Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Life Care Center of Elizabethton
Docket No. A-11-3
Decision No. 2367
March 22, 2011

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Life Care Center of Elizabethton (Life Care) appeals the August 10, 2010 decision of Administrative Law Judge (ALJ) Alfonso J. Montano upholding a determination by the Centers for Medicare & Medicaid Services (CMS) to impose remedies on Life Care for noncompliance with requirements for long-term care facilities participating in the Medicare program. *Life Care Center of Elizabethton,* DAB CR2201 (2010) (ALJ Decision).[1] CMS made its determination based on a survey done by the Tennessee state survey agency in July and August of 2007. The ALJ concluded, among other things, that: 1) Life Care was not in substantial compliance with the Medicare participation requirements at 42 C.F.R. §§ 483.25 and 483.25(m)(2); 2) the facility's noncompliance posed immediate jeopardy to resident health and safety; and 3) CMS was authorized to impose a civil money penalty (CMP) of $3,050 per-day, the minimum per-day CMP allowed for immediate jeopardy, from March 26 through August 14, 2007. Life Care appeals each of these conclusions.

For the reasons explained below, we affirm the ALJ Decision.

Applicable Law

Long-term care facilities participating in the Medicare and Medicaid programs are subject to the survey and enforcement procedures set out in 42 C.F.R. Part 488, subpart E, to determine if they are in substantial compliance with applicable program requirements which appear at 42 C.F.R. Part 483, subpart B. "Substantial compliance" means a level of compliance such that "any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm." 42 C.F.R.

[1] The ALJ also overturned CMS's finding of a deficiency involving abuse under 42 C.F.R. § 483.13(b) and reduced the daily amount of the CMP originally imposed by CMS from $4,550 to $3,050. CMS did not appeal these determinations.

§ 488.301. "Noncompliance," in turn, is defined as "any deficiency that causes a facility to not be in substantial compliance." *Id.*

Survey findings are reported in a Statement of Deficiencies (SOD). The SOD identifies each "deficiency" under its regulatory requirement, citing both the regulation at issue and the corresponding "tag" number used by surveyors for organizational purposes. The regulatory requirements at issue here are 42 C.F.R. §§ 483.25 and 483.25(m)(2). Section 483.25 provides: "Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care." Section 483.25(m) provides: "Medication Errors. The facility must ensure that . . . (2) Residents are free of any significant medication errors."

A long-term care facility found not to be in substantial compliance is subject to various enforcement remedies, including CMPs. 42 C.F.R. §§ 488.402(c), 488.406, 488.408, 488.430. The CMP range for noncompliance that constitutes immediate jeopardy is $3,050-$10,000 per-day. 42 C.F.R. §§ 488.438(a)(1)(i), 488.408(e)(1)(iii). When CMS imposes one or more of the alternative remedies in section 488.406 for a facility's present noncompliance, those remedies continue until "[t]he facility has achieved substantial compliance, as determined by CMS or the State based upon a revisit or after an examination of credible written evidence that it can verify without an on-site visit . . . ." 42 C.F.R. § 488.454(a)(1).

Factual background and proceedings below[2]

The noncompliance at issue here centers on medication errors involving Coumadin.

Life Care's expert, Dr. Clark, testified as follows about Coumadin.[3]

- Coumadin is an "anti-coagulant" and "blood thinner" that affects the blood's "tendency to clot." Transcript (TR) at 342. "Clinical indications" for the use of Coumadin include "blood clots in [] legs, strokes that are ischemic in nature, or [] chronic atrial fibrillation where [residents] have irregular heartbeat and they're at risk for building blood clots in their heart . . . ." *Id.*

- Many factors can influence the degree to which Coumadin affects a particular person's clotting tendency, including advanced age (over 65), conditions such as

[2] The information in this section is drawn from undisputed findings of fact in the ALJ Decision and undisputed facts in the record before her and is presented to provide a context for the discussion of the issues raised on appeal. Nothing in this section is intended to replace, modify, or supplement the ALJ's findings of fact or conclusions of law.

[3] Dr. Clark was the medical director at Life Care and the treating physician of the residents at issue herein. Tr. at 339-340.

heart disease (*id.* at 344), and other medications such as antibiotics (*id.* at 346). These factors can "interfere [with] or potentiate the effect of Coumadin." *Id.* at 343-344.

- Doctors evaluate the effect of Coumadin "by checking a blood test we call [the International Normalization Ratio or] INR," a universal standard measure. *Id.* at 344. Coumadin has a narrow therapeutic range of "between 2 and 3 of the INR." *Id.* at 344. "If your INR is less than 2, that means your blood is not thin enough. And that patient has a tendency to clot. If your INR is more than 3, that means your blood is too thin." *Id.* at 344-345.

The CMS surveyor, a registered nurse, testified that an elevated INR puts a patient at risk of bleeding, and that a "critically high" INR puts a patient at "great risk of adverse events" such as "a cerebral bleed, . . a GI bleed, a bleed from anyplace." *Id.* at 55. The ALJ paraphrased the guidance issued by Coumadin's manufacturer as follows:

> [Coumadin] can cause major or fatal bleeding. Bleeding is more likely to occur during the starting period and with a higher dose (resulting in a higher [INR]). Risk factors for bleeding include high intensity of anticoagulation (INR>4.0), age ≥65, highly variable INRs, history of gastrointestinal bleeding, hypertension, cerebrovascular disease, serious heart disease, anemia, malignancy, trauma, renal insufficiency, concomitant drugs . . ., and long duration of [Coumadin] therapy.

ALJ Decision at 13 n.11, relying on www.coumadin.com.[4]

Finally, Dr. Clark testified that "Vitamin K reverses the action of Coumadin [and] if you have someone who has a prolonged INR and you want to reverse that prolonged INR, you give them Vitamin K." Tr. at 354. Vitamin K has "an immediate effect. It acts within about five hours. It's gone by ten hours." *Id.*

Life Care does not dispute that its records establish that its staff committed errors involving Coumadin in the care of two residents.

Resident #22 (R22) was a 70-year old male with multiple medical conditions including atrial fibrillation. P. Ex. 18. R22 received Coumadin daily as prescribed to him by Dr. Clark. ALJ Decision at 9, citing P. Ex. 24, at 4; P. Ex. 25; P. Ex. 26. R22's Anticoagulant Administration Record (AAR) indicates that, on March 12, 16, and 19, 2007, Life Care gave R22 5 mg of Coumadin rather than the 7.5 mg ordered by Dr.

[4] Because this guidance was not submitted by either party, the ALJ should have given the parties notice of his intention to rely on it, as well as an opportunity to object. *See* 42 C.F.R. § 498.53(b), (c). Life Care, however, did not object to the ALJ's reliance on this guidance, which it refers to as "boilerplate" authority. P. Reply at 2, 3, 10, 11. Indeed, Life Care recognized that these "boilerplate assertions generally are accurate." *Id.* at 10. Nonetheless, as discussed below, Life Care argued that it did not follow from the guidance that the errors made here jeopardized the health or safety of either of the residents at issue. P. Reply Br. 2, 3, 10, 11.

Clark. *Id.* citing P. Ex. 27, at 13. On March 26, the AAR states that Life Care gave R22 an extra dose of Coumadin of 5 mg in addition to the ordered single dose of 7.5 mg. *Id.* An INR test on March 28, 2007 showed that R22 had critically high INR values (91.7/8.7). *Id.*, citing P. Ex. 31, at 6. Life Care's nursing staff notified Dr. Clark of the INR results, and Dr. Clark ordered it to hold the Coumadin and give R22 vitamin K "NOW" as an antidote. P. Ex. 25, at 5.

R25 was an 81-year old female with numerous medical conditions including atrial fibrillation, stroke, and prior blood clots in her legs. ALJ Decision at 10, citing P. Ex. 34; and Tr. at 362. R25's care plan indicated that the resident was at risk for bleeding tendencies related to taking Coumadin and instructed the facility staff to give R25 her Coumadin as ordered. ALJ Decision at 10, citing P. Ex. 40, at 3. On Friday, July 27, 2007, Dr. Clark changed R25's order for Coumadin to 7.5 mg on Monday, Wednesday and Friday and 5 mg on Tuesday, Thursday, Saturday and Sunday. *Id.*, citing P. Ex. 1, at 30; P. Ex. 42, at 22. The AAR for the period of July 27, 2007 through July 31, 2007 states that R25 "was given 7.5 mg five days in a row, rather than the alternating dose." *Id.*, citing P. Ex. 43, at 35. This would constitute three incorrect doses of 7.5 mg (instead of 5 mg) on July 28, 29, and 31. Tr. at 252-254; 362-364.

Life Care appeals the following numbered and unnumbered findings of fact and conclusions of law in the ALJ Decision:

> 2. [Life Care] failed to comply with the requirements of 42 C.F.R. § 483.25(m)(2) (Tag F333).
>
> 3. [Life Care] failed to comply with the requirements of 42 C.F.R. § 483.25 (Tag F309).
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> 5. The evidence supports CMS's immediate jeopardy determinations with respect to the noncompliance under Tags F309 and F333.
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> [unnumbered] I conclude that CMS was authorized to impose a per-day CMP of between $3,050 and $10,000 for [the period March 26, 2007 through August 14, 2007].

ALJ Decision at 9, 15, 17, 18.

Standard of Review

We review a disputed finding of fact to determine whether the finding is supported by substantial evidence on the record as a whole, and a disputed conclusion of law to determine whether it is erroneous. *Guidelines – Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's Participation in the Medicare and Medicaid Programs* at http://www.hhs.gov/dab/divisions/appellate/guidelines/prov.html;

Batavia Nursing and Convalescent Inn, DAB No. 1911, at 7 (2004), *aff'd*, *Batavia Nursing & Convalescent Ctr. v. Thompson*, 143 F. App'x 664 (6th Cir. 2005).

Analysis

Life Care raises three primary issues on appeal.[5] It asserts that: (1) the ALJ incorrectly held that any Coumadin error is a significant error under section 483.25(m)(2), a violation of section 483.25, and constitutes immediate jeopardy (Request for Review (RR) at 2); (2) the ALJ did not properly credit Life Care's expert testimony as to whether the medication errors with respect to R22 and R25 were significant or resulted in immediate jeopardy (*id.)*; and (3) there is no legal basis for the 142-day duration of noncompliance adopted by the CMS and affirmed by the ALJ (*id.* at 3).[6]

As a preliminary matter, we note that Life Care repeatedly misdescribes the evidence and makes unsupported statements in its appeal before us. For example, it asserts, without supporting citations, that "the evidence is undisputed that an error *of the sort alleged* -- i.e., getting alternating doses out of sequence or even a single double dose – not only did not, but *could not*, significantly alter the titration or effectiveness of the medication." RR at 23 (emphasis in original). Elsewhere in its request, Life Care asserts that its witnesses "testified without contradiction that . . . the sorts of errors CMS alleged posed no realistic possibility of causing *any* impact on the Resident's level of function." *Id.* at 26. In its Reply Brief, Life Care writes that the "evidence makes clear that [the errors] did not . . . pose even any remote or hypothetical possibility of harm to anyone . . . ." (P. Reply at 1) and "CMS . . . cannot, and does not, dispute that this is *not* a case where the sorts of medication errors that actually occurred even potentially could cause measurable adverse effect on *any* patient." (*id.* at 2). (Emphasis in original). In fact, our review of the record shows that these claims were indeed disputed and evidence to the contrary was offered.

Because the ALJ Decision is clear and thorough, we do not identify every instance in which Life Care's statements are simply incorrect. Instead, we address below its main legal arguments on appeal, explaining how they are based on erroneous premises, or a misreading of the law, the record, or past Board decisions. We explain why we reject Life Care's assertions about the lack of an evidentiary basis for the ALJ's findings. We ultimately conclude that the ALJ Decision as to 42 C.F.R. § 483.25(m)(2) and the CMP imposed is free of legal error and is based on substantial evidence in the record as a whole. We do not address the section 483.25 citation because the section 483.25(m)(2)

[5] We have considered all the arguments presented by Life Care although particular arguments may not be specifically addressed.

[6] Life Care appeals the duration of the CMP but not the amount of the per-day CMP because that amount, $3,050, is the minimum per-day CMP for noncompliance that constitutes immediate jeopardy. 42 C.F.R. §§ 488.438(a)(1)(i), 488.408(e)(1)(iii).

citation supports the imposed CMP, which was the minimum amount in the immediate jeopardy range.

A. The ALJ's determination that Life Care was not in substantial compliance with 42 C.F.R. § 483.25(m)(2) is supported by substantial evidence in the record as a whole and free of legal error.

Contrary to what Life Care asserts, the ALJ did not hold that *any* Coumadin error constitutes a violation of section 483.25(m)(2). Rather, our review of the record indicates the ALJ properly evaluated the evidence in light of Board decisions construing section 483.25(m)(2), the preamble to the notice of rule-making adopting that section, and CMS's guidance to surveyors.

As the ALJ noted, the Board has previously held that compliance with section 483.25(m)(2) "turns solely on whether [the facility] made a medication error or medication errors that were 'significant'," not whether there was a pattern of errors. ALJ Decision at 11, citing *Franklin Care Center*, DAB No. 1900 (2003). The ALJ also recognized that no showing of actual harm to a resident is necessary to conclude that an error is significant. ALJ Decision at 11; *Life Care Center of Tullahoma*, DAB No. 2304 (2010); *Northern Montana Care Center*, DAB No. 1930 (2004); *Rosewood Care Center of Peoria*, DAB No. 1912 (2004).

In applying section 483.25(m)(2) in other cases, the Board has relied on statements in the preamble to the rule-making adopting that section and CMS's guidance to surveyors. In the preamble, the Secretary wrote:

> A significant medication error is judged by a surveyor, using factors which have been described in interpretive guidelines since May 1984. The three factors are: (1) Drug category. Did the error involve a drug that <u>could result</u> in serious consequences for the resident[?;] (2) Resident condition. Was the resident compromised in such a way that he or she could not easily recover from the error[?;] (3) Frequency of error. Is there any evidence that the error occurred more than once[?] Using these criteria, an example of a significant medication error might be as follows: A resident received twice the correct dose of digoxin, a potentially toxic drug. The resident already had a slow pulse rate, which the drug would further lower. The error occurred three times last week.

56 Fed. Reg. 48,826, at 48,853 (Sept. 26, 1991) (emphasis added).

These criteria are also set forth in CMS's interpretive guidelines for section 483.25(m)(2). ALJ Decision at 12, citing State Operations Manual (SOM), App. PP (tag F333). The guidelines state that a significant medication error is one that "causes the resident discomfort or jeopardizes his or her health and safety." SOM, App. PP (tag F333). In *Life Care of Tullahoma*, the Board held that:

> CMS need not prove actual harm to support a finding of noncompliance and, as CMS's interpretive guidelines state, a medication error may be considered significant if it "jeopardizes" — that is, has the potential to harm — the resident's health.

Life Care of Tullahoma, DAB No. 2304, at 44 (2010) (emphasis in original).

The ALJ also quoted the following discussion of the three factors in the SOM:

> **"Resident Condition" -** The resident's condition is an important factor to take into consideration. For example, a fluid pill erroneously administered to a dehydrated patient may have serious consequences, but if administered to a resident with a normal fluid balance may not. If the resident's condition requires rigid control, a single missed or wrong dose can be highly significant.
>
> **"Drug Category" -** If the drug is from a category that usually requires the patient to be titrated to a specific blood level, a single medication error could alter that level and precipitate a reoccurrence of symptoms or toxicity. This is especially important with a drug that has a Narrow Therapeutic Index (NTI)(i.e., a drug in which the therapeutic dose is very close to the toxic dose). Examples of drugs with NTI are as follows: Anticonvulsant: phenytoin (Dilantin) . . . Anticoagulants: warfarin (Coumadin) . . . .
>
> **"Frequency of Error"** - If an error is occurring with any frequency, there is more reason to classify the error as significant. For example, if a resident's drug was omitted several times . . . , classifying that error as significant would be in order. This conclusion should be considered in concert with the resident's condition and the drug category.

ALJ Decision at 12-13, quoting the SOM, App. PP (tag 333) (bold in original; underlining added). Nothing in the guidance suggests that section 483.25(m)(2) requires a showing of actual harm (as Life Care argues here). Indeed, if the test of significance were limited to situations where a resident was actually harmed, CMS's discussion of the three factors would be superfluous. Where actual harm has resulted, the Board has discussed it as one reason for concluding that an error was significant, but actual harm is not a prerequisite for such a conclusion.

Here, as the ALJ discussed, the medication errors at issue involved all three of the aforementioned factors and put "[these] residents at risk for harm." ALJ Decision at 14. First, R22 and R25's conditions required "rigid control" as both residents evidenced additional risk factors for Coumadin therapy, including being of advanced age, having a history of highly variable INRs, and taking other medications, such as antibiotic therapy, that could interact with Coumadin. SOM, App. PP (tag 333); ALJ Decision at 14, citing Tr. at 345, 350, 365. Second, it is undisputed that Coumadin falls in the category of drugs that must be "titrated to a specific blood level" and have a "narrow therapeutic

index." SOM, App. PP (tag F333); *see* ALJ Decision at 14. Third, the errors were committed multiple times for each resident in a relatively short period of time. ALJ Decision at 9-10. The surveyor, a nurse with Coumadin experience, testified that, while not all Coumadin errors are significant medication errors (Tr. at 93, 95), a single error dose can be a problem for a person with an unstable INR (*id.* at 115) and that "the pattern [of errors] as established here" was significant (*id.* at 117). These considerations properly led the ALJ to conclude that the errors jeopardized the residents' health and safety and constituted significant medication errors under section 483.25(m)(2). Accordingly, the ALJ concluded Life Care was not in substantial compliance with section 483.25(m)(2).

Below, we explain why we reject other arguments made by Life Care on section 483.25(m)(2).

1. Life Care's experts misunderstood the applicable regulatory standard and did not otherwise establish that there was no "significant medication error" under 42 C.F.R. § 483.25(m)(2).

Life Care argues that the ALJ failed to properly credit its witnesses' testimony that the errors with respect to R22 and R25 were not "significant medication errors" under section 483.25(m)(2). *See, e.g.*, RR at 22-25. We reject this argument because, as the ALJ recognized, the witnesses plainly misunderstood the regulatory standard. ALJ Decision at 13. They testified that, in their view, "significant medication errors" include only those errors that cause actual harm. On direct examination, Dr. Clark testified that:

> As a clinician, my idea of significant error is that it has caused harm and damage to the patient. That's what I would consider significant.

Tr. at 341. In response to a question on cross examination, Dr. Clark further testified as follows:

> Q. What would be your response to this statement, "Medication errors then would not be significant unless a resident has some sort of documentable bad outcome or injury from the error"?
>
> A. Correct.

Id. at 371.

Similarly, the Regional Director for Clinical Services for Life Care Centers of America (regional director), who is a registered nurse, testified that the medication errors in this case "were not significant" because "there was no adverse outcome to the residents." *Id.* at 240; *see also id.* at 254-255. She therefore concluded, "based on my understanding of the Regulation, [the medication errors here] would not be considered significant errors." *Id.* at 255; *see also id.* at 232.

Moreover, for the following reasons, the ALJ's conclusion that these errors jeopardized R22's and R25's health and safety is not inconsistent with these witnesses' other testimony.

- Although Life Care's witnesses testified they believed R22 and R25 suffered no actual harm from the mistakes, they did not testify that the medication errors did not have the potential to cause more than minimal harm. For example, in answering a question as to whether missed doses could be a "big deal," Dr. Clark stated "it shouldn't be if it did not cause any harm to the patient." *Id.* The focus of the answer was on whether the resident was actually harmed by the medication error. Dr. Clark's testimony did not address the *potential* for harm from incorrect successive doses or the extra dose given to a medically fragile elderly person. Moreover, it is reasonable to infer from Dr. Clark's explanation of what she tells people about missed doses that taking two doses of Coumadin on one day is not a safe practice. *Id.* at 372 (stating that she tells patients who have missed a dose on one day "don't double your dose the following day"); *see also Life Care Center of Tullahoma*, DAB No. 2304, at 44 (it is reasonable to infer from nurse practitioner's reaction to a medication error that there was a potential to cause harm to the resident). Indeed, Dr. Clark acknowledged that "there's always the potential harm in Coumadin therapy in any patient whether healthy, not healthy, with multiple medical problems." Tr. at 372; *see also* i*d.* at 367 ("[F]or my elderly patients on multiple medications and multiple other medical problems, they can be very highly sensitive to Coumadin.").

- Dr. Clark testified that it was "unlikely" that the extra dose of Coumadin on March 26th resulted in R22's critically high INR on March 28 because the extra dose "would have reflected three or four days after" March 26 and therefore "would not have reflected in the March 28th result . . . ." *Id.* at 360. Thus (according to Dr. Clark) the extra dose was counteracted by the Vitamin K administered on the 28th after an INR test revealed R22's critically high INR. *See id.* at 353, 360. However, she did not testify that the extra dose, as it took effect, would not jeopardize R22's health or that, absent the Vitamin K, it would not have raised his critically high INR even further.[7]

Finally, undiscovered dosage errors (which the ALJ found these were) "make it nearly impossible for the physician to correctly determine whether the dosage prescribed was the correct therapeutic dose for that patient" because the doctor is assuming, in monitoring the resident's response, that the prescribed amount of Coumadin was administered while the resident had in fact received a different dosage. ALJ Decision at

[7] The fact that R22's need for Vitamin K was discovered shortly after the extra dose was administered was fortuitous for R22 and the facility. However, this fortuity does not make the extra dose insignificant because the extra dose could have easily been given three or four (or more) days before an INR test, in which case it would have had its full negative impact on R22.

17. Thus, subsequent INRs, which are meant to inform the doctor about the effect of prescribed doses, are unreliable and place residents at risk of having their Coumadin adjusted (or not adjusted) based on incorrect assumptions.

2. R22's and R25's highly variable INRs made it more likely that errors in administering Coumadin would jeopardize their health and safety.

It is undisputed that R22 and R25 had highly variable INRs. Tr. at 350-353; 365. Life Care repeatedly relies on this fact in arguing that the medication errors were not significant. *See, e.g.*, RR at 13-14, 20, 25. Life Care does not, however, point to any evidence indicating that Coumadin medication errors pose less risk to individuals with unstable INRs than to individuals with stable INRs.

Indeed, contrary to what Life Care argues, unstable INRs would make the accurate administration of Coumadin even more critical because, according to Coumadin's manufacturer, "[r]isk factors for bleeding" include "highly variable INRs." www.coumadin.com. Moreover, as discussed by the ALJ, unknowingly underdosing or overdosing the residents risked undermining the predictive value of their INRs and Dr. Clark's future efforts to titrate the doses to achieve therapeutic Coumadin ranges for these unstable residents. *See* ALJ Decision at 14, 17.

3. The fact that Life Care administered many other doses of Coumadin during this period without being cited for errors is not relevant.

Life Care argues that the cited errors are insignificant because "the number of errors . . . was miniscule in relation to the total number of Coumadin doses [its] nurses administered during the pertinent period [i.e., 142 days of alleged noncompliance]." RR at 23.

This argument conflates the purpose of subsection 483.25(m)(2) with that of subsection 483.25(m)(1), which requires a facility to ensure that it does not have a medication error rate that is greater than five percent. Furthermore, the factual premise of this argument is not supported by the evidence in the record.

The medication error regulation, section 483.25(m), addresses two aspects of medication administration: (1) an excessive rate of errors and (2) errors that are, in themselves, medically significant.[8] As CMS explained in the preamble:

> Since medication errors vary in their significance (e.g., from significant errors such as a double dose of a potent cardiac drug

[8] Section 483.25(m) provides: "Medication Errors. The facility must ensure that (1) It is free of medication error rates of five percent or greater; and (2) Residents are free of any significant medication errors."

> like digoxin to a small error in the dose of an antacid like milk of magnesia), we have based sanctions on two different criteria. First, if a facility has a significant medication error, then it is sanctioned. This policy satisfies consumers, who maintain that a five percent tolerance in medication errors is too lenient and that one medication error could be disastrous for a resident. Second, a facility is sanctioned if it has an error rate of five percent or greater. This satisfies providers who maintain that there must be some tolerance of errors because all systems have some errors . . . .

56 Fed. Reg. at 48,853 (emphasis added).

Under section 483.25(m)(2), as opposed to section 483.25(m)(1), the number of errors in relation to the doses administered (i.e., the rate of error) is irrelevant.

Moreover, the record in this case does not support Life Care's assertion that its nurses administered "3000 doses of Coumadin" correctly during this period. RR at 23. First, the surveyors cited the errors they found in reviewing a sample of six residents prescribed Coumadin; they found multiple errors for two of the six – a third of the sample. ALJ Decision at 9. The surveyors' findings therefore do not establish that Life Care correctly administered Coumadin to residents not in the sample.[9] Second, Life Care cites no evidence purporting to show that it did correctly administer doses of Coumadin to other residents receiving Coumadin over this period. (A Life Care witness testified only that she examined the records of R22 and R25 and found that, from March to August, the amount of Coumadin given did not "exceed the threshold given the rest of [their] medications." Tr. at 240; *see also id*. at 227 (regional director found no transcription errors for doctor's telephone orders for these residents).) Indeed, at the hearing when CMS attempted to question the regional director about an AAR from April allegedly showing missed Coumadin doses for R22 (P. Ex. 19), Life Care successfully objected to this line of inquiry. Tr. at 290-299.

Therefore, Life Care's assertion that it accurately administered all other Coumadin doses during this period is neither relevant nor supported by the record.

B. The ALJ's determination that Life Care failed to show that CMS's immediate jeopardy determination was clearly erroneous is supported by substantial evidence in the record as a whole and free of legal error.

[9] Life Care asserts, without citation, that "CMS' witnesses testified that they found no medication errors of any kind – relating to Coumadin or otherwise – between a handful in March and a handful in July, 2007." RR at 28. We do not see any such testimony in the record.

"Immediate jeopardy" is defined as "a situation in which the provider's noncompliance with one or more requirements of participation has caused or is likely to cause, serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301 (emphasis added). A finding of actual harm is not a prerequisite for a finding of immediate jeopardy. ALJ Decision at 17, citing *Stone County Nursing & Rehab Center*, DAB No. 2276, at 19 (2009).

The regulations governing this appeal require that "CMS's determination as to the level of noncompliance of a skilled nursing facility or a nursing facility must be upheld unless it is clearly erroneous." 42 C.F.R. § 498.60(c). Under that standard, CMS's determination of immediate jeopardy here is presumed to be correct, and Life Care has a heavy burden to demonstrate clear error in that determination. *See Brian Center Health and Rehabilitation/Goldsboro*, DAB No. 2336, at 9 (2010), *citing Barbourville Nursing Home*, DAB No. 1962, at 11 (2005), *aff'd, Barbourville Nursing Home v. U.S. Dep't of Health & Human Servs.*, No. 05-3241 (6th Cir. April 6, 2006). Moreover, once CMS presents evidence supporting a finding of noncompliance, CMS does not need to offer additional evidence to support its determination that the noncompliance constitutes immediate jeopardy; rather, the burden is on the facility to show that that determination is clearly erroneous. *Liberty Commons Nursing and Rehab Center–Johnston*, DAB No. 2031, at 18-19 (2006), *aff'd*, *Liberty Commons Nursing and Rehab Center – Johnston v. Leavitt*, 241 F. App'x 76 (4th Cir. 2007); *see also Barbourville Nursing Home*, DAB No. 1962, at 11.[10]

For the reasons discussed below, the ALJ correctly determined that Life Care failed to prove that CMS's finding of immediate jeopardy was clearly erroneous.

1. Life Care repeatedly misadministered a dangerous drug that is commonly used in nursing facilities.

Life Care misadministered alternating doses of Coumadin four times to R22 in March and three times to R25 in July. Coumadin has a narrow therapeutic range and can result in blood clots below the therapeutic range and bleeding above that range. Nursing home residents often require such anticoagulants. Tr. at 342 (at "any given time" 20 to 25 residents at Life Care are receiving Coumadin). The use of alternating doses (as with R22 and R25) to achieve therapeutic levels of the drug is not uncommon in nursing homes. *Id*. at 129, 356, 368. Therefore, the opportunity for such errors to reoccur with these or other residents was present here.

[10] Life Care cites *Grace Healthcare of Benton v. DHHS*, 598 F.3d 926 (8th Cir. 2009). *Grace Healthcare* stated that an ALJ's determination that a facility has failed to show that CMS's immediate jeopardy finding was clearly erroneous must be supported by substantial evidence in the record as a whole. It did not, as Life Care tries to assert here, disturb the Board's holding in *Liberty Commons* or criticize the Fourth Circuit's affirmance of *Liberty Commons*. RR at 18.

In disputing the immediate jeopardy determination, Life Care repeatedly argues that these errors were of no "clinical" significance. *See, e.g.*, RR at 2, 14, 19, 21; P. Reply at 1, 10. We take this to be a reference to its witnesses' testimony that, in their opinion, these the errors had not resulted in actual harm to R22 and R25. Tr. at 240, 255, 341, 372. Because actual harm is not required to support a finding of immediate jeopardy, this testimony is not relevant and does not demonstrate that CMS's immediate jeopardy determination was clearly erroneous.

Similarly, Life Care's evidence does not establish that CMS was clearly erroneous in concluding that these errors were likely to cause serious harm. That evidence includes the following:

- When asked directly whether the medication errors at issue were likely to cause serious harm, the regional director did not address the risk posed by the extra dose of Coumadin given to R22 on March 26. Tr. at 258. His answer as to the other medication errors focused on the facts that R22's underdoses (on March 12, 16, and 19) and R25's overdoses occurred at a time that R22's coumadin level became elevated and R25's was low.[11] *Id.* In other words, here as elsewhere, the regional director's answer focused on *what happened* instead of what could have happened or what was *likely to happen* if residents did not receive their proper doses of Coumadin.

- As for the error on March 26 and the INR of 8.7 on the 28th, Dr. Clark agreed that this INR was "critically high which means immediate attention is necessary" (*id.* at 359) and that R22 was given Vitamin K in response to the INR (*id.* at 353-354). However, neither she nor the regional director addressed the risk the extra dose would have posed if R22 had not had his INR measured and received Vitamin K on March 28.

- When the doctor was asked about R22's history of high INRs, she agreed that there was no "time when [she] was alarmed at or where his condition was so serious that he was at risk of significant harm." *Id.* at 353. However, this testimony was preceded and followed by her testimony about the need to give R22 Vitamin K as an "immediate intervention" to address these high INRs. *Id.* at 353-

[11] Q. Now in your clinical opinion, your opinion as a clinician, were any of the errors that we've pointed to here likely to cause serious harm or death to either of the residents?
A. The errors themselves, no.
Q. And why do you say that?
A. Because in one circumstance they're getting less than what was ordered. Which less Coumadin in his order would result in a lower blood level of the Coumadin which would result in a longer time to clot. The other resident received more Coumadin than what was ordered on a previous illustration which actually benefited the resident which is really bizarre because it actually brought their level up closer to therapeutic range. Had it been administered the way it was ordered, it would have been lower which would have put the resident at more risk for clotting. Tr. at 258.

> 355. The fact that Vitamin K is an antidote for a critically high INR, however, does not mean that that critically high INR does not pose a risk of serious harm.

Therefore, Life Care's witnesses' testimony provided no basis for the ALJ to conclude that CMS's determination of immediate jeopardy was clearly erroneous.

2. Life Care's INR testing did not remove the risk of serious harm from its misadministration of Coumadin.

Central to Life Care's argument that these or other medication errors posed no risk of serious harm was its assertion that it conducted frequent and regular INR testing and relied on these tests as "audits" of Coumadin administration.[12] Tr. at 257; *see, e.g.*, RR at 13, 14, 22, 25, P. Reply at 3. Life Care represents that "the evidence shows that [the residents at issue] received blood tests every few days." RR at 1.

We reject this argument for the following reasons. First, the INR testing records submitted by Life Care do not show routine testing every few days or even weekly. P. Exs. 31, 44. For example, R22, who was misdosed in March, was tested only once in February and just twice in March. P. Ex. 31. R25, who was misdosed in July, was tested on June 27 with an order to "recheck INR 7/25/07." P. Ex. 42, at 18. Second, while it is apparent from the record that Dr. Clark used the INR results to audit and adjust residents' Coumadin dosage (P. Exs. 25, 42), the type of undiscovered administration mistakes evidenced here risked making this "audit" process unreliable. ALJ Decision at 14, 17. Third, as discussed below, Life Care has not shown that it, as opposed to the doctor, was using the tests that it did conduct to "audit" its administration of Coumadin to determine if staff was making errors.

3. Life Care failed to discover, or take corrective action on, any of these errors until the surveyors identified them.

The ALJ found that Life Care was unaware that its staff had made these errors until they were identified by the surveyors. ALJ Decision 14, 18. This fact indicates that Life Care was not, as its argues here, using the INR results to "audit" its staff's administration of Coumadin and this failure makes additional errors in R22's and R25's Coumadin administration as well as that of other residents more likely.

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[12] Life Care makes repeated representations about such testing, asserting that its Coumadin "medication regimen . . . featured meticulous blood testing" (P. Reply at 3); that this "frequent testing" was "central to the regimen" here (RR at 22); that it was "close[ly] monitoring [INRs] as frequently as every few days" (RR at 7); that R22's INR levels "were taken routinely at least every week" (RR at 13); that Dr. Clark expressed no alarm about R22's March 28 INR because of her reliance on a "regimen what consisted of several elements, including *frequent* testing . . ." (RR at 14 (emphasis in original)); and that for R22 "it was the frequent monitoring, and not a specific dose of Coumadin, that was the most important part of the overall regimen" (RR at 14).

Life Care disputes the ALJ's finding about its failure to discover these errors only as to the March 26 error. RR at 10, n.6. For the following reasons, we conclude that the ALJ's finding about the March 26 error is supported by substantial evidence in the record as a whole.

As evidence that it discovered the March 26 error before it was identified by the surveyors, Life Care relies on an "Incident Follow-up & Recommendation Form" and an "Incident/Accident Data Entry Questionnaire" that it completed on the March 26 error. P. Ex. 32. The only person who testified about the documents, the regional director, had no present recollection about being notified of the mistake in March, as the follow-up form indicated he was. Tr. at 280-281. The ALJ found his testimony that the forms established that he was notified on March 28 (and, by implication, that the forms were in existence before the July/August survey) not credible because other senior staff did not sign the forms or enter the incident into Life Care's Incident Data Archive until after the survey. ALJ Decision at 10 n.9. Moreover, the facts that the documentation indicates that the offending nurse was first corrected for this mistake after the survey (P. Ex. 33) and could not remember her actions on March 26 at the time of the facility's August investigation (RR at 10 n.6; Tr. at 230) are consistent with the conclusion that there was no contemporaneous investigation of this error.[13]

Moreover, Life Care's failure to discover the medication errors as to R22 is disturbing in light the obviousness of the errors on the AAR. The nursing supervisor testified that "everyone" that "handles the clinical records" is responsible for identifying errors. Tr. at 306. The March AAR shows that, in the vertical column for March 26th unlike any other column, there are two initials, indicating that R22 was given Coumadin twice instead of once. P. Ex. 27, at 13. In the column for the 28th and 29th, a nurse wrote "hold" because of the high INR. The lack of persuasive evidence that she reported any error at the time indicates the nurse failed to notice, or at a minimum failed to report, the two initials on the 26th evidencing the extra dose, or the fact (obvious on the face of the document) that the initials earlier in the month did not alternate as ordered between the horizontal lines designated for the 5 mg and the 7.5 mg doses. Even a cursory review of the AAR after March 26 should have alerted the nurses handling it that mistakes had been made. These facts indicate that Life Care's staff was not alert or responsive to obvious anomalies in its Coumadin administration records.

Finally, even if Life Care did discover the March 26 error prior to the survey, it failed to show or even allege on appeal that it took any corrective action on discovering the error to prevent future errors, such as the similar errors which then occurred in July.

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[13] On appeal, Life Care alleges that its March 26 time records show that the offending nurse left the facility prior to the time for Coumadin administration and that the extra dose recorded on the AAR was only a "documentation error." RR at 9-10. To the extent Life Care is arguing the extra dose did not happen, we reject this argument. Life Care does not identify and we are unaware of supporting time records in the record; the nurse who documented the extra dose did not testify, and Life Care's regional director conceded that, in nursing, when an action is documented "then we have to believe it." Tr. at 230.

C. The ALJ did not err in concluding that the duration of the CMP was supported by law.

The ALJ upheld CMS's imposition of a CMP of $3,050 per-day, the minimum per-day amount under immediate jeopardy, from March 28 through August 14, 2007, 142 days. As Life Care recognizes, the start date of the CMP correlated to the day R22 received a extra dose of Coumadin. RR at 27. Life Care protests, however, that "the ending point seems to correlate only with the day in August when [Life Care] terminated the CNA [involved in a different citation]." *Id.* at 27; *see also* P. Reply at 30. This is incorrect. As the ALJ stated, the "duration of the penalty is in direct correlation with days that [Life Care] was not in substantial compliance with participation requirements [at the immediate jeopardy level]," which the ALJ found to be from the extra dose on March 26 to "August 15, 2007, when [Life Care] submitted a multi-step corrective action plan with respect to the administration of Coumadin, which was implemented and the state verified that the plan removed the immediate jeopardy situation." ALJ Decision at 18; *see also* Tr. at 138.

Life Care argues that "there is no basis for a CMP extending for 142 days." RR at 27. Life Care's arguments are without merit.

Longstanding Board precedent holds that the regulatory scheme governing noncompliance "assumes that any deficiency that has a potential for more than minimal harm is necessarily indicative of problems in the facility which need to be corrected**.**" *Lake City Extended Care Center*, DAB No. 1658, at 14 (1998). Thus, "a facility's noncompliance is deemed to be corrected or removed only when the incidents of noncompliance have ceased and the facility has implemented appropriate measures to ensure that similar incidents will not recur." *Florence Park Care Ctr.*, DAB No. 1931, at 30 (2004) (emphasis added), citing *Lake City*, DAB No. 1658, at 14. Similarly, immediate jeopardy is deemed to have been removed only when the facility has implemented necessary corrective measures. *See Fairfax Nursing Home, Inc.*, DAB No. 1794 (2001) (finding that the SNF had taken inadequate steps to abate the immediate jeopardy), *affd, Fairfax Nursing Home v. Dep't of Health & Human Servs.*, 300 F.3d 835 (7th Cir. 2002), *cert. denied*, 537 U.S. 1111 (2003). Finally, "[a] determination by CMS that a SNF's ongoing compliance remains at the level of immediate jeopardy during a given period ... is subject to the clearly erroneous standard of review under [42 C.F.R. §] 498.60(c)(2)." *Brian Center*, DAB No. 2336, at 7-8.

Life Care argues that, even if the extra dose on March 26 did pose immediate jeopardy, there is a "fundamental problem with applying [in this case] any 'presumption' that such noncompliance continued unabated for any period of time." RR at 27. Life Care points to cases in which medication errors occurred over "lengthy courses" or "extended periods" or cases which the errors "illustrate systemic breakdowns" in medication management. *Id.* at 27-28. It argues that, in those cases, "it is a straightforward exercise to construct a legal and logical

rationale for a period of continuing noncompliance that extends through the correction of the systemic problem, training of staff, monitoring the corrective action, etc." *Id.* at 28. Life Care asserts that there were no such "systemic" errors here and that these were merely "isolated human errors" and therefore no presumption should apply. *Id.* at 29.

We reject these arguments. As explained above, CMS is not required to prove that medication errors occurred over any particular time period or involved systemic failures. Moreover, Life Care has failed to show that it was clearly erroneous to rely on this presumption where: (1) staff repeatedly misadministered a commonly used and dangerous drug to residents; (2) Life Care was unaware that its staff had made these errors until they were identified by the surveyors even though the errors were apparent on the AARs and one immediately preceded the discovery of a critically high INR; (3) Life Care's assertions that other procedures (such as INR testing and use of INRs to audit medication administration) necessarily protected residents from such mistakes are not supported by the evidence; and (4) even if we accept Life Care's assertion that it did timely identify the March 26 error, there is no evidence that Life Care, on identifying it, took action to ensure that its staff did not continue to misadminister Coumadin and continue to fail to recognize errors that were apparent on the AARs.[14]

Having not taken earlier action to correct the noncompliance, Life Care cannot now complain about a presumption that a finding of noncompliance indicates that a facility has a problem that needs to be corrected and continues until the facility demonstrates that it has been corrected.

Life Care also asserts that CMS's arguments in support of an immediate jeopardy penalty of this duration "are illogical and serve no regulatory purpose." P. Reply at 14. We disagree. Surveyors review only a small fraction of care that is provided in long-term care facilities. The quality of that care must therefore rest primarily on the diligence of facilities in complying with federal participation standards, in ascertaining when they fail to comply, and in addressing such failures. The presumption of continuing noncompliance and resulting CMPs give facilities an incentive to recognize and self-correct noncompliance and to remain in substantial compliance whether or not surveyors are on the scene. *See* 59 Fed. Reg. 56,116, at 56,206 citing H.R. Report No. 391, 100th Cong., 1st Sess., 473-6 (1987), and 56,175 (1994); *Mountain View Manor*, DAB No. 1913, at 3-4, 12 (2004).

[14] If Life Care had corrected the noncompliance in March or April, CMS could still have elected to impose a CMP, but the CMP would have been of shorter duration. Section 1819(h)(1) of the Social Security Act provides that CMPs may be imposed on a finding of noncompliance in a "previous period." The implementing regulations provide that CMS may impose a CMP "for the number of days of past noncompliance since the last standard survey, including the number of days of immediate jeopardy." 42 C.F.R. § 488.430(b).

Conclusion

For the reasons stated above, we affirm the ALJ Decision.

_____/s/_____
Judith A. Ballard

_____/s/_____
Leslie A. Sussan

_____/s/_____
Stephen M. Godek
Presiding Board Member