Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Heritage Healthcare & Rehabilitation Center (CCN: 10-5178),

Petitioner

v.

Centers for Medicare & Medicaid Services.

Docket No. C-08-609

Decision No. CR2116

Date: April 20, 2010

DECISION

Petitioner, Heritage Healthcare & Rehabilitation Center, violated 42 C.F.R. §§ 483.25(h)(1), 483.70(c)(2), and 483.75, as determined by a survey of Petitioner's facility completed on April 25, 2008. However, the determination that the regulatory violations posed immediate jeopardy for Petitioner's residents was clearly erroneous. A civil money penalty (CMP) of \$250 per day from April 21 through 23, 2008, is a reasonable enforcement remedy.

Petitioner did not request a hearing as to deficiency citations that were the basis for the imposition of a CMP of \$250 per day from April 24 through June 2, 2008, and a denial of payments for new admissions (DPNA) from May 27 through June 2, 2008. Petitioner also did not request a hearing as to the reasonableness of those enforcement remedies. Accordingly, those deficiencies and enforcement remedies are not subject to my review and decision.

¹ Citations are to the version of the Code of Federal Regulations (C.F.R.) in effect at the time of the survey, unless otherwise indicated. Here, the citations reflect the 2007 C.F.R., i.e., 42 C.F.R. § 483.25(h)(1) (2007).

I. Background

Petitioner, located in Naples, Florida, is authorized to participate in Medicare as a skilled nursing facility (SNF) and in the Medicaid program as a nursing facility (NF). Petitioner was subject to a recertification survey and a life safety code survey by the Florida Agency for Health Care Administration (the state agency) that were completed on April 25, 2008. Joint Stipulation (Jt. Stip.). The Centers for Medicare and Medicaid Services (CMS) notified Petitioner by letter dated May 12, 2008, as amended by the CMS letter dated May 15, 2008, that CMS was imposing the following enforcement remedies: a CMP of \$5550 per day effective April 21, 2008 through April 23, 2008; a \$250 per day CMP beginning April 24, 2008, and continuing until Petitioner returned to substantial compliance; a DPNA beginning on May 27, 2008, and continuing until Petitioner returned to substantial compliance; and termination of Petitioner's provider agreement on October 25, 2008, if Petitioner did not return to substantial compliance before that date. CMS also advised Petitioner that its authority to conduct a Nurse Aide Training and Competency Evaluation Program (NATCEP) was withdrawn. CMS Exhibit (CMS Ex.) 12 at 1-8. CMS notified Petitioner by letters dated June 26 and 30, 2008, that a revisit survey completed on June 3, 2008, determined that Petitioner had returned to substantial compliance on June 3, 2008. CMS Ex. 12 at 9, 10. Thus, the CMP stopped accruing on June 2, 2008, the DPNA ended June 2, 2008, and the termination was rescinded.

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Petitioner requested a hearing on July 7, 2008. The request for hearing was docketed and assigned to me for hearing and decision on July 30, 2008. A Notice of Case Assignment and Prehearing Case Development Order (Prehearing Order) was issued at my direction on July 30, 2008.

A hearing was convened in Naples, Florida on December 10, 2008. CMS offered, and I admitted, CMS exhibits 1 through 18. Petitioner offered Petitioner's exhibits (P. Ex.) 1 through 19 but only P. Exs. 1 through 18 were admitted at the hearing.² On February 20, 2009, Petitioner filed an unopposed motion to have P. Ex. 20 admitted as evidence. Petitioner's motion to admit P. Ex. 20 is granted and the document is considered as evidence.³ CMS called as witnesses: Charles J. Kibert, Ph.D.; Fire Protection Specialist

Petitioner's witness could not authenticate P. Ex. 19 and therefore it was not admitted. Tr. 27-28.

³ According to the motion, one page of the document was offered by CMS and admitted at hearing and CMS witnesses referred to the document at hearing. Accepting the complete document in evidence is consistent with completing the record. The document is the guidance of the state agency to surveyors regarding procedures to be followed when testing for excessively hot tap water and it is relevant to the issues before me.

Gary Furdell; Surveyor Geri Wolfe; and Surveyor Marilyn Steiner. Petitioner called as witnesses: LeeAnn Pica, Registered Nurse (R.N.), Petitioner's Director of Nursing; Martha Mugford, Petitioner's Risk Manager; and William McFarlane, Master Plumber. The parties filed post-hearing briefs and post-hearing reply briefs.

II. Discussion

A. Issues

The issues in this case are:

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

Whether the declaration of immediate jeopardy was clearly erroneous; and,

Whether the remedy imposed is reasonable.

B. Applicable Law

The statutory and regulatory requirements for participation by a long-term care facility are found at sections 1819 (SNF) and 1919 (NF) of the Act and at 42 C.F.R. Part 483. Section 1819(h)(2) of the Act vests the Secretary of Health and Human Services (Secretary) with authority 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. Pursuant to 1819(h)(2)(C), the Secretary may continue Medicare payments to a SNF not longer than six months after the date the facility is first found not in compliance with participation requirements. Pursuant to 1819(h)(2)(D), if a SNF does not return to compliance with participation requirements within three months, the Secretary must deny payments for all individuals admitted to the facility after that date – commonly referred to as the mandatory or statutory DPNA. In addition to the authority to terminate a noncompliant SNF's participation in Medicare, the Act grants the Secretary authority to impose other enforcement remedies, including a discretionary DPNA, civil money penalties, appointment of temporary management, and other remedies such as a directed plan of correction. Act § 1819(h)(2)(B).

⁴ Section 1919(h)(2) of the Act gives similar 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 complying substantially with federal participation requirements. "Substantial compliance means 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 (emphasis in original). 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. Facilities that participate in Medicare may be surveyed on behalf of CMS by state survey agencies in order 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.

The regulations specify that 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 a CMP, \$3050 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 (emphasis in original). The lower range of a CMP, \$50 per day 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).

The Act and regulations make a hearing before an administrative law judge (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. Anesthesiologists Affiliated, DAB CR65 (1990), aff'd, 941 F.2d 678 (8th Cir. 1991); Emerald Oaks, DAB No. 1800 at 11 (2001); Beechwood Sanitarium, DAB No. 1906 (2004); Cal Turner Extended Care, DAB No. 2030 (2006); The Residence at Salem Woods, DAB No. 2052 (2006). A facility has a right to appeal a "certification of noncompliance leading to an enforcement remedy." 42 C.F.R. § 488.408(g)(1); 42 C.F.R. §§ 488.330(e), 498.3. However, CMS's choice of remedies or 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 found by CMS if a successful challenge would affect the range of the CMP that CMS could impose 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. *See Hillman Rehab. Ctr.*, DAB No. 1611 (1997), No. 98-3789, 1999 WL 34813783 (D.N.J. May 13, 1999); *Cross Creek Health Care Ctr.*, DAB No. 1665 (1998); *Emerald Oaks*, DAB No. 1800; *Batavia Nursing & Convalescent Ctr.*, DAB No. 1904 (2004), *aff'd*, *Batavia Nursing & Convalescent Ctr.* v. *Thompson*, 129 F. App'x. 181 (6th Cir. 2005); *Batavia Nursing & Convalescent Inn*, DAB No. 1911 (2004).

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

The survey completed at Petitioner's facility on April 25, 2008, concluded that Petitioner was not in substantial compliance with program participation requirements due to the following regulatory violations that posed more than minimal harm to Petitioner's residents: 42 C.F.R. §§ 483.10(e), 483.75(1)(4) (Tag F164, scope and severity (s/s) D); 483.10(f)(2) (Tag F166, s/s F); 483.10(k) (Tag F174, s/s E); 483.15(a) (Tag F241, s/s D); 483.15(b) (Tag F242, s/s D); 483.15(e)(1) (Tag F246, s/s D); 483.15(h)(2) (Tag F253, s/s D); 483.15(h)(7) (Tag F258, s/s D); 483.20(g)-(j) (Tag F278, s/s E); 483.20(d), 483.20(k)(1) (Tag F279, s/s D); 483.20(d)(3), 483.10(k)(2) (Tag F280, s/s D); 483.20(k)(3)(i) (Tag F281, s/s G); 483.25(a)(3) (Tag F312, s/s D); 483.25(h) (Tag F323, s/s K); 483.25(m)(1) (Tag F332, s/s D); 483.25(n) (Tag F334, s/s D); 483.35(c) (Tag F363, s/s E); 483.35(g) (Tag F369, s/s D); 483.35(i)(2) (Tag F371, s/s F); 483.60(b), (d), (e) (Tag F431, s/s D); 483.65(a) (Tag F441, s/s D); 483.65(b)(3) (Tag F444, s/s D); 483.65(c) (Tag F445, s/s F); 483.70(c)(2) (Tag F456, s/s K); 483.70(d)(1)(iv)-(v) (Tag F460, s/s D); 483.75 (Tag F490, s/s K); 483.75(j)(1) (Tag F502, s/s G); 483.75(l)(1) (Tag F 514, s/s E); and 483.75(o)(1) (Tag F520, s/s G). CMS Ex. 1. Counsel for Petitioner agreed at hearing that Petitioner only requested review as to the three deficiencies cited as posing immediate jeopardy: 42 C.F.R. § 483.25(h) (Tag F323, s/s K); 483.70(c)(2) (Tag F456, s/s K); and 483.75 (Tag F490, s/s K). Counsel for Petitioner also agreed that Petitioner had not preserved a challenge to: the remaining deficiencies; the DPNA and the CMP in the lower range, based on the unchallenged deficiencies; or the duration of the noncompliance determined by CMS. Tr. 31-33. The deficiencies not cited at the immediate jeopardy level, the DPNA, and the CMP in the lower range, and the duration of the DPNA and CMP, are therefore not before me for review but rather stand as the final decisions of the Secretary. The violations alleged to pose immediate jeopardy, the duration of the immediate jeopardy, if any, and the CMP based upon the immediate

jeopardy citations are at issue. Due to my conclusion that there was no immediate jeopardy, it is necessary for me to reassess the CMP during the period when immediate jeopardy was alleged to have existed.

I conclude that Petitioner violated 42 C.F.R. §§ 483.25(h)(1), 483.70(c)(2), and 483.75, but that the violations did not pose immediate jeopardy. However, the violations amounted to substantial noncompliance, as they posed more than minimal harm without evidence of actual harm to Petitioner's residents. The CMP is reassessed as discussed hereafter.

My conclusions of law are in bold followed by my findings of pertinent facts and analysis.

- 1. Petitioner violated 42 C.F.R. § 483.25(h)(1) (Tag F323).
- 2. Petitioner violated 42 C.F.R. § 483.70(c)(2) (Tag F456).
- 3. Petitioner violated 42 C.F.R. § 483.75 (Tag F490).

Pursuant to 42 C.F.R. § 483.25(h)(1), Petitioner is obligated to ensure that "[t]he resident environment remains as free of accident hazards as is possible." The State Operations Manual (SOM), CMS's guidance to surveyors, instructs surveyors that the intent of 42 C.F.R. § 483.25(h)(1) is that the facility prevents accidents by providing "an environment that is free from accident hazards over which the facility has control." SOM, Appendix (App.) PP, Tag F323. The Board has provided some further interpretative guidance for adjudicating alleged violations of the section:

The standard in section 483.25(h)(1) itself -- that a facility "ensure that the environment is as free of accident hazards as possible" in order to meet the quality of care goal in section 483.25 -- places a continuum of affirmative duties on a facility. A facility must determine whether any condition exists in the environment that could endanger a resident's safety. If so, the facility must remove that condition if possible, and, when not possible, it must take action to protect residents from the danger posed by that condition. [Footnote omitted.] If a facility has identified and planned for a hazard and then failed to follow its own plan, that may be sufficient to show a lack of compliance with [the] regulatory requirement. In other cases, an ALJ may need to consider the actions the facility took to identify, remove, or protect residents from the hazard. Where a facility alleges (or shows)

that it did not know that a hazard existed, the facility cannot prevail if it could have reasonably foreseen that an endangering condition existed either generally or for a particular resident or residents.

Maine Veterans' Home – Scarborough, DAB No. 1975 at 6-7 (2005); see Liberty Nursing & Rehab. Ctr. -Mecklenberg County, DAB No. 2095 (2007); Sunbridge Care & Rehab. for Pembroke, DAB No. 2170 (2008). Pursuant to 42 C.F.R. § 483.70(c)(2), Petitioner must maintain all essential mechanical, electrical, and patient care equipment in safe operating condition. Petitioner is also obligated to administer its facility in a manner that "enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident." 42 C.F.R. § 483.75.

The surveyors allege that Petitioner violated 42 C.F.R. § 483.25(h) (Tag F323) by exposing residents to scalding burns by excessively hot water due to the fact that: hot water temperatures in residents' rooms measured by surveyors were above 115 degrees Fahrenheit (F) and up to 130 degrees F; Petitioner failed to obtain approval from the state agency when replacing boilers in 2005 and 2007; and Petitioner failed to ensure that its hot water system included a mixing valve. CMS Ex. 1 at 36. The surveyors allege that Petitioner violated 42 C.F.R. § 483.70(c)(2) (Tag F456), because Petitioner failed to maintain its hot water system to ensure that the temperature of water delivered to Resident rooms did not exceed 115 degrees F, thereby exposing residents to serious injury. CMS Ex. 1 at 70. The surveyors allege that Petitioner violated 42 C.F.R. § 483.75 (Tag F490) because Petitioner failed to ensure staff was trained to properly monitor water temperatures and failed to maintain its hot water system to ensure that hot water delivered to residents' rooms did not exceed 115 degrees F, thereby exposing residents to the potential for serious harm. CMS Ex. 1 at 78. The surveyors and CMS allege that each of the three violations posed immediate jeopardy for Petitioner's residents.

The three alleged violations are all based upon the surveyors measuring water temperatures in bathrooms on one wing of the facility described as Ward 2 South, the second floor of the south wing of the building. According to the Statement of Deficiencies (SOD) for the survey completed on April 25, 2008, the water temperatures measured by the surveyors on April 21, 2008, ranged from 120 to 130 degrees F. CMS Ex. 1 at 38; CMS Ex. 3 at 1. The water in the bathroom sink in room 221 tested as 130 degrees F, the hottest water temperature determined by the surveyors. Tr. 43; CMS Ex. 1 at 38. The SOD lists the following water temperatures in the bathrooms of resident rooms between 10:20 a.m. and 10:40 a.m. on April 21, 2008.

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Room Number	Degrees Fahrenheit
216	120
217	124
218	120
219	120
220	128
221	130
222	128
223	128
224	128
225	126
226	126
227	120
228	121
229	129
230	120
231	124
232	124

CMS Ex. 1 at 38. Surveyor notes are consistent with the allegations of the SOD (CMS Ex. 2 at 21, 24, and 25-27), except that the notes support a finding that the temperature in room 223 was 124 degrees F not 128 degrees F (CMS Ex. 2 at 27), in room 229 the water temperature was 121 degrees F not 129 degrees F. (CMS Ex. 2 at 26), and in room 230 the temperature was 121 degrees F not 120 degrees F. (CMS Ex. 2 at 26). Tr. 43-44. Despite the minor inconsistencies between the surveyor notes and the SOD, I conclude that the credible evidence demonstrates that temperatures were measured at 120 degrees F or greater for the rooms listed in the foregoing table. Furthermore, to the extent that the statement of temperatures in the SOD is incorrect, I conclude that the notice provided by the SOD was not so defective as to have prejudiced Petitioner's ability to defend in this case.

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⁵ The surveyors also recorded receiving statements from several residents and one family member that the water was too hot or very hot. CMS Ex. 1 at 38-39, 42; CMS Ex. 2 at 7, 26, 43. I find those statements have little probative value. The evidence does not suggest that the residents determined that the water was too hot based upon any objective criteria. The evidence also does not establish the residents' ability to determine that the water was too hot. Rather, the resident's opinion that the water was very hot, or too hot, was purely their subjective opinion, which does not aid me in resolving the issues in this case.

Petitioner alleges that the temperatures determined by the surveyors were not reliable. P. Brief at 9-10. However, the testimony of the two surveyors is unrebutted that the thermometers used to measure the water temperature were calibrated prior to the testing. Surveyor Marilyn Steiner and Surveyor Geri Wolfe testified that they calibrated their thermometers together by placing them in ice water. CMS Ex. 2 at 25; Tr. 40-41, 90. The method of calibration of the thermometers described by the surveyors is consistent with the method described in evidence submitted by Petitioner. P. Ex. 20 at 7, 15. Petitioner presents no evidence that its staff or others tested water temperatures on April 21, 2008 before the surveyors that conflicts with the temperature readings obtained by the surveyors. Petitioner argues that the surveyors' temperatures are inconsistent with Petitioner's temperature logs from the period before the surveyors' testing. P. Brief at 9-10. Petitioner's records of its roughly weekly testing of water temperatures in residents' rooms between June 4, 2007 and April 16, 2008, consistently records temperatures below 115 degrees F. CMS Ex. 6. The last testing by Petitioner was done on April 16, 2008, five days prior to the surveyors testing on April 21, 2008. Petitioner's testing on April 16, 2008, recorded 108 degrees F for all rooms tested. I do not find that Petitioner's evidence of testing either rebuts the surveyors' testing or supports Petitioner's position that the surveyors test results are not credible. Petitioner's hot water system is obviously a complex system that could be impacted by many variables during a five day period. Absent evidence that the system was unchanged or not impacted by changed variables during the five days between April 16 and April 21, 2008, I do not find the April 16 temperatures recorded by Petitioner persuasive evidence that Petitioner's system was operating correctly on April 21, 2008, or that the surveyors testing was in error.⁶

According to the surveyors, the facility's risk manager told them that Ward 2 South had the hottest water in the facility, and the maintenance man told them that the thermostat was set at 123 degrees F. CMS Ex. 2 at 29-31; Tr. 45-48. When the surveyors brought their findings of excessively hot water to Petitioner's attention on April 21, 2008, a five degree adjustment was made to the thermostat at 10:30 a.m., and a second undetermined adjustment was made at 12:15 p.m. that day. CMS Ex. 10 at 5. After the second adjustment, the temperature of the water on Ward 2 South fell below 115 degrees F, though the water temperature also fell as low as 92 degrees F for some rooms on the first floor of the facility. CMS Ex. 10 at 5; CMS Ex. 5. Petitioner tested the water temperatures throughout the building three to four hours after the surveyors' tests on the afternoon of April 21, 2008. CMS Ex. 10 at 5. Petitioner's testing was done after the thermostat on the hot water system was adjusted downward twice. Petitioner's tests

⁶ CMS argues that Petitioner's recorded water temperatures are not credible, because they are consistent from room-to-room on any given day. CMS Brief at 6, 10-11. However, it is not necessary for me to pass upon the credibility of Petitioner's recordings of temperatures in this case.

showed a drop in temperature but also confirmed that the water in Ward 2 South was the hottest in the building, and the water on the first floor was cooler. CMS Ex. 5 at 1-2. After the two downward adjustments of the thermostat, Petitioner's water log on the afternoon of April 21, beginning at 3:30 p.m. and all day on April 22, show water temperatures ranging from 92 degrees F to 114 degrees F in the residents' rooms. CMS Ex. 5. Petitioner's water log, following the two downward adjustments to the thermostat, from the afternoon of April 21 and all day on April 22, 2008, supports the credibility of the surveyors' finding excessively hot water temperatures on the morning of April 21, 2008.

CMS's expert witness, Charles Kibert, ⁷ testified that he agreed that Petitioner's system for heating water was actually a system that used hot water heaters, rather than a boiler. He testified that a "mixing valve" may also be called an "anti-scald device" or a "safety device." Tr. 171. A mixing valve mixes cold water with hot water in the hot water system to maintain the temperature below a set temperature. He testified that a mixing valve is an important safety device given the fact that there is a potential for failure of recirculating devices. He also recommends against relying upon a water heater thermostat for control of water temperature, due to the possibility for failure and that water in the tank may be several degrees hotter than the thermostat set point. He testified that there are other possible approaches, but the mixing valve is adequate and less expensive. He testified that he would not recommend a mixing valve for use in every construction project but described projects where mixing valves would be appropriate such as residential living, where there is a large draw from a common hot water system. In such an environment, he would recommend both a re-circulating system and a mixing valve. Although he never visited Petitioner's facility, he testified that Petitioner had a recirculating loop in its hot water system, which he opined is appropriate for such a facility as it saves water, saves energy, and provides a level of safety against water being excessively hot. Dr. Kibert described a re-circulating loop as having a circulating pump that circulates water through the hot water re-circulating loop to help maintain a more consistent temperature. He testified that if the circulating pump fails or is inadequate, it can cause water to stratify in the hot water tanks into levels of hotter and cooler water with the hottest water on top and being drawn from the tanks first. A mixing valve senses when water exceeds the set temperature and adds cold water to moderate the hot water temperature to the temperature set on the mixing valve. He opined that the high temperatures reported by the surveyors may have been caused by failure of the recirculating system or a faulty thermostat. Tr. 170-82.

Petitioner's plumber, William McFarlane, testified that he serviced Petitioner's hot water system for six years and that it did not have a mixing valve until he installed one after the

⁷ Charles Kibert, Ph.D., M.S., was qualified and accepted to offer opinions as an expert witness in the field of mechanical engineering, particularly water systems. Tr. 169.

survey. He testified that he determined that the cause of the excessively hot water discovered by the surveyors was an undersized circulating pump on the hot water recirculating loop. Though not specifically stated, I infer from the totality of his testimony that he installed a correct circulating pump after the survey. Mr. McFarlane testified that he installed a mixing value subsequent to the survey and that he felt the device was necessary for Petitioner's hot water system for temperature control. Tr. 153-64. Petitioner does not dispute that the circulating pump was inadequate or that it had malfunctioned prior to the survey. P. Br. at 9. There is no dispute that Petitioner's water system did not have a mixing valve. Tr. 153, 189, 214; P. Brief at 9. Both Petitioner's plumber and CMS's expert agreed that a mixing value is an important safety feature and Petitioner's plumber testified that it was necessary for Petitioner's system. Tr. 157, 171.

I find, based upon the credible evidence, that on April 21, 2008, hot water temperatures in residents' rooms on Ward 2 South exceeded 115 degrees F with some rooms exceeding 120 degrees F, and one room at or near 130 degrees F.

The Florida administrative regulation, 59A-4.133, titled Plans Submission and Review and Construction Standards, specifies that all facilities must comply with the standard that "[t]he temperature of hot water supplied to resident use lavatories, showers, and baths shall be between 105 degrees Fahrenheit and 115 degrees Fahrenheit." Fla. Admin. Code Ann. 59A-4.133(16)(d); Tr. 211. The state agency's guidance to surveyors is consistent with the Florida administrative regulation. P. Ex. 20 at 2. There is no dispute that neither the federal regulations nor the SOM establish a specific temperature or range of temperatures that are permitted or considered safe in long-term care facilities. P. Ex. 20 at 2. Thus, the Florida regulation establishes an applicable standard of care for this case, or is good evidence of an applicable standard. The standard of care is further evidenced by the facility's own policy that hot water should be maintained between 105 and 115 degrees F and Petitioner's policy for monitoring water temperatures throughout the building. CMS Exs. 4-6.

I also find no dispute that water temperatures above 115 degrees F increase the risk for burns to residents exposed to water above that temperature. Tr. 34; P. Ex. 20 at 2-5; SOM Tag F323. However, as Petitioner points out 120 degrees F is specified as the maximum temperature at storage points for hot water to be used by patients in hospitals. P. Brief at 14 n.4; Fla. Admin. Code Ann. 59A-081(44)(e). According to the guidance to surveyors, 120 degrees F is also acceptable in other types of facilities. P. Ex. 20 at 2. There is no evidence that any resident was actually exposed to hot water above 115 degrees F on April 21, 2008, or any other date, or that any of Petitioner's residents have ever been injured by exposure to hot water. I find no requirement under either federal or

⁸ The replacement of the circulating pump and installation of the mixing valve are "subsequent remedial" measures. However, I do not construe the subsequent remedial measures as a concession or admission of fault by Petitioner.

state law for the installation of a mixing valve on hot water systems in residential living facilities.

I conclude that the evidence is sufficient to satisfy CMS's burden to make a prima facie showing that Petitioner was in violation of 42 C.F.R. § 483.25(h) (Tag F323) on April 21, 2008. Hot water temperatures above 115 degrees F in residents' rooms posed an accident hazard for the residents potentially exposed to the water. Other ALJs have reached similar conclusions. *Wisteria Care Ctr.*, DAB CR964 (2002), *aff'd*, DAB No. 1892 (2003); *Beechknoll Convalescent Ctr.*, DAB CR813 (2001). Although I have been presented with no legal requirement in state or federal law for Petitioner to have specific safety devices in its hot water system, such as a re-circulating loop, a mixing valve, or an operating thermostat, the weight of the evidence is that such devices are reasonable safety measures in a residential living environment to prevent hot water burns. Thus, while I do not find the absence of safety devices to constitute a regulatory violation, the absence of those devices is good evidence that Petitioner did not implement reasonable measures to mitigate or avoid the risk for accidents involving hot water burns from its hot water system. 9

I also conclude that the evidence amounts to a prima facie showing that Petitioner violated 42 C.F.R. § 483.70(c)(2) (Tag F456). Petitioner's plumber provided unrebutted testimony that the circulating pump on its hot water system was inadequate and that Petitioner had no mixing valve. The weight of the evidence is that a failed or inadequate circulating pump was the cause of the excessively hot water recorded by the surveyors in residents' rooms and that a mixing valve may have prevented delivery of excessively hot water in residents' rooms. Furthermore, the persuasive testimony is that a mixing valve is a reasonable safety device for a hot water system in a residential living facility. The regulation requires that Petitioner maintain all essential mechanical, electrical, and patient care equipment in a safe operating condition. 42 C.F.R. § 483.70(c)(2). Petitioner does not dispute before me that its hot water system is not essential or that it does not otherwise fall within the scope of the regulation. Petitioner did not maintain its hot water system in a safe operating condition.

⁹ The surveyors also allege that Petitioner violated 42 C.F.R. § 483.25(h) because Petitioner failed to file plans for modification of its hot water system with the state agency. CMS Ex. 1 at 36. Enforcement of a state law requirement to file plans for modification of a facility is not a matter within my limited jurisdiction. Even if I found the evidence showed it more likely than not that Petitioner failed to meet some state law requirement to file plans reflecting a modification of its hot water system, that evidence does not tend to show that the failure exposed Petitioner's residents to a risk for harm due to an accident hazard or that Petitioner failed to mitigate or eliminate such risk.

The evidence also amounts to a prima facie showing that Petitioner violated 42 C.F.R. § 483.75 (Tag F490), which requires Petitioner to administer its facility "in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident." Contrary to the allegations of the surveyors, the evidence does not show that Petitioner failed to ensure staff was trained to properly monitor water temperatures, and no evidence before me specifically addresses the skill of staff using a thermometer, or to otherwise detect when water was too hot. Rather, Petitioner violated this regulation because Petitioner failed to maintain its hot water system to ensure that hot water delivered to residents' rooms did not exceed 115 degrees F and pose a risk for harm. I have no difficulty finding a nexus between Petitioner's failed maintenance of its hot water system, a required resource, and the welfare of its residents.

Despite Petitioner's protests, I conclude that Petitioner was not in substantial compliance with Tags F323, F456, and F490. Petitioner has not rebutted the prima facie showing of CMS for reasons discussed above. Nor has Petitioner offered or established an affirmative defense by a preponderance of the evidence.

I conclude that Petitioner corrected the violation of 42 C.F.R. § 483.25(h) (Tag F323) on April 21, 2008. The evidence is undisputed that upon being advised of the results of testing by the surveyors, Petitioner immediately took action to adjust the hot water temperature to a safe level. It is also undisputed that beginning at 4:22 p.m. on April 21, 2008, Petitioner had staff frequently monitoring water temperatures to ensure that a safe temperature was maintained. CMS Ex. 5.

4. The determinations that the violations of 42 C.F.R. $\S\S$ 483.25(h)(1), 483.70(c)(2), and 483.75 posed immediate jeopardy are clearly erroneous.

A facility 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).

Regulations define immediate jeopardy as:

a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to

¹⁰ It is neither reasonable nor necessary for me to inquire as to whether the temperatures recorded in CMS Ex. 6 are accurate, as the allegation is that Petitioner was in violation beginning on April 21, 2008.

cause, serious injury, harm, impairment, or death to a resident.

42 C.F.R. § 488.301. An appellate panel of the Board concluded in *Daughters of Miriam Center*, DAB 2067 (2007) that CMS has no burden to make a prima facie showing regarding immediate jeopardy. Rather the determination of immediate jeopardy is presumed to be correct, and Petitioner has the heavy burden to show that the immediate jeopardy determination was clearly erroneous. The Board asserted:

Under [the regulatory definition], immediate jeopardy exists in either of the following two general circumstances. First, immediate jeopardy exists if the SNF's noncompliance has caused death or "serious" harm to one or more residents. (For discussion purposes, we use the word "harm" as shorthand for the regulatory terms "injury, harm, or impairment."). Second, immediate jeopardy exists if the SNF's noncompliance is or was "likely to cause" death or serious harm.

Id. at 8.

The Board went on to state that it is presumed that the harm or threatened harm resulting from the noncompliance was serious, and the facility has the burden to rebut the presumption by showing that the harm or threatened harm did not meet any reasonable definition of serious. The Board defined the term "likely" as follows:

The term "likely" is ordinarily or commonly used to describe an outcome or result that is "probable" or "reasonably to be expected" though "less than certain." Webster's New World Dictionary (2nd College Ed.); see also The American Heritage Dictionary of the English Language (4th ed.); Black's Law Dictionary (5th ed.) (defining "likely" to mean "probable"). Also, the term "likely" - and its synonym "probable" suggest a greater degree of probability that a particular event will occur than the terms "possible" or "potential." See Webster's New World Dictionary (2nd College Ed.) (definition of "probable"); Black's Law Dictionary (5th ed.) (defining "probable" as "having more evidence for than against," and defining "possible" as "capable of existing" and "free to happen or not"). In this regard, we have emphasized that a "mere risk" of serious harm is not equivalent to a "likelihood" of such harm. Innsbruck Healthcare Center. DAB No. 1948 (2004).

In *Innsbruck Healthcare Center*, DAB No. 1948 (2004), the Board indicated that immediate jeopardy also exists where serious injury or harm is the *likely* consequence of a deficiency, even when no actual harm has occurred. SOM Appendix Q, Guidelines for Determining Immediate Jeopardy, represents the CMS statement of policy to be used by state and federal surveyors in determining whether or not to declare immediate jeopardy. Under the section titled "Principles" CMS specifies that serious harm, injury, impairment, or death does not have to occur and that "[t]he high potential for these outcomes to occur in the very near future also constitutes Immediate Jeopardy." SOM app. Q, III. CMS does not list excessively hot tap water as a trigger for immediate jeopardy. SOM app. Q, IV.

I am bound by the regulations and must uphold the CMS determination of level of noncompliance, unless it is clearly erroneous. 42 C.F.R. § 498.60(c)(2). The Board has determined that the burden is upon Petitioner to show by a preponderance of the evidence that the CMS determination of immediate jeopardy was clearly erroneous, and CMS has no burden as the determination is presumed to be correct. I conclude that Petitioner has met the heavy burden imposed by the Board to show that the declaration of immediate jeopardy was clearly erroneous in this case, rebutting the presumption in favor of the determination.

The SOM states that water at 120 degrees F can cause third degree burns in five minutes; water at 127 degrees F can cause third degree burns in one minute; and water at 133 degrees F can cause third degree burns in 15 seconds. SOM, app. PP, Tag F323. A first degree burn causes redness and requires no treatment. A second degree burn on the hand or arm damages the skin and requires a protective bandage, but not hospitalization. A third degree burn would go through the cutaneous layer of the skin and could require hospitalization. P. Ex. 20 at 4-5; Tr. 229-31. A third degree burn: will destroy all layers of the skin; may involve fat, muscle, and bone; will require skin grafting for healing; cause skin to possibly become bright red, dry or leathery, charred, waxy white, tan or brown. Charred veins may be visible; and in areas of a full thickness injury, a person may be unable to feel touch. P. Ex. 20 at 5; SOM, App. PP, Tag F323. Based upon these accepted definitions of the types of burns, I conclude that the first and second degree burns do not amount to serious injury. However, the third degree burn is clearly a serious injury that is invasive and requires significant treatment to prevent infection and other secondary effects.

The evidence does not show that any resident suffered any actual injury due to the hot water on April 21, 2008. However, both CMS and the Board have determined there is a sufficient basis for immediate jeopardy if there is likelihood of serious harm. The mere risk for serious harm is insufficient and CMS instructs its surveyors that there must be a high potential for serious harm to occur in the very near future. The Board says that the serious harm must be probable. Thus, the issue boils down to whether or not there was a probability or high potential that any of Petitioner's present or future residents would suffer a third degree burn or whether there was a high potential for such a burn. Based

upon all the evidence before me, I do not find it either probable or that a high potential exists that any resident would expose his or her skin to water in excess of 115 degrees F for a sufficient period to cause a third degree burn. I have considered the evidence of record related to various residents and the fact that the excessively hot water was found in resident bathrooms. I conclude that Petitioner has shown by a preponderance of the evidence that the determination that there was immediate jeopardy was clearly erroneous.¹¹

5. The allocation of the burden of persuasion in this case did not prejudice Petitioner.

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). P. Brief at 4, 16-19. Petitioner prevails in this case on the issue of whether immediate jeopardy was clearly erroneous, and Petitioner suffered no prejudice by allocating to Petitioner the burden of persuasion on that issue. 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.

6. A CMP of \$250 per day from April 21 through 23, 2008, is a reasonable enforcement remedy.

I have concluded that Petitioner violated 42 C.F.R. §§ 483.25(h)(1) (Tag F323), 493.70(c)(2) (Tag F456), and 483.75 (Tag F490). Petitioner did not challenge deficiencies cited at less than the immediate jeopardy level, and there is no dispute that Petitioner is subject to a CMP in the lower range for the period April 21 through 23, 2008, based upon the unchallenged deficiencies. Because I have found that the

One of the surveyors testified at hearing that the decision to cite Petitioner at a level of immediate jeopardy was based on equating a potential for harm, which is part of the definition of a deficiency that is not immediate jeopardy, with the likelihood of serious injury or death, which is part of the definition of immediate jeopardy. Tr. 70. Even the surveyor's notes demonstrate confusion as to the proper meaning of immediate jeopardy. CMS Ex. 2 at 32. This fundamental confusion on the part of the surveyors citing the deficiency is consistent with my conclusion that the determination was clearly erroneous.

determination of immediate jeopardy was clearly erroneous, I must conclude that a CMP in the upper range of CMPs reserved for immediate jeopardy deficiencies is unreasonable. The lower range of a CMP, from \$50 per day 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). Accordingly, I must determine a reasonable CMP for the period April 21 through 23, 2008.

I must determine a reasonable CMP by considering 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 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); Community Nursing Home, DAB No. 1807 at 22 (2002); Emerald Oaks, DAB No. 1800 at 9 (2001); CarePlex of Silver Spring, DAB No. 1638 at 8 (1999).

CMS imposed a CMP of \$5550 per day for the period April 21, 2008 through April 23, 2008 based upon the erroneous determination that there was immediate jeopardy. CMS lowered the CMP to \$250 per day CMP beginning April 24, 2008, when CMS determined immediate jeopardy was abated and that the CMP continued through June 2, 2008. Petitioner is not culpable and acted promptly to remedy the deficiencies. Petitioner does not offer financial data to establish an inability to pay. Tr. 36. The evidence does not establish a history of noncompliance related to the same, or a similar, deficiency.

After considering all the required factors in the context of this case, I conclude that the CMP imposed by CMS after immediate jeopardy was abated, \$250 per day, is also a reasonable CMP for the period April 21 through 23, 2008.

III. Conclusion

For the foregoing reasons, I conclude that Petitioner violated 42 C.F.R. §§ 483.25(h)(1), 483.70(c)(2), and 483.75, as determined by a survey of Petitioner's facility completed on April 25, 2008. However, the determination that the violation of the foregoing regulations posed immediate jeopardy for Petitioner's residents was clearly erroneous. A CMP of \$250 per day from April 21 through 23, 2008, is a reasonable enforcement

remedy. The deficiencies that were the basis for imposition of a CMP of \$250 per day from April 24 through June 2, 2008, and a DPNA from May 27 through June 2, 2008, were not challenged. There also was no challenge to the reasonableness of those remedies, and they are undisturbed as a final decision of the Secretary.

/s/ Keith W. Sickendick Administrative Law Judge