveys, and must be surveyed 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. The state agency must also investigate all complaints. Act § 1819(g)(4).

Here, responding to complaints about the facility's electronic health information system, surveyors from the Health Facilities and Emergency Medical Services Division of the Colorado Department of Public Health and Environment (state agency) completed an abbreviated and partial extended survey on August 8, 2013. CMS Exs. 1, 2. Based on their findings, CMS determined that the facility was not in substantial compliance with:

- 42 C.F.R. § 483.25(m)(2) (Tag F333 – quality of care: medication errors) at scope and severity level K (pattern of noncompliance that poses immediate jeopardy to resident health and safety); and

- 42 C.F.R. § 483.75 (Tag F490 – administration) at scope and severity level K.

CMS imposed against the facility a per instance CMP of $8,750 based solely on the deficiency cited under section 483.25(m)(2). CMS Ex. 45.

CMS now moves for summary judgment. The parties filed pre-hearing briefs (CMS Br.; P. Br.) and proposed exhibits. With its brief, CMS submitted 50 proposed exhibits (CMS Exs. 1-50). Petitioner submitted eight proposed exhibits (P. Exs. 1-8). CMS subsequently filed a motion for summary judgment (CMS MSJ), and Petitioner filed a response (P. Response).

Issues

The parties allude to two issues that are not reviewable in this forum:

First, I have no authority to review the deficiency cited under section 483.75 (administration) because CMS did not impose a penalty for it.[1] A facility may challenge a finding of noncompliance for which CMS imposes one of the penalties specified in 42 C.F.R. § 488.406. 42 C.F.R. § 498.3(b)(13); *see* 42 C.F.R. § 498.3(a). A facility has no right to a hearing unless CMS imposes one of the specified remedies. *The Lutheran Home – Caledonia*, DAB No. 1753 (2000); *Schowalter Villa*, DAB No. 1688 (1999); *Arcadia Acres, Inc*., DAB No. 1607 (1997); *see San Fernando Post Acute Hosp.*, DAB No. 2492 at 7-8 (2012). The *remedy*, not the citation of a deficiency, triggers the right to a hearing. *Schowalter Villa*, DAB No. 1688; *Arcadia Acres, Inc.*, DAB No. 1607. Where CMS does not impose a remedy, Petitioner has no hearing right. *See Fountain Lake Health & Rehab., Inc.*, DAB No. 1985 (2005).

Nor may I review the immediate jeopardy finding. An administrative law judge may review CMS's scope and severity findings (which include a finding of immediate jeopardy) only if a successful challenge would affect the range of the CMP or if CMS has made a finding of substandard quality of care that results in the loss of approval of a facility's nurse aide training program. 42 C.F.R. §§ 498.3(b)(14); 498.3(d)(10); *Cedar Lake Nursing Home*, DAB No. 2344 at 9 (2010); *Evergreen Commons*, DAB No. 2175 (2008); *Aase Haugen Homes, Inc.*, DAB No. 2013 (2006). For a per-instance penalty, the regulations provide only one range ($1,000 to $10,000), so the level of noncompliance here does not affect the range of the CMP. 42 C.F.R. § 488.438(a)(2).

It seems that the facility lost approval of its nurse aide training program, but this does not make CMS's scope and severity determination reviewable. P. Br. at 3; CMS Ex. 47 at 1. By statute and regulation, if, as here, CMS imposes a penalty of $5,000 or more, the state agency cannot approve the program, so the facility would lose its approval without regard to the immediate jeopardy finding. Act § 1819(f)(2)(B); 42 C.F.R. § 483.151(b)(2)(iv). Thus, because the immediate jeopardy finding does not affect the range of the CMP nor cause the facility to lose approval of its nurse aide training program, the finding is not reviewable.

With respect to the issues that are properly before me, I first consider whether summary judgment is appropriate. On the merits, the sole issue is whether the facility was in substantial compliance with 42 C.F.R. § 483.25(m).[2]

---

[1] Based on the facility's substantial noncompliance with both regulations, CMS initially threatened to deny payments for new admissions (DPNA). CMS Ex. 45. Had CMS imposed that remedy, both deficiencies would have been reviewable. However, CMS subsequently rescinded the DPNA. CMS Ex. 46.

[2] Except to argue that it was in substantial compliance so no penalty should be imposed, Petitioner has not challenged the amount of the penalty ($8,750). The penalty is toward

Cont'd. on next page.

Discussion

Summary judgment. Summary judgment is appropriate if a case presents no genuine issue of material fact, and the moving party is entitled to judgment as a matter of law. *Bartley Healthcare Nursing & Rehab.,* DAB No. 2539 at 3 (2013) (citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-25 (1986)); *Ill. Knights Templar Home*, DAB No. 2274 at 3-4 (2009), and cases cited therein.

The moving party may show the absence of a genuine factual dispute by presenting evidence so one-sided that it must prevail as a matter of law, or by showing that the non-moving party has presented no evidence "sufficient to establish the existence of an element essential to [that party's] case, and on which [that party] will bear the burden of proof at trial." *Livingston Care Ctr. v. Dep't of Health & Human Servs.*, 388 F.3d 168, 173 (6th Cir. 2004) (quoting *Celotex Corp.*, 477 U.S. at 323-24). To avoid summary judgment, the non-moving party must then act affirmatively by tendering evidence of specific facts showing that a dispute exists. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.,* 475 U.S. 574, 586 n.11 (1986); s*ee also Vandalia Park,* DAB No. 1939 (2004); *Lebanon Nursing & Rehab. Ctr.,* DAB No. 1918 (2004). The non-moving party may not simply rely on denials, but must furnish admissible evidence of a dispute concerning a material fact. *Ill. Knights Templar Home*, DAB No. 2274 at 4; *Livingston Care Ctr.*, DAB No. 1871 at 5 (2003).

In examining the evidence for purposes of determining the appropriateness of summary judgment, I must draw all reasonable inferences in the light most favorable to the non-moving party. *Livingston Care Ctr.*, 388 F.3d at 172; *Brightview Care Ctr.*, DAB No. 2132 at 2, 9 (2007); *Guardian Health Care Ctr.,* DAB No. 1943 at 8 (2004); *but see Brightview*, DAB No. 2132 at 10 (entry of summary judgment upheld where inferences and views of non-moving party are not reasonable). However, drawing factual inferences in the light most favorable to the non-moving party does not require that I accept the non-moving party's legal conclusions. *Cf. Guardian Health Care Ctr.*, DAB No. 1943 at 11 ("A dispute over the conclusion to be drawn from applying relevant legal criteria to undisputed facts does not preclude summary judgment if the record is sufficiently developed and there is only one reasonable conclusion that can be drawn from those facts.").

Cont'd. from previous page.

the higher end of the range for a per-instance CMP ($1,000-$10,000), but is modest considering what CMS might have imposed. 42 C.F.R. § 488.408(e)(1)(iv); *see Plum City Care Ctr.*, DAB No. 2272 at 18-19 (2009) (observing that even a $10,000 per-instance CMP can be "a modest penalty when compared to what CMS might have imposed").

CMS is entitled to summary judgment because the undisputed evidence establishes that facility residents were not free of significant medication errors. Indeed, because the facility did not have in place a reliable medication administration records system, it could not ensure that any of its residents would be free of significant medication errors.[3]

Program requirements. Under the statute and the "quality of care" regulation, each resident must receive, and the facility must provide, the necessary care and services to allow a resident to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the resident's comprehensive assessment and plan of care. Act § 1819(b); 42 C.F.R. § 483.25. To this end, the facility must (among other requirements) ensure that its residents are *free of any significant medication errors* and that medication error rates are no greater than 5%. 42 C.F.R. § 483.25(m).

The State Operations Manual (SOM) provides guidance for determining when a medication error is "significant." The SOM recognizes that factors, such as the drug category and the resident's condition, can determine whether a medication error is significant. Certain drugs (including the anti-coagulent drug Coumadin, discussed below) have a high potential for creating problems for the typical resident of a long-term-care facility, and specific listed errors involving those drugs are presumed "significant" within the meaning of the regulation. CMS Ex. 43 at 2-3.

Problems associated with administering the anti-coagulant drug, Coumadin. Anti-coagulant drugs are "widely recognized" as among the medications most likely to cause harm to patients. CMS Ex. 32 at 2 (Hunt Decl. ¶ 7). They help prevent blood clots and are often prescribed to individuals who are at risk for dangerous blood clotting, such as those who have had heart attacks, strokes, or deep vein thrombosis. Unfortunately, bleeding – which can be serious and even cause death – is a major complication associated with anti-coagulants. CMS Ex. 38 at 1; CMS Ex. 39 at 1, 3; CMS Ex. 40 at 2; CMS Ex. 41 at 1, 3.

Among the factors known to increase the risk of complications to individuals taking anti-coagulant drugs, such as Coumadin, are the individual's age, medical conditions, and other medications. Individuals who are 65 years of age or older and those suffering from conditions such as high blood pressure, heart disease, and kidney problems are at higher risk. Because it interacts with many drugs in dangerous ways, prescribers must also take care when administering Coumadin to patients taking other medications, such as non-steroidal anti-inflammatory drugs (NSAIDS). CMS Ex. 29 at 4 (Ramos Decl. ¶ 15); CMS Ex. 38 at 1; CMS Ex. 39 at 1; CMS Ex. 41 at 8.

---

[3] I make this one finding of fact/conclusion of law.

For these reasons, the product label instructions include the following caveats (among many others) to those who prescribe and administer the drug to geriatric patients:

> Observe caution with administration of COUMADIN to elderly patients in any situation or with any physical condition where added risk of hemorrhage is present. Consider lower initiation and maintenance doses of COUMADIN in elderly patients.

CMS Ex. 41 at 9; *see* CMS Ex. 32 at 2 (Hunt Decl. ¶ 6) ("The dosing of Coumadin is very complex and difficult, particularly in the elderly, or when the patient has multiple complex medical conditions that necessitate other medications, as Coumadin interacts with many other drugs in dangerous, even fatal, ways. Small dosage variations or changes in the patient's overall medical condition can cause wide variations in his/her ability to clot with all the attendant sequelae . . . .").

Thus, Coumadin dosages must be individualized, carefully monitored, and adjusted frequently, based on the results of blood tests. CMS Ex. 29 at 4 (Ramos Decl. ¶ 15); CMS Ex. 31 at 3 (Reed Decl. ¶ 11); CMS Ex. 41 at 3, 4. If medication levels are too high, bleeding complications can occur; if too low, the resident could suffer the effects of a pathologic clotting condition, e.g., stroke or pulmonary embolism. CMS Ex. 29 at 4 (Ramos Decl. ¶ 15); CMS Ex. 32 at 2 (Hunt Decl. ¶ 5). A physician may change Coumadin doses after just a few days if the resident's lab values indicate such a change is necessary. CMS Ex. 31 at 3 (Reed Decl. ¶ 11).

Because Coumadin has such a high potential for creating problems for the typical resident of a long-term care facility, errors involving its excessive dosing are presumed "significant" within the meaning of section 483.25(m)(2). According to the SOM, administering *4 milligrams or more* of Coumadin without a physician's order would be considered a significant drug error, regardless of the resident's condition. CMS Ex. 43 at 2-3.

Resident 4 (R4). R4 was an 89-year-old woman, suffering from atrial fibrillation (irregular heartbeat), dementia, diabetes, stage 3 kidney disease, and congestive heart failure. Coumadin was one of her many medications. CMS Ex. 11 at 2-3. Given her age, multiple medical conditions, and medications (including Percocet, which contains the NSAID acetaminophen), R4 was at high risk of complications and could not safely ingest more Coumadin than ordered by her physician. CMS Ex. 38 at 1; CMS Ex. 39; CMS Ex. 40 at 3.

Surveyor Jody Ramos reviewed R4's medical record and testified that she found four instances of irregularities involving R4's Coumadin.[4] R4's physician prescribed 2.5 mg of Coumadin per day but, according to the resident's medication records, staff administered 2.5 mg *plus 5 mg* on May 25, May 26, May 30, and June 5, 2013. CMS Ex. 29 at 4 (Ramos Decl. ¶¶ 17, 18, 19).[5]

Petitioner does not challenge Surveyor Ramos's observation, but argues that, because the surveyor's conclusion concerning three of the four days in question is based solely on a review of the facility's faulty electronic Medication Administration Record (eMARs) (i.e., the *facility's own record-keeping system*) it "is not supported by reliable evidence and is certainly not conclusive regarding whether there were medication errors related to the administration of Coumadin to Resident #4." P. Response at 9-10. I discuss below why the facility does not get a pass because its wholly unreliable medication administration system makes it impossible to verify whether medications were administered as ordered. But even if I excused the facility for the three errors that Petitioner dismisses as "mere" reporting errors (which I do not), I would still find that, based on the remaining well-documented medication error, the facility did not ensure that R4 was free of significant medication errors.

---

[4] Citing the SOM, Petitioner criticizes Surveyor Ramos for relying on "paper" (in fact, electronic) review to determine medication errors. P. Response at 10 n.3; CMS Ex. 43 at 8. That she did so is understandable. She was investigating complaints that the facility's electronic medication administration records were seriously flawed – which turned out to be true. In the process of reviewing the records, she discovered actual errors. The SOM instructions do not preclude such review, and they acknowledge that it can reveal errors. They discourage the review based primarily on efficiency; it can be time-consuming without revealing the errors that are there. In any event, even if there were a problem with the surveyor's approach – and there is not – surveyor performance does not invalidate adequately documented deficiencies. 42 C.F.R. § 488.318(b).

[5] In one paragraph of her declaration, Surveyor Ramos mistakenly transposed numbers. In error, she wrote that R4 "received 2.5 mg of Coumadin in addition to her scheduled 5 mg . . . ." She then wrote, correctly, that R4 "received a total of 7.5 mg of Coumadin . . . as opposed to the 2.5 mg prescribed." CMS Ex. 29 at 4 (Ramos Decl. ¶ 17). As the facility's documents confirm, R4 received 5 mg of Coumadin in addition to her scheduled 2.5 mg. CMS Ex. 11 at 6. R4's medication orders confirm that her physician ordered 2.5 mg Coumadin on Monday, Tuesday, Wednesday, Thursday, and Friday, and 5 mg on Saturday and Sunday. CMS Ex. 11 at 7. May 30 was a Thursday.

A Medication Error Report, dated June 25, 2013, confirms that R4's physician ordered 2.5 mg of Coumadin daily. In error, on May 30, staff administered 2.5 mg *plus* 5 mg, for a total of 7.5 mg of Coumadin. The report attributes the error to two factors: staff did not compare the medication administered with the medication administration record (MARs); and staff did not check the dosage. CMS Ex. 11 at 5-6; *see* CMS Ex. 7. Petitioner has come forward with no evidence suggesting any dispute about the contents of this report. *See* P. Ex. 3 at 3 (Daumann Decl. ¶ 7).

Even if R4 were not otherwise at high risk, administering 4 mg (or more) of Coumadin than ordered is considered a significant medication error. By itself, this 5 mg medication error puts the facility out of substantial compliance with 42 C.F.R. § 483.25(m). *See Life Care Ctr. of Elizabethton*, DAB No. 2367 at 6 (2011) (observing that "compliance with section 483.25(m)(2) can turn on whether [the facility] made a medication error . . . that [was] 'significant,' not whether there was a pattern of errors").

Petitioner also maintains that R4 suffered no harm as a result of the error. *See* P. Ex. 3 at 2 (Daumann Decl. ¶ 6); P. Ex. 4 at 4 (Wallace Decl. ¶ 9). In fact, R4's Coumadin flow sheet shows no blood levels taken between May 21 and June 4, 2013. This is surprising – and troubling – inasmuch as her medication records show three instances of Coumadin over-dosing during this time. And, on May 21 and June 4, her INR (international normalized ratio) measured 3.4 and 3.3, respectively. P. Ex. 2. According to her physician, that level should have been between 2 and 3. P. Ex. 4 at 4 (Wallace Decl. ¶ 8). While the parties may dispute whether these elevated levels undermine Petitioner's claim of no harm, that dispute is not material. It is well-settled that CMS need not show actual harm to conclude that an error is significant. *Life Care Ctr. of Elizabethton*, DAB No. 2367 at 6, 7, and cases cited therein.

Moreover, in addition to this specific instance of a significant medication error, the undisputed evidence also establishes that the facility's medication administration record system was so unreliable that staff could not ensure that residents would be free of medication errors.

The facility's electronic medication administration records. MARs are the official documents used by medical providers to document the medications administered to a facility resident or patient. CMS Ex. 27 at 2 (Garramone Decl. ¶ 8); CMS Ex. 32 at 3 (Hunt Decl. ¶ 8).

In March 2013, the facility purchased and installed a new electronic health information system. CMS MSJ at 1; P. Response at 2, 4; *see* P. Ex. 1 at 3 (Bungam Decl. ¶ 7). P. Ex. 6 at 3 (Benjamin Decl. ¶ 6). When the system was up and running, facility staff were expected to generate and use eMARs rather than the paper records previously used. CMS MSJ at 4; P. Ex. 6 at 3 (Benjamin Decl. ¶ 7). Indeed, according to the facility's (then) acting director of nursing (DON), Portia Benjamin, the facility's administrator, Brad

Honl, "insisted" that nursing staff stop using the paper system (MARs) altogether, and use the eMARs exclusively. P. Ex. 6 at 4 (Benjamin Decl. ¶ 10).

Petitioner concedes that, from the beginning, serious problems pervaded the electronic system:

> [Facility] staff recognized immediately that the . . . system operated with some difficulty. [citation omitted] The issues . . . included the entire system crashing, medications dropping off the eMAR, and the eMAR allowing staff to indicate that medications were dispensed to patients on days or in dosage amounts other than what was prescribed.

P. Br. at 6, *citing* P. Exs. 1, 3, 5, 6 (Written Declarations of Bungum, Wallace, Benjamin, and Katta); *see* P. Response at 5.

Petitioner's witnesses, all of whom were working in the facility when the eMARs system was introduced, describe a system that presented a myriad of problems, any one of which compromised staff's ability to avoid significant medication errors and created the potential for more than minimal harm to facility residents:

- To put it mildly, the system was not user-friendly. According to Brian Bungam, the Business Analyst assigned to assist facility staff in implementing eMARs, the process for logging in was so cumbersome that staff thought the system was not responding. P. Ex. 1 at 1-2, 4 (Bungam Decl. ¶¶ 2, 10); *see* P. Ex. 3 at 3 (Daumann Decl. ¶ 6).

- Passwords expired unexpectedly. P. Ex. 6 at 3 (Benjamin Decl. ¶ 7).

- The system crashed periodically, rendering it "unusable." P. Ex. 1 at 4 (Bungam Decl. ¶ 11); P. Ex. 5 at 2-3 (Whitfield Decl. ¶ 5) ("the eMAR went down repeatedly"); P. Ex. 6 at 3 (Benjamin Decl. ¶ 7); *see* P. Ex. 4 at 3 (Wallace Decl. ¶ 6) .

- The system did not communicate with the pharmacy's medication system, which created a separate set of problems. P. Ex. 3 at 2 (Daumann Decl. ¶ 5); P. Ex. 6 at 3 (Benjamin Decl. ¶ 7). According to DON Benjamin, "there were [unspecified] issues faxing prescriptions to the pharmacy." P. Ex. 6 at 3 (Benjamin Decl. ¶ 7).

  A June 2013 pharmacy report is blistering in its criticism: "The documentation associated with medication ordering and accountability is **not satisfactory** and not in compliance with regulatory requirements." CMS Ex. 3 at 1 (emphasis in original). Among other problems, no policies and procedures explain how to

communicate to the pharmacy new orders and order changes; not all staff know how to enter orders directly, especially those involving "odd dosing" regimens. "The health record documentation associated with medication and treatment administration is **not satisfactory** and does not meet regulatory requirements." CMS Ex. 3 at 1 (emphasis in original). Although both paper and electronic systems are used "at times," both are not updated with new or changed orders. CMS Ex. 3 at 1. The report cites seven significant medication errors in June, six involving the wrong dose administered to the resident (two of the six for Coumadin). CMS Ex. 3 at 2.

- By design, the system discontinued medications after 30 days. The developers implemented what Analyst Bungam calls a "work-around," but their "solution" still meant that the system discontinued medications after 60 days. P. Ex. 1 at 4-5 (Bungam Decl. ¶ 12); *see* P. Ex. 3 at 3 (Daumann Decl. ¶ 6).

eMARs system's particular problems with Coumadin prescriptions. Everyone agrees that the system had particular problems with prescriptions for the anticoagulant drug, Coumadin.

As Janet Daumann, the facility's (then) Director of Quality Management, explains, Coumadin prescriptions appeared in an unfamiliar and unwieldy format. P. Ex. 3 at 3 (Daumann Decl. ¶ 6). "[I]t would have been easy for nurses to make mistakes" in administering Coumadin. P. Ex. 3 at 3 (Daumann Decl. ¶ 7); CMS Ex. 3 at 3 (reporting errors with "odd dosed" medication, such as Coumadin).

DON Benjamin explains that, under the MARs, nurses could mark with an X the days the drug was not to be administered. The eMARs system did not give them that option, which is a particular problem with Coumadin because physician orders often limit the days it should be given. P. Ex. 5 at 3 (Whitfield Decl. ¶ 8) ("eMAR prompted the administering nurses to give all prescribed dosages of Coumadin to patients receiving the medication, every day of the week, instead of only directing them to give certain dosages on certain days."); P. Ex. 6 at 4 (Benjamin Decl. ¶ 11).

Under the MARs, Coumadin could also be ordered at different dosages on different days. But under the eMARs system, both dosage amounts would show up at the same time on the computer screen, signifying that both doses should be administered. If the nurse initialed only one of the doses to confirm that she administered it, the other amount would flash on the screen, indicating that it too should be administered that day. "The only way the other dosage amount would stop flashing, was for the nurse to initial that it had been administered." So the nurse would initial that she had administered drugs that she did not, in fact, administer. P. Ex. 6 at 4-5 (Benjamin Decl. ¶ 11). Nurses could put a note in the eMARs indicating that the additional dose had not been administered, but

those notes had to be labeled and could not always be pulled up. P. Ex. 6 at 5-6 (Benjamin Decl. ¶ 14).

I accept Petitioner's representation that its medication administration records show that drugs were administered when, in fact, they were not. But this does not help Petitioner's case. The practice violates accepted professional standards and makes it impossible to ensure that its residents will be free of significant medication errors. Based on this alone, I can conclude that the facility was not in substantial compliance with 42 C.F.R. § 483.25(m)(2).

Petitioner nevertheless dismisses as insignificant its many "medication error reports," and argues that its witness declarations establish a factual dispute as to whether any *actual* medication errors were made. P. Response at 9-12. In fact, the declarations do not. After explaining the eMARs problems with Coumadin prescriptions, Director Daumann concedes that "one mistake was made" in May (presumably R4's Coumadin overdose). P. Ex. 3 at 3 (Daumann Decl. ¶ 7). She also says that the nurses responsible were subject to progressive discipline and additional training, but that only verbal counseling was actually performed. P. Ex. 3 at 4 (Daumann Decl. ¶ 9).

DON Benjamin, on the other hand, claims that no errors were made but bases this conclusion on faulty reasoning: even though they initialed that they administered excess dosages, the nurses did not report any errors to her.[6] P. Ex. 6 at 4-5 (Benjamin Decl. ¶¶ 11, 12). I am not aware of any support for disregarding a facility's medication administration records in favor of an employee's claim to the contrary. Moreover, according to DON Benjamin, nurses *could* indicate an entry error (i.e. that they reported administering medications they did not administer), but Petitioner has come forward with no evidence that anyone ever did.

Conclusion

The undisputed evidence establishes that the facility did not have in place a reliable medication administration records system and could not ensure that any of its residents would be free of significant medication errors. At least one vulnerable resident was administered a significantly excessive dose of Coumadin. The facility was therefore not in substantial compliance with 42 C.F.R. § 483.25(m)(2). CMS is therefore entitled to summary judgment.

---

[6] DON Benjamin also points to the purported absence of elevated INR levels to support her claim that no errors were made. As noted above, R4's physician, Dr. Wallace, testified that INR levels should be between 2 and 3. P. Ex. 4 at 4 (Wallace Decl. ¶ 8). Yet, R4 had INR levels of 3.4 and 3.3 on May 21 and June 4. P. Ex. 2.

/s/
Carolyn Cozad Hughes
Administrative Law Judge