Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Wingate at Beacon,
(CCN: 33-5828),

Petitioner,

v.

Centers for Medicare & Medicaid Services

Docket No. C-13-160

Decision No. CR3979

Date: June 22, 2015

DECISION

In this case, I consider a facility's responsibility for assuring that it provides proper treatment and care to residents who have gastronomy tubes (G-tubes)[1] or tracheostomies (trachs).[2]

Petitioner, Wingate at Beacon, is a long-term care facility located in Beacon, New York, that participates in the Medicare program. Based on the facility's annual survey, completed August 20, 2012, the Centers for Medicare & Medicaid Services (CMS) determined that, from August 17 through October 1, 2012, the facility was not in substantial compliance with Medicare program requirements and that, from August 17 through 22, 2012, its deficiencies posed immediate jeopardy to resident health and safety.

[1] A gastronomy tube is inserted through the skin and stomach wall directly into the stomach. *See* CMS Ex. 18 at 4 (McWeeney Decl. ¶ 11); CMS Ex. 19 at 4 (Moran Decl. ¶ 11).

[2] A tracheostomy is a surgically-created opening in the neck, which provides a direct airway into the trachea. The term also refers to the surgical procedure by which the opening is created. *See* CMS Ex. 19 at 7 (Moran Decl. ¶ 24).

CMS imposed civil money penalties (CMPs) of $5,650 per day for six days of immediate jeopardy and $150 per day for 40 days of substantial noncompliance that was not immediate jeopardy.

Petitioner admits that it was not in substantial compliance but challenges the deficiencies cited at the immediate jeopardy level and the immediate jeopardy determination itself. The parties have filed cross-motions for summary judgment.

The undisputed evidence establishes that: 1) from August 17 through October 1, 2012, the facility was not in substantial compliance with either the quality-of-care requirements governing G-tube and trach care (42 C.F.R. §§ 483.25(g)(2), 483.25(k)) or with the requirements for administration (42 C.F.R. §§ 483.75, 483.75(d)(1) – (2), 483.75(i)); and 2) from August 17 through 22, 2012, these deficiencies posed immediate jeopardy to resident health and safety. I therefore grant CMS's motion for summary judgment and deny Petitioner's.

Background

The Social Security Act (Act) sets forth requirements for nursing facility participation in the Medicare program and authorizes the Secretary of Health and Human Services to promulgate regulations implementing those statutory provisions. Act § 1819. The Secretary's regulations are found at 42 C.F.R. Part 483. To participate in the Medicare program, a nursing facility must maintain substantial compliance with program requirements. To be in substantial compliance, a facility's deficiencies may pose no greater risk to resident health and safety than "the potential for causing minimal harm." 42 C.F.R. § 488.301.

The Secretary contracts with state survey agencies to conduct periodic surveys to determine whether skilled nursing facilities are in substantial compliance. Act § 1864(a); 42 C.F.R. § 488.20. The regulations require that each facility be surveyed annually, with no more than fifteen months elapsing between surveys. 42 C.F.R. § 488.308(a). Facilities must be surveyed more often, if necessary, to ensure that identified deficiencies are corrected. Act § 1819(g)(2)(A); 42 C.F.R. § 488.20(a).

Here, on August 20, 2012, surveyors from the New York State Department of Health (state agency) completed a standard survey of the facility. Based on the survey findings, CMS determined that the facility was not in substantial compliance with multiple program requirements:

- 42 C.F.R. § 483.10(b) (Tag F156 – notice of rights and services) at scope and severity level D (isolated instance of noncompliance that causes no actual harm with the potential for more than minimal harm);

- 42 C.F.R. § 483.15(a) (Tag F241 – quality of life: dignity) at scope and severity level D;

- 42 C.F.R. § 483.15(e)(1) (Tag F246 – quality of life: accommodation of needs) at scope and severity level E (pattern of noncompliance that causes no actual harm with the potential for more than minimal harm);

- 42 C.F.R. § 483.15(h)(2) (Tag F253 – quality of life: environment) at scope and severity level E;

- 42 C.F.R. § 483.20(g) – (j) (Tag F278 – accuracy of resident assessments) at scope and severity level D;

- 42 C.F.R. §§ 483.20(d) and 483.20(k)(1) (Tag F279 – use of resident assessments and development of comprehensive care plans) at scope and severity level E;

- 42 C.F.R. § 483.20(k)(3)(ii) (Tag F282 – comprehensive care plans: services provided) at scope and severity level D;

- 42 C.F.R. § 483.25 (Tag F309 – quality of care) at scope and severity level E;

- 42 C.F.R. § 483.25(c) (Tag F314 – quality of care: pressure sores) at scope and severity level D;

- 42 C.F.R. § 483.25(d) (Tag F315 – quality of care: urinary incontinence) at scope and severity level D;

- 42 C.F.R. § 483.25(e)(2) (Tag F318 – quality of care: range of motion) at scope and severity level D;

- **42 C.F.R. § 483.25(g)(2) (Tag F322) – quality of care: naso-gastric tubes) at scope and severity level K (pattern of immediate jeopardy)**;[3]

- 42 C.F.R. § 483.25(h) (Tag F323 – quality of care: accident prevention) at scope and severity level D;

- **42 C.F.R. § 483.25(k) (Tag F328 – quality of care: special needs) at scope and severity level K**;

[3] Petitioner has not appealed most of the deficiencies cited. This list highlights, in bold, those that are the subject of this appeal.

- 42 C.F.R. § 483.25(n) (Tag F334 – quality of care: immunizations) at scope and severity level D;

- 42 C.F.R. § 483.35(i) (Tag F371 – dietary services/sanitary conditions) at scope and severity level E;

- 42 C.F.R. § 483.65 (Tag F441 – infection control) at scope and severity level E;

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

- **42 C.F.R. § 483.75(d)(1) – (2) (Tag F493 – administration: governing body) at scope and severity level K**;

- **42 C.F.R. § 483.75(i) (Tag F501 – administration: medical director) at scope and severity level K**; and

- 42 C.F.R. § 483.75 (l)(1) (Tag F514 – administration: clinical records) at scope and severity level E.

CMS Exs. 1, 2. Thereafter, CMS determined that the facility removed the immediate jeopardy effective August 23, 2012, and returned to substantial compliance on October 2, 2012. CMS has imposed CMPs of $5,650 per day for six days of immediate jeopardy ($33,900) and $150 per day for the remaining 40 days of substantial noncompliance ($6,000), for a total penalty of $39,900. CMS Exs. 2, 9.

Petitioner timely requested review, challenging the quality-of-care deficiencies cited at the immediate jeopardy level – 42 C.F.R. §§ 483.25(g) and 483.25(k) – and CMS's conclusion that the facility's deficiencies posed immediate jeopardy to resident health and safety. Hearing Request. In its brief, Petitioner added challenges to the deficiencies cited under the regulation governing administration (42 C.F.R. §§ 483.75, 483.75(d)(1) – (2), and 483.75(i)), which derive from the quality-of-care deficiencies and are also cited at the immediate jeopardy level. P. Br. at 19.

The parties have filed cross-motions for summary judgment. With its motion and brief (CMS Br.), CMS submitted 19 exhibits (CMS Exs. 1-19). With its motion and brief (P. Br.), Petitioner submitted 14 exhibits (P. Exs. 1-14).

Issues

Based on the uncontested issues, the facility was not in substantial compliance with Medicare program requirements from August 17 through October 1, 2012.

The remaining issues are: 1) Was the facility in substantial compliance with 42 C.F.R. §§ 483.25(g)(2), 483.25(k), 483.75, 483.75(d)(1) – (2), and 483.75(i); and 2) if not, did those deficiencies pose immediate jeopardy to resident health and safety.

Except to argue that its deficiencies did not pose immediate jeopardy, Petitioner has not challenged the amount of the CMP.

Discussion

Summary judgment. Summary judgment is appropriate if a case presents no genuine issue of material fact, and the moving party is entitled to judgment as a matter of law. *Illinois Knights Templar Home*, DAB No. 2274 at 3-4 (2009), and cases cited therein.

The moving party may show the absence of a genuine factual dispute by presenting evidence so one-sided that it must prevail as a matter of law, or by showing that the non-moving party has presented no evidence "sufficient to establish the existence of an element essential to [that party's] case, and on which [that party] will bear the burden of proof at trial." *Livingston Care Ctr. v. Dep't of Health & Human Servs.*, 388 F.3d 168, 173 (6th Cir. 2004) (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 323-24 (1986)). To avoid summary judgment, the non-moving party must then act affirmatively by tendering evidence of specific facts showing that a dispute exists. *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586 n.11 (1986); *see also Vandalia Park*, DAB No. 1939 (2004); *Lebanon Nursing & Rehab. Ctr.*, DAB No. 1918 (2004).

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

1. ***CMS is entitled to summary judgment, because the undisputed evidence establishes that facility staff could not and did not provide appropriate treatment and services to its residents with G-tubes and did not provide proper trach treatment and care; the facility therefore did not comply substantially with 42 C.F.R. §§ 483.25(g)(2) , 483.25(k), 483.75, 483.75(d)(1) – (2), and 483.75(i).***[4]

Program requirements. Under the statute and quality-of-care regulation, each resident must receive, and the facility must provide, the necessary care and services to allow a resident to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the resident's comprehensive assessment and plan of care. Act § 1819(b); 42 C.F.R. § 483.25. To this end, among other requirements, the facility must ensure that a resident who is fed by a G-tube receives appropriate treatment and services, in accordance with his comprehensive assessment, to prevent aspiration pneumonia, diarrhea, vomiting, dehydration, metabolic abnormalities, and nasal-pharyngeal ulcers and to restore, if possible, normal eating skills. 42 C.F.R. § 483.25(g)(2).

The facility must also ensure that residents receive proper trach treatment and care. 42 C.F.R. § 483.25(k).

In Petitioner's view, a facility is not out of substantial compliance simply because it lacks policies and procedures for G-tube or trach care or because it fails to ensure that its nurses are competent to provide that care. Disregarding the factual underpinnings of this case, Petitioner argues that no authority requires it to: 1) have in place written policies and procedures for changing G-tubes or providing trach care; or 2) assure that its nurses are adequately trained and competent to reinsert G-tubes and care for its residents with trachs. In Petitioner's view, the facility has no responsibility except to hire licensed nurses and hope for the best.

Petitioner begins with the remarkable claim that CMS's "own guidance documents . . . make clear that there are no current requirements for [G-tube] policies or training." P. Br. at 2. According to Petitioner, the requirements for G-tubes – including the requirements that the facility have in place "policies, practice, and training" – stems from a September 7, 2011 CMS transmittal, which CMS retracted and did not replace until September 27, 2012, after the time of this survey. P. Br. at 2; P. Exs. 1, 2.

This is nonsense. The transmittals in question – which are sent to the state survey agencies to guide them in conducting their surveys – made no substantive changes. They simply combined two F tags, eliminating Tag F321 and adding its provisions to Tag F322. In any event, while CMS's Survey and Certification Transmittals provide useful

[4] My findings of fact/conclusions of law are set forth, in italics and bold, in the discussion captions of this decision.

guidance to the state survey agencies, and may even include CMS's interpretations of applicable law, they do not constitute enforceable, substantive rules. *Beverly Health & Rehab. Servs. v. Thompson*, 223 F. Supp. 2d 73, at 99-106 (D.D.C. 2002); *Oakwood Cmty. Ctr.*, DAB No. 2214 at 16 (2008); *Aase Haugen Homes, Inc.*, DAB No. 2013 at 15 (2006). The regulations, on the other hand, constitute enforceable rules, and I am bound to follow them. Here, the regulations did not change. Since their inception, Medicare regulations have required facilities to have in place written policies and procedures for resident care and to ensure that nursing staff are trained and competent to provide needed services. Petitioner's view is incompatible with the basic regulatory scheme and with widely-accepted professional standards of quality.

The requirements in sections 483.25(g)(2) and 483.25(k) are part of a facility's "overall obligation under section 483.25 to provide each resident with 'the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the [resident's] comprehensive assessment and plan of care.'" *Autumn Ridge Rehab. Ctr.*, DAB No. 2467 at 3 (2012). Inherent in all quality-of-care requirements is the notion that the services provided meet professional standards of quality and be provided by qualified persons. 42 C.F.R. § 483.20(k)(3).[5] And a facility cannot assure that its staff are providing appropriate G-tube and trach care and services unless it: 1) defines for them what that care entails (hence, the need for written policies and procedures), particularly with respect to the individual needs of each resident (hence, the need for individualized care plan instructions); 2) trains them to provide that level of care; and 3) monitors them to assure that they have, in fact, provided that appropriate treatment and care.[6]

[5] Although CMS cited deficiencies under 42 C.F.R. § 483.20(k)(1) and (k)(3)(ii), it did not base those citations on the facility's failures with respect to its care for residents with G-tubes and trachs. The facility's failures with respect to G-tube and trach care likely put it out of substantial compliance with numerous regulations that were not cited for that purpose. But CMS is not required to cite every regulatory violation, and, while it might have cited the more general "professional standards" regulation, the fact that it did not do so does not preclude it from citing deficiencies under the more particular substantive provisions relating to G-tube and trach care. *See Premier Living & Rehab. Ctr.*, DAB No. 2146 at 18-19 (2008).

[6] I agree with Petitioner that facilities have flexibility in deciding how they will provide appropriate care. *See* P. Br. at 8-10. For example, a facility may decide that only specially-trained nurses will be authorized to perform some procedures. This is perfectly acceptable but must be spelled out in the facility policies so that all staff understand their responsibilities and their limitations.

Policies and procedures. The parties agree that the facility did not have in place written policies and procedures for providing G-tube and trach services, although the facility possessed a nursing manual, which staff were free to consult. CMS Ex. 18 at 3-4, 5, 6 (McWeeney Decl. ¶¶ 10, 18, 22); CMS Ex. 19 at 5, 8-9 (Moran Decl. ¶¶ 15, 31, 32, 33); P. Ex. 6 at 2 (Boulay Decl. ¶ 8).

According to CMS, the surveyors could not find the manual on any of the facility's four nursing units, and they discovered that the facility possessed only one copy. CMS Ex. 18 at 5 (McWeeney Decl. ¶ 18); CMS Ex. 19 at 6 (Moran Decl. ¶ 20). Petitioner disputes that assertion and claims that the facility maintained a copy of the manual at each of the four unit manager's offices and kept an additional copy at the Administrative Director's office. P. Ex. 6 at 3 (Boulay Decl. ¶ 9). For purposes of summary judgment, I accept Petitioner's claim but find it not material. A nursing manual is simply no substitute for written policies and procedures, particularly when no written policy directs staff to it or explains which sections apply. Moreover, a general nursing manual is not institution-specific. It will not assign responsibilities among the facility staff, indicate who is authorized to perform necessary procedures, nor specify the individuals within the facility to whom staff must report problems. *See* CMS Ex. 1 at 78; CMS Ex. 18 at 5 (McWeeney Decl. ¶ 19).

Staff training and competencies. The undisputed evidence also establishes that the facility had not provided its nursing staff with any formal training in trach or G-tube care in more than one year and that the facility had no safeguards in place to assure that nursing staff were competent to provide G-tube and trach care. *See* P. Br. at 16 ("[I]t is undisputed that the facility did not possess or administer competencies to its nursing staff regarding the management of tracheostomy tubes. . . .").

According to CMS, during an interview with Surveyor Roberta Moran, R.N., the facility's then director of nursing (DON), Marie Boulay, conceded that she was not aware that the facility had provided any formal G-tube or trach training to its nursing staff nor that the facility had a system in place to evaluate nurse competencies in reinserting G-tubes or providing trach care. CMS Ex. 19 at 5, 12 (Moran Decl. ¶¶ 15, 47); *see* CMS Br. at 9, 13-14; CMS Ex. 1 at 40-41, 49; CMS Ex. 18 at 2, 6 (McWeeney Decl. ¶¶ 3, 4, 22).

DON Boulay denies telling Surveyor Moran that she was not aware of any formal training relating to G-tube insertions or trachs. She claims that, with respect to G-tube training, she was unable to locate documentation of the training but believed that nurses had been trained. P. Ex. 6 at 2 (Boulay Decl. ¶ 6). She also claims that she produced evidence that the facility had provided trach training. P. Ex. 6 at 3 (Boulay Decl. ¶ 11). The facility has produced evidence that, on March 31, 2011, it provided approximately one hour of in-service training in trach care to at least some of its nurses. P. Ex. 3.

Petitioner also produces what appears to be a list of nurses and the dates of their in-service training in trach and (for some) G-tube care. Although Petitioner does not explain the list, and DON Boulay does not refer to it at all, it seems to indicate the dates on which each nurse attended training or was tested, and the duration of that training (generally an hour) and testing (half an hour). The list shows that, for the most part, nurses attended the G-tube in-service and were tested in March 2011. In June and July 2011, five LPNs and one RN attended an in-service on tube feeding/medication orders. P. Ex. 4 at 3. No one was trained or tested after August 5, 2011. P. Ex. 4. For purposes of summary judgment, I draw all reasonable inferences in Petitioner's favor and infer from its submissions that the facility provided its nurses with in-service training as indicated in P. Ex. 4.

But, even assuming that the facility's nursing staff did not change between March 2011 and August 2012, and that all of the facility's nurses attended the 2011 in-service training, I find the training simply too remote in time to establish that staff were capable of providing appropriate G-tube and trach care. Moreover, even if the training had been more recent, one hour of in-service training, with or without some testing, does not establish that facility staff are competent to provide the necessary care. The facility must also take steps to insure that the training has been effective.

Here, not only was the facility unable to show that its staff were *capable* of providing adequate care to its residents with G-tubes and trachs, the undisputed facts establish that, in fact, its staff *did not* provide adequate care.

First, two staff nurses (an R.N. and an LPN) told Surveyor Moran that they did not know what to do if a resident's trach became dislodged, but would ask their supervisor. However, DON Boulay admitted that the supervisor had not been trained to replace a trach tube. CMS Ex. 19 at 9 (Moran Decl. ¶ 33); *see* P. Ex. 6 (Boulay Decl.) (in which DON Boulay does not deny making that statement or claim that the supervisor in question had any training).

Even more disturbing, patient care reflected this absence of policies and procedures and the staff's incompetence:

Resident 8 (R8). R8 was a 90-year-old woman, admitted to the facility in November 2011, suffering from multiple ailments, including the effects of a stroke, dementia, and dysphagia (swallowing difficulties). CMS Ex. 16 at 1. Even though she had a G-tube in place to supplement her caloric and protein intake, her care plan included no instructions for changing that tube or for providing any other G-tube-related treatment and services. CMS Ex. 16 at 7. No physician order directed staff regarding when and how to change the tube. CMS Ex. 18 at 4 (McWeeney Decl. ¶ 13). Notwithstanding this complete absence of instructions, an August 7, 2012 nursing note establishes that one of the facility nurses changed R8's G-tube. Initially, the nurse tried to replace the tube with one of the

same size. But the resident complained of pain upon insertion, and the nurse could not complete the procedure, nor did she recognize the potentially serious complications associated with complaints of pain when a G-tube is inserted. *See* CMS Ex. 18 at 5 (McWeeney Decl. ¶ 14).

On her own – without the physician's knowledge or consent – the nurse replaced R8's G-tube with a smaller one.[7] Even worse, she admitted to Surveyor McWeeney that she had not been trained to reinsert a G-tube. Nor did the surveyors find any indication that this nurse – or anyone else – notified R8's physician of the incident or the resident's complaints of pain. CMS Ex. 18 at 4-5 (McWeeney Decl. ¶¶ 13, 14, 15, 16); *see* CMS Ex. 12 at 4; CMS Ex. 16.

The problems here – any one of which would put the facility out of substantial compliance with program requirements – are numerous and deeply disturbing. Failing to include G-tube care in the resident's comprehensive care plan virtually assures that she will not receive appropriate treatment and services, in accordance with her assessment.[8] The absence of a physician's order compounds that problem. An untrained and thus unqualified individual was simply left to her own devices do determine when and how to change the resident's G-tube. I cannot overstate the seriousness of allowing an untrained person to change a G-tube, especially without a care plan or physician's order. *See, e.g., Rosewood Care Ctr. of Rockford*, DAB No. 2466 at 13, 17-18 (finding the facility noncompliant with section 483.25(g)(2) where, without consulting the physician, a nurse practitioner replaced the resident's G-tube with one of a different size); *see* P. Ex. 7 at 2 (explaining that an improperly-placed tube can cause, among other complications, nausea, vomiting, bowel obstruction, or peritonitis).

I also agree with Surveyor Joan McWeeney, R.N., and CMS: standard nursing practices dictate that staff notify the physician if a G-tube needs to be reinserted, and the nurse violated standard nursing practice and federal regulations when she reinserted the tube

---

[7] Tube diameters are measured in "French units" (Fr). One Fr = 0.33mm. Here, the nurse replaced a #20 Fr G-tube with a #14 Fr G-tube. CMS Ex. 18 at 4 (McWeeney Decl. ¶ 13).

[8] Each resident must have in place a comprehensive plan of care, with measurable objectives and time tables, that describes the services the facility will provide so that the resident will attain or maintain his/her highest practicable physical, mental, and psycho-social well-being. 42 C.F. R. § 483.20(k). Based on other findings, CMS cited a lower-level deficiency under section 483.20(k), but did not include in that citation the facility's failure to include in R8's care plan instructions regarding her G-tube. It nevertheless seems plain that a resident's comprehensive care plan must include G-tube care, if the resident has a G-tube, and that omission from R8's plan put the facility out of substantial compliance with both section 483.20(k) and section 483.25(g)(2).

without a physician's order. That she changed the size of the tube without consulting the resident's physician compounded the violation. Further, the resident's complaints of pain should have been reported to the physician. *See* CMS Ex. 18 at 4-6 (McWeeney Decl. ¶¶ 14, 19, 21).[9]

Petitioner dismisses the dangers inherent in allowing untrained and unqualified individuals to re-insert G-tubes. According to Petitioner, "facility nurses have at their constant disposal the ability and corresponding responsibility to contact the resident's physician for guidance on how to respond to [clinical complications]." P. Br. at 6. Putting aside the immediate harm that can occur when an unqualified person attempts the procedure, R8's situation highlights the weaknesses in Petitioner's argument. For reasons that have not been explained, the nurse simply did not contact R8's physician to request a physician order, report the G-tube change, the resident's pain, or her decision to insert a significantly smaller G-tube.

Resident 5 (R5). R5 was a 56-year-old woman admitted to the facility in November 2011 with diagnoses that included respiratory failure, anoxic brain damage, and status post cardiac arrest. She was in a vegetative state and required a tracheostomy in order to breathe and a G-tube for nourishment. CMS Ex. 14 at 1, 29. Her care plan directed staff to "change tube as ordered." CMS Ex. 14 at 34. A physician's order directed staff to change her G-tube "per policy." CMS Ex. 14 at 53, 62; CMS Ex. 19 at 5 (Moran Decl. ¶ 15). Thus, in order to comply with the care plan instruction and the physician order, staff needed to consult the facility's policies. But the facility had no such policies. CMS Ex. 19 at 5 (Moran Decl. ¶ 15); P. Ex. 6 at 2 (Boulay Decl. ¶ 8).

R5's trach also required care. Her physician ordered staff to change it monthly. CMS Ex. 14 at 78. Surveyor Moran reviewed R5's respiratory assessment forms, which showed that her trach had last been changed almost three months earlier – on May 21, 2012. CMS Ex. 14 at 128, 142; CMS Ex. 19 at 9 (Moran Decl. ¶ 34). The DON did not claim that the trach had been changed since May and could not explain why it had not been changed. CMS Ex. 19 at 9 (Moran Decl. ¶ 35). Following the interview, R5's physician issued another order directing staff to "please change trach monthly" and "may change tomorrow." CMS Ex. 14 at 7.

R5's physician ordered staff to maintain R5's oxygen saturation levels (SpO_2) at 92% or above, with humidified oxygen (O_2) supplied via nasal canula at 30%. CMS Ex. 14 at 1, 66. But facility staff rarely followed the physician order. Instead they supplied R5 with 28% humidified O_2. CMS Ex. 14 at 101-120. One of the nurses caring for R5 told

[9] A facility must immediately consult the resident's physician of any significant change in the resident's physical, mental, or psychosocial status or a need to alter treatment significantly. 42 C.F.R. § 483.10(b)(11). Arguably, the facility violated this requirement, although CMS did not cite a deficiency under section 483.10 (b)(11).

Surveyor Moran that the "night nurse set it that way because she felt that it was all the resident needed and a lot of steam was coming from the tube and the physician order said to titrate the O_2 to keep above 92%." CMS Ex. 19 at 8 (Moran Decl. ¶ 28). No one informed R5's physician that the nursing staff had effectively changed his order. CMS Ex. 19 at 8 (Moran Decl. ¶¶ 28, 29).

Resident 12 (R12). R12 was a 60-year-old man, admitted to the facility in April 2012. He suffered from chronic respiratory failure and was in a persistent vegetative state caused by encephalopathy (brain damage due to lack of oxygen). CMS Ex. 15 at 1, 13. He was fed through a G-tube and had a tracheostomy in place to assist with his breathing. CMS Ex. 15 at 113, 114, 115, 124, 144; *See* CMS Ex. 19 at 5 (Moran Decl. ¶ 16).

The surveyors reviewed his history, care plan, progress notes, physician orders, physician notes and nurses notes, but could not find any indication as to the appropriate size of his G-tube nor instructions as to when to change the G-tube. CMS Ex. 15 at 142; CMS Ex. 19 at 5-6 (Moran Decl. ¶ 18). DON Boulay did not know that R12 had no order that addressed when to change the G-tube. CMS Ex. 19 at 6 (Moran Decl. ¶ 19). Following that interview, R12's physician ordered a G-tube change that day, every three months thereafter, and as needed. CMS Ex. 15 at 5.

With respect to R12's trach, on May 21, 2012, the facility's consultant respiratory therapist reported that an RN asked her to change R12's trach, which was "#8 Portex cuff," but the facility had no replacements. The respiratory therapist instructed the DON to order a replacement trach and reminded her that the facility should keep one at the resident's bedside. CMS Ex. 15 at 19; *see* CMS Ex. 19 at 14 (Moran Decl. ¶ 54). On May 30, the respiratory therapist changed the trach. CMS Ex. 15 at 18. In an order dated the following day – May 31, 2012 – R12's physician ordered a size "#8 Portex cuffed trach," and directed that it be changed monthly. CMS Ex. 15 at 56. But Surveyor Moran found no evidence that the trach was changed after May 31. CMS Ex. 19 at 11 (Moran Decl. ¶ 40). Again, the facility's DON was not aware that the trach had not been changed. CMS Ex. 19 at 11 (Moran Decl. ¶ 41).

Nor did staff follow physician orders regarding the amount of oxygen supplied to R12. His physician ordered 30% humidified O_2 via his trach collar to maintain SpO_2 levels above 92%. CMS Ex. 15 at 2, 56. But nurses notes show that the staff regularly disregarded this order, usually providing 45% humidified O_2, and, on one occasion, providing 28% humidified O_2. CMS Ex. 15 at 116-124; CMS Ex. 19 at 11 (Moran Decl. ¶ 42).

Petitioner dismisses these significant facts, characterizing CMS's position as "a factual recitation on whether doctors' orders were followed in a few cases." P. Br. at 6 n.4. Because CMS did not specifically cite the facility for failing to follow a doctor's order, Petitioner claims that CMS's arguments regarding staff's failure to follow physician

orders "should be ignored." P. Br. at 14 n.7. But in order to provide "appropriate" or "proper" care and treatment, nursing staff must follow physician orders, and their failing to do so puts the facility out of substantial compliance with 42 C.F.R. §§ 483.25(g)(2) and 483.25(k), as well as multiple other regulations, which CMS did not cite.[10]

Administration. The facility must be governed 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. 42 C.F.R. § 483.75. Among other requirements, it must have in place a governing body that is legally responsible for establishing and implementing policies regarding the management and operation of the facility. 42 C.F.R. § 483.75(d)(1). The governing body appoints the administrator, who is responsible for managing the facility. 42 C.F.R. § 483.75(d)(2). The governing body must also designate a physician to serve as medical director who is responsible for implementing resident care policies and coordinating medical care in the facility. 42 C.F.R. § 483.75(i).

A deficiency citation alleging noncompliance with section 483.75 (administration) may be derived from findings of noncompliance with other participation requirements.

> [W]here 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.

Asbury Ctr. at Johnson City, DAB No. 1815 at 11 (2002); *see also Woodland Oaks Healthcare Facility*, DAB No. 2355 at 17 (2010); *Stone Cnty. Nursing & Rehab. Ctr.*, DAB No. 2276 at 15-16 (2009); *Odd Fellow & Rebekah Health Care Facility*, DAB No. 1839 at 7 (2002). As discussed below, I find that the facility's deficiencies posed immediate jeopardy to resident health and safety, which, by itself, justifies the finding that the facility was not in substantial compliance with 42 C.F.R. § 483.75.

Moreover, the facility's shortcomings here were directly attributable to administrative failures. The facility's administration – including its governing body, administrator, and medical director – is responsible for having written policies in place. The administration is responsible for training and supervising staff. Because it had no policies and procedures in place for providing essential care and treatment to its residents; because its medical director was not even aware that the facility lacked those policies; because

[10] Moreover, failing to follow a physician's order means that staff do not meet professional standards of quality, which puts it out of substantial compliance with 42 C.F.R. § 483.20(k)(3)(i). *See* footnote 5.

administration did not assure that staff were capable of providing necessary care, the facility was not in substantial compliance with 42 C.F.R. §§ 483.75, 483.75(d)(1) - (2), or 483.75(i).

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

Immediate jeopardy. Immediate jeopardy exists if a facility's noncompliance has caused or is likely to cause "serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301. CMS's determination as to the level of a facility's noncompliance (which would include an immediate jeopardy finding) must be upheld unless it is "clearly erroneous." 42 C.F.R. § 498.60(c). The Board has observed repeatedly that the "clearly erroneous" standard imposes on facilities a "heavy burden" to show no immediate jeopardy, and has sustained determinations of immediate jeopardy where CMS presented evidence "from which '[o]ne could reasonably conclude' that immediate jeopardy exists." *Barbourville Nursing Home*, DAB No. 1931 at 27-28 (2004) (citing *Koester Pavilion*, DAB No. 1750 (2000)); *Daughters of Miriam Ctr.*, DAB No. 2067 at 7, 9 (2007).

I need not find that the facility's noncompliance actually caused serious harm or injury to a resident.[11] So long as the deficiencies are likely to cause serious injury or harm, they pose immediate jeopardy.

As discussed above, I cannot overstate the seriousness of allowing an untrained person to reinsert a G-tube or to attempt trach care, especially in the absence of written instructions, a physician's order, or in contravention of a physician's order. Residents requiring G-tubes are vulnerable. An untrained person inserting a G-tube can perforate the stomach, causing bleeding and peritonitis. CMS Ex. 19 at 12-13 (Moran Decl. ¶ 49); P. Ex. 7 at 2. Replacing a G-tube with one of a different size, particularly without the physician's order or knowledge, is dangerous. As Surveyor McWeeney explained, if the tube is too large, it can be painful; if too small, it might leave a dangerous open space, allowing the acidic gastric contents of the stomach to leak out, causing pain and skin breakdown. CMS Ex. 18 at 6 (McWeeney Decl. ¶ 21).

Residents with trachs are even more vulnerable.[12] They rely on the trachs to breathe. Trachs must be suctioned regularly, replaced periodically, and monitored to ensure that

---

[11] CMS did not press the point, but, when she attempted to change R8's G-tube, the untrained nurse inflicted pain, which is actual harm.

[12] Because R5 and R12 had both G-tubes and trachs, and because they were comatose, they were especially fragile. As the above discussion shows, the care they received did not reflect that staff recognized that fragility.

they are working properly. Complications are serious and include infection, hemorrhage, tracheal esophageal fistula, and interference with swallowing. P. Ex. 5, file M2U00077.MPG at 4:38. Furthermore, cuffed trachs, such as R12's (CMS Ex. 15 at 1), present their own potential hazards, including the esophageal wall tissue dying. In fact, during the 2011 trach training, the facility recommended that cuffed trachs be changed to uncuffed trachs. P. Ex. 5, file M2U00077.MPG at 5:09 - 6:10. But multiple residents did not receive the care their physicians had ordered. Trach tubes, which should have been changed monthly, were left in place months after they should have been replaced.

Notwithstanding the importance of providing appropriate treatment and services, staff regularly disregarded physician orders. They did not change trach tubes as ordered, but left them in place for months after they should have been changed. They simply refused to follow orders for oxygen, substituting their own judgment for that of the physician, without the physician's knowledge or consent.

Because the facility's deficiencies were likely to cause serious harm to vulnerable facility residents, CMS's determination that the deficiencies posed immediate jeopardy to resident health and safety is not clearly erroneous.

Conclusion

Petitioner has conceded that, from August 17 through October 1, 2012, the facility was not in substantial compliance with Medicare program requirements. For the reasons set forth above, I find that, during this period, the facility was not in substantial compliance with 42 C.F.R. §§ 483.25(g)(2), 483.25(k), 483.75, 483.75(d)(1) - (2), and 483.75(i) and that, from August 17 through 22, 2012, these deficiencies posed immediate jeopardy to resident health and safety. I therefore grant CMS's motion for summary judgment and deny Petitioner's.

/s/
Carolyn Cozad Hughes
Administrative Law Judge