Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Agape Rehabilitation of Rock Hill
Docket No. A-11-76
Decision No. 2411
September 9, 2011

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Agape Rehabilitation of Rock Hill (Agape) appeals the March 9, 2011 decision of Administrative Law Judge (ALJ) Carolyn Cozad Hughes upholding a determination by the Centers for Medicare & Medicaid Services (CMS) to impose remedies on Agape for its noncompliance with requirements for long-term care facilities participating in the Medicare program. *Agape Rehabilitation of Rock Hill*, DAB CR2335 (2011) (ALJ Decision). CMS made its determination based on the results of a recertification survey completed by the South Carolina Department of Health and Environmental Control (state agency) on July 31, 2009. The ALJ, with the parties' agreement, made her decision based on the written record, which she reviewed de novo. The ALJ concluded that Agape was not in substantial compliance with the Medicare participation requirements at 42 C.F.R. §§ 483.20(k)(3)(i), 483.25, 483.25(h) and 483.75(j)(2)(ii). The ALJ also concluded that CMS's determination that the noncompliance with sections 483.20(k)(3)(i), 483.25 and 483.75(j)(2)(ii) posed immediate jeopardy to resident health and safety was not clearly erroneous and that the civil money penalties (CMPs) imposed by CMS were reasonable.

Agape appeals the ALJ's conclusions that it was not in substantial compliance with sections 483.20(k)(3)(i), 483.25 and 483.75(j)(2)(ii); that CMS's determination of immediate jeopardy with respect to this noncompliance was not clearly erroneous; and, that the CMP amounts were reasonable. 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. § 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) which identifies each "deficiency" under its regulatory requirement.

"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." *Id.*

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. CMS has the option to impose a CMP whenever a facility is not in substantial compliance. 42 C.F.R. § 488.430. CMS may impose per-instance or per-day CMPs. *Id.* There are two ranges of per-day CMPs, with the applicable range depending on the scope and severity of the noncompliance. 42 C.F.R. § 488.438(a)(1). The 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). The range for noncompliance that is not immediate jeopardy is $50-3,000 per day. 42 C.F.R. §§ 488.438(a)(1)(ii), 488.408(d)(1)(iii). When CMS imposes one or more of the alternative remedies in section 488.406 for a facility's 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[1]

1. The survey, CMS determinations and ALJ proceedings

Based on the state agency's July 31, 2009 survey, CMS found Agape out of compliance with 14 requirements for long-term care facilities participating in Medicare. ALJ Decision at 2-3, 27; CMS Ex. 2 (SOD); CMS Ex. 3 (August 14, 2009 notice letter). CMS determined that the noncompliance with three requirements – 42 C.F.R. § 483.20(k)(3)(i), 483.25 and 483.75(j)(2)(ii) – posed immediate jeopardy to resident health or safety. ALJ Decision at 3; CMS Exs. 2, 3. CMS subsequently determined, based on revisit surveys, that the immediate jeopardy was abated as of August 5, 2009, and that Agape returned to substantial compliance with all requirements on August 24, 2009. ALJ Decision at 3; CMS Exs. 5, 54. CMS imposed remedies that included CMPs 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 noncompliance that was not immediate jeopardy (August 5 through 23, 2009) for a total CMP of $108,750.[2] ALJ Decision at 3; CMS Exs. 3, 5, 54.

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[1] 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.

[2] CMS also imposed a denial of payment for new admissions (DPNA) effective August 16, 2009 until Agape returned to substantial compliance. CMS Exs. 3, 54. Agape's request for review does not challenge the DPNA.

Agape appealed only five of the findings of noncompliance (including the three cited at the immediate jeopardy level) to the ALJ: 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/professional standards of quality); 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). ALJ Decision at 5. The ALJ upheld the findings of noncompliance with sections 483.20(k)(3)(i), 483.25 and 483.75(j)(2)(ii) and 483.25(h). She also upheld the immediate jeopardy determinations for sections 483.20(k)(3)(i), 483.25 and 483.75(j)(2)(ii). The ALJ concluded that she did not need to address the alleged noncompliance cited under section 483.13(c), "because the deficiency findings I have sustained, as well as the unappealed deficiencies, more than justify the penalties imposed."[3] ALJ Decision at 20, n.17.

2. Undisputed facts regarding anti-coagulant drugs and Agape's policies and procedures

Agape appeals to the Board only the ALJ's conclusions of noncompliance with sections 483.20(k)(3)(i), 483.25 and 483.75(j)(2)(ii). The facts underlying these conclusions center on alleged deficiencies in Agape's management of its residents' anticoagulant medications, deficiencies that the ALJ found placed the health and safety of Resident 41 (R41) and five other residents in immediate jeopardy.[4] ALJ Decision at 6-20.

a. Anti-coagulant drugs

Anticoagulant drugs such as Coumadin[5] and Lovenox help inhibit blood clot formation and are often prescribed for individuals with a history of inappropriate clotting associated

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[3] The ALJ also held that she had no authority to address constitutional issues Agape raised. ALJ Decision at 5. Agape alleges no error in that holding but preserves the alleged constitutional issues for judicial review. RR at 2, n.1. Agape asserts that CMS waived its opportunity to respond to the arguments Agape made on those issues. *Id.*, citing *Guardian Care Nursing & Rehabilitation Center,* DAB No. 2260 (2009). CMS disagrees, asserting that it merely recognized that the ALJ did not have authority to address the arguments. CMS Response at 4, n.3. *Guardian Care* does not support Agape's waiver argument. The ALJ in that case ruled that CMS waived its right to rely on deficiencies cited during the survey that CMS failed to address in its briefing or its motion for summary judgment, not that CMS waived its right to respond to constitutional arguments. The Board did not review the waiver ruling since CMS did not challenge it on appeal. Agape also asserts that CMS did not give notice of the statutory basis for the remedies imposed, but CMS correctly points out that its notice letter (CMS Ex. 3, at 1) opens with a reference to section 1819 of the Social Security Act. Section 1819(h)(2) authorizes the Secretary to impose remedies, including CMPs, for a long-term care facility's noncompliance.

[4] Agape does not appeal the ALJ's conclusion that it was not in substantial compliance with section 483.25(h) "because staff did not take reasonable steps to prevent foreseeable accidents [multiple falls sustained by one resident]; . . . consistently follow care plan instructions for preventing accidents and . . . adjust interventions that proved ineffective." ALJ Decision at 20-25. Accordingly, that conclusion and nine other findings of noncompliance that Agape did not appeal to the ALJ are final and binding.

[5] Coumadin is a brand name for Warfarin Sodium. RR at 5, citing P. Ex. 30; *see also* CMS Response at 4 (stating that Warfarin is the generic name for Coumadin); CMS Ex. 39 (manufacturer's notice); P. Ex. 13 at 14-16 (Jones Declaration (Decl.)(using the terms "Coumadin" and "Warfarin" interchangeably).

with such conditions as heart attacks, strokes or deep vein thrombosis. ALJ Decision at 6, citing CMS Exs. 38, 39; Petitioner (P.) Ex. 33, at 6. Bleeding is a major complication associated with anticoagulant drugs. *Id.*, citing P. Ex. 30. For that reason, blood levels must be monitored carefully to assure that they are within a safe and therapeutic range. *Id.*, citing CMS Ex. 39, at 2. Residents risk bleeding complications if levels are too high and stroke if levels are too low. *Id.*, citing 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." *Id.*, citing P. Ex. 13, at 14 (Jones Decl.); P. Ex. 30, at 5-6.

The ability of blood to clot properly is evaluated by means of a prothrombin time/international normalized ratio (PT/INR) test. ALJ Decision at 7, citing 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." *Id.* "A very low INR suggests the risk of a blood clot." *Id.* "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." *Id.*, citing CMS Ex. 39, at 4. "According to the manufacturer, an INR above 4.0 exposes the patient to a higher risk of bleeding without providing any additional therapeutic benefit." *Id.* The manufacturer provides a black box warning that Coumadin can cause major or fatal bleeding and that this is more likely to occur during the starting period of the medication. *Id.* An INR greater than 4 and being 65 or older are among the risk factors for bleeding. *Id.*, citing CMS Ex. 39, at 1. Physicians treating deep vein thrombosis commonly prescribe subcutaneous Lovenox, as well as Coumadin, until the patient's blood levels reach a therapeutic level and discontinue the Lovenox when the patient's INR reaches 2.0 to 3.0. *Id.*, citing P. Ex. 31, at 3; CMS Ex. 38, at 7.

b. Agape's policies and procedures

Meridian Laboratory provided the bulk of Agape's laboratory services pursuant to a written contract with Agape. *Id.*, citing P. Ex. 8.[6] Under the contract, Meridian agreed to send a phlebotomist to Agape on Tuesdays and Thursdays to perform routine blood draws. *Id.*, citing P. Ex. 8, at 5. Meridian also agreed to inform Agape of critical lab values by telephoning that information to the facility after completing the tests. *Id.*, citing P. Ex. 8, at 4; P. Ex. 2, at 3 (Henderson Decl. ¶21); CMS Ex. 35; *see also* RR at 7 (admitting Meridian required to follow this procedure). Meridian further agreed that it would give Agape routine lab results within 24 hours. *Id.*, citing P. Ex. 8, at 4. According to Agape's administrator, "non-critical lab results were 'typically faxed' to the office of the facility's nurse manager at some time in the afternoon." *Id.*, citing P. Ex. 2, at 3 (Henderson Decl. ¶¶19, 22); CMS Ex. 35.

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[6] Another laboratory provides emergency PT/INRs needed after hours and on weekends and holidays. RR at 7.

Agape's policies and procedures require staff to notify immediately Agape's nurse practitioner or the resident's attending physician of any critical test result received from the laboratory. *Id.*, citing P. Ex. 9 (Brown Decl. ¶5) ("The Facility's standard procedure is to immediately notify me or the resident's Attending Physician if a critical lab result is reported."); CMS Ex. 35; *see also* RR at 7 (admitting this is the procedure for critical lab results). The facility also had standing orders for Coumadin that required staff to decrease dosages by 0.05 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. ALJ Decision at 7. "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." *Id.*, citing CMS Ex. 32, at 15; CMS Ex. 40.

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 (Guidelines) (accessible 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).

Discussion

A. The ALJ's conclusion that Agape was not in substantial compliance with sections 483.25, 483.20(k)(3)(i) and 483.75(j)(2)(ii) because it did not follow its procedures for immediately notifying the attending physician (or nurse practitioner) of a resident's critical laboratory test results is supported by substantial evidence and error free.

Under the Medicare Act and "quality of care" regulations at section 483.25, each nursing home 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. 42 U.S.C. § 1395i-3(b); 42 C.F.R. § 483.25. As the ALJ noted, the Board has held that the Act and regulation "impose on facilities an affirmative duty designed to achieve favorable outcomes 'to the highest practicable degree.'" ALJ Decision at 6, quoting *Windsor Health Care Ctr.*, DAB No. 1902, at 16-17 (2003); *Woodstock Care Ctr.*, DAB No. 1726 at 25-30 (2000), *aff'd*, *Woodstock Care Center v. Thompson*, 363 F.3d 583 (6th Cir. 2003). The regulations also provide that services arranged for its residents by a nursing facility must meet professional standards of care. 42 C.F.R. § 483.20(k)(3)(i). With respect to laboratory services in particular, the nursing facility is responsible for the timeliness and quality of the laboratory services it provides or obtains for its residents.

42 C.F.R. § 483.75(j)(1). The facility is required to "[p]romptly notify the attending physician of the [laboratory] findings." 42 C.F.R. § 483.75(j)(2)(ii).

1. *Substantial evidence supports the ALJ's finding that Agape failed to follow its protocol requiring immediate reporting of R 41's critical test result.*

With one exception, noted below, the facts regarding R41 are undisputed. R41 was an 87-year-old woman admitted to the facility on July 14, 2009 "for short term rehab" after surgery to repair a right hip fracture. Her medical history included breast cancer, depression and vitamin B12 deficiency, and she was diagnosed with deep vein thrombosis. CMS Ex. 19, at 9-10. Her prescribed medications included the anticoagulants Coumadin (5 mg daily by mouth at 6:00 p.m.) and Lovenox (60 mg. subcutaneously at 9:00 a.m. and 9:00 p.m.). *Id.*, at 20. R41's physician ordered PT/INR testing to commence on July 16, 2009 (a Thursday) and weekly thereafter on Tuesdays. *Id.*

On July 16, 2009, R41 had a critically high INR reading of 9.96. ALJ Decision at 8, citing CMS Ex. 19, at 3 (lab report stating the reading and terming it "critical"). According to the laboratory report, Meridian completed the testing at 1:32 p.m. that day and phoned the results to "Susan Rice" at 1:33 p.m. No individual named "Susan Rice" worked at Agape; however, Licensed Practical Nurse (LPN) Susan Brice was assigned to care for R41. *Id.*, citing CMS Ex. 19, at 15, 31, 35, 37. Agape denies learning of the critical lab results via a phone call, raising a factual dispute that for reasons we will explain later is ultimately immaterial. Agape does <u>not</u> dispute that the laboratory faxed the report containing the critical results to Agape on July 16, at 10:18 p.m. *Id.* Agape's administrator, however, states that the room to which it was faxed was locked so that staff would not have found the fax until July 17. ALJ Decision at 9.

Agape does not dispute that its staff did not convey the critical lab results to either the nurse practitioner or R41's attending physician until an unspecified time on July 17 and that nurses administered the 6:00 p.m. dose of Coumadin and 9:00 p.m. dose of Lovenox on July 16 and the 9:00 a.m. dose of Lovenox on July 17. ALJ Decision at 9, citing CMS Ex. 19, at 24. Agape's nurse practitioner stated that she was not notified of the lab results until "some time on July 17." *Id*,, citing P. Ex. 9 (Brown Decl. ¶7). On July 17, 2009, R41's physician issued an order (no time is stated) to hold the Coumadin for three days, discontinue the Lovenox and repeat the PT/INR on Tuesday, July 21. *Id.* at 10, citing CMS Ex. 19, at 17.

The ALJ concluded that Agape did not substantially comply with the requirements of sections 483.20(k)(3)(i), 483.25 and 483.75(j)(2)(ii) because its staff, disregarding Agape's own procedures, failed to notify R41's physician of her critically high INR test result (9.96) on July 16, the date the laboratory reported the result, and continued to give R41 the anticoagulants Coumadin and Lovenox, putting her at risk for more than minimal harm.

> 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. 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.

ALJ Decision at 9, citing CMS Ex. 19 at 24.

Agape contends that the ALJ's finding is not supported by substantial evidence. Agape refers to the incident involving R41 as a "one-time circumstance that occurred through no failure of the Facility to recognize the importance of taking the appropriate steps when notified of a critical lab value." RR at 18. Agape further asserts that it had "sufficient policies and procedures in place to monitor and administer anticoagulant therapy" and that the ALJ pointed out that CMS did not fault any of these procedures. RR at 12-13, citing ALJ Decision at 8. Agape misapprehends the issue. The ALJ did not base her noncompliance conclusion on Agape's failure to have sufficient policies or procedures but, rather, on Agape's failure to follow its policies and procedures – in particular the procedure requiring immediate notification of the nurse practitioner or the resident's physician of critically high test results – in the case of R41's undisputed critically high July 16 INR result. *See, e.g.*, ALJ Decision at 10 ("[Agape's][s]taff did not follow the facility's own protocol, which created the potential for more than minimal harm."). The ALJ concluded, and we agree, that she could reasonably rely on this protocol "as evidence of the facility's 'own judgment as to what must be done to attain or maintain its residents' highest practicable physical, mental and psychosocial well-being, as required by section 483.25.'" *Id.* at 11, citing *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)). We further agree with the ALJ that Agape's failure to follow its own protocol with respect to R41's critical test result supports a conclusion that Agape was not in substantial compliance with sections 483.25, 483.20(k)(3)(i) and 483.75(j)(2)(ii). *Id.*

Agape argues that its staff did not fail to follow the immediate notification protocol because staff did not learn of the critical lab result until sometime on July 17 and reported the result to the nurse practitioner that day. Agape's claim that staff did not learn about the result on July 16 is based here, as it was below, on its contention that the lab did not phone the result to the facility, despite the representation to the contrary in the lab report. Agape cites telephone records it obtained after the survey showing calls received by the facility between 1:15 p.m. and 1:45 p.m. on July 16. RR at 8-9, citing CMS Ex. 34; P. Ex. 34. Agape also cites a statement by LPN Brice in her declaration that she "could not recall the lab on July 16." RR at 8, citing P. Ex. 28, ¶ 5. Agape contends that LPN

Brice's declaration "affirmed that she did not recall receiving the call."[7] *Id.* at 13. CMS relies here, as it did below, on the statement in the laboratory report that a lab employee did make the call at 1:33 p.m.[8] Response at 7.

This ongoing factual dispute is not material to our decision because, as Agape acknowledges, while the ALJ stated that she found CMS's arguments on this factual dispute "compelling," she ultimately did not rely on those arguments. RR at 15. The ALJ concluded that she did not need to resolve this factual dispute "because federal regulations hold the facility as responsible for the actions of its contractors as it is for the actions of its employees." ALJ Decision at 9, citing 42 C.F.R. § 483.20(k)(3)(i); 42 C.F.R. § 483.75(j)(1). As we discuss next this conclusion is legally correct.

2. *The ALJ did not err in holding Agape responsible for the laboratory's alleged failure to notify it of the critical test results by phone.*

Agape contends that it cannot be found out of compliance based on what it alleges was a failure on the part of laboratory personnel rather than its own staff. "The federal regulations do not and cannot require that facilities be strictly liable for any and all actions of their contractors under any set of circumstances." RR at 15. Agape is incorrect. Applying the plain language of the regulations, as the ALJ did, is not imposing strict liability on Agape. Section 483.20(k)(3)(i) expressly provides that services "arranged" by the facility, as well as services directly provided by it, "must . . . [m]eet professional standards of quality." Section 483.75(j)(1) expressly provides that facilities must either provide or "obtain" laboratory services "to meet the needs of its residents" and that "[t]he facility is responsible for the quality and timeliness of the services."

There is no dispute that Agape arranged with Meridian Laboratory to provide professional services that Agape deemed necessary for quality, timely care of its residents, including performing PT/INR testing and reporting the results. Indeed, the record contains the contract securing and defining the terms of those services; one of the terms is reporting critical test results to the facility on completion of the tests. P. Ex. 8 at 4. Nor is there any dispute that the laboratory completed the test yielding R41's critically high INR reading at 1:32 p.m. on July 16. These facts are substantial evidence supporting the ALJ's conclusion that Agape failed to comply with the cited requirements by not notifying the nurse practitioner of R41's critical INR result until July 17 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

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[7] The ALJ noted, however, that LPN Brice stated later in the same declaration that she told the surveyor she notified the nurse practitioner of lab results on July 16. *See* ALJ Decision at 9, citing P. Ex. 28 (Brice Decl. ¶¶5, 7; CMS Ex. 19, at 5 (surveyor interview notes).

[8] Before the ALJ, CMS also relied on surveyor notes of an interview with a laboratory supervisor who reportedly assured the surveyor that a lab employee made the call, pointing out that the lab employee would not otherwise have known Ms. Brice's name, although the notation about the call on the lab report misspelled that name. ALJ Decision at 8, citing CMS Ex. 19, at 3, 41.

or other serious bleeding." ALJ Decision at 11, citing CMS Ex. 38, at 12; CMS Ex. 39, at 1.[9]

Holding Agape responsible for the services provided to its residents by contractors, as well as staff, is consistent not only with the plain language of sections 483.20(k)(3)(i) and 483.75(j)(1), but with the quality of care requirements in section 483.25. As the Board has explained in cases such as *Liberty Nursing and Rehabilitation Center – Mecklenberg County*, DAB No. 2095, at 8 (2007), *aff'd, Liberty Nursing Rehabilitation Center – Mecklenberg County v. Leavitt*, No. 07-1667 (4th Cir. 2008) –

> "[W]hile the regulations do not make facilities unconditional guarantors of favorable outcomes, the quality of care provisions do impose an affirmative duty to provide services . . . designed to achieve those outcomes to the highest practicable degree." Estes Nursing Facility Civic Center, DAB No. 2000, at 6, citing Woodstock Care Center v. CMS, DAB No. 1726, at 25, aff'd, Woodstock Care Ctr. v. Thompson, 363 F.3d 583 (6th Cir. 2003). The Sixth Circuit described the federal standard as "a higher standard than the common law." 363 F.3d at 590.

The Board recently reiterated this high affirmative duty in *Fort Madison Health Center*, DAB No. 2403 (2011), when rejecting a facility's argument that it could not be found noncompliant based on a contractor's failure to follow what the facility asserted was a term of its contract to provide services to facility residents. *See also Maysville Nursing and Rehabilitation Facility*, DAB No. 2317, at 13-14 (2010)(holding nursing home responsible for pharmacy reviewer's failure to identify irregularity in Coumadin therapy regimen). In addition, as the Board noted in *Maysville*, holding a facility responsible for the quality and timeliness of contract services arranged for its residents is consistent with section 483.75(h)(2)(i) which specifically makes a facility responsible for the quality of the services provided by "outside resources." DAB No. 2317, at 14.

Even if Agape could not be held responsible for the laboratory's alleged failure to phone R41's test results to the facility on July 16, this would not shield Agape from the findings of noncompliance with respect to its care of R41. As the ALJ noted, there is no dispute that the laboratory faxed the results to the facility at 10:18 p.m. on July 16 and that the facility could have avoided providing one dose of Lovenox to R41 had staff been able to retrieve the fax. ALJ Decision at 12, n.7. However, as the ALJ further noted, staff could not retrieve the fax because the receiving fax machine was in a locked office accessible only to the Nurse Manager during her work hours. *Id.* at 12, n.7 and 9-10. The ALJ reasonably concluded, "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

[9] We also share the ALJ's concern about the lack of documentation in the facility's records of information such as precisely when the nurse practitioner first learned of R41's critical test results or when, if at all, staff consulted with other residents' physicians about significant test results. *See* ALJ Decision at 9, and n.4.

accessible to nursing staff only when the nurse manager was there." ALJ Decision at 12, n.7.

Agape takes issue with the ALJ's statement that the fax machine was accessible only when the Nurse Manager was there. Agape states that "in the absence of the Nurse Manager who is available until 9:00 p.m., well after the time when labs are faxed to the Facility by Meridian, the 300 Hall nurse reviews the faxed lab reports." RR at 17-18, n.11, citing P. Ex. 2, at 4, ¶ 24. That is not an accurate statement. The exhibit Agape cites is the declaration of Administrator Danielle Henderson. Paragraph 24 of Ms. Henderson's declaration states, "The facility has a Nurse Practitioner on staff Monday through Friday. Labs that are received on the weekend or after hours are reviewed by the Nurse Manager or 300 Hall nurse and called to the attending physician on call as required." P. Ex. 2, at 4, ¶ 24. However, the immediately preceding paragraph in the declaration states as follows:

> When the Nursing Manager leaves, the Nursing Manager's office is locked. Consequently, if the lab was faxed after the Nurse Manager left for the day, the fax would not be available until the following day. The Facility now requires Meridian to fax lab results to both the Nurse Manager's office and a fax machine that is accessible after the Nurse Manager leaves for the day.

Id., at ¶ 23(emphasis added). The highlighted language supports the ALJ's statement, and the ALJ could reasonably infer from the juxtaposition of the words "was" and "now" that Agape arranged for faxes to be delivered to another machine accessible to staff other than the nurse manager only after the survey.[10]

Moreover, as the ALJ noted, when facility staff picked up the faxed laboratory report at some unspecified time on July 17, they should have become aware of a significant breakdown in procedures for handling critical test results. Either the laboratory had falsified the statement on the report that a lab employee had phoned the facility or LPN Brice had failed to notify the nurse practitioner of a timely reported lab result. Yet, as the ALJ noted,

> 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.

ALJ Decision at 12. Our review of the record reveals no evidence undercutting this finding by the ALJ, and Agape does not specifically address this finding on appeal.

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[10] Agape's statement that "very few results have been faxed after 6:00 p.m." (RR at 15, n.8) constitutes an admission that some results have been faxed in the evening.

For all of the reasons stated above, we conclude that the ALJ's conclusion that Agape's care of R41 did not substantially comply with sections 483.20(k)(3)(i), 483.25 and 483.75(j)(2)(ii) is supported by substantial evidence and free of legal error.

B. The ALJ's undisputed findings of fact support her legal conclusion that Agape was not in substantial compliance with section 483.25 with regard to five other residents because of delays in implementing orders to adjust Coumadin dosages and other deficiencies related to Coumadin therapy.

In addition to concluding that Agape was noncompliant with section 483.25 because it disregarded its protocol and did not timely report R41's critical INR result to the physician or nurse practitioner, the ALJ concluded that Agape was not in substantial compliance with section 483.25 based on failures to provide Coumadin therapy meeting quality of care requirements for five other residents: R19, R20, R1, R39, and R42.[11] ALJ Decision at 13-20. The ALJ concluded that Agape put these five residents at risk for more than minimal harm "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." ALJ Decision at 13. She specifically found instances in which staff incorrectly implemented physician orders by holding Coumadin for two days instead of one, twice holding Coumadin for three days instead of two, and twice failing to administer any medications when they should have increased the resident's dosage. *Id.* at 20. These findings, as Agape acknowledges, were based on "a review of where the documentation [in Agape's records] reflects when the PT/INR [blood sample] was drawn, when Coumadin was ordered and when Coumadin was administered in accordance with the documentation on the MARs [medication administration records] of [the other five residents]." RR at 19-20, citing ALJ Decision at 13-18.

Before the ALJ, Agape argued 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.*" ALJ Decision at 13, citing P. Br. at 19 (emphasis added in ALJ Decision). The ALJ correctly noted that the test for noncompliance is whether the delays posed the potential for more than minimal harm, not whether they put residents at risk of serious harm. 42 C.F.R. § 488.301 (defining substantial compliance as "a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm"). On appeal to the

[11] The ALJ concluded she need not address another basis cited for the noncompliance with section 483.25, the alleged inadequacy of hospice services for three residents, "[b]ecause 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." ALJ Decision at 20, n. 16, citing *Claiborne-Hughes Health Ctr.*, No. 09-3239, at 11 (6th Cir. 2010); *Carrington Place of Muscatine*, DAB No. 2321, at 20-21 (2010). In its request for review, Agape "preserves its right to request review" of certain survey findings related to this alleged noncompliance but does not allege that the ALJ erred in not reaching the hospice services issue. RR at 22-23.

Board, Agape expressly states that, with one exception (which we discuss below), it does not dispute the ALJ's findings of fact relating to the five residents at pages 13-18 of the ALJ Decision but disputes only that those findings support the ALJ's conclusion that Agape was not in substantial compliance with section 483.25. RR at 20 ("Other than as specifically stated herein, Petitioner does not dispute the referenced documentation in evidence, but does dispute that the documentation supports the conclusion that the Facility was not in substantial compliance."). Thus, the only question before us is whether the undisputed findings of fact support the ALJ's conclusion that the repeated delays (and other Coumadin therapy deficiencies) discussed by the ALJ at pages 13-18 of her decision posed a potential for more than minimal harm to residents and whether that conclusion contains any legal error. We conclude that the findings do support her conclusion and are free of legal error.

1. Agape's delays in implementing ordered changes to Coumadin dosages posed a risk for more than minimal harm such as bleeding or stroke.

Agape does not dispute that among the risks associated with Coumadin therapy are bleeding if dosages are too large or stroke if they are too small. Nor does it dispute the importance of monitoring blood clotting time with the PT/INR test and implementing changes in Coumadin dosages as ordered based on the test results. Indeed, Agape's standing orders for Coumadin recognized those risks by instructing staff to decrease dosages by 0.05 mg. for one week when INR values were between 3.1 and 4.5, and to contact the nurse practitioner, physician assistant or 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 dosage by 0.5 mg. CMS Ex. 32, at 15; CMS Ex. 40. The ALJ's undisputed findings of fact show numerous instances where Agape did not follow these instructions, resulting in delayed adjustment of dosages; in some instances Agape also delayed implementing individual physician orders or advising physicians of critical test results. We need not discuss all of the ALJ's findings of fact since all but one are undisputed by Agape. However, we discuss the undisputed findings regarding R19 in order to illustrate the frequency with which Agape's deficient practices occurred, even with respect to one resident.

Under the standing order, based on lab findings reported to the facility at 1:35 p.m. on May 12, 2009, staff should have increased R19's Coumadin dosage by 0.5 mg. but did not do so until 6:00 p.m. on May 13. ALJ Decision at 13. Based on lab results showing an INR of 1.42, reported to the facility on May 26, 2009, at 12:56 p.m., staff should have increased R19's Coumadin dosage by 1.0 mg. but staff continued to administer the current 3.0 mg. dosage until 5:00 pm on May 28, more than two days later. Staff not only delayed implementing the change required by the standing order; they also delayed implementing a telephoned physician order for the same increase, written at 8:00 a.m. on May 27. The ALJ found the delay "especially puzzling" since R19's MAR indicated that the 3.0 mg. Coumadin order was discontinued on May 27. *Id.* at 13-14.

There were further failures to follow the standing order for R19. Based on blood drawn at 9:50 a.m. and test results "approved" at 11:38 a.m. on June 9, 2009, the standing order required a 0.5 mg. decrease in Coumadin dosage. *Id.* at 14. However, staff did not decrease the dosage until 6:00 p.m. on June 11, more than two days after receiving the report, despite the standing order and a telephone order from the physician to decrease the dosage that staff received on June 10 at 8:00 a.m. *Id.* Another failure to implement the standing order for R19 occurred with respect to test results reported to the facility on June 23 at 1:03 p.m. *Id.* Based on the resident's INR of 1.44, the facility should have increased the Coumadin dosage by 1 mg. (from 3.5 mg. to 4.5 mg.). *Id.* However, staff did not increase the dosage until the evening of June 24, after a physician had issued a telephone order increasing the dosage to 4.5 mg. at 12:20 p.m. that day. *Id.*

With regard to R19, the ALJ also found inconsistent instructions with respect to how long to hold Coumadin after the lab reported an elevated INR of 5.69 on July 7, 2009. *Id.* The lab report was followed by notes of bleeding on July 13 written by the nurse practitioner but without any mention of Coumadin. A follow-up note by the nurse practitioner on July 15 noted a July 14 INR result of 1.92 but directed staff to decrease Coumadin from 4 mg. to 3.5 mg. even though the standing order called for an increase in Coumadin dosage by 0.5 mg. *Id., at 15.* Finally, with respect to R19, the ALJ found that staff, without explanation, held Coumadin administration for three days, rather than the two days ordered by the nurse practitioner and the resident's physician, after the lab reported a critical INR result on July 21, 2009. *Id.* at 15 and, n.12, citing CMS Ex. 15, at 24; *see also* CMS Ex. 15, at 5 (lab report containing July 21 critical result with handwritten note stating "hold x 2 days then 4 mg. . . "). [12] R19's physician did not initial the report until July 22, even though the standing order required that he be notified immediately on the date the facility received the test results, which, as indicated, was July 21. *Id.*

On their face, these failings in R19's Coumadin therapy carried the potential for more than minimal harm, since they put R19 in danger of bleeding or stroke, which are undisputed risks associated with too much or too little Coumadin, respectively. The manufacturer of Coumadin issues a "black box warning" cautioning that the medication "can cause major or fatal bleeding . . ." and that risk factors for bleeding include an INR greater than 4 and the patient's age (65 or older). CMS Ex. 39, at 1. R19 was a 92-year-old woman with a history of pulmonary embolism and diagnoses that included deep vein thrombosis and chronic obstructive pulmonary disease, among other diseases. ALJ Decision at 13, citing CMS Ex. 15, at 1. The other residents discussed by the ALJ were 88, 87, 96 and 81 years old, respectively. Although Agape disputes the conclusion that it was not in substantial compliance, Agape does not assert that there was no potential for more than minimal harm but only that the residents at issue did not have "any signs or symptoms of bleeding or other hematologic-related events that evidenced serious injury or harm" and that there was no immediate jeopardy. RR at 21, 24. Whether there was

[12] The ALJ also found that staff twice failed to administer any Coumadin despite orders to administer an increased dose to each of the two residents involved, R. 39 and R. 42. ALJ Decision at 20.

serious harm or the likelihood thereof is irrelevant to the issue of noncompliance since, as indicated earlier, the potential for more than minimal harm is the basis for finding noncompliance. 42 C.F.R. § 488.301. Similarly, whether there was bleeding or another hematologic-related event is irrelevant since Agape's standing order, by its own terms, applied regardless of whether there was bleeding. CMS Ex. 40.

Agape also asserts that "none of the ordered changes in anticoagulant therapy cited in the Decision were changes related to critical lab values." RR at 21. It is not necessary for a lab value to be critical in order for the failure to implement an ordered Coumadin dosage change to pose a risk of more than minimal harm; the fact that a value is critical merely enhances the risk of bleeding that is inherently associated with Coumadin therapy. P. Ex. 33, at 6, 8; CMS Ex. 39, at 1-3. Moreover, the assertion is not true. The laboratory reported a critical INR reading of 5.69, for R19 on July 7, 2009. ALJ Decision at 14, citing CMS Ex. 15, at 14. The nurse practitioner noted the elevated INR and wrote "will hold Coumadin and resume at reduced dose . . . [f]ollow closely." *Id.*, citing P. Ex. 16, at 19. A telephone order of the same date instructed staff to "hold Coumadin" for 24 hours. *Id.*, citing CMS Ex. 15, at 16. Yet, contrary to this order, staff did not administer the drug for two days, July 7 and 8. *Id.*, citing CMS Ex. 15, at 24. Staff then resumed administering Coumadin for two days and then held it again without any explanation. *Id.* R39 also had a critical INR reading (5.77) on July 14, 2009. *Id.* at 18, citing CMS Ex. 18, at 4. A physician order, as well as a hand-written note on the lab report ordered Coumadin held for two days. *Id.*, citing CMS Ex. 18 at 4-5. However, the resident's MAR indicates that staff held the Coumadin for three days, not two, July 13, 14 and 15. *Id.*, citing CMS Ex. 18, at 6. As indicated, Agape disputes none of the evidence on which the ALJ based these findings of fact; thus, it cannot dispute that there was a failure to implement ordered Coumadin changes, in this instance the medication holds ordered for these residents.

The one finding of fact Agape does dispute relates, in part, to R19 and appears in a footnote. Agape asserts, "The ALJ states that the Facility 'twice held Coumadin for three days instead of two days' and references Resident #19. The MAR at CMS Ex. 15, p. 24 does not reflect that the Facility held Coumadin for three days." RR at 20-21, n.15, citing ALJ Decision at 20; *see also* RR at 10-11, n.5 (making essentially the same assertion). Neither Agape's description of the ALJ's finding nor its assertion about the MAR is accurate. The ALJ did find that Agape staff twice held Coumadin for three days instead of the two days ordered but based that finding on records for R39 as well as R19. ALJ Decision at 20. Furthermore, the MARs for R19 and R39 clearly support the ALJ's finding. R19's MAR shows that staff held the Coumadin July 21, July 22 and July 23. CMS Ex. 15, at 24. The MAR for R39 shows that staff held Coumadin July 13, 14 and 15. CMS Ex. 18, at 6. The record clearly shows that Agape's sole challenge to the ALJ's findings on pages 13-18 of her decision is baseless. In any event, Agape does not dispute the ALJ's more general finding that "up to two days could elapse before [staff] adjusted a resident's Coumadin dosage." ALJ Decision at 19. Indeed, Agape essentially admits the truth of this finding by stating that "[o]f the instances cited in the Decision, at

no time was there a greater than a two day difference in the date the PT/INR was drawn and the Coumadin order changes were implemented." RR at 10.

2. Agape's delays in adjusting Coumadin dosages were inconsistent with professional standards of care and the quality of care regulation.

The ALJ found the delayed implementation of Coumadin dosage changes inconsistent with evidence presented regarding the standard of care for Coumadin therapy.

> 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. [citations omitted] 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.

ALJ Decision at 18-19. The ALJ cited the Director of Nursing's (DON) statement to surveyors "that she would expect nurse to . . . change & administer new dose of Coumadin on day order was received (day labs were received) not the day after" and LPN Maria Goodnaugh's statements to surveyors that changed Coumadin dosages "should be started the same day the lab & dosage adjustment is received" and "the nurse on unit is responsible for medication (Coumadin) being started on the same day it (lab result) was received." *Id.*, citing CMS Ex. 10 at 32; CMS Ex. 26, at 1. The ALJ also cited the sworn statement of Agape's Medical Director, James Lee Jewell, M.D., that "it is ideal if the dosage is changed on the day the PT/INR is drawn." *Id.* at 19, citing P. Ex. 24 (Jewell Decl. ¶9).

Despite the undisputed statements of its DON, LPN and Medical Director, Agape asserts that a two-day delay in implementing Coumadin dosage changes does not violate professional standards or the quality of care requirements in section 483.25. RR at 20, 22. Agape asserts, "There certainly is a distinction between providing for the 'ideal' and the 'highest practicable' in providing care for the residents." *Id.* at 22. We need not decide whether such a distinction is valid since Agape has presented no evidence that either the professional standard of care for timely implementation of Coumadin dosage changes or the "highest practicable" care is anything less than the same-day standard which, as discussed, is the standard articulated by Agape's professional nursing staff. Agape also has not explained why its staff did not rely on the standing order for Coumadin dosage changes rather than waiting for individual physician orders. As we noted earlier, the standing order reflects Agape's own judgment as to what must be done to attain or maintain its residents' highest practicable physical, mental and psychosocial

well-being, as required by section 483.25. Agape does not dispute that following the standing order for the lab results subject to that order would have enabled staff to make the dosage changes discussed by the ALJ on the same day staff received the test results.[13]

Agape asserts that the ALJ improperly rejected "expert" opinions of two of its witnesses – Kelly Jones, Pharm.D., a clinical pharmacist, and Karon Goldsmith, a Registered Nurse (RN) legal nurse consultant – that the facility "met the applicable standards." RR at 17. Agape contends that the ALJ should have accepted that testimony since CMS presented no expert testimony refuting their opinions. *Id.* Ms. Goldsmith asserted, "Once the facility was alerted to the abnormal lab values, the facility acted appropriately and timely, including notification of the attending physician/nurse practitioner." P. Ex. 14, at 9; *see also id.*, at 7, 8 (opining that Agape was in substantial compliance with each of the unmet regulations). Dr. Jones asserted that Agape's "methods of managing and use of warfarin at the facility did not place residents in immediate jeopardy or present the potential for more than minimal harm and did not fail to meet professional and quality standards of practice." P. Ex. 13, at 14.

We find no merit to Agape's argument. Whether a facility is in substantial compliance is a legal issue, and an ALJ is not required to accept expert testimony on legal issues. *E.g. Dumas Nursing and Rehabilitation, L.P.*, DAB No. 2347, at 19 (2010), citing *Guardian Health Care Center*, DAB No. 1943, at 11 (2004). With regard to professional standards of care, which is a factual issue, neither witness identified a specific professional standard of care (or cited any treatise) for what constitutes timely physician reporting or implementation of Coumadin dosage changes based on PT/INR test results ordered for nursing home residents.[14] The closest Ms. Goldsmith came to articulating any standard was her suggestion that staff had a duty to "promptly" report test results and implement dosage changes and met that duty. *See* P. Ex. 14, at 7 (stating that "[w]hen the facility was notified of the lab values of PT/INR, they acted promptly in notifying the physician's nurse practitioner and followed orders to change medication dosages.") However, Ms. Goldsmith did not specify what qualifies as "promptly" under professional standards (or even in her own mind) or why two-day delays in implementing ordered Coumadin dosage changes (which Agape has admitted) would qualify as "promptly."

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[13] Agape's administrator and DON opined that delays in changing dosages may have been "due to the timing of obtaining the new dosage from the pharmacy." ALJ Decision at 19-20, citing P. Ex. 2, at 5 (Henderson Decl. ¶ 30); P. Ex. 3, at 3 (Wells Decl. ¶ 17). The ALJ found that this explanation, even if true, did not help the facility since Agape should have had in place a reliable method for promptly obtaining required dosages of Coumadin. *Id.* at 20. Agape does not challenge that finding on appeal. We also note that the declaration statements are undercut by the DON's statement to the surveyor that the "facility has a back-up pharmacy to ensure meds are available." CMS Ex. 10, at 32.

[14] Dr. Jones cited the 2010 Joint Commission National Patient Safety Goals intended for hospital practice and stated that Section 5 of Goal 3 "involves warfarin and other anticoagulant therapies. One goal in particular calls for protocols for the initiation and maintenance of warfarin therapy." P. Ex. 13 at 15, ¶ 2. However, Dr. Jones did not state whether or how that goal relates to timely implementation of Coumadin dosage changes.

Ms. Goldsmith blamed laboratory staff for the delay in reporting R41's critically high test results to the nurse practitioner but, as we have discussed, the ALJ quite properly rejected that assertion because the regulations and Board decisions make facilities responsible for the quality and timeliness of the laboratory services for which they contract. Agape also points to Dr. Jones' opinion that "[w]hen a critical INR laboratory value is reported, immediate action is not necessary unless the patient is bleeding." P. Ex. 13, at 15, ¶3. That opinion is not consistent with the facility's policy, which, according to Agape's nurse practitioner and Agape's request for review (RR at 7), requires immediate reporting of all critical test results.[15] Moreover, with respect to the delays in reducing or increasing the dosages, Agape is not being faulted for not taking "immediate" action, but for delays of up to two days.

Agape also faults the ALJ for "tak[ing] exception to Dr. Jones' statements concerning the consistency of the Facility's system of monitoring . . . ." RR at 20. In the testimony discussed by the ALJ, Dr. Jones suggested that the facility's practice of letting up to two days elapse before adjusting a resident's Coumadin dosage "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.'" ALJ Decision at 19, citing P. Ex. 13, at 16 (Jones Decl. ¶4). He further opined "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.'" *Id.* The ALJ stated:

> 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. 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."

Id. Although Agape objects to the ALJ's conclusion, Agape points to no evidence of record undercutting it. In fact, as previously indicated, Agape does not dispute any of the record facts cited by the ALJ regarding the timing of the blood draws, the lab reports or the implementation of Coumadin dosage changes. We find no error in the ALJ's treatment of the expert testimony, including that of Dr. Jones. The ALJ was not required

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[15] We also note that Dr. Jones has a doctorate in clinical pharmacy, not medicine. P. Ex. 13, at 14.

to consider whether CMS put on expert rebuttal with regard to testimony she rejected on its face.[16]

Dr. Jones's suggestion of a deliberate policy of delay is also inconsistent with the previously discussed statements by two members of Agape's nursing staff (DON Wells and LPN Goodnaugh) that staff were expected to implement dosage changes the same day the facility received the test results. The ALJ reasonably relied on the testimony of these members of Agape's professional staff as establishing Agape's policies and procedures. In *Spring Meadows Health Care Center*, DAB No. 1966, at 18 (2005), the Board held that "it is reasonable to presume that the facility's policy reflects professional standards of quality, absent convincing evidence to the contrary." The ALJ here could reasonably determine that the testimony of Dr. Jones and RN Goldsmith was not convincing evidence overcoming the presumption of the professional standard of care reflected in the statements to surveyors by Agape's own DON and LPN Goodnaugh.

For the reasons stated above, we affirm the ALJ's conclusion that Agape was not in substantial compliance with section 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.

C. The ALJ did not err in concluding that CMS's immediate jeopardy determination was not clearly erroneous.

Immediate jeopardy exists when 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. Agape acknowledges that "CMS's determination that a deficiency constitutes immediate jeopardy will be upheld unless the Facility is able to prove that the determination is clearly erroneous." RR at 23, citing 42 C.F.R. § 498.60(c)(2); *Woodstock Care Center,* DAB No. 1726 (1999). Agape also acknowledges that CMS's immediate jeopardy determination is presumed to be correct, and that the burden of proving the determination clearly erroneous is a heavy one.[17] *Id.* at 24; *see e.g. Maysville Nursing & Rehabilitation*

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[16] The ALJ also discounted Dr. Jones' testimony because he stated that the system he described was "very common in many private practice settings," including the physician practice with which he was associated, a "family medicine" practice. ALJ Decision at 19, n.14. The ALJ reasonably questioned Dr. Jones' suggestion that procedures developed for a "family medicine" practice could be applied in a nursing home setting, where the population consists largely of elderly, infirm residents. *Id.*

[17] Agape is not correct, however, when it says the standard for proving an immediate jeopardy determination clearly erroneous is preponderance of the evidence. RR at 24. The preponderance of the evidence standard applies to determining whether a facility has rebutted CMS's prima facie case of noncompliance, not to whether it has rebutted the presumption that CMS's determination of the level of noncompliance is correct. *See Brian Center Health and Rehabilitation/Goldsboro*, DAB No. 2336 at 7-8 (2010) (rejecting facility's assertion that preponderance of the evidence standard applied to determining when immediate jeopardy was abated). The decision Agape cites for the preponderance of the evidence standard, *Heritage Healthcare & Rehab. Center*, DAB CR2116 (2010), is an ALJ decision, and ALJ decisions do not bind the Board or other ALJs.

Facility at 11, citing *Stone County Nursing & Rehabilitation Center*, DAB No. 2276, at 17 (2009), and cases cited therein. The record amply supports the ALJ's conclusion that Agape did not meet its burden of showing CMS's immediate jeopardy determination to be clearly erroneous.

While acknowledging that a determination of immediate jeopardy can be based on the likelihood of serious harm in lieu of actual serious harm, Agape asserts that the facility's delays in notifying physicians of critical test results and implementing Coumadin dosage changes did not pose a likelihood of serious harm to any resident. RR at 24. "The evidence proffered by CMS did not demonstrate that any of the residents were under a real risk of imminent harm." RR at 24. Agape cites language in the CMS guidelines for determining immediate jeopardy in Appendix Q of the State Operations Manual (SOM) which Agape says "stresses that in order to make that determination . . . there must be 'immediacy,' that is, 'the harm or potential harm [must be] likely to occur in the very near future to this individual or others in the entity, if immediate action is not taken.'"[18] *Id.* at 24-25. The language "likely to occur in the very near future" does appear in the SOM, but it is guidance to surveyors not, as Agape suggests, a legally binding definition of immediate jeopardy. The legal definition of that term is found in the regulations and neither defines the term "likelihood" nor sets any parameters as to the timing of potential harm. As guidance issued by CMS on the issue of immediate jeopardy, the SOM is instructive, but unlike the regulations, it is not controlling authority.

On the other hand, we have no problem concluding here that the potential harm to R41 and other residents (excessive, possibly fatal, bleeding or stroke) caused by Agape's delay in following physician orders (whether standing or individual) with respect to adjusting Coumadin dosages was "likely to occur in the very near future." As indicated earlier, there is no dispute that too much Coumadin can cause major, even fatal, bleeding and that the risk is increased for persons over 65 years old, an age far exceeded by all six of the residents discussed in the ALJ Decision. As the ALJ noted,

> 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.

ALJ Decision at 25. There also is no dispute that "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." *Id.* Moreover, evidence shows a systemic problem of staff failing to follow physician standing orders. In our view, these undisputed facts more than suffice to establish that serious harm or

[18] The SOM guidelines on immediate jeopardy appear at SOM, Appendix Q, Guidelines for Determining Immediate Jeopardy (Rev. 1, 05-21-04)(accessible online at https://cms.gov/manuals/Downloads/som107ap q immedjeopardy.pdf).

potential serious harm was, as the SOM states, "likely to occur in the very near future." *See Daughters of Miriam Center*, DAB No. 2067 at 12 (2007)(citing Guidelines and concluding that CMS had ample reason to conclude that a nurse's medication errors would likely have caused death or serious harm to residents at issue "in the very near future," since it would have occurred in fact but for one resident's fortuitous refusal to accept the medication and staff stopping the nurse from administering medications to other residents).

Agape relies on the opinions of Dr. Jones and Ms. Goldsmith that there was no immediate jeopardy. RR at 24, citing P. Ex. 13; P. Ex. 14. As discussed above, the ALJ was not bound to accept these opinions since they were legal conclusions, not factual testimony. Moreover, the ALJ rejected Dr. Jones's attempt to minimize the risk posed by continuing to administer Coumadin to residents with high INRs. As noted above, Dr. Jones opined that "[w]hen a critical INR laboratory value is reported, immediate action is not necessary unless the patient is bleeding."[19] P. Ex. 13, at 15, ¶3. The ALJ concluded that the absence of active bleeding, "[w]hile fortuitous" was not sufficient to show no immediate jeopardy since "the immediate jeopardy standard does not require actual harm, and, given her blood level, R.41 was just a fall or bruise away from a true medical emergency." ALJ Decision at 25. Agape does not specifically dispute this conclusion, and we find no error in it. Indeed, we reiterate here the Board's statement in *Daughters of Miriam Center* (when rejecting that ALJ's conclusion that a non-diabetic resident's refusal of an attempted administration of insulin precluded finding a likelihood of serious harm), "assessment [by CMS] of the level of noncompliance should not hinge on the fortuity of a single resident's intervention, particularly when the noncompliance posed risks to other residents under the nurse's care." DAB No. 2067, at 14.

Agape also does not dispute the ALJ's finding that another part of Dr. Jones' testimony provided further support for the immediate jeopardy determination. Dr. Jones testified, the ALJ noted, that "[y]ou 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." ALJ Decision at 25, citing P. Ex. 13, at 16. The ALJ then noted that the "record contains multiple instances in which staff delayed increasing the dosages to residents with INR values below 2" and that "[a]t least twice the staff not only delayed increasing the dosages, they neglected to administer any of the ordered Coumadin." *Id.* at 25-26, citing CMS Ex. 18, at 14, 16-17; CMS Ex. 20, at 8, 10. We agree with the ALJ that these facts, in addition to those involving residents with high INR values, support the finding of immediate jeopardy based on the likelihood of serious harm. We also note that Dr. Jones and Ms. Goldsmith are both consultants, not employees of Agape. As previously discussed, members of Agape's nursing staff (including the DON) told surveyors that employees were expected to adjust Coumadin dosages the same day staff received the lab report. Thus, the testimony of the consultants

[19] Dr. Jones does not actually state that none of the residents was bleeding, only that they were assessed for bleeding, but we assume for purposes of this discussion that none of the residents at issue was bleeding.

attempting to minimize the need for immediate adjustments is undercut by Agape's own articulated professional standards.

For the reasons stated above, we affirm the ALJ's conclusion that Agape did not meet its heavy burden to show CMS's immediate jeopardy determination to be clearly erroneous.

D. The ALJ did not err in concluding that the CMPs were reasonable.

The ALJ found reasonable in amount both the $5,200 per-day CMP CMS imposed for the immediate jeopardy period (July 16 through August 4, 2009) and the $250 per-day CMP CMS imposed for the period of noncompliance at less than the immediate jeopardy level (August 5 through August 23, 2009) . The ALJ determined that these amounts were reasonable by considering, as she was required to do, the factors in 42 C.F.R. § 488.438(f): (1) the facility's history of noncompliance, including repeat deficiencies; (2) the facility's financial condition; (3) the factors specified in § 488.404; and, (4) the facility's degree of culpability. ALJ Decision at 26-27. The ALJ also noted that the $5,200 per-day CMP for the immediate jeopardy level noncompliance was "at the low-to-mid penalty range for situations of immediate jeopardy ($3,050-$10,000)" and the $250 per-day CMP for the continuing noncompliance that was not immediate jeopardy was "at the low end of the penalty range for per-day CMPs ($50-$3,000)." *Id.* at 26. In the heading for its CMP argument, Agape states that the ALJ erred in finding that the "penalties," plural, were reasonable. RR at 25. However, Agape specifically disputes only the $5,200 per day CMP and merely notes that the ALJ also upheld the $250 per-day CMP. RR at 25, n.19, 26. Agape also appears to concede that at least a lower level CMP would have been justified for the whole noncompliance period by asserting that "[i]f CMPs were to be assessed, which Petitioner posits likely would not have been assessed absent the immediate jeopardy determination, the amount should have been at the lowest range of 42 C.F.R. § 488.408(d)(1)(iii), which is $50-3000 per day."[20] RR at 26. Given Agape's failure to specifically dispute the $250 per-day CMP, we sustain that CMP without further discussion and explain below why we uphold the ALJ's conclusion that $5,200 per day is a reasonable amount for the immediate jeopardy level CMP.

Concerning Agape's history of noncompliance, the ALJ cited undisputed evidence that on Agape's prior annual survey CMS found the facility noncompliant with two of the same requirements (quality of care and accidents and supervision) found unmet here.[21] ALJ Decision at 27, citing CMS Ex. 6. In its request for review, Agape expressly states that it does not contest the ALJ's upholding of the findings of noncompliance cited under section 483.25(h) involving failure to provide R4 with adequate supervision to prevent accidents. RR at 27, n.21. Agape asserts, however, that the ALJ cannot rely on the

[20] Agape's suggestion that no CMP would have been imposed absent the immediate jeopardy is pure speculation, and we are not authorized to review CMS's exercise of discretion to impose or not impose a CMP. 42 C.F.R. § 488.438(e)(2). The Board also may not review CMS's choice of remedy. 42 C.F.R. § 488.408(g)(2).

[21] We note that the noncompliance under 42 C.F.R. § 483.25 (quality of care) cited on the prior survey involved incorrect administration of insulin. CMS Ex. 6, at 1.

uncontested noncompliance with section 483.25(h) when determining whether the amount of the immediate jeopardy level CMP is reasonable because the noncompliance with section 483.25(h) was cited at scope and severity level "G," not immediate jeopardy. Agape points to no authority for this position, and it is not consistent with section 488.438(f)(3). That section incorporates the factors in section 488.404, which provide for considering the relationship of one deficiency to other deficiencies resulting in noncompliance, as well as the scope and severity level of noncompliance. The ALJ did not err in considering all deficiencies resulting in a finding of noncompliance when determining the reasonableness of the immediate jeopardy level CMP imposed on Agape.

Agape also argues with respect to its prior history that "[s]ingle prior instances of noncompliance with very broadly applied categories of deficiencies that surveyors commonly cite in recertification surveys . . . do not justify the imposition of the CMPs at the immediate jeopardy level." RR at 26. This argument has no merit. Under the regulations, CMS had the discretion to impose a CMP for the noncompliance that posed immediate jeopardy and having chosen that remedy, CMS was required to impose a CMP at the level applicable to immediate jeopardy. 42 C.F.R. § 488.408(b), (e)(2)(ii). As previously indicated, that exercise of discretion is not reviewable. 42 C.F.R. § 488.438(e)(2). Furthermore, when determining whether a CMP is reasonable an ALJ is limited to considering the factors specified in section 488.438(f). 42 C.F.R. § 488.438(e)(3). Historical noncompliance (or the lack thereof) is one of those factors, but whether that historical noncompliance involves commonly cited or broadly applied categories (whatever that means) is not. Agape says it has had a deficiency-free survey since the appeal began. RR at 26. A facility's subsequent compliance is irrelevant to determining the reasonableness of the CMP under review. *Cf. Brian Center,* DAB No. 2336, at 13 ("Although a facility's prompt institution of corrective measures is certainly desirable, the Secretary of Health and Human Services has not made doing so a basis for reducing a CMP amount").

With regard to the second factor, the ALJ found that Agape had not argued that its financial condition affected its ability to pay the CMP. Agape does not challenge that finding on appeal. Agape asserts, however, that CMS was required to present evidence that it considered the facility's financial condition. This assertion is not factually or legally correct. CMS's notice letter states that CMS considered the factors in section 488.438(f). CMS Ex. 3 at 2. Moreover, the Board has held that "in assessing whether CMP amounts are within a reasonable range, the ALJ may not look into CMS's internal decision-making process but, rather, must make a de novo determination as to whether the amounts are reasonable, applying the regulatory criteria to the record developed before the ALJ." *Embassy Health Care Center*, DAB No. 2327, at 11 (2011), citing *Kingsville Nursing and Rehabilitation Center*, DAB No. 2234, at 13 (2009) and cases cited therein. Thus, how CMS assessed the factors is irrelevant.

Section 488.438(f) incorporates factors in section 488.404 relating to the seriousness of the facility's deficiencies, such as the scope and severity level of the cited noncompliance and the relationship of one deficiency to other deficiencies resulting in noncompliance. Here the ALJ considered the scope and severity level of the challenged deficiencies and the total number of deficiencies, including those Agape did not challenge on appeal. ALJ Decision at 27. The ALJ concluded, "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." *Id.* Agape alleges no error in this conclusion, and we find none. Agape alleges only that no immediate jeopardy existed, an allegation we have already rejected.

With regard to the culpability factor, the ALJ concluded that Agape did not have in place systems that would protect an especially vulnerable population. ALJ Decision at 27. She found the facility "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." *Id.* She also found the facility culpable for failing to adequately address R4's repeated falls. *Id.* Culpability "includes, but is not limited to, neglect, indifference, or disregard for resident care, comfort or safety," but the "absence of culpability is not a mitigating circumstance in reducing the amount of the penalty." 42 C.F.R. § 488.438(f)(4). Agape argues that the record establishes that it "was not neglectful of its residents, indifferent to its residents, and it did not disregard its resident's [sic] care, comfort or safety." RR at 27. Agape cites to no record support, and the ALJ expressly found otherwise with regard to Agape's care for 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." ALJ Decision at 27. Agape does not challenge any of the ALJ's findings regarding R4, including the repeated falls.

Based on the foregoing, we conclude that the ALJ did not err in concluding that the amount of the immediate jeopardy level CMP, as well as the undisputed amount of the non-immediate jeopardy level CMP, was reasonable. Substantial evidence on the record as a whole supports the findings of fact on which the ALJ based her conclusions.

Conclusion

For the reasons discussed above, we affirm the entire ALJ Decision.

/s/
Constance B. Tobias

/s/
Judith A. Ballard

/s/
Sheila Ann Hegy
Presiding Board Member