Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Lopatcong Center
(CCN: 31-5202),

Petitioner

v.

Centers for Medicare and Medicaid Services.

Docket No. C-09-322

Decision No. CR2420

Date: August 26, 2011

DECISION

Petitioner, Lopatcong Center, was not in substantial compliance with program participation requirements from November 6, 2008 through December 23, 2008, due to violations of 42 C.F.R. §§ 483.70(f) and 483.75, which posed immediate jeopardy. There is a basis for the imposition of enforcement remedies. A $3,050 per day civil money penalty (CMP) for the period November 6 through December 23, 2008, a total CMP of $146,400, is reasonable.

I. Background

Petitioner is located in Phillipsburg, New Jersey, and participates in Medicare as a skilled nursing facility (SNF) and Medicaid as a nursing facility (NF). On December 24, 2008, the Centers for Medicare and Medicaid Services (CMS) completed a federal comparative survey of Petitioner's facility. CMS found that Petitioner was not in substantial compliance with program participation requirements and that there was immediate jeopardy for Petitioner's residents. CMS notified Petitioner by letter dated January 15,

2009, that it was imposing the following enforcement remedies: $3,050 per-day CMP, effective November 6, through December 23, 2008, for forty-eight days[1] of immediate jeopardy; a $200 per day CMP, effective December 24, 2008 and continuing until Petitioner achieved substantial compliance or was terminated; a denial of payment for new admissions if Petitioner did not achieve substantial compliance by March 24, 2009; and termination of Petitioner's provider agreement, unless Petitioner achieved substantial compliance by June 24, 2009. CMS advised Petitioner by letter dated March 23, 2009, that Petitioner returned to substantial compliance effective January 30, 2009. Therefore, the $200 per day CMP accrued from December 24, 2008 through January 29, 2009, a period of 37 days, for a total of $7,400. CMS also notified Petitioner that the DPNA was rescinded and the termination would not be effectuated. P. Ex.5.

Petitioner requested a hearing before an administrative law judge (ALJ) on March 12, 2009. The case was originally assigned to ALJ Alfonso Montano for hearing and decision. An Acknowledgement, an Order, and a Notice of Hearing were issued at his direction. On June 29, 2010, a hearing was convened in Trenton, New Jersey before Judge Montano, and a transcript (Tr.) of the proceedings was prepared. CMS offered CMS Exhibits (Exs.). 1 through 14, and they were admitted as evidence. Tr. at 9. Petitioner offered Petitioner's exhibits (P. Exs.) 1 through 10, which were admitted as evidence. Tr. at 10. The parties discussed at hearing (Tr. at 14) that they had prepared a stipulation of fact related to background of the survey, and Petitioner cited to a joint stipulation in its post-hearing brief, but no joint stipulation was received from the parties for filing. CMS called Surveyor Ellita Nezbeth, Surveyor Barbara Ann Capers-Medwick, and Surveyor Joaquin Perez as witnesses. Petitioner called Elaine Bell, Petitioner's Administrator, Lynn Sysock, Petitioner's Director of Nursing (DON), and Chris Bogoly, Petitioner's Maintenance Director, as witnesses. The parties filed post-hearing briefs (CMS Br. and P. Br.) and post-hearing reply briefs (CMS Reply and P. Reply).

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[1] The CMS notice incorrectly stated that the $3,050 per day CMP was effective through December 24, 2008, for 47 days. However, it is clear from the context that the notice was intended to advise Petitioner that the $3,050 was in effect from November 6, 2008 through December 23, 2008, a period of 48 days, and that the $200 per day CMP began to accrue on December 24, 2008. CMS Exhibit (CMS Ex.) 1. An Amended Notice was provided by letter dated February 3, 2009, with handwritten corrections. CMS Ex. 3, at 3. CMS also issued a notice dated March 23, 2009, that correctly indicates that the $3,050 per day CMP accrued from November 6, 2008 through December 23, 2008, a period of 48 days, and that the total accrued CMP was $146,400. P. Ex. 5.

Judge Montano left the Departmental Appeals Board in August 2010, and this matter was reassigned to me. I have reviewed the transcript of the hearing, the documentary evidence, and the pleadings of the parties. I conclude that a supplemental hearing or additional briefing is not necessary.

II. Discussion

A. Issues

Whether there is a basis for the imposition of an enforcement remedy; and

Whether the remedy imposed is reasonable.

B. Applicable Law

The statutory and regulatory requirements for participation of a SNF in Medicare are found at section 1819 of the Social Security Act (Act) and at 42 C.F.R. Part 483. Section 1819(h)(2) of the Act authorizes the Secretary of Health and Human Services (Secretary) to impose enforcement remedies against a SNF for failure to comply substantially with the federal participation requirements established by sections 1819(b), (c), and (d) of the Act.[2] The Act requires that the Secretary terminate the Medicare participation of any SNF that does not return to substantial compliance with participation requirements within six months of being found not to be in substantial compliance. Act § 1819(h)(2)(C). The Act also requires that the Secretary deny payment of Medicare benefits for any beneficiary admitted to a SNF, if the SNF fails to return to substantial compliance with program participation requirements within three months of being found not to be in substantial compliance – commonly referred to as the mandatory or statutory DPNA. Act § 1819(h)(2)(D). The Act grants the Secretary discretionary authority to terminate a noncompliant SNF's participation in Medicare, even if, there has been less than six months of noncompliance. The Act also grants the Secretary authority to impose other enforcement remedies, including a discretionary DPNA, CMPs, appointment of temporary management, and other remedies such as a directed plan of correction. Act § 1819(h)(2)(B).

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[2] Participation of a NF in Medicaid is governed by section 1919 of the Act. Section 1919(h)(2) of the Act gives enforcement authority to the states to ensure that NFs comply with their participation requirements established by sections 1919(b), (c), and (d) of the Act.

The Secretary has delegated to CMS and the states the authority to impose remedies against a long-term care facility that is not in substantial compliance with federal participation requirements. A facility is in "substantial compliance" so long as no identified deficiency poses a greater risk to resident health or safety than the potential for causing minimal harm. 42 C.F.R. § 488.301. "Noncompliance" is any deficiency that causes a facility to not be in substantial compliance. 42 C.F.R. § 488.301. A deficiency is a violation of a participation requirement established by sections 1819(b), (c), and (d) of the Act, or the Secretary's regulations at 42 C.F.R. Part 483, subpart B. 42 C.F.R. § 488.301. CMS or state survey agencies survey facilities that participate in Medicare on behalf of CMS to determine whether the facilities are complying with federal participation requirements. 42 C.F.R. §§ 488.10-.28, 488.300-.335. The regulations specify the enforcement remedies that CMS may impose if a facility is not in substantial compliance with Medicare requirements. 42 C.F.R. § 488.406.

A CMP that is imposed against a facility on a per day basis will fall into one of two ranges of penalties. 42 C.F.R. §§ 488.408, 488.438. The upper range of CMPs, $3,050 per day to $10,000 per day, is reserved for deficiencies that pose 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). "Immediate jeopardy means a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301. The lower range of a CMP, $50 per day to $3,000 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).

Petitioner was notified in this case that it may be ineligible for approval to conduct a nurse aide training and competency evaluation program (NATCEP) for a period of two years and that any prior approval could be withdrawn. Pursuant to sections 1819(b)(5) and 1919(b)(5) of the Act, SNFs and NFs may only use nurse aides who have completed a training and competency evaluation program. Sections 1819(e) and 1919(e) of the Act impose upon the states the requirement to specify what NATCEPs they will approve that meet the requirements that the Secretary established and a process for reviewing and re-approving those programs using criteria the Secretary set. Pursuant to sections 1819(f)(2) and 1919(f)(2) of the Act, the Secretary was tasked to develop requirements for approval of NATCEPs and the process for review of those programs. The Secretary promulgated regulations at 42 C.F.R. Part 483, subpart D. Pursuant to 42 C.F.R. § 483.151(b)(2) and (e)(1), a state may not approve, and must withdraw any prior approval of a NATCEP offered by a SNF or NF that has been: (1) subject to an extended or partial extended survey under sections 1819(g)(2)(B)(i) or 1919(g)(2)(B)(i) of the Act; (2) assessed a CMP of not less than $5,000; or (3) subject to termination of its participation agreement, a DPNA, or the appointment of temporary management. Extended and partial extended

surveys are triggered by a finding of "substandard quality of care" during a standard or abbreviated standard survey and involve evaluating additional participation requirements. "Substandard quality of care" is identified by the situation where surveyors identify one or more deficiencies related to participation requirements established by 42 C.F.R. § 483.13 (Resident Behavior and Facility Practices), § 483.15 (Quality of Life), or § 483.25 (Quality of Care) that are found to constitute either immediate jeopardy, a pattern of or widespread actual harm that does not amount to immediate jeopardy, or a widespread potential for more than minimal harm that does not amount to immediate jeopardy and there is no actual harm. 42 C.F.R. § 488.301. There is no evidence that Petitioner had or desired a NATCEP, and the parties raise no issues related to NATCEP approval in this case.

The Act and regulations make a hearing before an ALJ available to a long-term care facility against which CMS has determined to impose an enforcement remedy. Act §§ 1128A(c)(2), 1866(h); 42 C.F.R. §§ 488.408(g), 498.3(b)(13). The hearing before an ALJ is a *de novo* proceeding. *Residence at Salem Woods*, DAB No. 2052 (2006); *Cal Turner Extended Care*, DAB No. 2030 (2006); *Beechwood Sanitarium*, DAB No. 1906 (2004); *Emerald Oaks*, DAB No. 1800, at 11 (2001); *Anesthesiologists Affiliated*, DAB CR65 (1990), *aff'd*, 941 F.2d 678 (8th Cir. 1991). A facility has a right to appeal a "certification of noncompliance leading to an enforcement remedy." 42 C.F.R. §§ 488.408(g)(1), 488.330(e), 498.3. However, the choice of remedies and the factors CMS considered when choosing remedies are not subject to review. 42 C.F.R. § 488.408(g)(2). A facility may only challenge the scope and severity level of noncompliance determined by CMS, if a successful challenge would affect the range of the CMP that may be imposed or impact the facility's authority to conduct a NATCEP. 42 C.F.R. § 498.3(b)(14), (d)(10)(i). The CMS determination as to the level of noncompliance, including the finding of immediate jeopardy, "must be upheld unless it is clearly erroneous." 42 C.F.R. § 498.60(c)(2); *Woodstock Care Ctr.*, DAB No. 1726, at 9, 38 (2000), *aff'd*, 363 F.3d 583 (6th Cir. 2003). The Departmental Appeals Board (the Board) has long held that the net effect of the regulations is that a provider has no right to challenge the scope and severity level assigned to a noncompliance finding, except in the situation 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). ALJ Review of a CMP is subject to 42 C.F.R. § 488.438(e).

The standard of proof, or quantum of evidence required, is a preponderance of the evidence. CMS has the burden of coming forward with the evidence and making a *prima facie* showing of a basis for imposition of an enforcement remedy. Petitioner bears the burden of persuasion to show by a preponderance of the evidence that it was in substantial compliance with participation requirements or any affirmative defense. *Batavia Nursing & Convalescent Inn*, DAB No. 1911 (2004); *Batavia Nursing & Convalescent Ctr.*, DAB No. 1904 (2004), *aff'd, Batavia Nursing & Convalescent Ctr. v. Thompson*, 129 F. App'x 181 (6th Cir. 2005); *Emerald Oaks*, DAB No. 1800; *Cross*

Creek Health Care Ctr., DAB No. 1665 (1998); *see Hillman Rehab. Ctr.*, DAB No. 1611 (1997), *aff'd, Hillman Rehab. Ctr. v. U.S.*, No. 98-3789 (GEB), 1999 WL 34813783 (D.N.J. May 13, 1999).

C. Findings of Fact, Conclusions of Law, and Analysis

My conclusions of law are set forth in bold text followed by my findings of fact and analysis.

CMS surveyors conducted a federal comparative monitoring survey of Petitioner's facility from December 18 through December 24, 2008. The federal survey followed a survey conducted by the state agency from November 7 through 17, 2008. The CMS surveyors cited the following deficiencies in the Statement of Deficiencies (SOD) for the survey that was completed on December 24, 2008: 42 C.F.R. §§ 483.13(c) (Tag F226); 483.25(h) (Tag F323); 483.35(l) (Tag F371), 483.60(b), (d), (e) (Tag F431); 483.65(b)(1) (Tag F442); 483.65(b)(3) (Tag F444), 483.70(f) (Tag F463); and 483.75 (F490). The deficiencies cited under Tags F323, F463, and F490 were alleged to pose immediate jeopardy to Petitioner's residents. The remaining deficiencies were alleged to pose a risk for more than minimal harm. P. Ex. 1; CMS Ex. 2. Petitioner requested a hearing only as to the three deficiencies that allegedly posed immediate jeopardy and the CMP based on those deficiencies – the proposed $3,050 per day CMP for the period November 6 through December 23, 2008, a total CMP of $146,400. Petitioner does not dispute the remaining deficiency citations or the $200 per day CMP that accrued from December 24, 2008 through January 29, 2009. Request for Hearing at 2; P. Br. at 5.

The specific issues are: (1) whether Petitioner violated 42 C.F.R. §§ 483.25 (Tag F323), 483.70(f) (Tag F463), and 483.75 (Tag F490) as alleged; (2) whether one or more of the violations posed a risk for more than minimal harm; (3) whether the declaration of immediate jeopardy based on one or more of the violations was clearly erroneous; and (4) whether or not the imposition of a daily CMP in the higher range was authorized and, if so, whether or not the CMP proposed is reasonable.[3] All three deficiencies are based upon the same operative facts and the proposed CMP is the lowest authorized by 42 C.F.R. § 488.438 for a deficiency that poses immediate jeopardy. I conclude that it is not necessary to analyze whether or not the facts support deficiency citations under both Tags F323 and F463, as both alleged deficiencies are based on the same alleged facts, and a single deficiency that poses immediate jeopardy is a sufficient basis for imposing the

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[3] Petitioner does not dispute the reasonableness of the daily CMP of $200 based upon the undisputed deficiencies.

CMP proposed by CMS in this case. Therefore, I do not analyze whether the problem with Petitioner's call system amounted to a failure to provide necessary supervision or assistive devices in violation of 42 C.F.R. § 483.25(h) (Tag F323).

I have carefully considered all the evidence and the arguments of both parties, although not all may be specifically discussed in this decision. I discuss the credible evidence given the greatest weight in my decision-making.[4] The fact that evidence is not specifically discussed should not be considered sufficient to rebut the presumption that I have considered all the evidence and assigned such weight or probative value to the credible evidence that I determined appropriate within my discretion as an ALJ. There is no requirement for me to discuss the weight given every piece of evidence considered in this case, nor would it be consistent with notions of judicial economy to do so.

1. Petitioner violated 42 C.F.R. § 483.70(f) (Tag F463).

2. Petitioner violated 42 C.F.R. § 483.75 (Tag F490).

3. Petitioner's violation of the conditions for participation posed a risk for more than minimal harm.

4. The declaration of immediate jeopardy was not clearly erroneous.

a. Facts

On November 6, 2008, a state agency survey team entered Petitioner's facility and began a survey. Following the entrance meeting with the survey team, Petitioner's Administrator, Elaine Bell, was advised by Petitioner's Maintenance Director, Chris Bogoly, that the call bell system for the 60-bed first floor unit had malfunctioned. Due to the malfunction, the lights and bells of the control panel at the nurses' station stopped working. The call lights above residents' doors continued to function, but there was no audible tone, light, or other indicator at the nurses' station if a call bell was activated. The system did not emit an audible sound in the hallway even when working properly. Mr. Bogoly decided that he could not repair the system, and he called Oliver Sprinkler Company (Oliver), a vendor who had previously repaired the system. Oliver assessed the system on November 6, 2008, and determined that the system needed to be replaced. Tr. at 162-63, 209-10; P. Ex. 9, at 2.

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[4] "Credible evidence" is evidence that is worthy of belief. *Black's Law Dictionary* 596 (18th ed. 2004). The "weight of evidence" is the persuasiveness of some evidence compared to other evidence. *Id*. at 1625.

Administrator Bell testified that 90 percent of the 57 first-floor residents were alert and oriented and could notify staff of their needs. The 10 percent of the residents who were not alert and oriented would not use the call bell system in any event. The unit manager offered the alert and oriented residents tap bells, but only four accepted the bells according to the surveyors. Tr. at 29, 36, 108, 164-65, 206.

Administrator Bell testified that other remedial measures included informing staff of the malfunction of the system by reporting it on the 24-hour report (P. Ex. 8) so that staff would be alerted to the need to monitor the call lights above residents' doors. She testified that the state survey team requested that the remedial measures be put in writing, and a document titled "First Floor Call Bell Action Plan" was prepared that listed the following remedial measures:

> Since 11/6/08 call bells have been monitored visually to ensure resident's needs are being met.
>
> Oliver Alarm Systems representative visited on 11/6/08 to assess & troubleshoot. Main Nurses Station call bell box on 1st floor was found to be inoperable.
>
> All call bells in resident rooms were checked to ensure visual functioning in hallways.
>
> Staff was educated on the need to observe for any activated call bells.
>
> 4PM-11PM Daily an additional CNA has been assigned to monitor call bells.
>
> 11PM-7AM Staff are conducting rounds on floor to ensure all call bells are answered.

Tr. at 164-66, 199-200; P. Ex. 7; CMS Ex. 8. No similar plan was prepared for the second floor. Tr. at 199, 218.

Administrator Bell testified that the state survey team found the remedial measures acceptable. She testified that she was not aware of any complaints by residents. Tr. at 166-67. No deficiency was cited by the state surveyors related to Petitioner's nonfunctional call bell system. P. Ex. 6, Tr. at 218. However, the evidence shows that on about November 12, 2008, the state surveyors threatened a deficiency citation, unless Petitioner could provide a date by which the system would be repaired or replaced. P. Ex. 9, at 1. Administrator Bell testified that Petitioner's quality assurance team found no

injuries related to not having a fully functioning call bell system. She testified that nurses and supervisors were instructed to ensure call lights were monitored. During the day shift, she believed fewer residents were in their rooms and there were sufficient staff members around to adequately monitor call lights above doors. But, during the evening and night shifts, a staff member was specifically designated to rove the halls and monitor lights above doors. She opined that the remedial measures adopted were as effective as a functional call light system because the nurses' station was not constantly staffed anyway. Tr. at 168-71.

DON Lynn Sysock's testimony was consistent with the testimony of Administrator Bell. She testified that she knew that staff responded to the call lights above residents' doors, as she checked herself to see that the lights were being answered, the residents were not complaining, and there was no increase in adverse clinical outcomes. Tr. at 227-31. She testified that no call bell action plan was prepared for the second floor call bell system because the problems with that system were identified on December 22, 2008, during the federal survey. Tr. at 235.

Administrator Bell testified that, when the federal survey commenced on December 18, 2008, the surveyors asked about the call bell system and she shared the plan she provided to the state surveyors. She testified that the federal surveyors did not indicate the plan was unacceptable until they notified her about the immediate jeopardy determination on December 23, 2008. The declaration of immediate jeopardy provoked the preparation of a second more detailed revision of the plan. The revised plan required designating two staff members on every shift to sit in the halls with two-way radios and watch for call lights above doors. If a call light was activated, the monitoring staff advised nursing staff members who were also equipped with two-way radios. CMS Ex. 7. The federal surveyors found the revised plan acceptable to abate immediate jeopardy, but Petitioner did not return to compliance with the participation requirement until after installation of the new call bell system. Tr. at 171-73, 207.

Documents show that Petitioner's call bell system malfunctioned on November 6, and Oliver determined that the unit at the nurse's station needed to be replaced. On November 12, Petitioner was concerned that the state agency was threatening to cite a deficiency if there was no date for completion of the repair. Petitioner decided to give the surveyors a letter from Oliver that explained the company was working to find a part. P. Ex. 9, at 1-2. On November 18, 2008, Petitioner's Maintenance Director, Chris Bogoly, advised a corporate official that a vendor, System Sales, had visited the facility and would provide a quotation for a replacement system. The corporate official advised Mr. Bogoly to hold on the System Sales quotation as the corporate office had a different system in mind, and Mr. Bogoly was instructed to contact the vendor, SymTech Solutions, for a quotation for the cost for replacement. P. Ex. 9, at 4-5. On November 20, 2008, System Sales provided Petitioner a quotation for a replacement system. P. Ex. 9, at 3. Petitioner's Administrator Bell urged proceeding quickly in an email. P. Ex. 9, at

6. On November 24, 2008, a corporate official requested that SymTech Solutions proceed as quickly as possible, as funding would be found to pay for the replacement of the system. P. Ex. 9, at 8. SymTech visited the facility on December 3, 2008. P. Ex. 9, at 9, 11. SymTech provided its quotation on December 4, 2008, and stated that installation would be expedited. P. Ex. 9, at 12-13. On December 8, 2008, Mr. Bogoly requested guidance from his corporate office regarding submitting the SymTech quotation and a request for funding, which he subsequently sent to the corporate office on December 8 and 9. P. Ex. 9, at 14-18. Another vendor submitted a quote dated December 12, 2008. P. Ex. 9, at 19. The decision to proceed with the SymTech proposal was made and communicated on December 18, 2008, the first day of the federal survey. The request was characterized as an emergency and the need for replacement of the system was characterized as being urgent. P. Ex. 9, at 20-23. SymTech acknowledged the order on December 19, 2008 and estimated that the new system would be installed by January 16, 2009. P. Ex. 9, at 24. The call bell system was replaced and operational as of December 31, 2008. Tr. at 180; P. Ex. 9, at 27. Maintenance Director Bogoly's testimony was consistent with the history reflected in P. Ex. 9. Tr. at 244-53. He also testified that problems with the second floor call lights were not discovered until the federal survey. Tr. at 271.

b. Analysis

A long-term care facility must be designed, constructed, equipped, and maintained to protect the health and safety of its residents, personnel, and the public. 42 C.F.R. § 483.70. The regulation specifically requires:

> *Resident Call System.* The nurse's station **must be** equipped to receive resident calls through a communication system from –
>
> (1) Resident rooms; and
>
> (2) Toilet and bathing facilities.

42 C.F.R. § 483.70(f) (emphasis added). The State Operations Manual (SOM), app. PP, Tag F463, advises surveyors that the intent of the regulation is that residents in their rooms or bath and toilet areas have a means of directly contacting caregivers. If there is a central nurses' station, the means of communication may be by audible or visual signals and may be wireless. If there is no central nurses' station, the regulation may be satisfied by other electronic systems that provide direct communication from the resident to caregivers. The SOM further advises that the regulatory requirement is satisfied only if all portions of the system are functioning and calls are being answered. *Care Ctr. of Opelika*, DAB No. 2093, at 4-5 (2007).

The regulations also require that a long-term care facility be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the

highest practicable physical, mental, and psychological well-being of each resident. 42 C.F.R. § 483.75 (Tag F490).

The surveyors allege that Petitioner violated 42 C.F.R. § 483.70(f) (Tag F463) because Petitioner failed to ensure that the call bell systems on the first and second floors were maintained and functioning properly, affecting 54 residents on the first floor and 5 residents on the second floor. CMS Ex. 2, at 16-17.

There is no dispute that the call bell system on Petitioner's first floor was not functioning as it was designed to function.[5] The undisputed evidence shows that, when the call bell system was activated in a resident's room on the first floor, the light above the resident's door lighted, but the light on the control board at the nurses' station did not light and there was no audible sound at the nurses' station. The undisputed evidence shows that the malfunction began on November 6, 2008, and it continued through the federal survey until the system was replaced on December 31, 2008. It is also undisputed that staff at the nurses' station could not see all the rooms or the call lights above the rooms due to the configuration of the first floor. CMS Ex. 10. The participation requirement established by 42 C.F.R. § 483.70(f) requires that: (1) the nurse's station be equipped to receive resident calls; (2) through a communication system from resident rooms; and (3) through a communication system from toilet or bath facilities. The evidence shows that Petitioner had a centralized nurses' station on the first floor. Under the interpretive guidance of the SOM, app. PP, Tag F463, the means of communication could be by audible or visual signals. The evidence shows that Petitioner had no audible or visual communication between resident rooms and bath/toilet facilities between November 6 and December 31, 2008, a violation of the regulation. Petitioner's instructions to staff to monitor call lights above doors, the use of tap bells, and the subsequent use of walkie-talkies did not remedy the regulatory violation as neither approach satisfied the requirement of the regulation that the nurses' station be equipped to receive resident calls from their rooms, bathrooms, or toilet rooms. The evidence also shows that there was no system for resident calls to be made directly to nursing staff, the alternative permitted by the more liberal interpretation of the regulation found in the SOM. The unrebutted and credible testimony of the surveyor is that long-term care facility residents are subject to more than minimal harm if they require assistance with toileting, transfers, or other

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[5] It is undisputed that during the federal survey call-lights were not functioning for several rooms on the second floor. The evidence shows that the failure on the second floor was not related to the failure on the first floor and that repairs were promptly made on the second floor. The failure of the system on the first floor is sufficient alone to support my conclusions. Thus, further discussion of the call light problems on Petitioner's second floor is unnecessary.

activities of daily living but are unable to call for and receive assistance. Tr. at 42-45. Accordingly, I conclude that CMS has made a *prima facie* showing of a deficiency based on a violation of 42 C.F.R. § 483.70(f) that posed a risk for more than minimal harm to the Petitioner's first-floor residents.

I also find that CMS made a *prima facie* showing of a violation of 42 C.F.R. § 483.75 (Tag F490) that posed a risk for more than minimal harm. The regulation requires that a long-term care facility be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychological well-being of each resident. In this case, there is no dispute that it took 56 days for Petitioner to replace the malfunctioning call bell system on the first floor. Petitioner used 29 days to collect bids or quotations for repair or replacement, but then it took only 27 days for funding to be approved, the contract to be awarded, and installation to be completed. The fact that it took 29 days for Petitioner to decide the system was broken beyond repair and to collect bids shows that Petitioner was not proceeding diligently, effectively, or efficiently. Petitioner's lack of diligence, effectiveness, and efficiency, following the state survey, is particularly apparent when one considers that Petitioner only required 27 days to fund, contract for, and install the new system when the federal surveyors expressed interest. Petitioner's evidence does not show it was impossible to proceed more expeditiously with replacement of the call bell system. Furthermore, the evidence shows that between November 6 and December 24, 2008, Petitioner failed to devise and adopt an adequate alternative system for direct communication to the central nurses' station or between residents and caregivers. The risk for more than minimal harm was present to the same extent and for the same reason it was present due to the violation of 42 C.F.R. § 483.70(f).

Because CMS made a *prima facie* showing of deficiencies, the burden is upon Petitioner to rebut the *prima facie* case or to establish an affirmative defense. In this case, Petitioner does not attempt to establish an affirmative defense. Rather, the gist of Petitioner's approach is to rebut the *prima facie* showing by showing that it took sufficient steps to eliminate the risk for more than minimal harm.

Petitioner argues that CMS seeks to hold Petitioner strictly liable for the failure of its call bell system. P. Br. at 2, 10; P. Reply at 12. This is no defense for Petitioner. Strict liability is "[l]iability that does not depend on actual negligence or intent to harm, but that is based on the breach of an absolute duty to make something safe." *Black's Law Dictionary* 934 (18th ed. 2004). The regulation clearly requires that Petitioner have a resident call system with nurses' stations equipped to receive resident calls through a communication system from resident rooms and toilet and bath facilities. There are no exceptions to the requirement listed in the regulation. 42 C.F.R. § 483.70(f). Petitioner agrees to comply with participation requirements as a condition for entering a provider agreement with the Secretary. 42 C.F.R. §§ 424.500, 424.505, 424.520(d)(3), 483.1, 483.5(a), 488.330(b) and (f). Whether or not failure of the call system was due to some

neglectful act, intentional act, or unintentional act or failure by Petitioner is not the issue. The absence of neglect, or an act by Petitioner, is no defense or excuse for a failure to comply with participation requirements established by the regulations. Petitioner violated the regulatory requirement, when the call bell system malfunctioned. The regulatory violation continued until the new system was installed and became operational on December 31, 2008.

The regulatory violation standing alone, however, does not amount to noncompliance as Petitioner remains in substantial compliance so long as no deficiency, *i.e.*, violation of a condition of participation, poses a risk for more than minimal harm to one or more residents. 42 C.F.R. § 488.301. Petitioner does not deny that the system malfunctioned from November 6 to December 31, 2008. Therefore, Petitioner must necessarily show that there was no risk for more than minimal harm to credibly argue that it remained in substantial compliance with this program participation requirement despite the regulatory violation. Petitioner attempts to make the required showing in this case arguing that its staff intervened immediately to attempt repairs, protect residents, and obtain a replacement system when it became clear the old system could not be repaired. Petitioner also argues that no resident complained and no resident suffered any injury or was inconvenienced, as staff responded even more quickly than usual due to heightened attentiveness. P. Br. at 1-2, 4, 8-9.

Petitioner has failed to show by a preponderance of the evidence that its remedial measures, from November 6 through December 23, 2008, ensured that there was no risk for more than minimal harm. The remedial actions Petitioner's staff implemented on November 6, 2008 were: checking to ensure call lights above resident doors on the first floor functioned; issuing tap bells to alert and orient residents, but only 4 of 54 or 57 residents on the first floor accepted the bells; instructing staff to monitor call lights above doors; assigning a CNA during the 4:00 p.m. to 11:00 p.m. shift to walk the halls monitoring call lights above doors; and instructing staff on the 11:00 p.m. to 7:00 a.m. shift to conduct rounds and monitor call lights. Tr. at 29, 36, 108, 164-66, 199-200, 206; P. Ex. 7; CMS Ex. 8. Petitioner should have ensured that call lights above resident doors worked and that staff monitored the call lights even when the call bell system functioned properly. Thus, the only interventions specifically to address the malfunction of the call bell system at the nurses' station were issuing tap bells to the four residents and assigning a CNA to walk the halls during the evening shift. Issuing tap bells was not an effective intervention in this case as too few residents accepted the bells, and the evidence does not show whether those bells were placed in the residents' rooms and toilet and bath facilities. The remedy of having a CNA roam the halls may have been sufficient, if done for every shift by two CNAs (one for each leg of the "L" shaped hall), and the CNAs were given no duties other than watching for call lights and alerting nursing staff of calls. However, Petitioner assigned only one CNA to walk the halls, rendering that intervention ineffective. While the CNA walked in one leg of the "L" shaped hallway, he or she could not observe rooms in the other leg of the hall. CMS Ex. 10, at 1. Furthermore,

Petitioner did not show that the CNA was not allowed or expected to deliver care in addition to monitoring call lights. Allowing or expecting the monitoring CNA to deliver care and services rendered the intervention ineffective, as the CNA delivering care in a room could not reliably monitor lights in the hallway.

Between November 6 and December 24, 2008, during the day shift, Petitioner implemented no interventions or remedies to address the malfunctioning call bell system, except telling staff that the system was not working and reminding staff to pay particular attention to the lights above the doors. The testimony of Administrator Bell and DON Sysock revealed that the system at the nurses' station was often not relied upon, as the nurses' station was often not occupied. Thus, staff must already have been watching for lights above the doors to determine whether residents needed assistance. However, staff responsiveness to either the call bell system at the nurses' station or the call lights above doors is in question based on the testimony of the DON and the Administrator. Both the DON and Administrator testified that simply reminding staff to pay attention to the call lights resulted in improvement in staff responding to call lights – both testified that residents were happier, and there were fewer adverse incidents. The evidence that staff was attending more diligently to the door lights and being more responsive did not remedy the malfunctioning system at the nurses' station. Rather, the reminder to staff to pay attention to the call lights was simply an instruction to the staff that they should do their jobs. Further, the testimony of the Administrator and the DON regarding the effectiveness of the intervention was effectively rebutted, as the surveyors testified that they were concerned because they observed several times during the day shift that there were no staff present in the hallways to observe call lights. Tr. at 98-99, 129-30.

The fact that the Administrator and the DON did not consider the call bell system at the nurses' station particularly useful or important is troubling. The testimony is also not helpful to Petitioner. The fact that Petitioner, as a matter of practice, did not ensure that the nurses' station was staffed, and the call bell system monitored and responded to when it was working, is no excuse for Petitioner not promptly repairing or developing an appropriate remedy to minimize the risk for harm associated with residents being unable to contact nursing staff. Certainly, the regulatory requirement that Petitioner have a system includes the requirement that the system be appropriately monitored. Petitioner's failure to ensure that the call bell system was effectively used for the benefit of its residents supports that conclusion that Petitioner violated 42 C.F.R. § 483.75.

It is undisputed that the state agency did not cite Petitioner for this violation during the state survey in November 2008. The evidence does not establish why no deficiency was cited. Even if I infer that the state agency was satisfied with Petitioner's efforts to resolve the problem, I nevertheless conclude that CMS is not bound by the state agency action or inaction in this case. *See* 42 C.F.R. § 488.452(a). The state agency's failure to cite Petitioner is no defense for Petitioner.

The surveyors declared that there was immediate jeopardy in this case, beginning November 6, 2008 and continuing until December 24, 2008, when Petitioner implemented its revised plan to use walkie-talkies and dedicated staff. Surveyor Nezbeth explained that the declaration of immediate jeopardy was based upon Petitioner not ensuring that staff and residents could communicate with the central nurses' station in the event of an emergency, including emergencies involving serious injury or death. Tr. at 66-67, 71, 75. Petitioner failed to show that the determination that there was immediate jeopardy was clearly erroneous. Immediate jeopardy exists if the 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 includes an immediate jeopardy finding, must be upheld unless it is "clearly erroneous." 42 C.F.R. § 498.60(c). The Board has previously concluded that the regulation imposes upon Petitioner a heavy burden to show that the CMS determination that there was immediate jeopardy is clearly erroneous. *Magnolia Estates Skilled* Care, DAB No. 2228, at 23 (2009) (and cases cited therein). The surveyor's testimony establishes that there was a likelihood of serious injury, harm, or death of a resident due to the resident's and/or staffs' inability to summon help when the call bell system malfunctioned. The surveyor's testimony is credible and unrebutted. I conclude that there was a likelihood of serious harm or death, if a resident was unable to summon staff via the call bell system in case of an emergency medical situation. Petitioner's interventions did not minimize or eliminate the risk until the revised plan was implemented on December 24, 2008. I conclude that Petitioner has not met the heavy burden to show that the declaration of immediate jeopardy was clearly erroneous.

5. Other issues raised by Petitioner are without merit or are not within my authority to decide.

Petitioner argues that the allocation of the burden of persuasion in this case, according to the rationale of the Board in the prior decisions cited above, violates the Administrative Procedures Act, 5 U.S.C. § 551 *et. seq.*, specifically 5 U.S.C. § 556(d). Request for Hearing at 4; Petitioner's Prehearing Brief (P. P. Br.) at 10; P. Br. at 12, n. 5. Pursuant to the scheme for the allocation of burdens adopted by the Board in its prior cases, CMS bears the burden to come forward with the evidence and to establish a *prima facie* showing of the alleged regulatory violations in this case by a preponderance of the evidence. If CMS makes its *prima facie* showing, Petitioner has the burden of coming forward with any evidence in rebuttal and the burden of showing by a preponderance of the evidence that it was in substantial compliance with program participation requirements. Petitioner bears the burden to establish by a preponderance of the evidence any affirmative defense. The allocation of burdens suggested by the Board is not inconsistent with the requirements of 5 U.S.C. § 556(d), as CMS is required to come forward with the evidence that establishes its *prima facie* case. Furthermore, the evidence is not in equipoise in this case, the allocation of burden of persuasion did not affect my decision, and Petitioner suffered no prejudice.

Petitioner also argues that the Medicare Act is violated and Petitioner is deprived of due process if CMS is not required to submit evidence to prove it considered the regulatory criteria established by 42 C.F.R. §§ 488.404 and 488.438(f). Request for Hearing at 4; P. Br. at 10; P. Br. at 12 n.5. I reviewed the evidence related to the regulatory factors de novo and perceive no prejudice to Petitioner because I did not require CMS to submit evidence related to its consideration of the regulatory factors.

6. The CMP of $3,050 per day is reasonable.

I have concluded that Petitioner was not in substantial compliance with program participation requirements due to violations of 42 C.F.R. § 483.70(f) (Tag F463) and 42 C.F.R. § 483.75 (Tag F490) and that the declaration of immediate jeopardy related to those violations is not clearly erroneous. Thus, CMS has the authority to impose one or more of the enforcement remedies listed in 42 C.F.R. § 488.406, including a CMP. In cases where the deficiencies pose immediate jeopardy, CMS is authorized to impose a daily CMP for the number of days of noncompliance, but the CMP must be in the upper range of $3,050 to $10,000 per day. 42 C.F.R. § 488.438(a)(1)(i), (d)(2).

The only enforcement remedy at issue is the proposed CMP of $3,050 per day from November 6, 2008 through December 23, 2008. I previously concluded that the declaration of immediate jeopardy for this entire period was not clearly erroneous. Therefore, the minimum CMP authorized under the regulations is $3,050, and, as a matter of law, the proposed CMP is reasonable.

III. Conclusion

For the foregoing reasons, I conclude that Petitioner was not in substantial compliance with program participation requirements from November 6 through December 23, 2008, and the imposition of a CMP of $3,050 per day for that period is reasonable.

/s/
Keith W. Sickendick
Administrative Law Judge