Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Appellate Division

Cedar Lake Nursing Home
Docket No. A-10-77
Decision No. 2344
November 18, 2010

FINAL DECISION ON REVIEW OF ADMINISTRATIVE LAW JUDGE DECISION

Cedar Lake Nursing Home requests review of the May 21, 2010 decision of Administrative Law Judge (ALJ) Carolyn Cozad Hughes in *Cedar Lake Nursing Home*, DAB CR2137 (2010)(ALJ Decision). The ALJ concluded CMS was entitled to summary judgment that Cedar Lake was not in substantial compliance with the Medicare participation requirement at 42 C.F.R. § 483.25(k) and that the $6,000 per-instance civil money penalty (CMP) imposed for that noncompliance was reasonable. ALJ Decision at 4, 7. The ALJ also concluded Cedar Lake was not entitled to review of CMS's determination that the noncompliance with section 483.25(k) constituted immediate jeopardy because a successful challenge to that determination would not affect the range of the CMP.[1] *Id.* at 3. Finally, the ALJ concluded that Cedar Lake was not entitled to review of CMS's determination that Cedar Lake was not in substantial compliance with 42 C.F.R. § 483.75 since CMS had withdrawn the per-instance CMP imposed for that alleged noncompliance. *Id.* Before the Board, Cedar Lake appeals only the ALJ's entry of summary judgment on the issue of its noncompliance with section 483.25(k) and the ALJ's determination that the CMP imposed for that noncompliance was reasonable. Cedar Lake alleges that there are disputed material facts that preclude summary judgment for CMS. We affirm the ALJ Decision.

Applicable Law

Long-term care facilities participating in the Medicare and Medicaid programs are subject to the survey and enforcement procedures set out in 42 C.F.R. Part 488, subpart E, to determine if they are in substantial compliance with applicable program

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[1] The ALJ concluded that the immediate jeopardy level determination was not appealable for the additional reason that, because CMS imposed (and she upheld) a CMP of $5,000 or more, Cedar Lake would lose approval to conduct nurse aide training regardless of whether Cedar Lake successfully challenged the level of noncompliance. ALJ Decision at 3.

requirements which appear at 42 C.F.R. Part 483, subpart B. "Substantial compliance" means a level of compliance such that "any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm." 42 C.F.R. § 488.301. "Noncompliance," in turn, is defined as "any deficiency that causes a facility to not be in substantial compliance." *Id.* Survey findings are reported in a Statement of Deficiencies (SOD). The SOD identifies each "deficiency" under its regulatory requirement, citing both the regulation at issue and the corresponding "tag" number used by surveyors for organizational purposes.

A long-term care facility found not to be in substantial compliance is subject to various enforcement remedies, including CMPs. 42 C.F.R. §§ 488.402(b), (c); 488.406; 488.408. CMS may impose per-instance or per-day CMPs, and there are two ranges of per-day CMPs, with the applicable range depending on the scope and severity of the noncompliance. 42 C.F.R. §§ 488.438(a)(1), 488.408(d)(iii), (e)(iii). There is only one range for a per-instance CMP, $1,000-$10,000. 42 C.F.R. §§ 488.438(a)(2), 488.408(d)(1)(iv), (e)(1)(iv). Once a facility is found not in substantial compliance, remedies continue until "[t]he facility has achieved substantial compliance, as determined by CMS or the State based upon a revisit or after an examination of credible written evidence that it can verify without an on-site visit . . . ." 42 C.F.R. § 488.454(a)(1).

Standard of Review

Whether summary judgment is appropriate is a legal issue that the Board addresses de novo. *1866ICPayday.com, L.L.C.*, DAB No. 2289, at 2 (2009), citing *Lebanon Nursing and Rehabilitation Center*, DAB No. 1918 (2004). Summary judgment is appropriate when the record shows that there is no genuine issue as to any material fact, and the moving party is entitled to judgment as a matter of law. *See 1866ICPayday.com* at 2, citing *Celotex Corp. v. Catrett*, 477 U.S. 317, 322-25 (1986).

On appeal, Cedar Lake cites court cases addressing summary judgment standards under Rule 56 of the Federal Rules of Civil Procedure (FRCP 56). FRCP 56 does not apply by its own terms to administrative proceedings under 42 C.F.R. Part 498, and Part 498 does not specify summary judgment procedures. However, as indicated in the pre-hearing order in this case, ALJs in this forum generally look to the principles of FRCP Rule 56 for guidance when deciding cases on summary judgment. Order of May 11, 2009, at 5.

Basic summary judgment principles are well-settled. The party moving for summary judgment bears the initial burden of demonstrating that there is no genuine issue of material fact for trial and that it is entitled to judgment as a matter of law. *Celotex*, 477 U.S. at 323. The moving party may show the absence of a genuine factual dispute by presenting evidence so one-sided that it must prevail as a matter of law, or by showing that the non-moving party has presented no evidence "sufficient to establish the existence of an element essential to [that party's] case, and on which [that party] will bear the

burden of proof at trial." *Livingston Care Ctr. v Dep't of Health & Human Servs*., 388 F.3d 168, 173 (6th Cir. 2004)(quoting *Celotex.*, 477 U.S. at 322). If a moving party carries its initial burden, the non-moving party must "come forward with 'specific facts showing that there is a genuine issue for trial.'" *Matsushita Elec. Industrial Co. v. Zenith Radio, Ltd.*, 475 U.S. 574, 587 (1986)(quoting FRCP 56(e)).

To defeat an adequately supported summary judgment motion, the non-moving party may not rely on the denials in its pleadings or briefs, but must furnish evidence of a dispute concerning a material fact -- a fact that, if proven, would affect the outcome of the case under governing law. *Id*. at 586, n.ll (quoting FRCP 56(c)); *Celotex*, 477 U.S. at 322-323. In order to demonstrate a genuine issue, the opposing party must do more than show that there is "some metaphysical doubt as to the material facts . . . . Where the record taken as a whole could not lead a rational trier of fact to find for the nonmoving party, there is no 'genuine issue for trial.'" *Matsushita*, 475 U.S. at 586. In making this determination, the reviewer must view the evidence in the light most favorable to the non-moving party, drawing all reasonable inferences in that party's favor. *See e.g*., *U.S. v. Diebold, Inc*., 369 U.S. 654, 655 (1962).

Background[2]

A. The survey and CMS's determinations

Based on a complaint survey that ended on February 8, 2009, CMS determined that Cedar Lake was not in substantial compliance with the Medicare requirements for long-term care facilities at 42 C.F.R. § 483.25(k)(Tag F328), which addresses residents' special needs, and 42 C.F.R. § 483.75(Tag F490), which addresses facility administration. ALJ Decision at 2. CMS cited both findings of noncompliance at scope and severity level K, which means that CMS found a pattern of deficiencies posing immediate jeopardy to resident health and safety. *Id*. CMS initially imposed per-instance CMPs, in the amounts of $6,000 and $4,000, respectively, for the noncompliance with these two requirements. *Id*., citing CMS Ex. 1. CMS subsequently rescinded the $4,000 per-instance CMP for the noncompliance with section 483.75. *Id.*, citing CMS Ex. 1 at 4-5. Cedar Lake timely requested a hearing, the parties filed briefs and exhibits, and CMS filed a motion for summary judgment to which Cedar Lake filed a response. *Id*.

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

B. The ALJ's findings of undisputed fact.

The evidence, which the ALJ found undisputed, involved care rendered to Resident 1 (R. 1) during an episode of respiratory distress. R. 1, a 72-year-old woman, had medical diagnoses that included pulmonary disease and risk of respiratory distress/failure. ALJ Decision at 5, citing CMS Ex. 11, at 1; CMS Ex. 9, at 23. R. 1's care plan directed staff to monitor her for signs and symptoms of respiratory infection, "to apply oxygen per order," and to "provide respiratory treatments per order." *Id.*, citing CMS Ex. 9, at 23. R. 1's physician ordered oxygen "PRN" (as needed) at the rate of two liters per minute "per [nasal] cannula." *Id.*, citing CMS Ex. 8, at 8; CMS Ex. 11, at 3.

Cedar Lake's policies and procedures direct staff to obtain a physician's order for the "'rate of flow and *route of administration* of oxygen (i.e., by tank, concentrator, nasal cannula, mask, etc.).'" *Id.*, citing P. Ex. 2, at 18; CMS Ex. 19, at 1 (emphasis added by ALJ). They also direct appropriate staff (registered nurse or licensed respiratory care practitioner) to obtain "appropriate oxygen delivery system (a nasal cannula, simple mask, or transtracheal oxygen)." *Id.*, citing P. Ex. 2, at 19. Facility policy also confirms that oxygen administered by nasal cannula should flow at a rate of 1-5 liters per minute while oxygen delivered by a simple mask requires a flow rate of 6-10 liters per minute. *Id.*, citing P. Ex. 2, at 15, 17; CMS Ex. 19, at 4; CMS Exs. 20, 21; CMS Ex. 24; CMS Ex. 27, at 3 (Hunter Declaration); CMS Ex. 28, at 3 (Jensen Declaration). Surveyor Jensen testified that providing fewer than 5 liters of oxygen per minute when using a mask places the resident at risk of suffocation. *Id.* citing CMS Ex. 28, at 3. Cedar Lake's policies and procedures specifically state, "Use of oxygen mask NOT recommended if flow is less than five liters." *Id.*, citing CMS Ex. 19, at 4.

R. 1 vomited at 10:10 p.m. on February 4, 2009, and again at 2:40 a.m. on February 5, 2009. During the second episode, R. 1 made "'gurgling' – wet sounds," and staff were unable to obtain an oxygen level. *Id.* at 5, citing CMS Ex. 14, at 3; CMS Ex. 23, at 3; P. Ex. 5, at 3 (Morgan Affidavit); P. Ex. 7, at 2 (Sparks Affidavit). A nurse called R. 1's physician who told her to administer oxygen and send R. 1 to the hospital. *Id.*, citing CMS Ex. 14, at 3. Staff said that since an "as needed" order for oxygen was already in place, they did not ask the physician for an order. *Id.*, citing P. Response at 5-6. The nurse administered oxygen at the rate of 2 liters per minute by mask, rather than by cannula. *Id.* at 6, citing CMS Ex. 14, at 3. When the emergency medical technicians arrived at 2:55 a.m., they found R. 1 in respiratory distress, with rapid and labored respirations, and took her to the hospital. *Id.*, citing CMS Ex. 13, at 2; CMS Ex. 14, at 3.

The ALJ found that these facts were undisputed in any material respect, and that the evidence "establishes that facility staff did not follow the physician's order, the resident's care plan instructions, nor its own policies and procedures when staff provided care to a resident in respiratory distress." ALJ Decision at 4. The ALJ noted that the evidence presented by CMS consisted "primarily [of] the facility's own documents and statements from facility staff" and found that Cedar Lake had not come forward with evidence

suggesting a dispute over those facts. *Id*. The ALJ concluded that these deficient practices created a likelihood of serious harm for R. 1 and other residents. *Id.* at 6-7. The ALJ granted CMS's motion for summary judgment that Cedar Lake was not in substantial compliance with section 483.25(k). *Id*. at 4, 7.

In addition to concluding that Cedar Lake was not in substantial compliance with section 483.25(k), the ALJ concluded that the $6,000 per-instance CMP imposed for that noncompliance was reasonable because it was in the middle of the penalty range, the amount was relatively modest in light of the severity of the deficiencies, and Cedar Lake had not argued that its financial condition affected its ability to pay the CMP. *Id*. at 7-8. The ALJ also noted that Cedar Lake had been found out of substantial compliance on a 2008 survey, albeit with a different participation requirement. *Id*. at 8, n. 4.

C. Cedar Lake's assertions on appeal

On appeal, Cedar Lake asserts that it was in substantial compliance with section 483.25(k). RR at 4. Cedar Lake argues that it was inappropriate for CMS to cite the facility's alleged failure to provide proper respiratory treatment and care to R. 1 under section 483.25(k). *Id*. at 5-6. Cedar Lake also argues that it presented evidence showing that the facts here, construed most favorably to Cedar Lake, do not support the deficiency findings and that the nurse surveyor who wrote those findings was not qualified to determine the medical cause of a resident's injury or potential injury. *Id*. at 6-10. With respect to the CMP amount, Cedar Lake argues that one of its witnesses created a fact issue "by demonstrating that, under the circumstances of this case and for the reasons outlined [earlier in its RR], the proposed penalty of $6,000 . . . is not reasonable." *Id*. at 12. Cedar Lake further argues that the CMP amount is excessive in light of the circumstances of the case, an alleged absence of culpability on the facility's part and the absence of a history of noncompliance under section 483.25(k).

Analysis

A. CMS is entitled to summary judgment that Cedar Lake was not in substantial compliance with 42 C.F.R. § 483.25(k).

1. The respiratory care failures were properly cited under section 483.25(k).

Cedar Lake argues that the respiratory care deficiency was not properly cited as noncompliance with section 483.25(k) because "[m]any of the surveyors' findings center on Cedar Lake's alleged failure to properly train its staff regarding use of oxygen." RR at 5. Cedar Lake also notes that the findings on the SOD do not refer to any of the "probes" listed in the State Operations Manual (SOM) Survey Interpretive Guidelines (Survey Guidelines) for section 483.25(k). *Id*. at 5-6. We find no merit to this argument.

Section 483.25(k) provides that facilities "must ensure" that residents receive "proper treatment and care" for "special services." 42 C.F.R. § 483.25(k). One of these "special services" is "[r]espiratory care." 42 C.F.R. § 483.25(k)(6). All of the special services delineated in section 483.25(k) are subject to the general quality of care requirement in the introductory statement in section 483.25.

> 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 language of the regulation controls in determining whether a particular set of facts supports a finding of noncompliance with section 483.25(k). The Board has repeatedly explained that while the SOM may provide useful guidance as to CMS's interpretations of applicable law, the SOM itself does not have the force of law. *E.g. Columbus Nursing & Rehabilitation Center*, DAB No. 2247, at 23 (2009); *Cal Turner Extended Care Pavilion*, DAB No. 2030, at 13 (2006).[3] The subject matter of the deficiency, the alleged failure to ensure that R. 1 received proper respiratory care, falls squarely under section 483.25(k), since subsection (6) of that regulation specifically addresses "[r]espiratory care." The findings on the SOD focus on specific respiratory care deficits, including staff failure to use the oxygen delivery system required by R. 1's physician and the facility's policies. *See generally* CMS Ex. 2, at 1-8.

Although the SOD also contains findings on staff training deficits – such as inability to correctly articulate the appropriate oxygen administration device depending on the prescribed flow rates – it does so in the context of how these deficits relate to the focal failure to provide respiratory care that meets the quality of care requirement. *See* CMS Ex. 2, at 6. Cedar Lake cites no language in section 483.25 that even remotely suggests surveyors cannot consider the adequacy or inadequacy of staff training when determining whether a facility has provided respiratory care consistent with the quality of care requirement. Nor does Cedar Lake explain why staff training in the proper provision of respiratory care (including the proper method of administering oxygen for prescribed flow rates) would not be an important part of assuring that residents receive respiratory care in a manner that comports with their assessments and care plans and will help them attain the "highest practicable physical . . . well-being." 42 C.F.R. § 483.25. We reject Cedar Lake's position on this issue as illogical and unsupported by the law.[4]

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[3] The SOM is at CMS's public website at http://www.cms.hhs.gov/Manuals/IOM/list.asp.

[4] Cedar Lake calls the issue it raises as to whether it was appropriate to cite the failures of care found by the ALJ under section 483.25(k)(6) "[t]he first fact issue in question." RR at 5. However, this is a legal issue (i.e., whether the facts found, if undisputed, support a conclusion of noncompliance with the regulation), not an issue of fact. Thus, to the extent Cedar Lake is asserting that the citation issue it raises is a factual dispute that, assuming materiality, would bar summary judgment, we reject that assertion.

2. There is no genuine dispute that Cedar Lake failed to follow R. 1's care plan, the orders of R. 1's physician and its own policies when it did not use a nasal cannula to administer oxygen to R. 1.

The material facts regarding the alleged failure to render respiratory care to R. 1 are those found by the ALJ, as stated above. We agree with the ALJ that Cedar Lake "has not come forward with evidence suggesting a dispute over these facts." ALJ Decision at 4. For the most part, what Cedar Lake disputes on appeal is the ALJ's conclusion that these facts show noncompliance with section 483.25, not the facts themselves. The Board has held that disagreement over the legal conclusions to be drawn by applying undisputed facts to the law does not preclude summary judgment if the record is sufficiently developed and only one reasonable conclusion can be drawn from these facts. *Guardian Health Care Ctr.*, DAB No. 1943, at 11 (2004). Here the record is well-developed, and supports only one reasonable conclusion, that Cedar Lake did not afford R. 1 the necessary respiratory care required by section 483.25(k) when it failed to provide care required by the resident's care plan, her doctor's orders and Cedar Lake's own policies. Cedar Lake does not dispute that R. 1's care plan required oxygen to be administered as ordered and that her physician's orders, as written, specified both the rate of oxygen administration, 2 liters per minute, and the method of administration, by nasal cannula. Nor does Cedar Lake dispute that despite the care plan and physician orders, when R. 1 experienced respiratory distress on February 5, 2009, and her doctor instructed staff to administer oxygen and send her to the hospital, staff used a simple mask to administer the oxygen rather than a nasal cannula.

Cedar Lake argues that the ALJ should have inferred that staff complied with the doctor's orders notwithstanding the failure to use the nasal cannula since staff did administer oxygen at the two liters per minute flow rate required by the orders. However, an ALJ (or the Board on de novo review) is required to draw only <u>reasonable</u> inferences in the light most favorable to the non-moving party when determining whether to grant summary judgment. *Brightview Care Ctr.*, DAB No. 2132 at 2, 9 (2007); *Guardian*, DAB No. 1943, at 8 (emphasis added). It is not reasonable to infer that staff complied with the express written directives in the physician's order by complying only with the oxygen flow rate part of the order and not the part of the order that specified the method for administering the oxygen, use of a nasal cannula. Certainly, it is not reasonable to draw such an inference absent evidence that the physician did not necessarily require compliance with both parts of his order, and Cedar Lake put on no such evidence.

Cedar Lake asserts that staff could comply with the physician's order by only following the prescribed oxygen flow rate because it is "of no significance whether oxygen was administered via nasal cannula or via breather mask." RR at 7. Either type of administration complies with the physician's orders, Cedar Lake asserts, "because the critical thing is to provide oxygen to the resident when needed." *Id.* at 7-8. In support of these assertions, Cedar Lake cites affidavits it submitted from C. Lynn Morgan, R.N., a consultant (P. Ex. 5), Douglas Humble III, Cedar Lake's Director of Operations (P. Ex.

6) and Jo Sparks, R.N, Cedar Lake's Director of Nursing (DON)(P. Ex. 7). However, the cited affidavits do not support these assertions. Indeed, they do not even address whether using either the mask or the cannula would comply with the physician's orders or whether it is significant how oxygen is administered. Instead the affiants aver facts that are not material to these issues, such as that staff turned off R. 1's feeding tube when she vomited and used the prescribed oxygen flow rate and that Cedar Lake conducted in-service training for staff and spent money to purchase appropriate equipment. The affidavits totally ignore the fact that the doctor's orders required the oxygen to be administered via nasal cannula. Thus, these affidavits raise no material dispute of fact.

Furthermore, Cedar Lake's assertions are directly contradicted by its own policies and procedures. A document describing procedures for administering oxygen directs staff to use particular delivery systems for particular flow rates, expressly states that "it is important to use the proper delivery system for O2 administration" and directs staff to use a nasal cannula for delivery of oxygen at the rate of 1-5 liters. P. Ex. 2, at 15, 17. Cedar Lake's oxygen administration policy cautions, "*Use of oxygen mask NOT recommended if flow is less than five liters.*" *Id.* at 21 (emphasis in original); s*ee also* CMS Ex. 20 (Oxygen Administration Chart obtained during the survey stating that no fewer than 6 liters per minute should be administered through a simple face mask). Cedar Lake's assertions are also contradicted by the testimony of surveyor Jensen, that providing fewer than 5 liters of oxygen per minute when using a mask places the resident at risk of suffocation. CMS Ex. 28, at 3. Cedar Lake provides no evidence to counter this testimony. Cedar Lake also does not dispute CMS's evidence that when the emergency medical technicians arrived to take R. 1 to the hospital, R. 1 had labored breathing and was gasping with her mouth wide open, causing a tight suction seal of the simple mask around her mouth. CMS Ex. 2, at 4 (SOD discussion of surveyor interview with one of the technicians). In summary, Cedar Lake has not raised a material dispute of fact because it has not provided any evidence to support its assertion that staff complied with the physician's order by merely using the prescribed oxygen flow rate or that use of the mask in place of the cannula was without significance and has not disputed the evidence of record to the contrary.

While not disputing that its staff failed to follow Cedar Lake's own respiratory care policies when they used a simple mask rather than a cannula to administer oxygen to R. 1, Cedar Lake makes a legal argument that a failure to follow its own policies cannot form the basis for a deficiency. RR at 10. On the contrary, the Board has held that a facility's failure to follow its own policies (as well as its failure to comply with physician orders or to provide services in accordance with a plan of care based on a resident's comprehensive assessment) can constitute a deficiency under section 483.25. *Woodland Village Nursing Center*, DAB No. 2053, at 9 (2006), citing, *e.g.*, *Lakeridge Villa Health Care Center*, DAB No. 1988, at 22 (2005). The Board has based this holding on the lead-in language of the Quality of Care regulation, section 483.25, which reflects the statutory description of the care and services required of SNFs in section 1819(b) of the Social Security Act, 42 U.S.C. § 1395i-3(b), and on the premise in the statute and

regulations as a whole that the facility has (or can contract for) the expertise to plan for and provide care and services to maintain the resident's highest practicable functional level. *Woodland Village,* at 8-9, citing *Spring Meadows Health Care Center*, DAB No. 1966, at 17-18 (2005)("Thus, '[w]hen a facility adopts a policy that calls on the nursing staff to take affirmative actions to safeguard resident health and safety, it is reasonable to infer (in the absence of evidence to the contrary) that the facility did so because such actions are necessary to attain or maintain resident well-being.'"). *Id*. at 9, citing *Spring Meadows* at 20. Consistent with this precedent, we conclude that it is appropriate to infer that Cedar Lake's policies and procedures on respiratory care reflect its determination that use of a nasal cannula rather than a mask when giving oxygen at the rate of two liters per minute was necessary care to permit R. 1 and other residents requiring respiratory care to attain or maintain the highest practicable physical, mental, and psychosocial well-being as required by section 483.25. Thus, there is no genuine dispute that by not following Cedar Lake's policies and procedures when giving R. 1 respiratory care, Cedar Lake's staff did not comply with section 483.25(k), even apart from Cedar Lake's additional failure to follow the orders of R. 1's physician.

3. A finding that Cedar Lake's deficient practices caused R. 1's respiratory distress is not necessary to find noncompliance, and there is no genuine dispute that those deficient practices carried the potential for more than minimal harm.

Cedar Lake asserts that the ALJ should have denied summary judgment because "the surveyor who wrote the deficiency is not legally qualified to determine whether the facility's actions constituted harm to the resident in question (i.e., whether the facility's alleged lack of compliance was the cause of this resident's respiratory distress)." RR at 10. Cedar Lake cites Texas cases purportedly holding that nurses are not qualified or legally authorized to determine the medical cause of an injury or death. There is no merit to Cedar Lake's argument.

Cedar Lake made this same argument below, but did so in the context of its attempt to challenge CMS's determination of immediate jeopardy, not CMS's determination of noncompliance. *See* Cedar Lake's Pre-Hearing Brief at 7-8; P. Ex. 5 at 5. The ALJ did not reach the argument because she concluded that Cedar Lake had no right to appeal the immediate jeopardy determination since a successful challenge to that determination could not affect either the range of the per-instance CMP (which is a single range) or the loss of Cedar Lake's approval to do nurse aide training (since the amount of the CMP sustained by the ALJ would also cause that loss). ALJ Decision at 3. On appeal, Cedar Lake does not specifically assert error in these ALJ legal conclusions. However, if, by its "cause" argument, Cedar Lake is indirectly suggesting such error, there is none. The ALJ's conclusion that Cedar Lake had no right to appeal the immediate jeopardy determination is legally correct for the reasons stated in her decision, and we need not discuss this issue further.

To the extent that Cedar Lake is asserting that a finding of noncompliance requires a finding of actual harm, there is no legal basis for such an assertion. Whether Cedar Lake's failure to deliver necessary and proper respiratory care to R. 1 actually caused respiratory distress is irrelevant. Federal law, not State law, governs what constitutes substantial compliance (or noncompliance) with the requirements for long-term care facilities participating in the Medicare program. *See Woodstock Care Center*, DAB No. 1726 (2000), *aff'd*, *Woodstock Care Ctr. v. Thompson*, 363 F.3d 583 (6th Cir. 2003)(duty of care owed residents by a nursing home under common or state law is unrelated to the duty of care owed by a long-term care facility to a severely-disabled resident under federal regulations). Federal law defines "[s]ubstantial compliance" as 'a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm" and "noncompliance" as "any deficiency that causes a facility to not be in substantial compliance." 42 C.F.R. § 488.301 (emphasis added). Thus, to conclude that Cedar Lake was noncompliant with section 483.25(k), the ALJ was not required to find that Cedar Lake's deficient respiratory care practices caused actual harm to R. 1. It was sufficient for the ALJ to conclude, as she did, that those deficient practices created the potential for more than minimal harm.

In addition to being based on a false legal premise, Cedar Lake's argument is a "straw man." CMS did not conclude that Cedar Lake was noncompliant with section 483.25(k) based on a finding that Cedar Lake's failure to use a nasal cannula when administering oxygen to R. 1 caused respiratory distress but, rather, on a finding that Cedar Lake's failure to use a nasal cannula when administering oxygen to R. 1 was an improper and inadequate response to an existing episode of respiratory distress. The ALJ found that "respiratory distress is a serious, potentially fatal, event" and that a facility must be "prepared to respond quickly and appropriately" to such events and "must follow the physician's order." ALJ Decision at 7. The ALJ found that Cedar Lake not only responded inappropriately to R. 1's respiratory distress by failing to follow the physician's orders to use a nasal cannula, but admitted it was not adequately prepared to respond appropriately by conceding that the crash cart did not contain a nasal cannula. *Id*. at 6-7. The ALJ concluded that this "inadequate preparation put R. 1 at risk of serious harm." *Id*. at 7. She also concluded that this lack of preparedness put at risk 45 other residents who had oxygen administration orders virtually identical to R. 1's. *Id*.

Cedar Lake does not challenge the ALJ's findings about the serious risk of harm associated with respiratory distress and the need to be adequately prepared to handle such an episode. At one point in its request for review, Cedar Lake suggests that R. 1 was not actually in respiratory distress. "Cedar Lake has presented evidence showing that the oxygen was administered to [R. 1] only as a precaution due to the resident's vomiting and deteriorating condition, and not because the resident was in respiratory distress." RR at 8. However, the evidence cited (the affidavits of Cedar Lake's consultant and DON) does not support this statement. While the affidavits state that "oxygen was administered only as a precaution due to the resident's vomiting and deterioration condition," they do

not include the further statement "not because the resident was in respiratory distress." Nor do the affidavits otherwise deny that R. 1 was in respiratory distress. See P. Exs. 5, 7. In addition, Cedar Lake's suggestion on page 8 of its request for review that R. 1 was not in respiratory distress is belied by its subsequent statement (also discussed above) that the ALJ should have denied summary judgment because "the surveyor who wrote the deficiency is not legally qualified to determine whether the facility's actions constituted harm to the resident in question (i.e., whether the facility's alleged lack of compliance was the cause of this resident's respiratory distress)." RR at 10. Finally, the evidence of record, which consists largely of Cedar Lake's records, overwhelmingly shows that R. 1 was in respiratory distress. There can be no genuine dispute about this fact.

Cedar Lake also argues that not having nasal cannulae on the crash cart is not a regulatory violation because nasal cannulae "are not generally kept on the crash cart . . . ." RR at 8. We first note that this response does not rebut but, rather, reinforces the ALJ's conclusion that Cedar Lake was not prepared to properly respond to a respiratory crisis involving R. 1. (Cedar Lake has not asserted that it kept a nasal cannula in R. 1's room or in any other location where it was readily available if R. 1 began to experience an episode of respiratory distress despite its awareness that she had an outstanding order for oxygen via cannula.) Second, the argument as to what the regulation covers, or does not, is a straw man because the absence of nasal cannulae on the crash cart was not itself the basis for finding noncompliance with section 483.25(k). Rather, the basis for finding noncompliance was the facility's failure to deliver the respiratory care required by section 483.25(k) because the care delivered to R. 1 was inconsistent with her assessed needs, her physician's orders and the facility's policies. The absence of nasal cannulae on the crash cart merely illustrated that Cedar Lake was not equipped to deliver such care when it was needed during an episode of respiratory distress.

Cedar Lake asserts that R. 1's oxygen saturation rate rose to "nearly 90%" after staff used the face mask but before the emergency technicians began working on her. RR at 9. The record contains evidence to the contrary, such as a statement by one of the emergency technicians who treated R. 1 that her oxygen saturation rate was actually in the 60s before they treated her. CMS Ex. 2, at 4. For purposes of summary judgment, we resolve this evidentiary dispute in Cedar Lake's favor but find that it is immaterial. Cedar Lake does not contend that raising R. 1's saturation rate to "nearly 90%" removed the potential for more than minimal harm that we have already concluded existed. Instead, Cedar Lake contends only that the purported increase in the oxygen saturation rate to "nearly 90%" is a desired consequence of administration of oxygen therapy. Moreover, Cedar Lake's policies state that "[n]ormal oxygen saturation levels . . . are 90% to 100%" and that "lower levels may indicate hypoxemia that warrants intervention" according to "the physician's orders . . . ." P. Ex. 2, at 9. Thus, the increased saturation rate Cedar Lake claims resulted from staff use of the mask would still be considered below normal and serious enough to warrant intervention.

For the reasons stated above, we conclude that there is no genuine dispute that Cedar Lake engaged in deficient respiratory care practices that posed the potential for more than minimal harm and, therefore, constituted noncompliance with section 483.25(k).

B. There is no dispute of material fact regarding the reasonableness of the $6,000 per-instance CMP.

Applying the factors listed in 42 C.F.R. § 488.438(f), the ALJ concluded that the $6,000 per-instance CMP was reasonable. ALJ Decision at 7. The ALJ found, in principal part, that $6,000 was "in the middle of the [applicable] penalty range ($1,000-10,000);" was a modest amount, compared to what CMS might have imposed; and, was a serious deficiency that affected multiple residents who were at risk for respiratory distress and had physician orders requiring the use of nasal cannulae. *Id*. at 7-8 (citations omitted). The ALJ noted that CMS could have imposed a CMP for each day that Cedar Lake was unprepared to administer oxygen using a nasal cannula for the many residents whose physicians had ordered that method of oxygen administration. *Id*. at 7, n. 3 (citing 42 C.F.R. § 488.438(a)(1).

On appeal, Cedar Lake argues that it created a material dispute of fact as to whether the amount of the CMP is reasonable. RR at 12. The determination of whether a CMP amount is reasonable is a conclusion of law, not a finding of fact. To show a dispute of fact precluding summary judgment for CMS on the "reasonableness" issue, Cedar Lake would have to show a genuine dispute about the findings of fact underlying that legal conclusion, that is, the ALJ's findings of fact regarding the regulatory factors. Cedar Lake has not done this. In particular, Cedar Lake does not dispute the ALJ's findings regarding the seriousness of the facility's deficient respiratory care practices for R. 1 and for other residents having essentially identical physician orders for oxygen administration. This was a critical factor in the ALJ's conclusion. *See* ALJ Decision at 8 ("I consider the severity of the deficiencies significant enough to warrant this relatively modest penalty."); *see also* 42 C.F.R. §§ 488.438(f) and 488.404 (providing for consideration of the seriousness of deficiencies in determining the amount of a CMP).

Cedar Lake does assert that "there is no culpability on the part of Cedar Lake." RR at 12, citing P. Exs. 5, 6, and 7 (affidavits of Morgan, Humble and Sparks). The ALJ, however, found that Cedar Lake "bears a significant degree of culpability." ALJ Decision at 8. She cited the fact that although Cedar Lake's staff "must have known that they were not capable of following the physician orders [for multiple residents] because they had no available nasal cannulae . . . [they] . . . neither asked for alternative orders nor obtained the necessary equipment." *Id*. She also cited the facility's failure to follow its own policies for administering oxygen when it used a mask rather than a nasal cannula for R. 1 and other residents. The ALJ found that these actions "demonstrate staff indifference or disregard for the safety of all its residents with orders for oxygen prn, to be delivered via nasal cannula." *Id*. The affidavits cited by Cedar Lake do not create a material dispute of fact regarding these findings; rather, they make bare assertions of fact

regarding matters not material to the culpability issue. These assertions relate to the facility's compliance history, which is a separate regulatory factor; the facility's having taken steps to correct its deficiencies, which is not responsive to its culpability for having the deficiencies in the first instance; and, the facility's having spent thousands of dollars on unspecified equipment for oxygen and related respiratory care, which does not address the absence of the equipment material to this deficiency, nasal cannulae. *See* P. Exs. 5 at 7-8, 6 at 1, 7 at 4.

Cedar Lake also argues that the ALJ inappropriately referred to a March 2008 survey that was the subject of an earlier appeal because that survey did not find a deficiency under section 483.25(k), and Cedar Lake appealed the Board decision in that case to the United States Court of Appeals for the Fifth Circuit. RR at 12. *See* ALJ Decision at 8, n.4 (citing *Cedar Lake Nursing Home*, DAB No. 2288 (2009), which upheld a determination of noncompliance under section 483.25(h) and concluded that a $5,000 per-instance CMP was reasonable). The fact that the 2008 survey found noncompliance with a different quality of care requirement (accident prevention) than the one at issue here (respiratory care) is immaterial. The relevant fact is that Cedar Lake, as the ALJ noted, does not have an unblemished compliance history. *Id*. Furthermore, the Fifth Circuit has now upheld the Secretary's final decision in the *Cedar Lake* case. *Cedar Lake Nursing Home v. U. S. Dep't of Health & Human Servs*., 619 F.3d 453 (5th Cir. 2010).

Conclusion

For the reasons stated above, we affirm the ALJ's Decision in its entirety, including the ALJ's conclusions that Cedar Lake was not in substantial compliance with the Medicare participation requirement governing respiratory care, 42 C.F.R. § 483.25(k), and that a per-instance CMP of $6,000 is reasonable.

/s/
Constance B. Tobias

/s/
Leslie A. Sussan

/s/
Sheila Ann Hegy
Presiding Board Member