Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
The Clairmont Tyler, LP	)	
(CCN: 45-5485),	)	Date: March 12, 2008
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-06-462
	)	Decision No. CR1748
Centers for Medicare & Medicaid	)	
Services.	)	
	)	

DECISION

I sustain the decision of the Centers for Medicare & Medicaid Services (CMS) to impose a per-instance civil money penalty (PICMP) of $3500 upon Petitioner, The Clairmont Tyler, LP, for a violation of 42 C.F.R. § 483.70(a), based on a finding of immediate jeopardy and cited as Life Safety Code (LSC)[1] Tag K-106.

I. Background

Petitioner is a long-term care facility located in Tyler, Texas, and is authorized to participate in the Medicare and Medicaid programs. It is required to be in substantial compliance with program requirements to remain a participant.

[1] Pursuant to 42 C.F.R. § 483.70(a), long-term care facilities are required to comply with the LSC of the National Fire Protection Association (NFPA), 2000 edition (NFPA 101), which contains procedural safeguards to prevent and respond to fires and other types of accidents, including power failure.

This case arose from a survey of Petitioner's facility conducted by the Texas Department of Aging and Disability Services (state agency) on March 9, 2006. The state agency found multiple instances of noncompliance with program requirements.[2] Among the findings was a violation of 42 C.F.R. § 483.70(a), for which multiple LSC Tags were cited. Of those Tags, Tag K-106, which concerns one resident (Resident 18, hereinafter, "R-18"), is the subject of this decision.

On March 23, 2006, the state agency notified Petitioner of its survey findings. Based on its review of those findings, on March 24, 2006, CMS notified Petitioner that it was not in substantial compliance with program requirements; that its provider agreement would be terminated effective August 9, 2006, unless the facility returned to substantial compliance before that date; and that a denial of payment for new admissions (DPNA) would become effective April 8, 2006, to continue until the facility achieved substantial compliance or its provider agreement was terminated, whichever occurred first. As monetary sanctions, Petitioner was assessed a civil money penalty (CMP) of $7000, $3500 of which represented a PICMP for a violation of 42 C.F.R. § 483.70(a) (LSC Tag K-106).[3] Petitioner also was advised that the survey findings and remedies imposed could affect the approval status of the facility's Nurse Aide Training and Competency Evaluation Program (NATCEP) and Competency Evaluation Program. On May 25, 2006, CMS informed Petitioner that based on the state agency's conclusion that the facility had returned to substantial compliance, it rescinded the proposed termination of the facility's provider agreement, but that the DPNA in effect from April 8, 2006, through April 23, 2006, and the $7000 CMP would not be rescinded.

By letter dated May 15, 2006, Petitioner, by counsel, requested a hearing before an administrative law judge (ALJ) and disputed all noncompliance findings and remedies imposed or proposed. The parties filed their pre-hearing briefs and complied with my October 11, 2006 Order. I scheduled a hearing to be convened on March 19, 2007, to continue through March 22, 2007, in Dallas, Texas. On November 9, 2006, CMS filed its Witness and Exhibit List, along with exhibits (CMS Exs.) 1 through 37. On December

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[2] The regulatory bases for noncompliance findings made following the March 9, 2006 survey were: 42 C.F.R. §§ 483.13(c)(1)(ii) and (iii)(2),(3), and (4) (Resident Behavior/Facility Practices); 483.15(h)(2) and (5) (Quality of Life); 483.25(a)(3) (Quality of Care); 483.25(c) (Quality of Care); 483.25(k) (Quality of Care); 483.35(c)(1)-(3) (Dietary Services); 483.35(d)(1) and (2) (Dietary Services); 483.60(a) (Pharmacy Services); 483.70(a) (Physical Environment; LSC Tags K-18, K-21, K-29, K-39, K-62, K-76, K-106, and K-141); and 483.75 (Administration).

[3] A PICMP of $3500 was cited for a violation of 42 C.F.R. § 483.25(k).

13, 2006, Petitioner filed its Witness List, Exhibit List, and exhibits (P. Exs.) 1, 2, and 3. Without objections to the exhibits as submitted, I admit CMS Exs. 1-37 and P. Exs. 1-3.

On February 20, 2007, I convened a telephonic pre-hearing conference, at which time counsel informed me that the parties reached partial compromise such that the only matter remaining for my adjudication is the dispute concerning LSC Tag K-106, for which a $3500 PICMP was imposed. Counsel and I agreed that an in-person hearing would be unnecessary in light of the partial settlement and that I would adjudicate the remaining dispute (LSC Tag K-106) based on written submissions.[4] On February 22, 2007, I issued an Order Cancelling Hearing and Setting Briefing Schedule.

Pursuant to my February 22, 2007 Order, on March 22, 2007, CMS filed its brief, titled "Respondent's Brief Submitted for Decision" (CMS Brief), along with a Motion to Supplement Pre-Hearing Exchange with two additional exhibits (CMS Exs. 38 and 39) and CMS Exs. 38 and 39.[5] On April 23, 2007, Petitioner filed its brief, titled "Petitioner's Written Submissions In Lieu of Oral Hearing" (P. Brief). Without objection to CMS Exs. 38 and 39, or opposition to CMS's Motion to Supplement Pre-Hearing Exchange, I admit CMS Exs. 38 and 39. And although my February 22, 2007 Order permitted the parties to file reply briefs, they declined to do so, by letters dated May 18, 2007 (CMS) and May 21, 2007 (Petitioner). Therefore, the record is complete for my decision.

Petitioner has raised allegations of due process violations and constitutional challenges in its request for hearing (at 2) and Pre-Hearing Brief (at 2), and in P. Brief at 2-3. I do not have jurisdiction over these matters, but Petitioner has raised them with sufficient clarity that they are preserved for any future appeal in a forum that enjoys jurisdiction to consider them.

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[4] CMS stated (CMS Brief at 3) that the parties "mutually entered into settlement of all tags and remedies except the Life Safety Code tag K-106 and its corresponding civil money penalty in the amount of $3,500.00, which is the remaining issue on appeal."

[5] CMS Exs. 38 and 39 are affidavits of two surveyors (one, an engineer; the other, a registered nurse), and the latter includes copies of certain medical journal materials and Internet-based medical information. CMS Exs. 38 and 39 were submitted with cover sheets marked "CMS Exhibit #38" and "CMS Exhibit #39," but the exhibits themselves are not marked accordingly. Rather, the pages constituting CMS Ex. 38 are marked CMS Ex. 1 and the pages constituting CMS Ex. 39 are marked CMS Ex. 2; and neither CMS Ex. 38, nor CMS Ex. 39, duplicates previously-submitted exhibits. Any reference to either of these exhibits will be to CMS. Ex. 38 or CMS Ex. 39.

II. Applicable Law and Regulations

Sections 1819 and 1919 of the Social Security Act (Act) and regulations in 42 C.F.R. Part 483 govern Medicare/Medicaid program participation requirements for long-term care facilities. Pursuant to Sections 1819 and 1919 of the Act, the Secretary of Health and Human Services may impose remedies against a facility for noncompliance with federal participation requirements. Facilities participating in Medicare are subject to surveys by state agencies on behalf of CMS to determine whether they are so compliant. 42 C.F.R. §§ 488.10-488.28, 488.300-488.335.

CMS may impose various sanctions for failure to substantially comply with participation requirements, including a PICMP or per-day CMP. 42 C.F.R. §§ 488.406; 488.408; 488.430. Per-day CMPs fall into one of two ranges of penalties. 42 C.F.R. §§ 488.408, 488.438. The upper range, from $3050 to $10,000 per day, is reserved for deficiencies that constitute immediate jeopardy to a facility's residents and, in some circumstances, for repeated deficiencies. 42 C.F.R. §§ 488.438(a)(1)(i), (d)(2). The lower range, from $50 to $3000 per day, is reserved for deficiencies that do not constitute immediate jeopardy, but either cause actual harm to residents, or cause no actual harm, but have the potential for causing more than minimal harm. 42 C.F.R. § 488.438(a)(1)(ii). As for PICMPs, the regulations provide for one range of CMP from $1000 to $10,000, which could be imposed whether or not immediate jeopardy is found. 42 C.F.R. §§ 488.408(d)(1)(iv); 488.438(a)(2).

A long-term care facility against which CMS has determined to impose a CMP is entitled to a hearing before an ALJ. Act, section 1128A(c)(2); 42 C.F.R. §§ 488.408(g); 498.3(b)(13). A hearing before an ALJ is a *de novo* proceeding. *Anesthesiologists Affiliated, et al.*, DAB CR65 (1990), *aff'd*, *Anesthesiologists Affiliated, et al. v. Sullivan*, 941 F.2d 678 (8th Cir. 1991). The facility has a right to appeal a "certification of noncompliance leading to an enforcement remedy." 42 C.F.R. § 488.408(g)(1); *see also* 42 C.F.R. § 488.330(e). However, the choice of remedies by CMS or the factors CMS considered in choosing remedies are not reviewed. 42 C.F.R. § 488.408(g)(2). A facility may only challenge the scope and severity level of a noncompliance found by CMS if a successful challenge would affect the CMP amount that could be collected by CMS or have an impact upon the facility's NATCEP. 42 C.F.R. §§ 498.3(b)(14), (d)(10)(i). CMS's determination as to the level of noncompliance is upheld unless it is "clearly erroneous." 42 C.F.R. § 498.60(c)(2). This includes its finding of immediate jeopardy. *Woodstock Care Center*, DAB No. 1726, at 9, 38 (2000), *aff'd, Woodstock Care Center v. Thompson*, 363 F.3d 583 (6th Cir. 2003). The DAB has long held that a provider has no right to challenge the scope and severity level assigned to a noncompliance finding, except where that finding was the basis for an immediate jeopardy determination. *See, e.g.*, *Ridge Terrace*, DAB No. 1834 (2002); *Koester Pavilion*, DAB No. 1750 (2000). The review of a CMP by an ALJ is governed by 42 C.F.R. § 488.438(e).

In a case where a CMP was imposed, CMS must make a *prima facie* case that the facility failed to comply substantially with participation requirements. To prevail, a facility must overcome CMS's showing by a preponderance of the evidence. *Hillman Rehabilitation Center*, DAB No. 1611 (1997), *aff'd, Hillman Rehabilitation Center v. U.S. Dep't of Health and Human Services*, No. 98-3789 (GEB), slip op. at 25 (D.N.J. May 13, 1999).

III. Issues

The issues in this case are:

(1) Whether Petitioner was in substantial compliance with 42 C.F.R. § 483.70(a) (LSC Tag K-106).

(2) Whether the finding of immediate jeopardy is clearly erroneous.

(3) Whether the PICMP of $3500 is reasonable.

IV. Findings and Discussion

The following findings of fact and conclusions of law are italicized and followed by a discussion of each.

A. Petitioner violated 42 C.F.R. § 483.70(a) (LSC Tag K-106).

Petitioner did not maintain specialized patient care electrical receptacles in R-18's sleeping room 117 that required the use of life-support equipment where the specialized patient care electrical receptacles were connected to the Critical Electrical Branch of Type I Emergency Electrical System consistent with NFPA 99.

A facility must be designed, constructed, equipped, and maintained to protect the health and safety of residents, personnel, and the public. 42 C.F.R. § 483.70. It must meet applicable provisions of NFPA 101. 42 C.F.R. § 483.70(a)(1)(i). NFPA 101 requires hospitals, nursing homes, and hospices that have life-support equipment to have a Type 1 Essential Electrical System (EES) powered by a generator with a transfer switch and separate power supply. The EES is in accordance with NFPA 99 (Standard for Health Care Facilities), 3.4.2.2, 3.4.2.1.4. CMS Ex. 9, at 34.

On March 9, 2006, the surveyor concluded that Petitioner was not substantially compliant[6] with 42 C.F.R. § 483.70(a)(1) because it failed to maintain specialized patient care electrical receptacles in a single area (R-18's sleeping room 117) that required the use of life support equipment where the specialized patient care electrical receptacles were connected to the Critical Electrical Branch of Type I EES consistent with NFPA 99. CMS Ex. 3, at 52. In the event of a power outage, there would be no alternate power source from the emergency generator to continue operating R-18's life-support equipment while R-18 is in sleeping room 117. Therefore, this deficiency was categorized as an immediate jeopardy finding. CMS Ex. 3, at 52-53. R-18 was transferred from the facility and, after Petitioner submitted a plan of correction, the immediate jeopardy finding was removed on March 8, 2006. The surveyor determined that the deficiency remained uncorrected pending the facility's monitoring to determine the effectiveness of the corrective action.[7] CMS Ex. 3, at 53, 55-56.

I have considered Petitioner's arguments as to why the citation of LSC Tag K-106 based on a finding of immediate jeopardy and the imposition of a $3500 PICMP should not be sustained. Petitioner does not dispute the one crucial determination made by the surveyor that defeats its case: that Petitioner failed to ensure the availability of an alternate electricity source in the event of a power failure to prevent risk of harm to residents relying upon electricity to power life-sustaining equipment. Rather, the central theme of its various arguments is that R-18's ventilator was not a life-support device, but was a supplemental breathing aid that R-18, mostly independent, used if and when *he* wanted to use it, and therefore, there was no actual, or even potential for, harm.

R-18 apparently told the surveyor that he used the ventilator only while lying down or during night-time, and that he could breathe independently while in an upright position, typically during daytime. Petitioner's Director of Nurses reported similarly. CMS Exs. 3, at 53-54, and 9, at 1. (But there is some indication that R-18 did not limit his use of the ventilator only to times when he is in a reclining position, or while in bed. CMS Ex. 39, at 6.) Also, Petitioner proffered R-18's clinical records, including Dr. R. Becker's statements and nursing notes (see in particular P. Ex. 1, at 2, 5, 8, 10, 11, 13, 15, 17, 19; P. Ex. 3, at 1-3), to show that R-18 was not truly vulnerable and was mostly independent; that he used the non-invasive ventilator electively and only to supplement his own breathing capability; and that R-18's ventilator was not a life-support device.

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[6] "Substantial compliance" is "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." 42 C.F.R. § 488.301.

[7] The scope and severity level was decreased to "isolated potential for more than minimal harm that is not immediate jeopardy." CMS Ex. 3, at 53.

I am not convinced by these arguments. First, the issue of whether Petitioner violated 42 C.F.R. § 483.70(a)(1) does not turn on whether R-18 actually depended on his ventilator at all times to sustain his life, or whether R-18 was actually harmed or was at risk of actual harm. The cornerstone of that provision is that *any* resident using a life-support device powered by electricity should have available an alternate power source should the primary power source fail, to prevent interrupted operation of the device. The undisputed evidence before me is that Petitioner did not meet that requirement. That the violation was cited only as it applied to R-18 does not affect my conclusion.[8] Nor does the absence of surveyor observation of R-18 in respiratory distress at the time of the survey. The regulation exists to safeguard residents against *potential* harm from failure of equipment due to power failure; Petitioner is not absolved from a deficiency finding based on after-the-fact assertion that R-18 did not actually suffer harm. Also on this point, while I have considered the statements of two staff-persons that the facility had in place an emergency protocol, which included the availability of a disaster kit containing extension cords that could connect a red emergency plug to R-18's bed area (P. Ex. 3, at 4-5), that protocol does not comply with the specific regulation at issue.

Further, I find Petitioner's assertions to the effect that R-18 was never truly in danger because the ventilator was not a life-support device, and which had an internal battery that would have operated as a back-up power source in the event of power failure, and that the facility's staff merely needed to place R-18 in an upright position to keep him breathing continuously, specious. On this point, S. Cruz (a nurse) said, based on her survey findings, that the facility staff either said the battery would operate for 30 minutes or that they were uncertain as to the expected life of the battery; and that the battery needed routine maintenance, but that they did not know when it was last serviced. CMS Ex. 39, at 6-7. Petitioner itself admitted that its staff lacked knowledge about R-18's ventilator, and Dr. Becker called it "an antique." Prehearing Brief at 29-30; P. Ex. 3, at 1. R-18 could not move on his own while he is in bed at night (CMS Ex. 3, at 20), which would suggest that he would have difficulty operating, or would be unable to operate, the ventilator on his own. It would follow, then, that in the event of power failure, at night,

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[8] The surveyor noted that *no* resident room had electrical receptacles connected to the Critical Electrical Branch of EES. CMS Exs. 3, at 53, 54, and 9, at 1-2. Nonetheless, it is evident that only Tag K-106 was cited because R-18 alone would have been affected by the violation. But, Petitioner's argument that the citation of K-106 only, notwithstanding the lack of emergency receptacles in other areas, is indicative of surveyors' lack of knowledge of the purpose and use of R-18's ventilator (P. Brief at 11-12) muddles the issue, which is simply whether there was a back-up power source to prevent risk of harm to residents relying on electricity to power life-support equipment, consistent with the LSC of NFPA 101.

R-18 very well could have been in danger if the battery did not operate, or, even if it operated for a short duration, if staff unfamiliar with the ventilator or the battery in it could not react timely.

Based on the foregoing, I conclude that Petitioner violated 42 C.F.R. § 483.70(a), cited as LSC Tag K-106.

B. An immediate jeopardy finding for LSC Tag K106 is not clearly erroneous.

Immediate jeopardy exists where a "provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301. For a finding of immediate jeopardy, it is not necessary to show that the noncompliance actually caused serious injury, harm, impairment, or death; rather, it is sufficient to show that the noncompliance was likely to cause, or had the potential for causing, serious injury, harm, impairment, or death. *Fairfax Nursing Home, Inc.*, DAB No. 1794, at 14 (2001). I must uphold CMS's immediate jeopardy determination unless Petitioner meets the burden to show the finding was clearly erroneous. 42 C.F.R. § 498.60(c)(2).

In this case there is strong *prima facie* evidence of immediate jeopardy-level deficiency inasmuch as a vulnerable resident was placed at risk of serious, imminent harm of respiratory failure or death. It is evident that upon admission into Petitioner's facility in November 2005, R-18 was diagnosed with chronic respiratory failure and history of Polio, and was on life support. CMS Exs. 39, at 6, 3, at 54, and 9, at 1; P. Exs. 1, at 1, 2, 5, and 3, at 1. Petitioner acknowledged that R-18 also had a history of kyphosis, marked by curvature of the spine, which could play a role in compressing lung space and, thus, contribute to labored breathing. P. Brief at 9-10; P. Ex. 1, at 1 (showing a diagnosis of kyphoscoliosis). These considerations are indicative of R-18's susceptibility to harm should his breathing device fail to operate for *any* reason and, thus, should have heightened the vigilance with which Petitioner's staff should have cared for R-18. Under the circumstances, I cannot conclude that Petitioner has met its burden to show that the immediate jeopardy finding was clearly erroneous. I therefore uphold CMS's finding.

C. The PICMP of $3500 imposed for LSC Tag K-106 is reasonable.

I find a basis for a noncompliance finding and, thus, there is a basis for an enforcement remedy. I also conclude that the immediate jeopardy finding for a violation of 42 C.F.R § 483.70(a), cited as LSC Tag K-106, is not clearly erroneous. The final inquiry is whether the $3500 PICMP is reasonable.

To determine whether the CMP is reasonable, factors in 42 C.F.R. § 488.438(f) must be considered: (1) the facility's history of noncompliance, including repeated deficiencies; (2) its financial condition; (3) the seriousness of the deficiencies as set forth in 42 C.F.R. § 488.404; and (4) the degree of culpability.

If a facility is not in substantial compliance with program requirements, then CMS may impose one or more of the enforcement remedies listed in 42 C.F.R. § 488.406, including a DPNA and a CMP. The CMP may be either a per-day CMP for the number of days that a facility is not in compliance, or a PICMP. 42 C.F.R. § 488.430(a). In this case CMS could have imposed a per-day CMP within the upper range ($3050 per day to $10,000 per day) based upon an immediate jeopardy finding (42 C.F.R. §§ 488.438(a)(1)(i), (d)(2)), but it instead elected to impose a PICMP.

Within the sole range from $1000 to $10,000 permitted for a PICMP, which could have been imposed even without immediate jeopardy (42 C.F.R. §§ 488.408(d)(1)(iv); 488.438(a)(2)), CMS elected to impose $3500, which is at the lower end of this range. I do not find evidence of a history of noncompliance, or of inability to pay the PICMP. There is, however, evidence of a serious deficiency and of culpability. Petitioner said, "[a]t worst, a failure of the total machine would [have] cause[d] [R-18] some lost sleep and, maybe, anxiety." P. Brief at 16. I disagree, and the effect of my disagreement will be seen at once. The deficiency at issue posed the possibility of significant danger. In the event of a power failure, there would have been no power source to ensure continued operation of R-18's ventilator while R-18 is in room 117. I make this point again because it is at the core of the issue of this facility's culpability. The deficiency in this case and Petitioner's statement as quoted above, in my opinion, suggest indifference and, therefore, culpability, on the facility's part. Based on the foregoing, I conclude that the $3500 PICMP is reasonable.

V. Conclusion

CMS's determination that Petitioner was not compliant with federal requirements governing participation of long-term care facilities in Medicare and Medicaid programs at the immediate jeopardy level, cited as a violation of 42 C.F.R. § 483.70(a) (LSC Tag K-106), and its imposition of a PICMP of $3500 is, in all respects

AFFIRMED.

/s/
Richard J. Smith
Administrative Law Judge