Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Life Care Center of Bardstown
Docket No. A-12-66
Decision No. 2479
September 28, 2012

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Life Care Center of Bardstown (LCCB), a skilled nursing facility (SNF) located in Bardstown, Kentucky, requested review of the decision of Administrative Law Judge (ALJ) Richard J. Smith in *Life Care Center of Bardstown*, DAB CR2509 (2012). This case was before the ALJ pursuant to a March 2009 remand by the Board. *Life Care Center of Bardstown*, DAB No. 2233 (reversing in part and remanding DAB CR1818).

On remand, the ALJ sustained the determination by the Centers for Medicare & Medicaid Services (CMS) that LCCB failed to comply substantially with the Medicare and Medicaid participation requirements at 42 C.F.R. § 483.10(b)(11) (notification of changes-physician consultation); 42 C.F.R. § 483.25 (quality of care); and 42 C.F.R. § 483.75 (facility administration). The ALJ also upheld CMS's determination that LCCB's noncompliance posed immediate jeopardy to LCCB residents from January 3, 2007, through March 27, 2007. The ALJ sustained the $4,050 per-day civil money penalty (CMP) imposed by CMS for the immediate jeopardy period.

For the reasons discussed below, we uphold the ALJ Decision. Because we uphold the ALJ's decision that immediate jeopardy existed from January 3 through March 27, 2007, and the $4,050 per-day CMP for that period, we also clarify that the $100 per-day CMP our remand decision found reasonable based on the uncontested noncompliance with 42 C.F.R. §§ 483.20(d)(3) and 483.10(k)(2) is in effect only from March 28 through April 9, 2007.

Legal Background

To participate in Medicare and Medicaid, a SNF must comply with the requirements in 42 C.F.R. Part 483, subpart B. A facility's compliance with the participation

requirements is assessed through surveys performed by state agencies. Sections 1819 and 1919 of the Social Security Act (Act); 42 C.F.R. Parts 483, 488, and 498.[1]

"Substantial compliance" means a level of compliance with the participation requirements 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," is defined as "any deficiency that causes a facility to not be in substantial compliance." 42 C.F.R. § 488.301.

CMS may impose remedies against a facility that is not in substantial compliance with the participation requirements. 42 C.F.R. §§ 488.408, 488.440(a). CMS determines the seriousness of each deficiency in order to select the appropriate remedies, if any, to impose on the facility. *See* 42 C.F.R. § 488.404. The level of seriousness is based on an assessment of scope (whether the deficiency is isolated, a pattern, or widespread) and severity (the degree of harm, or potential harm, to resident health and safety posed by the deficiency). *Id.* The highest level of severity is "immediate jeopardy," defined at section 488.301 as "a situation in which the provider's noncompliance . . . has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident."

When CMS imposes a per-day CMP for noncompliance at the immediate jeopardy level of severity, it must set the CMP amount within the "upper range" of $3,050 to $10,000 per day. 42 C.F.R. §§ 488.408(d)(3)(ii), 488.438(a)(1)(i). A per-day CMP for noncompliance below the immediate jeopardy level must be set within the "lower range" of $50 to $3,000 per day. *Id.* § 488.408(d)(1)(iii), 488.438(a)(1)(ii).

Factual Background

The following facts are undisputed:

• Resident 1 was an 87-year-old woman who was initially admitted to LCCB in the summer of 2006. LCCB Ex. 6; CMS Ex. 17, at 1. Resident 1 had diagnoses that included Alzheimer's disease, hypothyroidism, diabetes, and hypertension. *Id.*

[1] The current version of the Social Security Act can be found at http://www.socialsecurity.gov/OP_Home/ssact/ssact.htm. Each section of the Act on that website contains a reference to the corresponding United States Code chapter and section. Also, a cross-reference table for the Act and the United States Code can be found at 42 U.S.C.A. Ch. 7, Disp Table.

• Following a brief hospitalization in mid-November 2006, Resident 1 was readmitted to LCCB on November 17, 2006, at which time her treating physician ordered, among other things, oxygen saturation readings to be monitored "daily," and vital signs "routinely." CMS Ex. 17, at 9; P. Ex. 13, at 2.

• Resident 1 vomited profusely at approximately 8:00-8:30 p.m. on January 2, 2007. CMS Ex. 17, at 30-31; Tr. at 35-36, 215-216.

• At approximately 1:00 a.m. on January 3, 2007, Resident 1 was observed by LCCB staff to have a "sm[all] amount of emesis" on her night clothes. CMS Ex. 17, at 31; CMS Ex. 3, at 6.

• At approximately 4:00 a.m. on January 3, 2007, LCCB certified nursing assistants (CNAs) and the licensed professional nurse on duty, Nurse Suffoletta, found Resident 1 unresponsive and with unstable vital signs. Nurse Suffoletta attempted to consult with the on-call physician about Resident l's condition, but she was unable to reach the physician by telephone. Nurse Suffoletta telephoned LCCB's Director of Nursing (DON), who ordered Resident 1 to be sent to the hospital emergency room. CMS Ex. 17, at 31.

• At approximately 4:15 a.m. on January 3, 2007, Nurse Suffoletta called emergency medical services. CMS Ex. 18, at 1. Emergency medical technicians arrived at LCCB at approximately 4:20 a.m. to transport Resident 1 to the hospital. *Id.*

• Resident 1 was thereafter transferred, and she died at the hospital at approximately 7:10 a.m. on January 3, 2007. CMS Ex. 18, at 3.

Case History

The surveys and CMS determinations

The Kentucky Division of Health Care Facilities and Services (State Agency) completed an abbreviated and partial extended survey of LCCB on April 3, 2007. CMS Ex. 3. The State Agency found LCCB was not in substantial compliance, at the immediate jeopardy level of severity, with the notification of changes-physician consultation requirement at 42 C.F.R. § 483.10(b)(11), the quality of care requirement at 42 C.F.R. § 483.25, and the facility administration requirement at 42 C.F.R. § 483.75. *Id.* The State Agency also found LCCB in noncompliance with the comprehensive care planning requirements at 42 C.F.R. §§ 483.20 (d)(3) and 483.10(k)(2) at a severity level of no actual harm but with the potential for more than minimal harm that is not immediate jeopardy. *Id.*

Based on the State Agency's survey findings, CMS issued a determination on April 20, 2007 that LCCB was out of substantial compliance, at the immediate jeopardy level of severity, as of January 3, 2007. CMS Ex. 5; LCCB Ex. 2. CMS stated it would impose on LCCB a CMP of $4,500 per day effective January 3, 2007, and continuing until LCCB returned to substantial compliance or its provider agreement was terminated. *Id.*

On April 23, 2007, the State Agency conducted a revisit survey of LCCB and found that LCCB had completed corrections relating to the deficiencies cited under sections 483.10(b)(11), 483.25 and 483.75 on March 28, 2007. CMS Ex. 10. The revisit survey further found, however, that LCCB continued to be not in substantial compliance with the comprehensive care planning requirements. CMS Ex. 11; LCCB Ex. 3. On May 1, 2007, CMS issued a notice to LCCB stating that the April 23 revisit survey found that LCCB continued to be not in substantial compliance and that the CMP would continue to accrue, but at a lower rate of $100 per day, effective March 28, 2007, and continuing until LCCB achieved substantial compliance. CMS Ex. 9. A second revisit survey of LCCB, completed May 11, 2007, found that LCCB had achieved substantial compliance as of April 10, 2007. CMS Exs. 13, 24.

The subsequent proceedings and ALJ decision (DAB CR1818)

LCCB requested an ALJ hearing to contest CMS's determinations. The ALJ conducted an in-person hearing on February 19-20, 2008. In a decision dated July 16, 2008, the ALJ determined that LCCB established by a preponderance of the evidence that it was in substantial compliance with 42 C.F.R. §§ 483.10(b)(11), 483.25, and 483.75. DAB CR1818 (findings of fact and conclusions of law (FFCL) 1-3). The ALJ further determined that "CMPs of $4,050 and $100 per day respectively, are unreasonable based on the facts of this case as there are no violations and therefore no basis for the imposition of CMPs." *Id.* at 13 (FFCL 4).

CMS appealed the July 2008 ALJ decision to the Board.

The Board decision and remand order (DAB No. 2233)

On review, the Board reversed the ALJ decision in part and remanded the case to the ALJ for further action. DAB No. 2233 (2009). The Board determined that the ALJ clearly erred in concluding that "there [were] no violations and therefore no basis" to impose any CMP. *Id.* at 7-10. During the ALJ hearing, LCCB admitted that it was not in substantial compliance with the comprehensive care plan requirements at sections 483.20(d)(3) and 483.10(k)(2), and that it expected the ALJ to impose a CMP for its care plan deficiencies. Tr. at 17, 22. In light of LCCB's admission, the Board determined, the ALJ's conclusions that the facility had been in substantial compliance with all participation requirements and that there was no basis to impose any CMP were plainly incorrect.

The Board also upheld the $100 per-day CMP imposed for the care plan deficiencies because LCCB did not argue that any regulatory factor used to determine the penalty amount merited a reduction. DAB No. 2233, at 9, *citing Coquina Center*, DAB No. 1860, at 32 (2002) (it is presumed that CMS considers the factors in section 488.438(f) when it sets a penalty amount and that those factors support the amount; unless a facility argues that a particular regulatory factor does not support the amount, the ALJ must sustain it). Accordingly, the Board vacated FFCL 4 of the July 2008 decision. The Board concluded that the $100 per-day CMP was reasonable and applied "to the entire period of time for which LCCB conceded the existence of the [care plan] deficiency, January 3, 2007 through April 9, 2007." DAB No. 2233, at 9-10, 29, (FFCLs A-1, A-2).

The Board further concluded there were clear errors and compelling reasons to vacate FFCLs 1-3 of the July 2008 decision and to remand the case to the ALJ for further action. On review of the entire record, the Board determined that the ALJ had not addressed material evidence that conflicted with his factual findings and his descriptions of the record. "The lack of acknowledgment of this evidence in the ALJ Decision, or indication of any grounds for its rejection, [left the Board] unable to determine whether the ALJ duly considered and reasonably rejected, or simply overlooked, this evidence in reaching FFCLs 1, 2 and 3." *Id.* at 11. The Board further concluded that FFCLs 2 and 3 of the July 2008 decision reflected errors of law involving the extent to which CMS's allegations of LCCB's noncompliance with sections 483.25 and 483.75 were merely duplicative and exclusively derived from CMS's findings of noncompliance with other, separately identified deficiencies. *Id.* at 11, 23, 28. Accordingly, the Board vacated FFCLs 1, 2 and 3 of the July 2008 decision and remanded the case to the ALJ for further deliberations, further development of the record if necessary, and a revised decision.

The ALJ's findings and conclusions on remand (DAB CR 2509)

On remand, the ALJ accepted additional briefs by the parties and admitted into the record additional evidence submitted by LCCB. The parties agreed that a second evidentiary hearing was not required. After considering the parties' additional arguments and the entire record, the ALJ made the following findings of fact and conclusions of law (FFCLs):

1. Petitioner failed to substantially comply with the physician consultation requirement at 42 C.F.R. § 483.10(b)(11).

2. Petitioner failed to substantially comply with the quality of care regulation at 42 C.F.R. § 483.25.

3. Petitioner failed to substantially comply with the facility administration requirement at 42 C.F.R. § 483.75.

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

5. Petitioner's noncompliance at a level of immediate jeopardy extended from January 3 through March 27, 2007.

6. The CMP imposed for the period of immediate jeopardy, $4,050 per day from January 3 through March 27, 2007, is reasonable.

DAB CR2509. LCCB timely requested review by the Board of the ALJ Decision.

Standard of Review

The Board's standard of review on a disputed conclusion of law is whether the ALJ decision is erroneous. The standard of review on a disputed finding of fact is whether the ALJ decision is supported by substantial evidence in the record as a whole. *Guidelines for Appellate Review of Decisions of Administrative Law Judges Affecting a Provider's participation in the Medicare and Medicaid Programs* (Board Guidelines), http://www.hhs.gov/dab/guidelines/ prov.html.

Analysis

We explain below why, applying the governing standard of review, we uphold the ALJ's decision on remand. At the outset, we note that LCCB's appeal and reply briefs repeatedly mischaracterize the scope of the deficiency allegations underlying the State Agency's survey findings and CMS's determinations. According to LCCB's unsupported characterizations, CMS changed its theories about LCCB's noncompliance over a period of several years to justify the penalties it imposed on the facility. LCCB's contentions also misrepresent what we determined in our prior decision in this case, what we instructed the ALJ to do on remand, and what the ALJ did and found on remand. Most notably, with respect to FFCL 1, LCCB mischaracterizes our prior decision as improperly interfering with the ALJ's assessment of a witness' credibility and our remand order as an instruction to the ALJ to "cobble together" alternative grounds for finding LCCB noncompliant. P. Br. at 3, 38. Finally, as we discuss where relevant throughout this decision, LCCB repeatedly mischaracterizes the evidence in the record, regularly fails to support its representations with any record citation, and frequently cites documents that do not support the representation made.

Accordingly, below we first address LCCB's allegations that from the State Agency survey process through the appeals proceedings, CMS has changed its theory of the case. We describe the survey findings on which CMS based its determinations about LCCB's noncompliance, which were set forth in the survey statement of deficiencies (SOD) that

was furnished to LCCB when the survey was completed. We show that the operative facts and theories of noncompliance argued by CMS on appeal and addressed by the ALJ were plainly set forth in the survey findings on which CMS relied. Moreover, the Board has held that an ALJ does not err in permitting issues to be raised during the hearing that were not clearly raised on the SOD provided the facility has notice and a meaningful opportunity to be heard on those issues. *Livingston Care Center*, DAB No. 1871 (2003), *aff'd, Livingston Care Ctr. v. U.S. Dep't of Health and Human Servs*., 388 F.3d 168 (6th Cir. 2004). We find that LCCB had ample notice and opportunity to respond to all of the alleged facts and deficiencies addressed by the ALJ.

We next discuss the ALJ's FFCLs seriatim, explaining why we conclude that each is supported by substantial evidence in the record as a whole and free from legal error. We also address LCCB's contentions to the contrary as they relate to specific findings and conclusions.[2]

I. LCCB was provided sufficient notice and opportunity to respond to CMS's noncompliance allegations and the grounds on which the ALJ relied to sustain CMS's determinations.

LCCB argues that CMS changed its theory of the facility's noncompliance over the course of this appeal and that "this case has become a penalty in search of a theory of noncompliance." P. Br. at 2; P. Reply at 1; *see also* P. Br at 7-8 (the "supposed basis for the sanction morph[ed] into a series of considerably different allegations and conclusions" than cited in the survey findings).[3] LCCB asserts that the State Agency

[2] Although we do not expressly address all of the arguments and assertions contained in LCCB's appeal briefs, we have, in fact, considered them all and determined that none warrant a reversal or modification of the ALJ decision on remand. Similarly, it is not efficient or useful to correct every individual misstatement or inaccurate characterization in LCCB's briefing. Our silence should not be read as accepting any of LCCB's comments.

[3] LCCB protests the duration of the survey process, stating that the survey began on February 12, 2007 as a complaint investigation relating to charges that LCCB and the hospital had not implemented Resident 1's do-not-resuscitate advance directive. P. Br. at 5; *see also.* Tr. at 97-100. LCCB states that it was not until March 21, 2007, that the State Agency "declared 'immediate jeopardy'" and "began an extended survey," which at one point focused on whether Resident 1 had been "neglected" by LCCB staff. *Id. citing* Tr. at 245. LCCB cites no authority limiting the time in which a partial extended survey triggered by information obtained during a complaint survey must be completed.

We further note that the CMS State Operations Manual (SOM), Appendix P, "Survey Protocol for Long Term Care Facilities," provides: "If a possible noncompliant situation related to any requirement is identified while conducting the information gathering tasks of the survey, investigate the situation to determine whether the facility is in compliance with the requirements." Section II.B.2. of Appendix P explains that a "partial extended survey explores the extent to which structure and process factors such as written policies and procedures, staff qualifications and functional responsibilities . . . may have contributed to the outcomes," including deficiencies in quality of care.

"cited, and CMS pressed, the deficiency as Nurse Suffoletta's failure to call the physician when the Resident vomited about 8 P.M." P. Br. at 15. LCCB argues that it was not until the ALJ hearing that "CMS first alleged that Resident #1 suffered 'at least two episodes' of vomiting, and other symptoms such as 'mental changes' that were significant enough to require an immediate report to the Resident's attending physician several hours before Nurse Suffoletta actually called." P. Br. at 8, citing CMS Request for Review at 7-8. Moreover, LCCB argues, CMS and the ALJ "conjured a web of 'systemic' noncompliance that is nothing like that described by the survey team, and that has no basis in the evidentiary record." P. Reply at 3; *see also* P. Br. at 3. According to LCCB, neither CMS nor the ALJ explained how "Nurse Suffoletta or anyone else could have been on notice of all of the various arguments and theories raised during the past five years." P. Br. at 3-4.

These contentions are baseless. The April 2007 SOD, as well as the April 2007 notice of CMS's determination referencing the SOD, show that all of the deficiency allegations and underlying operative facts addressed by the ALJ were clearly identified during the survey process and in the survey report. A SOD notifies a facility "of the nature, scope, and severity of the deficiencies found and the factual basis for the survey agency's conclusion that regulatory standards had been violated." *Western Care Management Corp., d/b/a Rehab Specialties Inn*, DAB No. 1921 (2004), *citing Pacific Regency Arvin*, DAB No. 1823 (2002). The Board has consistently held that the SOD may function to notify a facility of alleged deficiencies as well as forming prima facie evidence of the facts asserted in it. *See, e.g.*, *Pacific Regency Arvin*, DAB No. 1823 (2002).

In this case, the April 2007 SOD notified LCCB that the State Agency and CMS found LCCB noncompliant with the notification of changes-physician consultation requirement at section 483.10(b)(11), at the immediate jeopardy level of severity, based on findings that included:

- "Resident #1 was observed to vomit profusely and had a change in mental status between 6:30-8:30pm on 01/02/07."

- "Between 12:00am and 1:00am, the resident was observed by a nursing assistant to have vomited a second time."

- ". . . the physician was not notified of the resident's repeated vomiting or significant decline in mental status until 4:00am on 01/03/07 when the resident was found unresponsive, gray, and gurgling with vomit on her night clothes."

- ". . . the facility failed to assure all nursing staff was trained on the revised [notification of changes-physician notification] policy (November 2006) on identifying significant changes in condition and the need for notification of the physician . . ."

- ". . . the facility failed to ensure that the resident's vital signs and oxygen saturation levels were monitored per physician's orders."

- "This failure posed an Immediate Jeopardy to the health and safety of all residents who may experience a change in condition and require altered treatment plans."

CMS Ex. 3, at 3-4. Furthermore, the presence of arguments contained in CMS's posthearing brief refute LCCB's contention that CMS did not allege that Resident #1 suffered at least two episodes of vomiting until CMS requested review of the ALJ's initial decision. Consistent with the range of deficient practices identified in the SOD, CMS argued in its posthearing brief that the record evidence "demonstrates that Resident #1 experienced, at a minimum, two to four episodes of emesis," and "the facility did not actually record Resident 1's vital signs after either the first or second time she vomited." CMS Posthearing Br. at 11. "Consequently," CMS argued, LCCB's noncompliance with section 483.10(b)(11) could be based on, among other things, "the repeated episodes of emesis." *Id.* at 11-12.

The SOD, as well as CMS's arguments before the ALJ, thus put LCCB on notice that CMS's determination of LCCB's noncompliance with section 483.10(b)(11) involved more than the question whether Nurse Suffoletta was required, but failed, to consult with Resident 1's physician when the resident began to vomit at approximately 8:00 p.m. Indeed, the SOD plainly set forth the range of factual allegations of noncompliance that the ALJ considered, including that Resident 1 had a separate episode of emesis at approximately 1:00 a.m. and that the resident was not sufficiently monitored throughout the evening of January 2-3, 2007.

Moreover, the SOD shows that the State Agency and CMS determinations were not limited to findings and allegations of noncompliance under 483.10(b)(11). Rather, the SOD details a series of additional survey findings (addressed by the ALJ and discussed below) to support determinations of immediate jeopardy noncompliance with the quality of care standards at 483.25 and the facility administration requirements at 483.75, and noncompliance at less than immediate jeopardy with the comprehensive care plan requirements at sections 483.20(d)(3) and 483.10(k)(2). That CMS "pressed" the additional operative facts and allegations of LCCB's noncompliance under sections 483.25 and 483.75 is evident in CMS's prehearing brief, posthearing brief and testimony offered at the hearing. *See, e.g.,* CMS Prehearing Br. at 11 (LCCB was in noncompliance

with the administration requirements at 483.75 because it "failed to: 1) take necessary actions to correct deficient practices, including investigating contributing events, involving residents who experience a significant change in condition, and 2) ensure all staff were trained properly regarding procedures to effectuate the facility's physician notification policy"); Tr. at 145-147 (testimony of Surveyor Branham relating to investigation of facility training practices).

Accordingly, we reject LCCB's contentions that CMS changed and expanded the bases for imposing penalties after the survey and that the ALJ made a series of findings of "systemic" breakdown in LCCB's clinical and administrative processes that were not cited as grounds for CMS's determinations.[4] Thus, we conclude that LCCB had ample notice and opportunity to address all of the deficiency allegations evaluated in the ALJ decision.

II. The ALJ's determination that LCCB failed to comply substantially with 42 C.F.R. § 483.10(b)(11) (FFCL 1) is supported by substantial evidence and free from legal error.

The notification of changes-physician consultation requirement

Section 483.10(b)(11), titled, "Notification of changes," provides in relevant part:

> (i) A facility must immediately . . . consult with the resident's physician . . . when there is—
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> * * *
>
> (B) A significant change in the resident's physical, mental, or psychosocial status (i.e., a deterioration in health, mental, or psychosocial status in either life threatening conditions or clinical complications); or
> (C) A need to alter treatment significantly (i.e., a need to discontinue an existing form of treatment due to adverse consequences, or to commence a new form of treatment) . . . .

[4] We note that even if the SOD did not provide clear notice to LCCB of all of the operative facts underlying the State Agency and CMS noncompliance determinations (which it did), it would not have been error for the ALJ to develop the record further and evaluate the evidence. The ALJ review is de novo, and the "issue before the ALJ is whether 'the evidence as it is developed before the ALJ' supports the finding of noncompliance, 'not . . . how CMS evaluated the evidence as it stood at whatever point CMS made its assessment.'" *Sunbridge Care and Rehabilitation for Pembroke* DAB No. DAB 2170 (2008), *aff'd, Sunbridge Care & Rehabilitation for Pembroke v. Leavitt*, 340 F. App'x 929 (4th Cir. 2009), *quoting Emerald Oaks*, DAB No. 1800, at 13, 16 (2001).

LCCB's policy, "Identifying Change in Resident Condition, Proper Notification of Physician," is based on the American Medical Directors Association (AMDA) clinical practice guidelines on recognizing and evaluating acute changes of condition.[5] The policies provide under the "condition" of "emesis" that the practitioner/physician must be notified immediately if: 1) emesis is "bloody or coffee ground vomit;" 2) the resident has more than one "episode" of emesis within 24 hours; or 3) emesis is accompanied by abdominal pain and changes in vital signs. LCCB Ex. 29, at 20; LCCB Ex. 30, at 2. A "one time episode" or "single episode" may be reported to the physician on the "next office day." *Id*. The parties in this case agree that the AMDA and LCCB policies represent the applicable standard of care under section 483.10(b)(11) for identifying significant changes in a resident's status requiring immediate physician consultation.[6]

The ALJ's findings in DAB CR1818

The ALJ initially found that Resident 1 had a single episode of emesis on the night of January 2-3, 2007, at approximately 8:30 p.m.; that LCCB properly monitored and assessed Resident 1 throughout the evening; and that Resident 1 did not have a significant change in condition until approximately 4:00 a.m. DAB CR1818, at 6-11. In reaching these findings, the ALJ explained that he relied on the "common understanding of the word 'episode'" as "an event that is distinctive and separate although part of a larger series." *Id.* at 10, *citing* Merriam-Webster's Collegiate Dictionary (10th ed. 2001). The ALJ also stated that he had relied on Nurse Suffoletta's hearing testimony that Resident 1 had a single vomiting episode on the night of January 2-3, 2007, and that she took Resident 1's vital signs twice between 8:00 p.m. and 2:00 a.m. but did not record them because they were stable. *Id.* at 11. The ALJ stated that he had found Nurse Suffoletta's testimony to be credible based on "her demeanor and candor while testifying" and his conclusion that the nurse's testimony was "consisten[t] . . . with all other written and oral evidence, her own experience and training," and not impeached by any "evidence whatsoever on the point." *Id*. Based on these findings, the ALJ concluded that LCCB was in substantial compliance with the applicable policies and section 483.10(b)(11).

[5] The AMDA guidelines define an "acute change of condition" as "a sudden clinically important deviation from a patient's baseline in physical, cognitive, behavioral or functional domains" and "clinically important" to mean "a deviation that, without intervention, may result in complications or death." P. Ex. 29, at 17.

[6] LCCB is thus mistaken in its claims that CMS somehow repudiated earlier survey findings that the *policy* (which LCCB adopted to correct prior deficiencies) was appropriate. The issue throughout has been whether LCCB properly implemented the policy in the events at issue.

The Board's determination and remand instructions in DAB No. 2233

The Board determined on review that the ALJ's definition of what may be considered a single "episode" of emesis was "unsubstantiated and ill-defined." DAB No. 2233, at 14-16. Accordingly, the Board instructed the ALJ to develop the record and clarify what constitutes an "episode" of vomiting under the LCCB and AMDA policies. *Id.* at 15-16.

The Board also determined that the ALJ's analysis failed to address evidence that conflicted with Nurse Suffoletta's hearing testimony and the ALJ's characterization of "all other written and oral evidence" as fully consistent with the nurse's testimony. *Id.* at 16-21. Accordingly, the Board instructed the ALJ to evaluate the evidence in the record suggesting that Resident 1 vomited more than once prior to 8:30 p.m., and again between midnight and 1:00 a.m. *Id.* at 16. In addition, the Board directed the ALJ to evaluate evidence that appeared to contradict his initial finding that Nurse Suffoletta took Resident 1's vital signs twice between January 2 at 8:00 p.m. and January 3 at 2:00 a.m. *Id.* at 18-21. The Board instructed the ALJ to explain in a revised decision his assessments of the cited evidence and whether the evidence led him to alter his prior findings. *Id.* at 15-21.

The ALJ's findings and conclusions on remand

On remand, the ALJ began his analysis of LCCB's compliance under section 483.10(b)(11) with a discussion of the "credibility of Nurse Suffoletta's testimony." DAB CR2509, at 10. The ALJ noted that in making his original decision, he had found the nurse's hearing testimony to be credible, consistent with all other record evidence, and unimpeached. But the evidence pointed out by the Board, the ALJ stated, "should have, and has, caused me to re-evaluate Nurse Suffoletta's testimony and nursing notes against other evidence of record." *Id.* The ALJ continued, "Although I do not doubt that Ms. Suffoletta's testimony and the notes she prepared are essentially accurate, I find them in retrospect to be incomplete." *Id.* Further, the ALJ stated, where Nurse Suffoletta "testified that Resident 1's vital signs were taken on the evening of January 2-3, 2007 prior to 4:00 a.m., I now find that testimony to be outweighed by a preponderance of evidence to the contrary." *Id.*

The ALJ next made three separately numbered determinations relating to LCCB's compliance. In "Determination 1," the ALJ addressed the meaning of the term "episode" in the LCCB and the AMDA policies, and the evidence relating to the number of "episodes of emesis" Resident 1 had on the night of January 2-3, 2007. The ALJ noted that CMS asserted on remand that the term "episode" should be given its "ordinary meaning." *Id.* at 12. LCCB asserted that there was no standard medical definition for the term "episode," that vomiting may "involve repeated gagging and regurgitation until the stomach is purged," and that "what constitutes an episode of emesis requires some degree of nursing judgment." *Id. citing* P. Supplemental Br. on Remand at 14-16. After

considering these assertions, and the evidence submitted by the parties on the issue, the ALJ concluded that he was "left with no definition of 'episode,'" as used in LCCB's and the AMDA policies, other than the one used in his original decision, to mean "an event that is distinctive and separate although part of a larger series." *Id.* at 8, 14.

Using this definition of "episode," and on reevaluation of the hearing testimony and evidence, the ALJ determined that Resident 1 had a second episode of emesis at approximately 1:00 a.m. on January 3, requiring LCCB to consult immediately with Resident 1's physician under the regulatory standard. The ALJ stated that while he previously relied on Nurse Suffoletta's hearing testimony that the resident had a single episode of emesis (at approximately 8:30 p.m.), he should have considered Nurse Suffoletta's statement to the surveyor, reflected in the SOD, "that Resident 1 vomited *again,"* together with Nurse Suffoletta's 1:00 a.m. nursing note that there was emesis on Resident 1's night clothes. *Id.* at 8, 15. Relying on this documentation, the ALJ found on remand, "the preponderance of the evidence indicated that Resident 1 did have at least a second episode of emesis on the night in question." *Id.* at 15 (emphasis in ALJ decision).[7] Moreover, the ALJ concluded, the evidence showed that at "the relevant time, that is certainly what Nurse Suffoletta believed and her description of it after the fact does not change that she believed it to be an episode of emesis." *Id.* "This conclusion" the ALJ added, "fits within what I found before and find now — in the absence of any other suggested definition to the contrary — to be the common understanding of the word 'episode' as an event distinctive and separate, although part of a larger series." *Id.*

In his second determination, the ALJ addressed the Board's order to evaluate evidence, including a surveyor summary of an interview with one of the CNAs and the testimony of Resident 1's granddaughter, that Resident 1 vomited more than once in the early part of the evening. While it was not contested that Resident 1 vomited more than once while her granddaughter was visiting Resident 1 in the early evening, the ALJ wrote on remand, the evidence was "not clear as to the amount of time constituting the gap between the two incidents or its portent." *Id.* After analyzing in detail and re-weighing all of the relevant evidence, the ALJ determined that the incidences of Resident 1 vomiting in the early evening of January 2-3, 2007 constituted a "continuing," single "episode of vomiting"

[7] In an ALJ proceeding concerning a SNF's alleged noncompliance with Part 498 requirements, CMS has the burden of coming forward with evidence related to disputed findings that is sufficient (together with any undisputed findings and relevant legal authority) to establish a prima facie case of noncompliance with a regulatory requirement. *Evergreen Nursing Care Center*, DAB No. 2069, at 7. If CMS makes this prima facie showing, then the SNF must carry its ultimate burden of persuasion by showing, by a preponderance of the evidence, on the record as a whole that it was in substantial compliance during the relevant period. *Id.; see also Batavia Nursing and Convalescent Inn*, DAB No. 1911 (2004), *aff'd, Batavia Nursing & Convalescent Ctr. v. Thompson*, 143 F. App'x 664 (6th Cir. 2005).

and that Resident 1 did not have more than one episode of emesis prior to the episode at approximately 1:00 a.m. *Id.* at 16.

In his third determination relating to the notification of changes-physician consultation requirement, the ALJ reasoned, "Unless Nurse Suffoletta took Resident 1's vital signs she would not know whether [there was a change in her vital signs] that, combined with Resident 1's profuse vomiting, required immediate physician notification." *Id.* at 20. The ALJ noted that while LCCB might argue that Resident 1 did not have pain, "given Resident 1's mental acuity, it is not clear whether or not she would be a valid reporter of pain." *Id.* n. 2. Thus, the ALJ determined "it was even more incumbent that Nurse Suffoletta ensure that vital signs be taken." *Id.* On review of the entire record and the parties' arguments on remand, the ALJ found that Nurse Suffoletta "did not properly monitor and assess Resident 1 on the night in question" and that his "initial finding that Nurse Suffoletta took unrecorded but normal vital signs of Resident 1 twice between 8:00 p.m. and 2:00 a.m. is erroneous." *Id.* at 20.

Applying the LCCB and AMDA policies on significant changes of condition that require immediate physician notification to his factual findings, the ALJ concluded that LCCB was not in substantial compliance with section 483.10(b)(11).

Discussion

LCCB's arguments that the Board interfered with the ALJ's authority to assess witness credibility and independently evaluate the evidence are without merit.

LCCB objects to the ALJ's reevaluation of Nurse Suffoletta's credibility, arguing that the Board improperly reversed the ALJ's original assessment of the nurse's testimony. LCCB states that the Board has repeatedly held that "it will not interfere with this basis for an ALJ Decision absent 'clear error' or a 'compelling' basis to do so, yet it did exactly that here." P. Br. at 2; *see also* P. Br. at 29, citing Board decisions. According to LCCB, the Board "abandoned the traditional rule for developing a record in order to assure a specific result." P. Br. at 31. Moreover, LCCB contends, the Board "essentially instruct[ed] the ALJ to find some way to sustain a penalty." *Id.* at 9. In turn, LCCB maintains, the ALJ "stated that he understood that the Board had directed him to find Nurse Suffoletta ipso facto could not be considered 'credible' should any surveyor, CMS official, CMS lawyer, or the Board question her judgments." *Id.* at 7. LCCB argues that

the ALJ seems to have understood the Board's remand order to have required him to "cobble together a new basis for a sanction from CMS's various allegations and arguments" during the course of the appeal. *Id.* at 3.

These arguments mischaracterize our earlier decision and the ALJ's clear, thorough and independent analysis of the evidence and testimony on remand. As stated in our prior decision in this matter, the Board's role as an appellate body is not to re-weigh evidence or substitute its own evaluation of evidence for that of the ALJ. DAB No. 2233, at 10, *citing Odd Fellow and Rebekah Health Care Facility*, DAB No. 1839, at 4 (2002). Nor will the Board "disturb an ALJ's assessment about the relative credibility of testimony by witnesses who appear in person at the hearing absent a compelling reason to do so." *Koester Pavilion*, DAB No. 1750, at 15 (2000). However, the Board's role is not a mere formality to simply "rubber stamp" an ALJ's decision. In order to properly evaluate whether an ALJ's factual findings are supported by substantial evidence in the record as a whole, the Board reviews all of the arguments and evidence and "take[s] into account whatever in the record fairly detracts from the weight of the decision below." *Britthaven, Inc.*, DAB No. 2018, at 2 (2006), *citing Universal Camera Corp. v. NLRB*, 340 U.S. 474, 488 (1951). The Board considers "whether conflicting evidence in the record has been addressed by the ALJ and whether the inferences drawn by the ALJ are reasonable." *Britthaven* at 2, citing *Barry D. Garfinkel, M.D.*, DAB No. 1572, at 5-6 (1996), *aff'd, Garfinkel v. Shalala*, No. 3-96-604 (D. Minn. June 25, 1997). Thus, the Board cannot determine whether factual findings are supported by substantial evidence unless the ALJ decision includes "not only an expression of the evidence considered which supports the result, but also some indication of the evidence which was rejected . . . ." *Cotter v. Harris*, 642 F.2d 700, 705 (3rd Cir. 1981).

In this case, we found on review of the ALJ's original decision compelling reasons to require the ALJ to reassess his credibility determinations, as well as clear errors of law requiring reversal of the decision in part, and remand for further development, reconsideration by the ALJ, and a revised decision. Specifically, the ALJ's initial conclusion that LCCB was in substantial compliance with *all* participation requirements and that there was *no* basis to impose any penalties (FFCL 4) was plainly contradicted by LCCB's own admission of noncompliance with the care planning requirements and expressed expectation that a CMP would be imposed for that noncompliance. DAB No. 2233, at 7-10. Accordingly, we vacated FFCL 4 of the ALJ's initial decision and adopted new findings and conclusions that LCCB failed to substantially comply with the comprehensive care plan requirements and that the $100 per-day CMP imposed for the care plan deficiencies from January 3, 2007 through April 9, 2007, was reasonable. DAB No. 2233, at 29.

We further found on review of the other FFCLs in the ALJ's first decision both material legal errors and an array of evidence contradicting the ALJ's characterization of the record evidence as entirely consistent with Nurse Suffoletta's hearing testimony. *Most importantly, we did not reverse those findings and conclusions*. Rather, we remanded the matter for the ALJ to correct the legal errors, to address the evidence that was inconsistent with the nurse's hearing testimony, and to reweigh the evidence under the applicable burdens of proof and persuasion.

The ALJ Decision on remand clearly and thoroughly addressed all of the evidence that the Board instructed the ALJ to evaluate, together with the other record documentation and testimony. The ALJ provided detailed explanations of why he concluded in certain instances, but not in others, that the preponderance of the evidence conflicted with his prior factual findings (and Nurse Suffoletta's hearing testimony) in a material manner. For example, as reflected in the ALJ's second determination described above, the ALJ found no such conflict on reconsideration of the evidence and testimony, stating, "There is no way for me on this evidence to determine by a preponderance of the evidence that the gap between the two incidents of vomiting [in the early evening] was as long as an hour." DAB CR2509, at 17. The ALJ then found "on solely the issue of whether or not the two incidences of vomiting prior to 8:30 constitute more than one episode of vomiting, I find Petitioner was not required to contact Resident 1's physician." *Id.*

In sum, the ALJ's decision on remand makes it clear why he ultimately concluded that Nurse Suffoletta's testimony was "essentially accurate" but "incomplete" regarding the emesis, and on the question whether the resident's vital signs were taken prior to 4:00 a.m., "outweighed by a preponderance of evidence to the contrary." *Id.* at 10. The ALJ's careful, detailed explanation of his findings and conclusions further demonstrates that, consistent with our remand order, he conducted a comprehensive and impartial review of the evidence proffered and issues posed in this case and did not simply "cobble together" reasons to uphold the CMP.

> *The ALJ's determinations of LCCB's noncompliance with section 483.10(b)(11) are supported by substantial evidence and free from legal error.*

LCCB argues that "CMS did not establish even a prima facie case of noncompliance." P. Br. at 34-36. LCCB contends that the ALJ's finding that Resident 1 had a second episode of emesis at about 1:00 a.m. was "completely inconsistent with clear – and undisputed – evidence to the contrary." P. Br. at 16. LCCB acknowledges that Nurse Suffoletta "wrote a nursing note at 1 A.M. which recites that she saw a '[small] amount of emesis [on] night clothes. Night clothes [changed].'" P. Br. at 16, *quoting* P. Ex. 16, at 9. LCCB argues, however, that the nurse wrote during LCCB's investigation and

testified later at the hearing that what she saw was a small orange stain on the resident's bedclothes; the nurse testified that she did not think that the Resident had vomited again but had "coughed up" medication administered earlier in the evening. P. Br. at 16-17, *citing* Tr. at 192-193, 219.

LCCB further contends that the statement in the SOD, "Further interview with [Nurse Suffoletta] revealed the resident vomited again between 12:00am and 1:00 am," is not supported by any surveyor notes memorializing the alleged interviews and reflects merely a surveyor's conclusion. According to LCCB, "the ALJ says the fact that the surveyors actually did *not* interview Nurse Suffoletta is immaterial because he must accede to the Board's interpretation of the Statement of Deficiencies (that is, to mean that there actually *was* an interview in which Nurse Suffoletta made various 'admissions,' even though there is no evidence of such an interview in the record, and the surveyor said that there was none)." P. Br. at 17 (emphasis in original). "CMS' case," LCCB argues "depended entirely upon no more than a surveyor's opinion that Resident #1 suffered more than one 'episode' of emesis as described in the AMDA Guidelines and Petitioner's policy." *Id.* at 36.

LCCB's arguments mischaracterize the ALJ's findings and conclusions as well as the evidence on which he relied. For example, contrary to LCCB's statement, the ALJ did *not* find that the surveyors failed to interview Nurse Suffoletta. *See* ALJ Decision at 11. Indeed, the ALJ noted that "Petitioner states that while surveyors Beard and Branham both testified that they interviewed Nurse Suffoletta, there are no notes memorializing those interviews." *Id*.; *see also* Tr. at 86-87 (Surveyor Beard testified that she interviewed Nurse Suffoletta); Tr. at 131-133,139, 146-47 (Surveyor Branham testified that she interviewed Nurse Suffoletta). What the ALJ actually found was that although "CMS did not produce surveyor notes *memorializing* Nurse Suffoletta's interviews with surveyors, that alone does not impeach the statements in the SOD unless those statements are rebutted by Petitioner by a preponderance of the evidence." *Id*. (emphasis added). The ALJ found the SOD statements evidence of the interviews that LCCB needed to rebut regardless of whether there were surveyor notes on those interviews, and he committed no error in doing so.

Weighing the conflicting testimony and documentation relating to Resident 1's condition over the course of the evening and the nursing staff's observations, the ALJ also reasonably relied on Nurse Suffoletta's contemporaneous nursing notes from the night – in particular, her use of the term "emesis" to describe what she observed on Resident 1's night clothes at 1:00 a.m. – as clear and persuasive evidence that Resident 1 had a second episode (*i.e.*, a distinctive and separate event, although part of a larger series, as the ALJ

defined it) of emesis at that time.[8] CMS Ex. 17, at 31. Furthermore, because Nurse Suffoletta herself wrote the note, it was also reasonable for the ALJ to conclude Nurse Suffoletta believed at the time that Resident 1 had a second emesis episode.

Consistent with these findings, the SOD evidences that one of the certified nursing assistants (CNA) on duty later "stated [to the surveyors that] Resident #1 was found at 12:00 am with vomit on her night clothes and she informed the nurse of the resident's condition." CMS Ex. 3, at 6. In addition, we note, LCCB's own "Incident Investigation" indicates that the facility's administrators themselves believed that there had been more than one emesis episode: "Nurse should have documented [resident's] status between *episodes of emesis*," the report states. P. Ex. 24, at 3 (emphasis added). We note, moreover, that while Nurse Suffoletta testified at the hearing that what she observed on Resident 1's nightclothes at 1:00 a.m. "was a very, very small amount, like she had maybe burped and, you know, just -- or coughed up something," her contemporaneous nursing notes show there was enough "emesis" on the resident's gown that the staff determined Resident 1's clothes should be changed again. Tr. at 219; CMS Ex. 17, at 31. The fact that Resident 1's clothes were changed at one o'clock in the morning further indicates that Nurse Suffoletta thought at the time that the amount of emesis was significant and, consistent with the ALJ's finding, that a second episode of vomiting had occurred.

Further, contrary to LCCB's misrepresentations of the evidence and the ALJ's findings, the ALJ reasonably relied on the SOD summary of the surveyor interviews with Nurse Suffoletta, together with the nursing notes, as persuasive evidence that Resident 1 had a second episode of emesis at 1:00 a.m. As noted, the SOD may constitute prima facie evidence of the facts asserted therein. In addition, the Board has determined, if a finding in an SOD is not disputed, CMS need not present additional evidence in support of the finding. *Batavia Nursing and Convalescent Center*, DAB No. 1904 (2004), *aff'd, Batavia Nursing and Convalescent Center v. Thompson*, 129 F. App'x 181 (6th Cir. 2005). If a facility disputes a finding in an SOD, "the issue once both parties have presented their evidence . . . is whether the petitioner showed substantial compliance by a preponderance of the evidence." *Oxford Manor*, DAB No. 2167, at 2-3 (2008). Mere denials are not enough. *Id.* If the evidence on which the petitioner relies is unreliable or outweighed by evidence to the contrary, the petitioner has not met its burden. *Id.*

Here, the ALJ reasonably construed the assertion in the SOD, "Further interview with [Nurse Suffoletta] revealed the resident vomited again between 12:00am and 1:00am," as prima facie evidence that the nurse told the surveyors that Resident 1 had vomited again

[8] We accept the ALJ's definition of an "episode" for purposes of this case since the parties do not challenge it.

between 12:00 and 1:00 a.m. on January 3, 2007. ALJ Decision at 11; CMS Ex. 3, at 7. Moreover, both Surveyor Beard and Surveyor Branham testified at the ALJ hearing that they interviewed Nurse Suffoletta about her observations and the care that she provided Resident 1 on the night of January 2-3, 2007. Tr. at 86-87 (Beard); Tr. at 131-133, 139, 146-47 (Branham). In response to cross-examination, Surveyor Beard testified that she did not specifically ask Nurse Suffoletta whether the nurse thought "this was one episode of emesis or two." Tr. at 105. Surveyor Beard further testified, however, that even if Nurse Suffoletta had told the surveyors that the Resident had only one episode of emesis during the evening (which she did not), the nurse's own note documenting emesis on Resident 1's gown at 1:00 a.m. "stated otherwise." Tr. at 105-106.

We also concur in the ALJ's assessment that there is "no material difference between the surveyors' use in the SOD of the word 'said' or the word 'revealed' with regard to what Nurse Suffoletta or any other individual may have told the surveyors during the survey." DAB CR2509, at 11. It was reasonable for the ALJ to conclude that either word refers to what the individuals interviewed told the surveyors, not the surveyors' conclusion. We further agree with the ALJ that the absence of surveyor notes memorializing the surveyors' interviews with Nurse Suffoletta does not alone impeach the statements in the SOD. As we stated, the SOD itself constitutes prima facie evidence of the facts asserted in it. Thus, as the ALJ accurately explained, the issue before him was whether LCCB rebutted the underlying factual assertion in the SOD, that Resident 1 had another incident of emesis at 1:00 a.m., by a preponderance of the evidence. Properly weighing the relevant evidence and testimony, including Nurse Suffoletta's contemporaneous nursing notes, the summary of the survey interviews in the SOD, and the nurse's subsequent hearing testimony, the ALJ reasonably concluded that LCCB "did not prove by a preponderance of the evidence that the SOD statements were erroneous or inaccurate." *Id.*

LCCB further contends that the "evidence plainly does not support the ALJ's discussion" regarding LCCB's responsibility to monitor Resident 1 or his finding on remand that Nurse Suffoletta did not adequately monitor the resident. P. Br. at 14. LCCB does not dispute that the nursing notes from the evening in question do not include any recorded vital signs for Resident 1 before 4:00 a.m. CMS Ex. 17, at 30-31. LCCB nevertheless argues that the undisputed evidence establishes that Nurse Suffoletta "personally took vital signs at least three times, about 8:30, then at 4 and 4:10 A.M; that she did rounds and eyeballed the resident; and that her CNAs took vital signs and reported [them] to her in the interim." *Id.* at 14. LCCB states, "Nurse Suffoletta testified – and Director of Nursing Morgeson confirmed that Nurse Suffoletta contemporaneously reported – that she or her CNAs took the Resident's vital signs . . . at least one or two more times" after they were taken and recorded at 8:30 p.m.; "that the Resident's vital signs always were within normal limits; and that the Resident did not appear to be in distress,

uncomfortable, etc., and slept unremarkably." *Id.* at 13, citing Tr. at 193, 201, 221, 227, 237, 240-241. According to LCCB, Nurse Suffoletta did not record these observations or vital signs because LCCB's policy of "documentation by exception," provided that it was not necessary to document ordinary, normal observations. *Id.* at 13-14, n. 11, *citing* P. Ex. 31, Tr. at 218, 220. Moreover, LCCB contends, "CMS offered no evidence that any professional standard required Nurse Suffoletta or her assistants to take the Resident's vital signs once, five times, or a thousand times during the hours in question, or to record normal signs." *Id.* at 14-15.

LCCB's arguments are not persuasive. The ALJ logically surmised that in order to implement LCCB's own change of condition-physician notification policy, which provides that immediate physician notification is necessary where emesis is accompanied by a change in vital signs and pain, LCCB's staff was required to take Resident 1's vital signs when she vomited at approximately 8:00-8:30 p.m. and when staff observed emesis on her gown at 1:00 a.m. DAB CR2509, at 20. Furthermore, LCCB's contention that CMS offered no evidence regarding the professional standard of care for monitoring a patient in Resident 1's condition during the night of January 2-3, 2007 is unfounded. It is well settled that an ALJ may rely on a surveyor's expertise as to applicable standards of professional care where the evidence shows that the surveyor has training, experience and knowledge in the subject field. *See, e.g., Embassy Health Care*, DAB No. 2327, at 7-8 (2010); *The Residence at Salem Woods*, DAB No. 2052, at 7-8 (2006). In this case, Surveyor Beard, a licensed nurse and surveyor with over 14 years experience in nursing, testified that when staff observed Resident 1 to have vomited, personnel should have fully assessed the resident and recorded her vital signs and oxygen saturation levels based on professional standards of nursing care as well as Resident 1's physician's orders to monitor oxygen saturation levels "daily" and vital signs "routinely." Tr. 72-74, 83-87. Similarly, Surveyor Branham testified that "[a]s a nurse, when . . . a family member reports to you that their significant other is not feeling well, an assessment is the only way that you can determine what might be the problem." Tr. at 115.

Contrary to LCCB's characterization of the evidence, the record includes, and the ALJ relied on, both documentary evidence and hearing testimony that Resident 1's vital signs were *not* taken from the time she began vomiting at approximately 8:00 p.m. until approximately 4:00 a.m. Specifically, Resident 1's granddaughter, Ms. Wherry, testified that she was with the resident throughout the early evening period (approximately 8-8:30 p.m.) when the resident vomited profusely and that nursing staff did not take the resident's vital signs at any time during that period. Tr. at 36-37, 66. Consistent with Ms. Wherry's testimony, the SOD summary of the February 2007 survey interviews with Nurse Suffoletta states that the nurse "revealed she did not listen to the resident's lungs, take vital signs or check to see if the resident had any medication to control the vomiting" during the early evening. CMS Ex. 3, at 7. The interview summary further provides: "The nurse stated she failed to assess the resident or notify the physician [between

12:00am and 1:00am]" and that "she was busy that night with other residents and did not think to assess the resident including obtaining vital signs, listening to the resident's lungs or notifying the physician at 1:00am." *Id.* During the ALJ hearing, the surveyors confirmed their survey interviews with Nurse Suffoletta. Surveyor Branham testified, "When we questioned her did she take the vital signs, did she, you know, perform any other type of assessment, she said no." Tr. at 116. Furthermore, according to the SOD summary of the survey interview with one of the CNAs on duty during the night, the CNA told the surveyors that "at 12:00 am the resident was found with vomit on her night clothes and she informed the nurse," but also "stated she was not instructed to take Resident #1's vitals at 8:30 pm or at 1:00 am." CMS Ex. 3, at 18-19. Moreover, as we discuss below, the evidence does not support that a practice of documentation by exception was in place at LCCB.

We conclude that the ALJ properly evaluated and weighed the foregoing evidence against Nurse Suffoletta's hearing testimony. The ALJ reasonably found that the nurse's notes and survey interview summary, "in conjunction with the lack of documentation regarding whether vital signs were taken," led to the conclusion that Resident 1's vital signs were not taken during the night of January 2-3, 2007 until 4:00 a.m., when they were first recorded. DAB CR2509 at 20. We find no fault in the ALJ's assessment of the evidence or his reasoning and therefore conclude that substantial evidence in the record supports the ALJ's finding that LCCB failed to monitor sufficiently Resident 1 as required under LCCB's change in condition-physician notification policy and section 483.10(b)(11).

Based on the foregoing analysis, we conclude that the ALJ's determination that LCCB was in noncompliance with section 483.10(b)(11) is supported by substantial evidence and free from legal error.

III. The ALJ's determination that LCCB failed to comply substantially with the quality of care regulation at 42 C.F.R. § 483.25 (FFCL 2) is supported by substantial evidence and free from legal error.

The quality of care requirement

The opening provision of 42 C.F.R. § 483.25 (quality of care), which implements sections 1819(b)(2) (Medicare) and 1919(b)(2) (Medicaid) of the Act, states:

> 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.

The quality of care legislation and regulatory requirements are "based on the premise that the facility has (or can contract for) the expertise to first assess what each resident's needs are (in order to attain or maintain the resident's highest practicable functional level) and then to plan for and provide care and services to meet the goal." *Spring Meadows Health Care Ctr.*, DAB No. 1966, at 16 (2005). The regulation thus "imposes on facilities an affirmative duty designed to achieve favorable outcomes to the highest practicable degree." *Windsor Health Care Center*, DAB No. 1902, at 16-17 (2003), *aff'd, Windsor Health Care Ctr. v. Thompson*, No. 04-3018 (6th Cir. 2005). The facility must take "reasonable steps" and "practicable measures to achieve that regulatory end." *Clermont Nursing & Convalescent Ctr.*, DAB No. 1923, at 21 (2004), *aff'd, Clermont Nursing & Convalescent Ctr. v. Leavitt*, 142 F. App'x 900 (6th Cir. 2005), *citing Josephine Sunset Home*, DAB No. 1908, at 14 (2004).

Accordingly, the Board has repeatedly held that the language of section 483.25 requires skilled nursing facilities to furnish the care and services set forth in a resident's care plan, to implement doctors' orders, to monitor and document the resident's condition, and to follow its own policies. *See, e.g., Alexandria Place*, DAB No. 2245 (2009) (failure to provide care in accordance with the doctor's order); *Kenton Healthcare, LLC*, DAB No. 2186 (2008) (failure to follow standards in the care plan for supervision); *Spring Meadows* at 17 ("the clearest case of failure to meet [section 483.25] is failure to provide one of the specific services outlined in the subsections or failure otherwise to follow the plan of care based on the comprehensive resident assessment"); and *St. Catherine's of Findley*, DAB No. 1964, at 13 n.9 (2005) (facility admission that it failed to follow its own supervision care plan may make summary judgment appropriate). The quality of care provision also implicitly imposes on facilities a duty to provide care and services that, at a minimum, meet accepted professional standards of quality "since the regulations elsewhere require that the services provided or arranged by the facility must meet such standards." *Spring Meadows* at 17, *citing* 42 C.F.R. § 483.75.

The ALJ's findings in DAB CR1818

The ALJ stated in his initial evaluation of LCCB's compliance with section 483.25 that CMS's allegations under the regulation were "essentially based on the same set of facts and circumstances involving Resident 1" that were at issue in the first deficiency citation. DAB CR1818, at 12. In addition, the ALJ stated, there had been no "allegation or evidence that [LCCB's] care plans, or assessments failed to meet Resident 1's needs." *Id.* Accordingly, the ALJ summarily concluded that LCCB was in substantial compliance with section 483.25 because he had already found that LCCB "staff acted in a manner consistent with professional standards of quality care" and properly monitored the resident.

The Board's determination and remand instructions in DAB No. 2233

The Board determined that "the ALJ erred by limiting his analysis of whether LCCB complied with the quality of care regulation to essentially the same questions addressed, and resolved in the facility's favor, under FFCL 1." DAB No. 2233, at 23. The Board pointed out that the quality of care deficiency allegations "were not merely duplicative or derivative" of the allegations of noncompliance regarding physician consultation, nor were they limited to the care and services provided to Resident 1 between 6:00 p.m. on January 2, 2007 until 4:00 a.m. on January 3, 2007, when she was found unresponsive. *Id.* The Board therefore instructed the ALJ on remand to address the additional grounds on which CMS's determination of noncompliance under section 483.25 were based, including allegations that between the times that Resident 1 began vomiting, and Resident 1's transport to the hospital, LCCB did not institute any interventions to help her condition or alleviate her symptoms.

The Board further directed the ALJ to consider LCCB's admissions that it did not follow the physician's orders to monitor Resident 1's oxygen saturation levels daily or update Resident 1's care plan to reflect the physician orders. In addition, the Board stated, "should the ALJ revise his assessment of the weight of the evidence or credibility of the witnesses' testimony relating to" the physician consultation requirement, "we would expect those changes to be reflected in a revised analysis of whether LCCB was in substantial compliance with the quality of care requirements . . . ." *Id*.

The ALJ's findings and conclusions on remand

The ALJ determined on remand that LCCB was not in substantial compliance with section 483.25. The ALJ based this conclusion on his findings that the facility failed to: 1) implement Resident 1's physician orders to monitor Resident 1's oxygen saturation levels daily; 2) take and document Resident 1's vital signs during the night of January 2-3, as required under the facility's own change of condition-physician notification policy; 3) provide necessary care and services, including administering oxygen, to Resident 1 between 4:00 and 4:20 a.m. on January 3, 2007; 4) convey important information about Resident 1's decline in condition and recent bout of vomiting to Emergency Medical Services (EMS) personnel; and 5) update Resident 1's care plan to implement the physician's order that vital signs be taken routinely and oxygen saturation readings daily. DAB CR2509 at 23-26.

Discussion

LCCB argues that CMS "pressed" the facility's noncompliance under the quality of care requirements "only cumulatively" and that CMS lawyers "*subsequently* raised all sorts of additional issues in [CMS'] Request for Review filed before this Board." P. Br. at 36

(emphasis in original). Moreover, LCCB contends, "CMS' prima face case *somewhere* must include an explanation how Petitioner's staff's actions or inactions failed to meet some applicable clinical or regulatory standard of care of which they reasonably could be on notice." *Id*. at 37 (emphasis in original). Here, LCCB maintains, "CMS simply failed to offer any such evidence, much less to connect the catalog of supposed failures it later alleged to any actual or potential bad outcome for this or any other Resident." *Id.* According to LCCB, this case "involves no more or less than retrospective second-guessing of the professional judgments of a single nurse on a single occasion," and "CMS never offered evidence that the nurse's professional judgments failed any professional standard; in fact, it is undisputed that they met the literal terms of an unremarkable clinical policy . . . ." P. Reply Br. at 3.

LCCB's arguments mischaracterize the survey findings relating to the quality of care requirements, the history of this appeal, and the evidence and testimony supporting the ALJ's decision on remand. As the SOD shows, while CMS's allegations of noncompliance under section 483.25 did include the same issues and findings involved in the first deficiency, the State Agency and CMS alleged that LCCB's noncompliance with section 483.25 also involved the following:

• From November 17, 2006 through early January 2007, the facility failed to implement physician orders to monitor Resident 1's vital signs regularly and oxygen saturation levels daily. CMS Ex. 3, at 19-20.

• Between 4:00 and 4:21 a.m. on the morning of January 3, 2007, the facility failed to provide suctioning or administer oxygen to Resident 1 when her oxygen saturation "was noted to be 46% and rapidly dropped to 36%." CMS Ex. 3, at 13-14, 17.

• LCCB "did not give [EMS] a verbal report of the resident's allergies, recent medical history or that the resident had been vomiting" when EMS arrived to transport Resident 1 to the hospital on January 3, 2007. CMS Ex. 3, at 16.

• The transfer "paperwork prepared by the facility [for EMS and the hospital] did not reveal the resident had been profusely vomiting . . . ." CMS Ex. 3, at 16.

In light of the findings cited in the survey SOD, we reject LCCB's contention that prior to CMS's request for review by the Board, CMS had not alleged the facility's noncompliance under section 483.25 involved issues other than whether Resident 1 experienced a significant change in condition requiring physician consultation prior to 4:00 a.m. on the night of January 2-3, 2007. Similarly, the SOD findings refute LCCB's argument that this case involves no more than an exercise in retrospective second-guessing the judgment of "a single nurse on a single occasion."

We also conclude that substantial evidence in the record as a whole supports the ALJ's findings that LCCB failed to meet the quality of care requirements at section 483.25. As noted, the Board has held that to provide each resident "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," the facility must ensure that doctors' orders are followed. Here, the ALJ's finding that LCCB failed to implement Resident 1's physician's orders to monitor Resident 1's oxygen saturation levels daily, beginning November 17, 2006, is supported by LCCB's admission at the ALJ hearing, the facility's own records, and the surveyors' findings on review of the facility records. At the hearing, counsel for LCCB stated, "Yes, it is true that the documentation of the resident's breathing status was not done in a way that was ordered." Tr. at 22. The record also includes the physician's November 2007 orders to "Monitor O2 [oxygen] Sats [saturation levels] daily. V/S [vital signs] routinely," as well as LCCB's Treatment Administration Records for Resident 1 showing, as the surveyors observed, "only 10 SPO2 readings were recorded from November 17, 2006 through December 31, 2006, and none for January 2007." CMS Ex. 17, at 9; P. Ex. 13, at 2; P. Ex. 14, at 4; CMS Ex. 3, at 19-20. We further note that the summary of the survey interview with LCCB's Director of Nursing reads: "the Director of Nursing . . . stated the nurses were to record the resident's vital signs and oxygen saturation on the TAR [Treatment Administration Record]. She stated the care plan should have been revised when new orders were obtained, and implement the interventions as ordered." CMS Ex. 3, at 12.

Moreover, the ALJ's finding that LCCB was required, but failed, to take and record Resident 1's vital signs on the evening of January 2-3, 2007 before 4:00 a.m. is supported by substantial evidence and free from legal error. Referencing his evaluation of the evidence as well as his analysis of LCCB's compliance with section 483.10(b)(11), the ALJ noted that he had previously found that LCCB personnel failed to take Resident 1's vital signs when she began vomiting at approximately 8:00 p.m. and again when they observed emesis on her night clothes at 1:00 a.m. (For the reasons explained above, we found substantial evidence to support this finding.) These omissions, the ALJ had logically concluded, constituted a failure to follow LCCB's own emesis policy, which requires immediate consultation with the physician when emesis is accompanied by changes in vital signs changes and abdominal pain. DAB CR2509, at 23. Because that policy could not be implemented unless staff in fact actually took the resident's vital signs when they observed the emesis on her clothing, the failure to take the vital signs constituted a failure to follow the facility's own policy. In light of the Board's prior holdings that a facility's failure to follow its own care policies constitutes noncompliance under the quality of care standards, the ALJ correctly concluded LCCB's failure to take Resident 1's vital signs before 4:00 a.m. constituted noncompliance under section 483.25.

With regard to the absence of documentation of Resident 1's vital signs on the night of January 2-3, 2007 before 4:00 a.m., the ALJ also addressed LCCB's contention that Nurse Suffoletta took Resident 1's vital signs but did not record them because they were normal. According to LCCB, the nurse's alleged action was consistent with the facility's "documentation by exception policy," under which only abnormal readings are recorded. The ALJ described the testimony that LCCB introduced to support this contention, including Nurse Lincoln's testimony that documentation by exception is a "customary practice," and excerpts from nursing textbooks and manuals quoted in LCCB's briefs. DAB CR2509, at 24. The ALJ assigned little weight to this evidence, however, noting that LCCB had not produced any written facility policy instructing staff to document residents' status by exception, nor did LCCB show that it trained its employees to follow such a practice. *Id.* We agree with the ALJ's analysis of this testimony, especially in the context of the evidence we discuss next.

LCCB's argument is contradicted by statements contained in LCCB's own documents. The facility's "Incident Investigation . . . (Root Cause Analysis) Form" regarding the January 3, 2007 "incident," states that: "Nurse [Suffoletta] should have *documented* [resident's] *status* between episodes of emesis. Nurse [Suffoletta] should have *documented vital signs* obtained [at] 8:30 p.m." P. Ex. 24, at 3 (emphasis added). The investigation report further states that "However, Nurse [Suffoletta] did not document any status between 8:00 pm to1:00 am or 1:00 am to 4:00 am." *Id*. Thus, even if LCCB had a policy of "documentation by exception," the record indicates that Nurse Suffoletta did not follow it. Indeed, the investigation report went on to state: "In conclusion this nurse failed to follow facility policy [and] procedure of documentation, assessment and physician notification." *Id*. at 7.

In addition, we also find on review of the record that LCCB's nursing notes on Resident 1 from the November-December period include several entries, two of which are signed by Nurse Suffoletta, with recordings of normal vital signs.[9] CMS Ex. 17, at 19-20. Thus, the facility's statements contained in its own investigation report and the presence of the nursing note entries documenting normal vital signs undercut LCCB's arguments on appeal that Nurse Suffoletta properly did not record the resident's vital signs before 4:00 a.m. as well as Nurse Suffoletta's testimony that, "According to policy at the time if the vital signs were stable, we didn't have to document them." Tr. at 217-218. We therefore find no fault in the ALJ's evaluation of the evidence and conclusion that LCCB did not prove by a preponderance of the evidence that documentation by exception was a common and accepted practice at LCCB.

[9] When asked to explain this inconsistency during cross-examination, Nurse Suffoletta responded that "I can't really answer the question of why[]" that occurred. Tr. at 239.

Substantial evidence in the record also supports the ALJ's finding that LCCB failed to provide Resident 1 necessary emergency care and services, as ordered by Resident 1's physician, between 4:00 - 4:20 a.m. on January 3, 2007. LCCB acknowledges that Resident 1's doctor had issued a standing order to administer oxygen if her oxygen saturation fell below 88%. P. Ex. 12, at 1. LCCB also acknowledges that after a CNA and Nurse Suffoletta found the resident at 4:00 a.m., unresponsive to verbal stimuli and "slight[ly] moaning," staff measured her oxygen saturation level and found it had dropped to 46%. CMS Ex. 17, at 31. LCCB does not deny that staff failed to administer oxygen to Resident 1, notwithstanding the doctor's orders and the Resident's condition. As Surveyor Branham testified, "Even when [Resident 1] was found at 4:00 a.m. unresponsive . . . and her O2 SATs was . . . 46, there was no – there was nothing provided to this resident . . . there was no suctioning, there was no oxygen provided for her." Tr. at 147-48. While LCCB argues that CMS did not show that administering oxygen was even feasible given the compressed time frame and the nurse's actions to contact the physician, the ALJ accurately explained that LCCB "misapprehends its burden on this point." DAB CR2509, at 25. Moreover, as the ALJ noted, LCCB did not show that contacting Resident 1's physician and treating the resident were mutually exclusive activities. Accordingly, we find substantial evidence supports the ALJ's conclusion that LCCB's failure to administer oxygen to Resident 1 between 4:00 and 4:20 a.m. on January 3, 2007 was a failure to comply substantially with the quality of care requirement.

We also conclude that the ALJ's determination that LCCB's nursing staff was required but failed to provide important clinical information about Resident 1 to the EMS personnel and the hospital is supported by substantial evidence. The ALJ found that, as alleged by the State Agency and CMS, LCCB failed to give the EMS response staff a verbal report of the resident's allergies, her recent medical history or her vomiting, and the transfer paperwork prepared by the facility for EMS and the hospital did not show that the resident had been profusely vomiting. CMS Ex. 3, at 16. As the ALJ found, the "run report prepared by EMS contains no evidence of Resident 1's allergies, recent medical history, or that the Resident had been vomiting." DAB CR2509 at 25, *citing* CMS Ex. 18, at 1-2. Furthermore, the SOD showed that the Emergency Room (ER) physician caring for Resident 1 on January 3, 2007, told the surveyor that "the paperwork prepared by the facility did not reveal the resident had been profusely vomiting and EMS did not provide any information concerning Resident 1's recent history of vomiting." CMS Ex. 3, at 16. According to the SOD, the ER physician told the surveyor that the vomiting "could have contributed to Resident 1's decline in condition." CMS Ex. 3, at 16. We find the summary of the survey interview constitutes substantial evidence to support the ALJ's finding that even if "Nurse Suffoletta may have believed that [Resident 1's] vomiting was due to a minor stomach upset caused by medicine or a minor flu bug, that the Resident had just been ill was something EMS personnel should have been made

aware of so that they, in turn, could relay that information to the ER." DAB CR2509, at 26. Thus, the ALJ made no error in concluding, that "the information was not given to the EMS personnel . . . constitute[s] noncompliance with the participation requirement." *Id*.

Based on the foregoing analysis, we conclude that the ALJ's findings and conclusions that LCCB was not in substantial compliance with the quality of care requirements at section 483.25 are free from legal error and supported by substantial evidence in the record.

IV. The ALJ's determination that LCCB failed to comply substantially with the facility administration regulation at 42 C.F.R. § 483.75 (FFCL 3) is supported by substantial evidence and free from legal error.

The facility administration requirements

The regulation governing facility administration at 42 C.F.R. § 483.75 provides:

> A facility must be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.

The ALJ's findings in DAB CR1818

The ALJ initially rejected CMS's allegation that LCCB failed to comply substantially with section 483.75. The ALJ concluded that CMS's allegation of LCCB's noncompliance with the facility administration regulation was wholly derivative of CMS's other noncompliance allegations. Having found LCCB in substantial compliance with sections 483.10(b)(11) and 483.25, the ALJ concluded that CMS's determination that LCCB failed to comply substantially with the requirements of section 483.75 must be reversed.

The Board's determination and remand instructions in DAB No. 2233

The Board found that the ALJ erred in his analysis of whether LCCB was in substantial compliance with section 483.75. The Board noted that it previously had held that where a deficiency finding under section 483.75 was derivative, that is, "based on the surveyors' identification of other deficient practices," the existence of those separately identified deficiencies "may constitute a prima facie case that a facility has not been administered efficiently or effectively as required by section 483.75." DAB No. 2233, at 28, *citing Odd Fellow and Rebekah Health Care Facility*, DAB No. 1839 (2002). The Board pointed out, however, that CMS's allegation of LCCB's noncompliance with the facility

administration requirements in this case was not exclusively derived from the findings of noncompliance with other, separately identified deficiencies. Accordingly, the Board stated, even if the ALJ concludes on remand that LCCB complied substantially with sections 483.10(b)(11) and 483.25, the ALJ should consider CMS's non-derivative allegations, i.e., that LCCB failed to conduct a timely and thorough investigation of the circumstances surrounding Resident l's death and that the facility did not ensure that staff was properly trained in facility policy and procedures.

The ALJ's findings and conclusions on remand

The ALJ determined on remand that LCCB failed to comply substantially with the facility administration requirements based on his findings of LCCB's noncompliance with sections 483.10(b)(11) and 483.25. In addition, the ALJ determined that LCCB's administrators failed to ensure that staff was properly trained in the facility's change in condition policy and procedures. The ALJ also concluded that administrators failed to timely and thoroughly investigate the events of January 2-3, 2007 and thereby identify practices requiring correction. The ALJ concluded that these additional deficiencies also constituted noncompliance under section 483.75.

Discussion

The Board previously has held that where a finding of noncompliance under section 483.75 is derivative – that is, based on the identification of other deficient practices – the existence of the separately identified deficiencies "may constitute a prima facie case that a facility has not been administered efficiently or effectively, as required by" the facility administration requirement. *Odd Fellow and Rebekah Health Care Facility,* DAB No. 1839, at 16 (2002), *citing Asbury Center at Johnson City,* DAB No. 1815 (2002). As the Board previously explained, "where a facility has been shown to be so out of compliance with program requirements that its residents have been placed in immediate jeopardy, the facility was not administered in a manner that used its resources effectively to attain the highest practicable physical, mental, and psychosocial well-being of each resident." DAB No. 1815, at 11. Thus, the ALJ correctly concluded that LCCB's noncompliance with the notification of changes-physician consultation and quality of care requirements, at the immediate jeopardy level (as discussed below), would alone support a finding that LCCB was out of substantial compliance with the facility administration requirement.

In addition to contesting the deficiency findings cited under sections 483.10(b)(11) and 483.25, LCCB argues that the ALJ's additional findings of LCCB's noncompliance with section 483.75 are unfounded. LCCB also argues that the additional findings cannot be used to sustain the determination that LCCB was not in substantial compliance with the facility administration requirement because, LCCB alleges, CMS did not base its noncompliance determination on those findings. P. Br. at 38. Consistent with its

arguments relating to the notification of changes and quality of care deficiencies, LCCB argues that only after the hearing did CMS raise allegations of additional deficient practices. *Id.* LCCB contends that the ALJ "cobble[d] together . . . some kind of 'administration' deficiency from inferences about training, supervision, investigation and the like . . . [that] have no basis in the evidence." *Id.*

These arguments are belied by the SOD, which alleges that the facility's noncompliance under section 483.75 included the failure to "investigate the incident of 01/02/07-01/03/07 to determine the causative factors related to the care and services that were not provided Resident #1." CMS Ex. 3, at 21. This failure, the State Agency wrote, "posed an Immediate Jeopardy to the health and safety of all residents who may experience a change in condition . . . ." *Id.* The SOD additionally alleged that the Administrator failed to ensure all nursing personnel were properly trained in the facility's change in condition policy, citing, among other things, interviews with the DON and Administrator to support the allegation. *Id.* at 20-24. Furthermore, CMS witnesses gave testimony at the hearing to support the additional administration deficiencies. For example, Surveyor Branham testified that the surveyors reviewed training records and interviewed staff and administrators regarding LCCB's efforts to in-service staff on the change in condition policy. Tr. at 144-146. The evidence and testimony show that LCCB provided Nurse Suffoletta with written training materials for her review and a test on those written materials. CMS Ex. 3, at 23-24; Tr. at 145-146. According to the SOD and surveyor testimony, a review of the test "revealed the nurse missed 3 out of the 10 questions," and an interview with the DON "revealed the post test results had been placed in a binder and nobody had reviewed [them] to ensure the facility's nurses understood the material." CMS Ex. 3, at 23-24; Tr. at 144-46. Moreover, the SOD evidences that Nurse Suffoletta told the surveyors that she did not recall receiving training on the revised change in condition policy. CMS Ex. 3, at 23. The nurse further told the surveyors that "she reviewed what information was provided [in an educational packet left in a binder] and took the post test but nobody . . . reviewed the post test or the information left in the binder with her." *Id*. This evidence indicates that whatever training Nurse Suffoletta received was insufficient and thus is consistent with the ALJ's conclusion that the revised policy had not been effectively implemented. Accordingly, we reject LCCB's argument that after the hearing CMS and the ALJ expanded the grounds for finding that LCCB failed to comply substantially with section 483.75 without any basis in the evidence.

LCCB further argues that a January 2007 finding of compliance by the State Agency undercuts the ALJ's conclusion that LCCB failed to ensure that staff was properly trained in the facility's change in condition policy and procedures. P. Br. at 32. Specifically, LCCB states that the State Agency concluded at the end of a survey in late 2006 that LCCB's prior change of condition policy was deficient. According to LCCB, the facility thereafter adopted and implemented a new change of condition policy – the policy in effect during the period at issue in this case. LCCB states that a January 3-4 State

Agency revisit survey found that the facility had returned to substantial compliance. LCCB argues that it therefore "was entitled to rely" on the State Agency's "finding of compliance to conclude that both the substance of the policy," and the facility's "training and implementation, complied with all applicable substantive and 'administration' requirements at that time – and at least until the [State Agency] said otherwise." P. Br. at 33.[10]

This argument misses the point. As the Board has previously stated, CMS, not the surveyor or state survey agency, makes the ultimate determination about when a facility has achieved substantial compliance. *Rosewood Care Center of Rockford*, DAB No. 2466, at 11 (2012). Therefore, LCCB was not entitled to infer that it had achieved substantial compliance merely from what it alleges the state surveyors found during the January revisit survey. Moreover, even assuming LCCB could rely on the alleged surveyor findings during the January revisit, those findings were based on the limited evidence that the surveyors reviewed at that time (which included the administration's representations about the training provided and a sampling of some audit documents and some staff interviews) and would not preclude a finding on the subsequent April survey, based on the circumstances existing at the facility at that time, that training on the new policy had not been adequately implemented after all. Tr. at 158. In particular, Surveyor Branham testified, the earlier surveyors were not able to interview night staff. *Id*. Given the performance of Nurse Suffoletta, her undisputed low score on the post-test for the training, and the failure by management to review the post-test, it is reasonable to conclude that management failed to ensure that all staff working with residents had been properly trained. Accordingly, substantial evidence in the record supports the ALJ's conclusion that LCCB administrators failed to ensure that staff was properly trained in facility policy and procedures, as required under section 483.75.

In response to the ALJ's determination that LCCB administrators did not conduct a timely, comprehensive investigation into the events of January 2-3, 2007, LCCB initially argued in its brief on appeal that "the evidence actually indicates that [LCCB's] staff did review the matter immediately after the event, as part of its routine 'root cause analysis'" and that the review determined the nurse "*had* followed proper notification procedures, but could have documented her observations better." P. Br. at 21 (emphasis in original), *citing* P. Ex. 17, at 2; P. Ex. 24; Tr. at 245 (Lincoln testimony). LCCB argued, "Neither the Statement of Deficiencies, CMS, nor the ALJ or Board has ever mentioned this self-analysis." P. Br. at 21. LCCB contended that "it makes no policy or practical sense for

[10] We note that the record does not include the SODs or plans of correction relating to the December 2006 survey. Instead, LCCB relies on the testimony of Nurse Morgeson, Surveyor Branham and Nurse Lincoln to support its contentions. *See* P. Br. at 4-5 *citing* Tr. at 185, 158-159, 246-249.

CMS and the ALJ to disregard the 'root cause analysis,'" and that there is "no legal or logical basis to substitute a post hoc (or 'de novo') critique by the Board for Petitioner's actual conclusions without first finding that Petitioner's review somehow was inconsistent with some governing standard." P. Br. at 33-34.[11]

These arguments are not persuasive and mischaracterize the evidence cited by LCCB, misrepresent the SOD, the ALJ's and our prior decision in this case, and show a lack of understanding of the administrative appeals process. The first document cited by LCCB, Petitioner's Exhibit 17, page 2, is a written review of the care provided Resident 1 on the night of January 2-3, 2007, signed by her attending physician and dated March 19, 2007. In the note the physician states, among other things, "I feel that the failure to call when the pt. [patient] first started profusely vomiting was an exercise in poor judgment and not neglect. She obviously was doing what she thought was right, because the pt. appeared stable." P. Ex. 17, at 2. This document, dated more than two months after the night at issue, does not demonstrate that LCCB initiated an investigation "immediately after the event" in which the facility concluded that the nurse had followed proper notification procedures. Indeed, LCCB itself acknowledges in its reply brief that the physician's assessment is dated March 2007. P. Reply at 8-9. LCCB also cited Nurse Lincoln's testimony in support of its argument that the facility "did review the matter immediately after the event." P. Br. 21. On the page of the hearing transcript cited by LCCB, however, the nurse testifies that the survey investigation was "confusing" and that it was not until "around February, towards March," after the surveyors had brought the physician notification issue to the facility's attention, that it became clear that "the focus was on the alleged inappropriate response to the resident's supposed change in condition." Tr. at 245; *see also* CMS Ex. 3, at 22-23.

The second document cited by LCCB, Petitioner's Exhibit 24, is the "Incident Investigation . . . (Root Cause Analysis) Form" regarding the January 3, 2007 "incident," which is undated, filled out in handwriting, and signed by Nurse Morgeson. P. Ex. 24, at 1, 7. As previously noted, the document provides: "In conclusion this nurse failed to follow facility policy [and] procedure[s] of documentation, assessment and physician notification." *Id.* at 7. Thus, this document not only fails to establish that LCCB's investigation was conducted immediately after the event, but also shows that LCCB concluded that the nurse had *failed* to follow proper notification and documentation procedures. Indeed, in a footnote in LCCB's reply brief on appeal, the facility contradicts its earlier contention about the timing of its "root cause analysis," stating that the internal investigation was conducted in mid-March 2007. LCCB Reply Br. at 14.

[11] We note that this argument is inconsistent with LCCB's contention before the ALJ that there was nothing sufficiently noteworthy about the final illness and death of Resident 1 that the Administrator should have investigated. P. Remand Reply Br. at 14. Further, LCCB acknowledged that only after the State Agency brought the issue of physician notification to the facility's attention did LCCB conduct its full investigation. *Id.* at 47-48.

Moreover, contrary to LCCB's argument that neither the Board nor the ALJ ever mentioned this self-analysis, the Board's earlier decision, the ALJ decision on remand, and the SOD addressed the investigation document and found that LCCB's full internal investigation occurred in mid-March 2007, after the surveyors interviewed the Administrator and brought to his attention the issue of physician notification. DAB No. 2233, at 28 n.6, citing P. Ex. 24; CMS Ex. 3, at 23; DAB CR2509, at 29-30. In addition, as the ALJ decision on remand explains, while LCCB had conducted an earlier investigation relating to Resident 1's care on the night of January 2-3, 2007, that investigation was limited to the complaint that Resident 1's advance directive had not been implemented. DAB CR2509, at 29-30.

Furthermore, LCCB's contention that there is no legal basis to "substitute" a post-hoc or de novo evaluation by the ALJ or Board for LCCB's own investigation findings demonstrates a fundamental misunderstanding of the administrative appeals process. As the Board previously has stated, the "federal administrative appeals process addresses whether a proposed federal action is lawfully authorized." *Northlake Nursing and Rehabilitation Center*, DAB No. 2376, at 9 (2011). In this case, the process at 42 C.F.R. part 498, subpart D (Hearings) and E (Departmental Appeals Board Review) addresses whether CMS's determination of LCCB's noncompliance with the Medicare and Medicaid participation requirements is authorized under the governing sections of the Act and CMS regulations. The Board has repeatedly explained, resolution of that issue "hangs on the ALJ's de novo review of the evidence presented." *Id.* Under the de novo review standard, the ALJ addresses whether the evidence as it is developed before the ALJ supports the finding of noncompliance, not how CMS, or the facility, evaluated the evidence as it stood at whatever times CMS or the facility made their assessments. The ALJ hearing thus provides a fresh look by a neutral decision-maker at the legal and factual basis for the deficiency findings underlying the remedies. *Beechwood Sanitarium*, DAB No. 1906, at 28-29 (2004), *motions granted in part and denied in part, Beechwood v. Thompson*, 494 F.Supp.2d 181 (W.D.N.Y. 2007).

In this case, the findings of LCCB's internal investigation represent only one piece of evidence in the record developed before the ALJ. The ALJ was required to weigh that evidence against the other evidence relating to LCCB's compliance with sections 483.10(b)(11), 483.25 and 483.75. Under the applicable standard of Board review, the issue before us is whether substantial evidence in the administrative record as a whole supports the ALJ's factual findings and whether the ALJ's legal conclusions are free from error. Accordingly, LCCB's contention that there is no legal (or logical) basis to "substitute" the ALJ's or the Board's evaluation of the evidence for its internal investigation findings is meritless.

Based on the foregoing analysis, we conclude that the ALJ's findings and conclusions that LCCB was not in substantial compliance with the facility administration requirements at section 483.75 are free from legal error and supported by substantial evidence in the record.

V. We sustain the ALJ's conclusions that CMS did not clearly err in determining that LCCB's noncompliance posed immediate jeopardy to resident health and safety from January 3 through March 27, 2007 (FFCLs 4 and 5).

As noted, section 488.301 defines "immediate jeopardy" 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." The regulations require that "CMS's determination as to the level of noncompliance of [a skilled nursing facility] must be upheld unless it is clearly erroneous." 42 C.F.R. § 498.60(c). Under the "clearly erroneous" standard, CMS's immediate jeopardy determination – which is a determination about the "level of noncompliance" – is presumed to be correct, and LCCB has a heavy burden to overturn it. *Barbourville Nursing Home*, DAB No. 1962, at 11 (2005), *aff'd, Barbourville Nursing Home v. U.S. Dep't of Health & Human Servs.*, 174 F. App'x 932 (6th Cir. 2006). Furthermore, the Board has consistently held that "[a] determination by CMS that a [facility's] ongoing [noncompliance] remains at the level of immediate jeopardy during a given period [also] constitutes a determination about the 'level of noncompliance'" and is thus subject to the clearly erroneous standard of review. *Brian Center Health and Rehabilitation/Goldsboro*, DAB No. 2336, at 7-8 (2010).

LCCB asserts, "CMS never offered *evidence* – not just argument – that demonstrated a prima facie 'immediate jeopardy' violation of any of the regulations it cited." P. Br. at 35 (emphasis in original). Further, LCCB argues, the regulations provide that CMS is authorized to impose a per-diem CMP "only for 'the number of days a facility is not in substantial compliance with' all regulatory requirements." P. Br. at 38, citing 42 C.F.R. §§ 488.430(a); 488.440(b); 488.454(a). Thus, LCCB contends the regulation provides that "CMS *somehow* must associate the 'duration' of a 'per diem' CMP with *continuing* noncompliance." P. Br. at 39; P. Reply at 19 (emphasis in original). According to LCCB, the State Agency here "plainly focused on the judgments of a single nurse on a single night with respect to a single resident." P. Reply at 39. Thus, "If any penalty at all is appropriate," LCCB argues, "it should be for the one day on which Nurse Suffoletta, and thus Petitioner, supposedly was noncompliant." *Id.* at 39-40.

LCCB's contentions are without merit. As discussed above, LCCB, not CMS, has the burden of proof on the immediate jeopardy issue. The ALJ found that LCCB did not show that CMS's immediate jeopardy determination was clearly erroneous, and we agree.

Indeed, as the ALJ explained and as we discussed above, substantial evidence in the record shows that LCCB's noncompliance involved nursing staff's failure to recognize Resident 1's significant change in condition under the facility's own policy; failure to monitor Resident 1's vital signs on the night of January 2-3, 2007 to determine whether a change in vital signs would necessitate contacting the physician or treating the resident pursuant to the physician's order; and failure to implement the physician's order for oxygen when Resident 1 had dangerously low oxygen saturation levels. "This noncompliance," the ALJ reasonably concluded, "at the very minimum, was certainly likely to cause serious harm to the Resident even if it did not actually cause her death." DAB CR2509, at 31.

Moreover, LCCB's noncompliance extended beyond the actions of a single nurse on the single night of January 2-3, 2007. As the ALJ stated, it was clear from Nurse Suffoletta's actions, and inactions, that she "did not understand when she had a duty to contact Resident 1's physician." DAB CR2509, at 32. The ALJ reasonably "extrapolate[d] her failure to be a failure on the part of the facility," which, substantial evidence further showed, had not effectively trained the nurse on the facility's change in condition policy. *Id.* Because LCCB failed to conduct a timely and comprehensive investigation into the events of January 2-3, 2007, the facility remained unaware that its staff was not sufficiently trained, thus posing an ongoing risk of inadequate care and serious harm to other residents.

Although LCCB argues that it is CMS's responsibility to "associate the 'duration' of a 'per diem' CMP with continuing noncompliance," that argument is inconsistent with the Board's holding articulated in *Brian Center*. Moreover, the Board has consistently held that immediate jeopardy is abated "only when the facility has implemented necessary corrective measures so that there is no longer any likelihood of serious harm." *See, e.g., Pinehurst Healthcare & Rehabilitation Center*, DAB No. 2246, at 15 (2009). Given the nature and scope of the noncompliance involving Resident 1, CMS could reasonably determine that a likelihood of serious harm continued to exist at LCCB until all of the deficiencies on which the finding of immediate jeopardy level noncompliance was based were corrected. According to the post-certification revisit reports for the two revisit surveys and LCCB's plans of correction for the deficiencies identified in the April 3, 2007 and April 23, 2007 surveys, the corrections for the immediate jeopardy level deficiencies were completed March 28, 2007. CMS Exs. 3, 10, 13. We concur with the ALJ that LCCB has not carried its heavy burden to show that immediate jeopardy was abated any earlier.

VI. We sustain the ALJ's determination that the amount of the CMP imposed for the immediate jeopardy period, $4,050 per day, is reasonable (FFCL 6).

CMS may impose a CMP for "either the number of days a facility is not in substantial compliance" (a per-day CMP), or "for each instance that a facility is not in substantial compliance" (a per-instance CMP). 42 C.F.R. § 488.430(a). To determine the amount of a CMP, CMS considers the following factors: The facility's history of noncompliance (including repeated deficiencies), its financial condition, its degree of culpability for the cited deficiencies, the seriousness of the noncompliance, and the relationship of one deficiency to the other deficiencies resulting in noncompliance. 42 C.F.R. §§ 488.404, 488.438(f).

In evaluating the regulatory factors, the ALJ found that LCCB had not submitted evidence regarding its financial condition. In addition, the ALJ stated, CMS did not argue that there were aggravating factors in LCCB's history to take into account. The deficiency, the ALJ concluded, was serious and LCCB was culpable in that its actions "had a serious negative effect on Resident 1's care, comfort, and safety." DAB CR2509, at 33. Specifically, as the ALJ noted, LCCB's nursing staff failed to recognize Resident 1's change in condition, did not monitor her vital signs, and did not attempt to contact her physician until the Resident was unresponsive and had an oxygen saturation level of 46%. CMS Ex. 17, at 31. Even after discovering that the Resident's oxygen saturation level was dangerously low, LCCB failed to implement her physician's express order to administer oxygen to her. The ALJ noted that the CMP range for immediate-jeopardy level noncompliance is from $3,050 to $10,000 per day, as provided under 42 C.F.R. § 488.438(a)(1)(i). The ALJ concluded that the $4,050 per-day CMP imposed by CMS, which is at the lower end of the range, was reasonable in light of the seriousness of the noncompliance.

As noted, LCCB contests the duration of the penalty imposed. LCCB has not, however, directly contended that any of the particular regulatory factors considered does not support the per-day CMP amount and has not directly challenged the ALJ's findings under those factors. Accordingly, we have no basis to conclude that the per-day amount of the CMP should be revised. *See Coquina Center*, DAB No. 1860, at 32 (2002) ("[T]here is a presumption that CMS has considered the regulatory factors in setting the amount of the CMP and that those factors support the CMP amount imposed by CMS. Unless a facility contends that a particular regulatory factor does not support that CMP amount, the ALJ must sustain it."). Accordingly, we sustain the ALJ's conclusion that the amount of the CMP imposed, $4,050 per day, is reasonable.

Conclusion

For the reasons explained above, we sustain the ALJ Decision, DAB CR2509.

/s/
Sheila Ann Hegy

/s/
Leslie A. Sussan

/s/
Stephen M. Godek
Presiding Board Member