Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Cedar Lake Nursing Home,
(CCN: 67-5898),

Petitioner

v.

Centers for Medicare and Medicaid Services.

Docket No. C-09-577

Decision No. CR2252

Date: September 27, 2010

DECISION

Petitioner, Cedar Lake Nursing Home (Petitioner or facility), is a long-term care facility located in Malakoff, Texas, that participates in the Medicare program. The Centers for Medicare and Medicaid Services (CMS) determined that the facility was not in substantial compliance with Medicare requirements for respiratory care and that its deficiencies posed immediate jeopardy to resident health and safety. CMS has imposed a $9,500 per instance civil money penalty.

For the reasons set forth below, I find that the facility was not in substantial compliance with Medicare program requirements and that the penalty imposed is reasonable.

I. 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 once every twelve months and more often, if necessary, to ensure that identified deficiencies are corrected. Act § 1819(g)(2)(A); 42 C.F.R. §§ 488.20(a); 488.308.

Here, following an April 13-16, 2009 survey, CMS determined that the facility was not in substantial compliance with 42 C.F.R. § 483.25(k) (tag F328 -- special needs) and that its deficiency posed immediate jeopardy to resident health and safety.[1] CMS Exhibit (Ex.) 1 at 2-4; CMS Ex. 2. For this, CMS imposed a $9,500 per instance CMP.

Based on representations from the state survey agency, CMS apparently determined that the facility corrected its deficiency at the time of the survey. CMS Ex. 1 at 1.

Petitioner timely requested a hearing. CMS moved for summary judgment. I denied CMS's motion, finding that Petitioner had come forward with evidence establishing that material facts were in dispute. Ruling on Motion for Summary Judgment (May 10, 2010).

On June 29, 2010, I convened a hearing, via video teleconference, from the offices of the Departmental Appeals Board in Washington, D.C. The parties convened in Dallas, Texas. Ms. Delta S. Best and Ms. Allison L. Spruill appeared on behalf of Petitioner. Mr. Kermit R. Williams, III, appeared on behalf of CMS. I have admitted into evidence CMS Exhibits 1-22 and Petitioner's Exhibits 1-6, 8-10, and 14-25. Summary of Prehearing Conference (May 10, 2010); Transcript (Tr.) at 5.

CMS filed its Motion for Summary Judgment/Pre-hearing Brief (CMS Br.). Petitioner filed a Response to Motion for Summary Disposition/Pre-Hearing Brief (P. Br.). Following the hearing, the parties filed closing briefs (CMS Cl. Br.; P. Cl. Br.). Neither party submitted a reply brief.

II. Issues

Two issues are before me:

1. At the time of the April 16, 2009 survey, was the facility was in substantial compliance with 42 C.F.R. § 483. 25(k); and

[1] CMS determined that the facility was not in substantial compliance with three additional health requirements plus three provisions of the Life Safety Code of the National Fire Protection Association. However, CMS imposed no penalty for those violations, so the findings are not before me. *Schowalter Villa*, DAB No. 1688 (1999) (noting that the remedy, not the citation of a deficiency, triggers the right to a hearing).

2. If the facility was not in substantial compliance, is the penalty imposed – $9,500 per instance – reasonable?

Summary of Prehearing Conference at 2 (May 10, 2010); Tr. at 5.

I have no authority to review CMS's finding of immediate jeopardy. An ALJ may review CMS's scope and severity findings (which include a finding of immediate jeopardy) only if a successful challenge would affect the range of the CMP, or if CMS has made a finding of substandard quality of care that results in the loss of approval of a facility's nurse aide training program. 42 C.F.R. § 498.3(b)(14); 42 C.F.R. § 498.3(d)(10); *see Evergreen Commons*, DAB No. 2175 (2008); *Aase Haugen Homes*, DAB No. 2013 (2006). Here, the penalty imposed is a per instance CMP, for which the regulations provide only one range ($1,000 to $10,000), so the level of noncompliance does not affect the range of the CMP. 42 C.F.R. § 488.438(a)(2). Nor does CMS's scope and severity finding affect approval of the facility's nurse aide training program, since the facility has no such program in place. CMS Ex. 21 at 2. In any event, where, as here, the facility has been assessed a CMP of $5,000 or more, the state agency may not approve its nurse aide training program. Act § 1819(f)(2)(B); 42 C.F.R. § 483.151(b)(2)(iv).

III. Discussion

A. The facility was not in substantial compliance with 42 C.F.R. § 483.20(k), because facility staff did not provide two of its residents with proper respiratory treatment and care.[2]

Regulatory requirements: Under the statute and the "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. Among other specific mandates set forth in the regulation, the facility must ensure that residents with special needs receive "proper treatment and care" for certain special services, including respiratory care. 42 C.F.R. § 483.25(k).

CMS points to two residents who, in CMS's view, did not receive proper care and treatment for their respiratory ailments:

Resident 16 (R16). R16 was an 81-year-old woman suffering from congestive heart failure, peripheral vascular disease, seizure disorder, depression, and chronic obstructive pulmonary disease (COPD). She had had a stroke. CMS Ex. 5 at 3, 6. According to her March 25, 2009 Minimum Data Set (MDS), she was typically awake most of the day, engaging in activities ⅓ to ⅔ of the time. CMS Ex. 5 at 7. She required oxygen, and her

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

physician ordered it delivered by means of a nasal cannula at a rate of two liters per minute (L/M). CMS Ex. 5 at 8, 13; CMS Ex. 8 at 5; CMS Ex. 9; P. Ex. 10.

Citing CMS Ex. 9, CMS claims that R16's physician ordered that her oxygen saturation (O^2 sat) levels be maintained between 88% and 93%. CMS Cl. Br. at 9. I have carefully reviewed every line of that exhibit, and nowhere do I see any range listed. Nor could I find a range among any of the other orders relating to R16's oxygen. *See*, *e.g.*, CMS Ex. 11 at 35 ("She will continue on oxygen at two liters per minute via nasal cannula."); CMS Ex. 11 at 36; P. Ex. 10. In fact, the survey report form says "The physician orders contained no parameters for maintaining O^2 sats." CMS Ex. 2 at 4.[3] Petitioner concedes that R16's attending physician had not provided any parameters for O^2 sat levels. P. Cl. Br. at 4.

Surveyor Delores Williamson, R.N., testified that, at 10:52 a.m. on April 15, she observed R16 sitting in her wheelchair, alone in her room. The resident "appeared lethargic." She was not moving. Her eyes were closed. Her color was "dusky." She was slow to respond. The surveyor heard "crackling, rattling" sounds from the resident's breathing. Only one prong of her nasal cannula was in her nose. The resident complained that she was having difficulty breathing, did not feel well, and was tired. CMS Ex. 21 at 3; Tr. at 16, 18, 26. Fatigue, lethargy, and difficulty breathing are symptoms of oxygen deprivation. CMS Ex. 17; CMS Ex. 21 at 3.

The resident had a portable oxygen tank (E-tank) on the back of her wheelchair.[4] *See* CMS Ex. 18 at 4-5; CMS Ex. 20 at 13. Surveyor Williamson testified that she examined the tank's gauge and saw that it was empty, so she summoned a nurse. CMS Ex. 21 at 3 ("The red area was marked empty, the gauge was in the red area."); Tr. at 18-19. Licensed Vocational Nurse (LVN) Candace Sieber came into the room at 10:56 a.m. She assessed the resident: R16's O^2 sat level was 85%; her pulse was 103. Surveyor Williamson properly considered these findings significant. "In general, residents with oxygen saturation readings below 90% with pulse oximeter should have oxygen applied." CMS Ex. 15 at 7. A normal pulse is 70 to 80 beats per minute. A pulse of 103 is consistent with oxygen deprivation – the heart speeds up to pump more oxygenated blood throughout the body. CMS Ex. 17; CMS Ex. 21 at 3; Tr. at 23.

The resident asked to be put to bed, which involved disconnecting her from her portable oxygen tank and connecting her to her oxygen concentrator, a pump-like device that concentrates room oxygen and delivers it to the patient through a tube to a nasal cannula, or face mask. CMS Ex. 18 at 3; CMS Ex. 20 at 11-12; CMS Ex. 21 at 3; Tr. at 25-26. Of

[3] CMS may have confused R16 with R18, whose attending physician included with his order for oxygen the O^2 sat parameters, 88% to 93%. CMS Ex. 12 at 22; P. Ex. 15 at 6.

[4] The parties agree that R16 was attached to her E-tank when Surveyor Williamson came into her room at 10:52 a.m. on April 15. Inexplicably, the facility's documentation for that day and time says that she was using the oxygen concentrator. CMS Ex. 5 at 13.

course, the tube must be attached to both the oxygen concentrator and the cannula/face mask, or the patient will not get the oxygen. CMS Ex. 21 at 4.

LVN Sieber removed the E-tank and turned on the oxygen concentrator. She also rubbed R16's back, instructed her to take deep breaths, and, after a few minutes, re-checked R16's O^2 sat level, which had risen to 91%, according to the surveyor. Tr. at 30-31, 41.

Surveyor Williamson also testified that she remained in R16's room after LVN Sieber left. R16 remained tired and lethargic. At 11:21 a.m., when the resident again insisted that she wanted to go to bed, Surveyor Williamson fetched another nurse, LVN Terry McCan, who determined that R16's O^2 sat level was 86% and her pulse was 104. CMS Ex. 21 at 4 (Williamson Decl.); Tr. at 43-44. LVN McCan examined the concentrator and told Surveyor Williamson that the tubing had not been connected to the concentrator. The LVN connected it, and, within minutes, the resident improved significantly. She became alert and able to carry on a conversation; her color changed to pink. CMS Ex. 21 at 4; Tr. at 43-44, 48.

That afternoon, at 1:52 p.m., LVN McCan told Surveyor Williamson that she had called R16's attending physician, Dr. Sanner, who ordered that R16's oxygen be increased to three liters and that the resident's O^2 sat levels be kept above 90%. Tr. at 46.

Nurses' notes, dated April 15 and 16, are consistent with Surveyor Williamson's testimony with respect to all material facts. On April 15, LVN Sieber wrote that at "approx[imately] 10:45" she was notified that R16's oxygen tank "was out or turned off." She went to the resident's room and found R16 sitting in her wheelchair, saying that she wanted to go to bed. The resident was wheezing; her O^2 sat level was 85%. LVN Sieber took the resident off the wheelchair tank and "put on [the] concentrator" with nasal cannula. She rubbed the resident's back and told her to breathe in through her nose and out through her mouth. CMS Ex. 8 at 1. LVN Sieber also wrote that approximately three to five minutes later, the resident's O^2 sat level was up to 95%. She told the resident that she would send a nurse aide in to put her to bed, and, according to the note, she then informed the resident's charge nurse (Terry McCan) and the nurse aide of the incident. CMS Ex. 8 at 1; P. Ex. 4 at 1.

In a similar note, dated April 16, LVN Sieber wrote that she was sitting at the nurses' station when the surveyor approached to say that R16's oxygen tank "looks like its [sic] off."[5] According to the note, LVN Sieber went to the resident's room, found her wheezing and, at the surveyor's request, checked the resident's O^2 sat level, which was 85%. She put the O^2 concentrator's nasal cannula in place, and turned on the concentrator. She then rechecked R16's O^2 sat level, which – according to the note – read 95%. She also told the resident to breathe through her nose and out her mouth.

[5] LVN Sieber does not specify a date or time for these events. She apparently later wrote in "10:45 AM 10:50 AM on 4-15-09." P. Ex. 2 at 5.

LVN Sieber repeated that she left the room and advised the resident's charge nurse and nurse aide that the resident wanted to go to bed. P. Ex. 2 at 2.

Another note, signed by LVN McCan, says that, at 10:50 a.m., she was called into the resident's room and assisted the nurse aide in putting the resident back to bed.[6] According to the note, LVN McCan noticed that R16's nasal cannula was "connected to empty E-tank." The resident's O^2 sat was at 87%. She put the resident on the concentrator, which was set at 2 L/M (liters per minute). The resident began coughing up thick, yellow sputum. LVN McCan increased the O^2 to 3 L/M (although no physician's order authorized the higher rate) and encouraged the resident to breathe in through her nose and out through her mouth. She rechecked R16's O^2 sat, which had increased to 96%. According to the note, the resident complained that she had not slept well the night before because of her roommate's TV. CMS Ex. 8 at 1; P. Ex. 4 at 1.

In another note, LVN McCan wrote that, at 11:20 a.m., R16's O^2 sat was at 94%, with oxygen administered at 2 L/M via nasal cannula on concentrator. LVN McCan notified the resident's physician, who ordered that the oxygen be administered at 2-3 L/M via nasal cannula "to maintain O^2 sat [above] 88%." He directed staff to monitor the resident's O^2 sat level hourly for 24 hours. LVN McCan also noted that the resident was no longer listless. CMS Ex. 8 at 1; P. Ex. 4 at 1.

In a statement dated April 16, 2009, R16's attending physician, Paul Sanner, M.D., wrote that, at approximately 11:20 a.m. on April 15, he "was notified of the incident" involving R16. According to Dr. Sanner, staff reported that a state surveyor noticed that R16's oxygen tank was off. *Facility staff* (not the surveyor) determined that R16 had been without oxygen supplementation for approximately 30-45 minutes; her O^2 sat was 85%; she complained that she was tired; she was wheezing and had a cough with thick yellow sputum. Staff put her back on oxygen per nasal cannula at 2 L/M then increased the rate to 3 L/M, and her O^2 sat level rose to 96%. P. Ex. 3 at 2.

The facility's medical director, John Sawtelle, M.D., wrote a progress note at 4:00 p.m. on April 15. According to the note, "earlier today, patient's oxygen tank reportedly ran out while patient was up in a [wheelchair]. Patient was discovered after several minutes. O^2 sat was reported at 85%." She was put on an oxygen concentrator, and her oxygen level "came up readily." CMS Ex. 8 at 3-4; P. Ex. 3 at 1, 3.

I find not credible, although of marginal relevance, LVN Sieber's subsequent inconsistent claims that, when she entered R16's room on the morning of April 15, the resident's E-tank was not off, and the gauge was not on empty. P. Ex. 21 at 1 (Sieber Decl.); *See* P. Ex. 1.

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[6] Everyone agrees that LVNs Sieber and McCan were not in the room at the same time, so at least one of them is incorrect about the time she entered the room. In light of Surveyor Williamson's precise records, which account for all of her time at the facility, I find her accounting more reliable; although, as discussed, the precise timing of the events is not material to my decision.

Although not completely consistent with the surveyor's testimony and notes (nor with each other), these contemporaneous statements from the facility nurses, medical director, and R16's physician confirm that, on April 15, R16 was without the supplemental oxygen her physician had ordered and that she exhibited symptoms of respiratory distress. Fortuitously, Surveyor Williamson found her and intervened before her condition deteriorated further. *See*, *e.g.*, P. Ex. 4 at 5. How R16 reached this state – whether her nasal cannula was partially dislodged, her E-tank was empty, her E-tank was turned off, her O^2 concentrator tubing was not properly attached, or some combination of these – is irrelevant.[7] Because its staff failed to ensure that R16 consistently received supplemental oxygen as ordered by her physician, the facility was not in substantial compliance with 42 C.F.R. § 483.25(k).

Notwithstanding overwhelming evidence to the contrary, Petitioner argues that R16 was "never without oxygen at any time on April 15," was not in respiratory distress that morning, and was exhibiting her normal behavior. P. Cl. Br. at 7. Pointing out that Dr. Sanner neglected to include with his order for oxygen any parameters for an acceptable O^2 sat level, Petitioner claims that an O^2 level of 85% was acceptable for R16.[8] Nurse Consultant Morgan claimed that 85% was "the patient's general baseline." Tr. at 101. LVN Candace Sieber also testified that "an O^2 sat reading of 85% . . . was fairly common for this resident given her respiratory conditions." P. Ex. 21 at 1.

I reject these assertions as unsupported by any reliable evidence. In his April 15 progress note, Dr. Sawtelle was guarded. He wrote that R16 suffered no apparent effects "at present" from the oxygen "lapse." He noted that she would be monitored closely and that her attending physician was aware of the occurrence. CMS Ex. 8 at 3-4; P. Ex. 3 at 1, 3. This is not the type of note a physician would write for a resident who was having her normal day.

Nor did Dr. Sanner respond as if nothing unusual occurred. When notified that R16's O^2 sat levels had dropped to 85%, Dr. Sanner increased the amount of oxygen administered from 2 L/M to 2-3 L/M, ordered staff *to maintain her O^2 sat level at 88% or higher*, and

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[7] At the time of the incident, everyone seemed to agree that R16 was not getting oxygen from her E-tank either because it was turned off or it was empty. Had there been any question about the cause of her respiratory distress, the facility should have investigated the incident. The record includes no evidence of an investigation.

[8] Although CMS has not pressed the issue – probably because of its mistaken belief that Dr. Sanner had provided parameters – the facility's failure to obtain an acceptable O^2 sat range for R16 created a dangerous situation for her. Staff knew only that they were supposed to provide oxygen at 2 L/M without regard to her O^2 sat levels. The facility's nurse consultant, C. Lynn Morgan, R.N., C, testified that, to determine whether a particular O^2 sat rate was acceptable, she would have to see "what the doctor wanted to maintain." Tr. at 87. Here, staff simply did not know.

to monitor her levels hourly "to confirm that she had not deteriorated from her previous baseline." CMS Ex. 8 at 1; P. Ex. 3 at 2.

Moreover, if, in fact, 85% represented a common reading for R16, I would expect to find that number recorded somewhere. The record before me establishes that, prior to this incident, R16's lowest recorded O^2 sat level was 90%. On March 25, staff reported an O^2 sat level of 94%. CMS Ex. 11 at 24. Her levels, which staff recorded each shift from April 1-14, ranged from 90% to 98%. CMS Ex. 11 at 1; P. Ex. 9 at 1. On April 15, after the physician directed that her O^2 sat levels be maintained above 88%, they ranged from 90% to 94%. CMS Ex. 8 at 1-2: P. Ex. 4 at 3. At 2:00 a.m. on April 16, staff reported that R16's nasal cannula was off, and her O^2 sat level dropped to 88%. But they reapplied the cannula and her O^2 sat level rose to 90%. An hour later, it was down to 87%.[9] Staff increased her oxygen to 3 L/M, and it went back up to 92%. Aside from the two instances, R16's O^2 sat level remained at or above 90% and only once fell below the physician-ordered 88%. CMS Ex. 8 at 2; P. Ex. 4 at 3-4.

Thus, the objective evidence establishes that, so long as facility staff followed the physician order for supplemental oxygen, R16's O^2 sat levels stayed within the physician-ordered parameters. However, when the resident was deprived of supplemental oxygen, her O^2 sat levels dropped.

Ignoring this relationship between the facility's failure to provide supplemental oxygen and R16's plummeting O^2 sat levels, Petitioner claims:

> In fact, the medical records <u>after the survey</u> confirm that, even with the procedures in place that the surveyors insisted upon, [R16]'s saturation rates still frequently dropped below 88%, and[,] on one occasion, they dropped below 78%. (Ex. 4). However, on each occasion, adjustments were made to the treatment plan, and no adverse effects were noted (Ex. 3, 4, 9).

P. Cl. Br. at 5 (emphasis in original).

In fact, the "medical records <u>after the survey</u>" confirm that R16's O^2 sat levels dropped when she was deprived of supplemental oxygen. Records show that, at 3:30 a.m. on April 17, LVN Heather Green found that R16 had pulled off her nasal cannula. Her O^2 sat level was 88%. LVN Green reapplied the cannula, and the resident's O^2 sat level rose to 90%. At 4:30 a.m., LVN Green again found the cannula off. She reapplied it and reported O^2 sat levels of 89% and 90%. She described the resident as "agitated." P. Ex. 4 at 4. For reasons that are not explained, she then left the agitated resident alone and unsupervised until 5:20 a.m.

[9] The nurse's note is silent as to whether the nasal cannula was in place.

At 5:20 a.m. LVN Green found R16 lying in bed, her nasal cannula off. Her O² sat level was ***72%***. The LVN called for a crashcart, applied the nasal cannula with concentrator at 4 L/M. The charge nurse arrived with tank and simple mask; she applied the mask at *8 L/M* and R16's O² level rose to 88% and then to 93%. The resident coughed up sputum. Staff removed her mask and suctioned until clear of sputum. They reapplied the mask, again at 8 L/M and measured an O² sat level of 91%. Thereafter, according to the note, her levels fluctuated from 93% to 97%. The nurse lowered the oxygen to 6 L/M. Staff called emergency medical services, and the EMTs arrived to transfer R16 to the hospital. P. Ex. 4 at 5.[10]

So, in the early hours of April 17, R16 was without supplemental oxygen for no longer than 50 minutes. Her O² sat level dropped to 72%, and she ended up in an ambulance on her way to the emergency room, a circumstance that belies Petitioner's claim of "no adverse effects." This incident also undercuts Dr. Sanner's assertion that "even if [R16] had been without oxygen for an hour or more[,] it was unlikely that her respiratory condition would have deteriorated any further." P. Ex. 3 at 2.

Resident 18 (R18). R18 was a 72-year-old man diagnosed with COPD. CMS Ex. 12 at 3. Facility records describe him as anxious about his condition. CMS Ex. 12 at 19.

R18's physician ordered that R18 receive continuous oxygen via nasal cannula at a rate of 5 L/M to maintain O² sat levels from 88% to 93%. CMS Ex. 12 at 22. As Surveyor Teresa Horton, R.N. explained, because of their decreased lung function, patients with COPD often have difficulty fully exhaling carbon dioxide, so their physicians commonly order these comparatively low O² rates. CMS Ex. 22 at 3; *see* CMS Ex. 19.

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[10] CMS's determination that the facility corrected its deficiencies at the time of the survey is not before me. I note, however, that a facility's return to substantial compliance ordinarily must be established through a resurvey. The facility must show that it has corrected its deficiencies and implemented a plan of correction designed to assure that no additional incidents will occur. 42 C.F.R. § 488.454(a); *Lake City Extended Care*, DAB 1658 at 12-15 (1998). Inexplicably, here, the state survey agency and CMS apparently determined, without benefit of a follow-up survey, that the facility was back in substantial compliance. Had there been a follow-up, CMS would presumably have learned that, within hours of the surveyors' departure, R16 was again deprived of supplemental oxygen, with potentially dire consequences. Moreover, I
I find the regulators' willingness simply to accept the facility's allegations of correction, without a follow-up survey, particularly puzzling in light of the facility history. *See Cedar Lake Nursing Home*, DAB CR 2137 (2010) (finding that the facility was not in substantial compliance with 42 C.F.R. § 483.25(k), because staff failed to follow a physician order to administer oxygen by means of a nasal cannula); *Cedar Lake Nursing Home v. U.S. Dep't. of HHS*, 2010 WL 3528833 (5th Cir. 2010) (affirming the agency determination that the facility was not in substantial compliance with 42 C.F.R. § 483.25(h)). As discussed below, this facility has not demonstrated its ability to achieve and maintain substantial compliance.

R18's physician also ordered for him a bi-level positive airway pressure machine (BiPAP) at bedtime. BiPAP is an apparatus that provides constant flows of air pressure for inhaling and exhaling. It is frequently used to treat sleep apnea and other breathing disorders. CMS Ex. 12 at 30; CMS Ex. 16; CMS Ex. 22 at 3; Tr. at 58.

During the survey, Surveyor Horton saw R18's wife wheel him up to the nurses' station. His wife told the staff that R18's oxygen tank was empty and needed to be refilled. Tr. at 51-52. Surveyor Horton then interviewed R18, who told her that the nurses "put too much oxygen through his BiPAP machine," which scared him. Tr. at 54. Surveyor Horton then checked R18's treatment records, and saw that his O^2 levels were as high as 98% at night. Tr. at 58. At 1:00 a.m. on March 15, 2009, nurses recorded that they administered oxygen to him at the physician-ordered rate of 5 L/M. The resident's O^2 level increased to 98%. The resident complained that it was too high, so staff decreased the rate to 3 L/M, and his O^2 level dropped to 92%. P. Ex. 17 at 2; CMS Ex. 12 at 47; Tr. at 63.[11] No evidence suggests that the nurse contacted the physician before she decreased the amount of oxygen or anytime thereafter. *See* Tr. at 63.

Records show that R18's nightly O^2 sat levels were often too high. On the night of March 16, staff reported a level of 96%. CMS Ex. 12 at 44.

Petitioner, however, points out that the physician's order setting forth acceptable O^2 sat level parameters is dated March 18, and argues that the staff therefore cannot be faulted for allowing such high O^2 sat levels prior to that date. P. Cl. Br. at 11. But the parameters are included in the physician's order for supplemental oxygen. CMS Ex. 12 at 22 ("O^2 at 5 L/M per cannula cont. to maintain O^2 sat of 88-93%."). Under Petitioner's theory, staff would have been providing supplemental oxygen without any physician order, which is a serious deficiency. Presumably, however, an earlier order was in place that called for supplemental oxygen. That order should have included acceptable parameters for the resident's O^2 sat levels. If no parameters were in place, the facility should have obtained them from R18's attending physician, who was, after all, the facility's medical director. Otherwise, assuming that facility staff were following the physician's order, they were administering oxygen without regard to the resident's O^2 sat levels, putting him at risk for serious harm.

In any event, after March 18, R18's O^2 sat levels regularly exceeded the ordered parameters. On April 1, they ranged from 94% to 96% at night. P. Ex. 17 at 3, 4. On April 7, they were up to 97% with BiPAP in place. P. Ex. 17 at 13, 14. On April 10,

[11] Staff inconsistently recorded the O^2 levels for the night of March 15. The one-page synopsis says that for the night shift his O^2 sats ranges from 86-90; it does not mention that his O^2 sat level reached 98%. *Compare* P. Ex. 17 at 2 *with* P. Ex. 17 at 1.

they were 98% at night. P. Ex. 17 at 21. On April 13, they were at 94%. P. Ex. 17 at 61. The facility did not consult R18's physician about the high levels. Tr. at 59. [12]

In light of the relationship between high O^2 sat levels and excess carbon dioxide for those suffering from COPD, it is not surprising that R18's blood tests taken on March 16, 23, 30, and April 6 and 13 showed elevated levels of carbon dioxide. CMS Ex. 12 at 21.

So, when facility staff followed the physician's order, R18's O^2 sat level would be dangerously high. Occasionally, the LVN, on her own, decreased the rate of oxygen she supplied, without a physician's order, and without contacting the physician.

CMS also faults the facility because R18's physician did not provide instructions as to the BiPAP's settings. According to Surveyor Horton, standards of practice dictate that the facility obtain a physician's order for the BiPAP settings. If the physician does not include them in his orders, staff should let him/her know that they need the information. If, by following the physician's orders, staff are unable to maintain the desired O^2 levels, they must also notify him so he can adjust his orders. Tr. at 55-57.

Petitioner claims that only the physician or the respiratory therapist determines the BiPAP settings, so the physician did not need to include them in his orders. No one disputes that the physician determines what the settings should be, but CMS correctly maintains that the physician must include that information in his orders. Moreover, Petitioner's claim is inconsistent with R18's care plan, which says that *nurses* will maintain "BiPAP setting per orders." CMS Ex. 12 at 28. In order to maintain those settings, nurses obviously needed to know what they are supposed to be.

Based on these deficiencies, I agree that the facility was not providing proper respiratory treatment and care to R18, and the facility was therefore not in substantial compliance with 42 C.F.R. § 483.25(k).

Finally, Petitioner submits the opinion of Nurse Consultant Morgan, a former state surveyor, who claims that these deficiencies were not properly cited under 42 C.F.R. § 483.25(k)(6), because they are not among five specific examples listed in the State Operations Manual (SOM). In determining whether a facility provides proper respiratory treatment and care, the SOM instructs surveyors to consider the following: 1) are oxygen cylinders properly stored; 2) are "no smoking" signs posted in the correct places, if such signs are required; 3) if the survey team observes respiratory treatment, is the resident encouraged to participate in the treatment; 4) does the staff follow facility protocol regarding the use of ventilators and availability of manual resuscitators; and 5) if the resident is ventilator dependent, is routine machine maintenance care performed? According to Petitioner (and Nurse Consultant Morgan), because the survey findings "do

[12] In what it characterizes as an "order clarification," a physician order dated April 15 sets BiPAP settings with threaded oxygen at 2 L/M to 3 L/M to maintain an O^2 level of 88 to 93%. CMS Ex. 12 at 27.

not reference any of these probes, and the surveyors do not claim that Cedar Lake was deficient in any of these area," the citations should be deleted. P. Ex. 19 at 2-3 Moral Decl.); P. Br. at 4; *see* Tr. at 92-94.

I find the Petitioner's position wholly without merit.[13] I note first that the SOM may provide useful guidance as to CMS's interpretations of applicable law, but its provisions do not constitute enforceable, substantive rules. *Beverly Health and 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).

I am bound by the regulations, and SOM provisions must be read as compatible with the regulations, or they are not valid. Petitioner's narrow reading ignores the plain meaning of 42 C.F.R. § 483.25(k)(6): facility's must ensure that its residents receive "proper treatment and care," specifically including respiratory care. But under Petitioner's interpretation of the SOM provisions, facility staff could simply refuse to provide any respiratory care to a resident in distress without violating the regulation, since its failure to provide needed respiratory care does not fit within any of the five listed instructions.

The five examples listed in the SOM were never meant to be exclusive; they simply point out additional, less obvious areas that a surveyor might not necessarily consider in determining whether the facility is providing proper respiratory care.

B. The penalty imposed is reasonable.

I next consider whether the CMP is reasonable by applying the factors listed in 42 C.F.R. § 488.438(f): 1) the facility's history of noncompliance; 2) the facility's financial condition; 3) factors specified in 42 C.F.R. § 488.404; and 4) the facility's degree of culpability, which includes neglect, indifference, or disregard for resident care, comfort or safety. The absence of culpability is not a mitigating factor. The factors in 42 C.F.R. § 488.404 include: 1) the scope and severity of the deficiency; 2) the relationship of the deficiency to other deficiencies resulting in noncompliance; and 3) the facility's prior history of noncompliance in general and specifically with reference to the cited deficiencies.

In reaching a decision on the reasonableness of the CMP, I consider whether the evidence supports a finding that the amount of the CMP is at a level reasonably related to an effort to produce corrective action by a provider with the kind of deficiencies found, and in light of the above factors. I am neither bound to defer to CMS's factual assertions, nor free to make a wholly independent choice of remedies without regard for CMS's discretion. *Barn Hill Care Ctr.*, DAB No. 1848 at 21 (2002); *Cmty. Nursing Home*, DAB No. 1807 at 22 *et seq*. (2002); *Emerald Oaks*, DAB No. 1800 at 9 (2001); *CarePlex of Silver Spring*, DAB No. 1638 at 8 (1999).

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[13] Although Petitioner presented this argument in its opening brief, and vigorously defended it during the hearing, its closing brief does not even allude to it, which suggests that Petitioner may, wisely, have decided to abandon the argument.

CMS has imposed just one $9,500 per instance CMP, which is at upper end of the penalty range ($1,000-$10,000). 42 C.F.R. § 42 C.F.R. §§ 488.408(d)(iv), 488.438(a)(2). On the other hand, the penalty is modest considering what CMS might have imposed. *See Plum City Care Ctr.*, DAB No. 2272 at 18-19 (2009) (Even a $10,000 per instance CMP can be "a modest penalty when compared to what CMS might have imposed.").

Petitioner disingenuously asserts that it "does not have a history of uncorrected F328 violations." P. Cl. Br. at 13. In fact, just two months prior to this survey (February 2009), it failed to provide proper respiratory care to one of its residents and was therefore not in substantial compliance with 42 C.F.R. § 483.25(k). *Cedar Lake Nursing Home*, DAB CR2137 (2010). CMS imposed a $6,000 per instance CMP, which, based on these April 2009 survey findings, proved insufficient to produce ongoing corrective action. Based on a 2008 survey, this facility was not in substantial compliance with 42 C.F.R. § 483.25(h) (accident prevention), and CMS imposed a $5,000 per instance CMP. *Cedar Lake Nursing Home*, DAB No. 2288 (2009); *aff'd*., *Cedar Lake Nursing Home v. U.S. Dept. of HHS*, 2010 WL 3528833 (5th Cir. 2010). Again, the penalty was insufficient.

Petitioner has not argued that its financial condition affects its ability to pay the penalty.

With respect to the remaining factors, I consider the severity of the deficiencies significant enough to warrant this penalty. The facility is culpable. It did not follow physician orders and did not clarify ambiguous or incomplete orders, which caused its residents significant distress and put them at risk of even more serious harm.

I therefore find reasonable the $9,500 per instance CMP.

IV. Conclusion

The facility was not in substantial compliance with the Medicare requirements governing residents' special needs, 42 C.F.R. § 483.25(k), and the penalty imposed is reasonable.

/s/
Carolyn Cozad Hughes
Administrative Law Judge