Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Titusville Rehabilitation and Nursing Center
(CCN: 10-5448),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-12-294

Decision No. CR2980

Date: November 6, 2013

DECISION

Petitioner, Titusville Rehabilitation and Nursing Center, violated 42 C.F.R. §§ 483.20(d) and 483.20(k)(1), 483.20(k)(3)(i), and 483.25(h), during the period September 23, 2011 through November 14, 2011; and the violations posed immediate jeopardy for the entire period. The civil money penalty (CMP) of $6,050 per day for the 53 days from September 23 through November 14, 2011, a total CMP of $320,650, is a reasonable enforcement remedy.

I. Background

Petitioner is located in Titusville, Florida, and participates in Medicare as a skilled nursing facility (SNF) and in the state Medicaid program as a nursing facility (NF). From November 7 through 9, 2011, Petitioner was subject to a complaint investigation by the Florida Agency for Health Care Administration (state agency) and found not to be in substantial compliance with program participation requirements. The Centers for Medicare & Medicaid Services (CMS) notified Petitioner by letter dated November 23, 2011, that it was imposing the following enforcement remedies: a CMP of $6,050 per day beginning on September 23, 2011 and continuing until Petitioner abated immediate jeopardy to its residents or Petitioner's provider agreement was terminated; a discretionary denial of payments for new admissions (DPNA) effective November 25,

2011, if Petitioner did not return to substantial compliance before that date; and termination of Petitioner's provider agreement on December 2, 2011, if the immediate jeopardy to resident health and safety was not removed by that date. CMS also advised Petitioner that it was no longer eligible to conduct a nurse aide training and competency evaluation program (NATCEP). CMS Exhibit (Ex.) 20.

Petitioner requested a hearing before an administrative law judge (ALJ) on January 18, 2012. The case was assigned to me for hearing and decision on January 24, 2012, and an Acknowledgement and Prehearing Order (Prehearing Order) was issued at my direction. On November 14 and 15, 2012, a hearing was convened by video teleconference (VTC) with the parties' representatives, counsel, and witnesses appearing in Maitland, Florida, and the ALJ presiding from Kansas City. The hearing continued on November 28, 2012, by telephone, with counsel for Petitioner participating from her office in Virginia, Petitioner's representative appearing by telephone from Florida, counsel for CMS appearing by telephone from Georgia, and Petitioner's expert witness testifying by telephone from Florida. My attorney advisor and the court reporter participated by telephone from Washington, D.C., and I presided by telephone from Kansas City. A transcript (Tr.) of the proceedings was prepared. CMS offered CMS Exs. 1 through 22, of which CMS Exs. 1 through 21 and CMS Ex. 22, page 1 were admitted as evidence.[1] Tr. 31-33, 130-44. Petitioner offered Petitioner's exhibits (P. Exs.) 1 through 14 that were admitted as evidence. Tr. 34-35. CMS called the following witnesses during the hearing: Surveyor Mark Foronda, a nutritionist consultant, and Surveyor Supervisor Theresa DeCanio, Registered Nurse (RN). Petitioner called the following witnesses: Mekeeba Mathews, CNA; Julie Dawkins, RN, MSN, MBA; and Robin Bleier, RN (who testified as an expert in the area of nursing and CNA operations within a long-term care facility, as well as with regard to standards of nursing and CNA care). Tr. 705-06.

The parties filed post-hearing briefs (CMS Br. and P. Br., respectively) and post-hearing reply briefs (CMS Reply and P. Reply, respectively), as well as proposed findings of fact and conclusions of law.

On February 28, 2013, CMS filed with its post-hearing brief a motion for leave to supplement the record with CMS Exs. 23 and 24. CMS Ex. 23 purports to be U.S. Naval Observatory information related to sunrise, sunset, moonrise, moonset, and similar data

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[1] CMS Ex. 18 is not substantive evidence, but rather a sheet of paper on which is printed the statement that "CMS hereby incorporates all the Petitioner's Exhibits 1 – 15 exchanged on May 24, 2012." Similarly, P. Ex. 15 was included on Petitioner's list of proposed exhibits but not offered because the exhibit list described P. Ex. 15 as "[a]ll CMS exhibits 1-19 submitted on April 25, 2012." Tr. 34.

for the dates of September 23, 2011 and November 7, 2011. CMS Ex. 24 purports to be an extract from Mosby's Textbook for Long-Term Care Assistants, (4th ed.). Petitioner filed objections to the admission of CMS Exs. 23 and 24 on March 15, 2013. Petitioner's objections are sustained and neither document is admitted or considered as substantive evidence. The parties were advised by the Amended Acknowledgement and Prehearing Order dated January 26, 2012, § II.12.i that they would be given an opportunity to present a rebuttal case, but they must articulate why rebuttal should be allowed. Tr. 18. CMS does not assert that CMS Ex. 23 is offered to rebut any evidence offered by Petitioner. Rather, CMS Ex. 23 is offered by CMS in support of its position regarding the lighting level during the incident that underlies the deficiency citations in this case. CMS Br. at 3 n. 1. Accordingly, CMS Ex. 23 is not proper rebuttal evidence and should have been offered by CMS as evidence in its case-in-chief rather than after Petitioner's case-in-chief.[2] CMS has failed to show good cause for why it should be permitted to reopen its case for the admission of additional evidence. CMS has also failed to provide foundational evidence necessary to establish the authenticity of CMS Ex. 23. CMS Ex. 24 is also not appropriate rebuttal evidence and CMS has failed to show good cause to permit reopening its case-in-chief. CMS does not offer CMS Ex. 24 to rebut Petitioner's evidence. Rather, CMS Ex. 24 is offered by CMS as evidence in support of the CMS position on the appropriate standard of practice and this exhibit should have been offered as part of the CMS case-in-chief and not held for rebuttal. CMS Br. at 7.

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 at section 1819 of the Social Security Act (Act) and 42 C.F.R. pt. 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

[2] See generally, Kenneth S. Broun, 1 McCormick On Evid. § 4 (7th ed. 2013) and cases cited therein. Tr. 841-44.

participation requirements established by sections 1819(b), (c), and (d) of the Act.[3] 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 180 days 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).

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. pt. 483, subpt. B. Noncompliance refers to any deficiency that causes a facility not to be in substantial compliance. 42 C.F.R. § 488.301. 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.

CMS is authorized to impose a CMP for the number of days of noncompliance – a per day CMP – or for each instance of noncompliance – a PICMP. 42 C.F.R. § 488.430. 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 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

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[3] 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. SNFs and NFs are referred to generally as "long-term care facilities."

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 CMPs, $50 per day to $3,000 per day, is reserved for deficiencies that do not pose 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 only range for a PICMP is $1,000 to $10,000. 42 C.F.R. §§ 488.408, 488.438(a)(2).

Petitioner was notified that it was ineligible to conduct a NATCEP for two years. 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. 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. 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. The Secretary promulgated regulations at 42 C.F.R. pt. 483, subpt. D. Pursuant to 42 C.F.R. § 483.151(b)(2) and (f), a state may not approve and must withdraw any prior approval of a NATCEP offered by a skilled nursing or nursing facility 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.

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. *The 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, 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 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, 39 (2000), *aff'd*, 363 F.3d 583 (6th Cir. 2003). The Departmental Appeals Board (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 hearing before an ALJ is a de novo proceeding, i.e., "a fresh look by a neutral decision-maker at the legal and factual basis for the deficiency findings underlying the remedies." *Life Care Ctr. of Bardstown*, DAB No. 2479, at 33 (2012) (citation omitted). 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*, 129 F. App'x 181 (6th Cir. 2005); *Emerald Oaks*, DAB No. 1800; *Cross Creek Health Care Ctr.*, DAB No. 1665 (1998); *Hillman Rehab. Ctr.*, DAB No. 1611 (1997) (*remand)*, DAB No. 1663 (1998) (*aft. remand*), *aff'd*, *Hillman Rehab. Ctr. v. United States,* 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 numbered bold text and are followed by my findings of fact and analysis. 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] I also discuss any evidence that I find is not credible or worthy of weight. The fact that

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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.

evidence is not specifically discussed should not be considered sufficient to rebut the presumption that I 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.

CMS alleges, based upon a complaint survey that ended November 9, 2011, that Petitioner was not in substantial compliance with program participation requirements from September 23, 2011 through November 14, 2011 and that the noncompliance posed immediate jeopardy for the entire period of 53 days. CMS alleges that violations of 42 C.F.R. §§ 483.20(d) and 483.20(k)(1) (Tag F279); 483.20(k)(3)(i) (Tag F281); 483.25(h) (Tag F323); and 483.75 (Tag F490) posed immediate jeopardy (scope and severity of K) to one or more of Petitioner's residents. CMS also alleges that a violation of 42 C.F.R. § 483.70(h) (Tag F465) posed a risk for more than minimal harm (scope and severity E) to Petitioner's residents. CMS Prehearing Brief at 5-10; CMS Br. at 1, 5-20; Tr. 108-13. The parties stipulated that the complaint survey was triggered by the report that Resident 3 fell on September 23, 2011. Joint Stipulation of Undisputed Facts (Jt. Stip.) ¶ 3. The parties also stipulated that a revisit survey determined that Petitioner returned to substantial compliance effective November 15, 2011. Jt. Stip. ¶ 4; CMS Exs. 3, 21. The DPNA and termination remedies were cancelled because Petitioner returned to substantial compliance before the effective date of those remedies. CMS Exs. 3, 21. The only remedy at issue before me is the proposed CMP of $6,050 per day from September 23, 2011 through November 14, 2011, a period of 53 days, resulting in a total CMP of $320,650. Jt. Stip. ¶ 5.[5] Whether or not Petitioner was ineligible to conduct a NATCEP, while not an enforcement remedy, is also affected by the decision in this case.

1. Petitioner suffered no prejudice because the oral hearing was conducted by VTC and telephone and Petitioner was not denied due process.

On October 25, 2012, I advised the parties that on October 24, 2012, the ALJs of the Civil Remedies Division were advised by the Chair of the Board that: there was no

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[5] The parties' stipulation states that the CMP continued through November 15, 2011. However, because CMS found that Petitioner regained substantial compliance effective November 15, 2011, CMS could not impose a CMP for that day. The parties correctly state that the CMP was imposed for 53 days, which would be September 23, 2011 through November 14, 2011. Thus, I conclude the parties intended by their stipulation to state that the daily CMP continued to, not through November 15, 2011.

longer money for ALJs to travel to hearings; budgetary constraints were expected to continue through March 2013 and it was not foreseeable that there would be relief from budget constraints at that time; and that the hearing in this case would need to be conducted by VTC or not at all. Petitioner filed a motion and objection protesting my participation in the hearing of this case by VTC. On November 9, 2012, I advised the parties that I would receive oral argument and rule on the motion and objection the first day of hearing on November 14, 2012.

On November 14, 2012, I overruled Petitioner's objection to my conducting the hearing by VTC. I also denied Petitioner's motion that I be present in the same hearing room with the parties and witnesses for the hearing. In post hearing briefing, Petitioner renewed its objection to my participation in the hearing by VTC. Petitioner argues that: (1) the use of VTC is not authorized by the Administrative Procedure Act (APA) (5 U.S.C. §§ 551-559), the Act, or the regulations; (2) CMS's failure to provide Petitioner an "in-person" hearing violates Petitioner's right to due process; and (3) the appropriate remedy for the due process violation is to disapprove the CMP and abate the proceedings. P. Br. at 3-12.

Based upon my review of the record, including the transcript, and consideration of Petitioner's pleadings, I conclude that Petitioner suffered no prejudice and was not denied a meaningful opportunity to present its case. My rationale is unchanged from that stated in detail in the transcript of the proceedings. Tr. 50-76. There are two principal bases for my rulings. First, the Administrative Procedures Act (APA), 5 U.S.C. §§ 554, 555, 556, and 557, and sections 205(b) and 1866(h) of the Act do not require that an oral evidentiary hearing be conducted with all participants in the same hearing room or prohibit the participation of the judge by VTC. Second, I concluded based on application of the principles articulated by the Supreme Court in *Mathews v. Eldridge*, 424 U.S. 319, 334-35 (1976),[6] that Petitioner was not deprived of due process and suffered no prejudice

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[6] The Supreme Court addressed in *Mathews v. Eldridge* whether or not an evidentiary hearing was required prior to termination of disability benefits rather than post-termination. The Court decided no evidentiary hearing was required prior to termination. The Court did not describe in any detail how an evidentiary hearing must be conducted. Nevertheless, the principles articulated by the Court are helpful to determine whether or not the appearance of the judge by VTC amounts to a deprivation of due process. The application of the principles from *Mathews v. Eldridge* should not be considered to reflect a determination that Petitioner has any property interest in continued participation in Medicare and the receipt of reimbursement from Medicare. However, Petitioner certainly has a property interest in the CMP that CMS seeks to collect. *Mathews v. Eldridge*, at 332-33 ("Procedural due process imposes constraints on governmental decisions which deprive individuals of "liberty" or "property" interests within the

(Footnote continued next page.)

simply because I was not physically present in the hearing room with the parties, counsel, and the witnesses, but instead participated by VTC. Petitioner received the process due under the APA, the Act, and the regulations, i.e., a hearing on the record, with representation, an opportunity to present oral and documentary evidence, and to cross-examine witnesses. The fact that I heard the oral evidence and observed the witnesses via VTC, rather than in person, did not deprive Petitioner of any of the process due.[7]

2. Petitioner violated 42 C.F.R. §§ 483.20(d) and 483.20(k)(1).

3. Petitioner's violation of 42 C.F.R. §§ 483.20(d) and 483.20(k)(1) posed a risk for more than minimal harm.

4. Petitioner violated 42 C.F.R. § 483.20(k)(3)(i).

5. Petitioner's violation of 42 C.F.R. § 483.20(k)(3)(i) posed a risk for more than minimal harm.

6. Petitioner violated 42 C.F.R. § 483.25(h).

7. Petitioner's violation of 42 C.F.R. § 483.25(h) posed a risk for more than minimal harm.

(Footnote continued.)
meaning of the Due Process Clause of the Fifth or Fourteenth Amendment." "Court consistently has held that some form of hearing is required before an individual is finally deprived of a property interest.")

[7] The technical difficulties associated with conducting a proceeding by VTC, which are apparent on the transcript, make the job of the judge and counsel more difficult than when all parties are physically present in the same courtroom. However, the professionalism of counsel and their cooperation with the judge ensured that Petitioner had a full and fair hearing, despite some interruptions and delays. It is not possible to determine whether or not the discomfort experienced by the witnesses was the same, less, or greater, than that of inexperienced witnesses in any other hearing. However, whatever discomfort the witnesses experienced in this case had no perceptible impact upon their credibility or their ability to recall the matters to which they testified. Petitioner elected to elicit the testimony of its expert by telephone rather than VTC and any objection on that basis is waived. Tr. 522-27.

a. Facts

The complaint survey in this case was triggered by a report that Resident 3 fell and suffered injuries in a facility shower room on September 23, 2011. It is not disputed that Resident 3, who was 77 at the time, fell forward and out of her shower chair striking her head on the shower room floor while a CNA was assisting her with showering. Jt. Stip. ¶ 3; CMS Ex. 15 at 7; CMS Ex. 17; Tr. 113-14.[8] Resident 3 was evaluated and admitted to the hospital for observation on September 23, 2011, with a subarachnoid bleed and a laceration to the left forehead and frontal area that required suturing. CMS Ex. 15 at 17-18.

The evidence offered by CMS related to Resident 3 appears to have mostly been collected by the surveyors from Petitioner's clinical file for Resident 3.[9] CMS Ex. 15. Petitioner offered some evidence related to Resident 3, also apparently from its clinical record, and that evidence is not inconsistent with the evidence offered by CMS. The evidence shows that Resident 3 was 76 when admitted to Petitioner on August 6, 2010, with a medical history that included: a seizure disorder, spinal stenosis, weakness, impaired balance, meningioma that required a craniotomy, hypothyroidism, hypertension, dementia, anemia, rheumatoid arthritis, and chronic paralysis of her right arm and leg. Resident 3 or her representative elected at admission that that her records be annotated as DNR (do not resuscitate). CMS Exs. 10 at 6-9; 15 at 4, 6-8, 17, 20-21, 24.

There is no dispute that Resident 3 was at risk for falling.[10] Petitioner assessed Resident 3 as a fall risk based on her history of falls; her medical, cognitive, and musculoskeletal

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[8] There is no dispute that Resident 3 subsequently died, but the parties agree that her death has no relevance to the issues before me. Tr. 114-15.

[9] CMS placed in evidence 107 pages of hospital records related to Resident 3's May 2, 2011fall. CMS Ex. 10. It is not possible to determine from the face of these records whether they were taken from Petitioner's clinical records for Resident 3 or obtained directly from the hospital. The records are of minimal relevance.

[10] The assessment that Resident 3 was a risk for falls was confirmed when on May 2, 2011, Resident 3 suffered an un-witnessed fall in her room, sustaining a contusion and requiring hospitalization. CMS Exs. 10 at 6, 8-9, 89-90; 15 at 44. The hospital admission summary dated May 2, 2011 indicates that Resident 3 was in a postictal state on arrival, causing the physician to believe that the resident's un-witnessed fall was likely due to a seizure. She required no treatment for the fall. CMS Ex. 15 at 20-21. The hospital discharge summary lists a final diagnosis of probable seizure and possible cerebrovascular accident. CMS Ex. 10 at 6.

conditions; and the medications she was taking. Multiple interventions were care planned to address her fall risk. CMS Ex. 15 at 24. Resident 3 was bed and wheelchair bound. CMS Ex. 15 at 20. Resident 3 required extensive assistance for bed mobility and was dependent on staff for wheelchair propulsion off the unit, although she could independently propel her wheelchair on the unit. She required a one-person assist for her wheelchair and two-person assistance for transfers using a sit-to-stand mechanical (Sara) lift. Resident 3 was also assessed to have a swallowing problem that could result in aspiration. P. Ex. 9; CMS Ex. 15 at 28, 30, 32, 34; Tr. 547. Prior to October 4, 2011, Resident 3 was assessed and care planned as requiring the assistance of one staff member for a bed bath or shower. P. Ex. 9 at 1.

Resident 3's risk for falling forward from her wheelchair due to her difficulty maintaining upper body positioning caused her physician to issue an order for a restraint to prevent such a fall. On September 6 and 8, 2011, Resident 3's physician ordered that a lap tray be used on Resident 3's wheelchair when she was out-of-bed to help maintain a proper upper-body position. The physician ordered that the lap tray could be released when the resident had one-on-one supervision during meals, activities of daily living (ADLs), and activities. The order was issued based on the recommendation of occupational therapy. Petitioner's staff considered the use of the lap tray to be a restraint because the resident could not remove it on her own or on demand. CMS Ex. 15 at 22-23, 44; P. Ex. 10 at 17-18. The lap tray intervention and physician directions were added to Resident 3's care plan. P. Ex. 9 at 2. There is no evidence that Resident 3's care plan for bathing or showering was reevaluated or modified due to her assessed difficulty maintaining upper-body position.

There is no dispute about what happened to Resident 3 in the shower room September 23, 2011. At approximately 8:30 p.m., CNA Dyer took Resident 3 to the shower room to give her a shower. The shower room had a left side and a right side with a toilet room between that connected to the two shower rooms by doorways. Each shower room had its own window. The floors of the shower rooms were tiled with small, grouted, tiles. According to RN Blier, the floor design was intended to minimize the risk for slipping. CNA Dyer placed Resident 3 in the shower room on the left. P. Exs. 5, 6: Tr. 129, 589-92, 809-10. Petitioner's clinical record reflects that while receiving her shower, Resident 3 began to lean forward; CNA Dyer attempted to stop her but CNA Dyer slipped and fell; and then Resident 3 fell forward and hit her head on the floor resulting in the laceration to the left forehead and frontal area that required suturing and a subarachnoid bleed. CMS Ex. 15 at 17-18, 38, 44; P. Ex. 11.

The parties' witnesses agreed that shower rooms pose an increased risk for slips and falls. Tr. 182, 227-29, 497, 514-15, 579-80, 809. Petitioner's witnesses testified that it was facility practice to shower residents using a shower chair with one-on-one supervision, unless the resident suffered contractures, in which case they used a shower bed, or, in the rare circumstance, when the resident was assessed as capable to safely stand to shower.

It was also a facility practice, and a standard of practice, that residents were not left in the shower room by themselves. Tr. 554-57, 578-82, 733, 735-36, 743-44, 781.[11] It was also facility policy and a standard of practice that non-slip or non-skid shoes were to be worn by staff, particularly in the shower room. But the evidence does not show that Petitioner had a policy or that there was a standard of practice that required the use of a particular type of non-slip or non-skid shoe or the shoe of a particular vendor. Petitioner did provide non-slip foot wear for staff, referred to by witnesses as "Shoes for Crews®," but the evidence does not show that staff was not permitted to wear non-slip footwear from a different vendor. Tr. 123-25, 223-24, 273-75, 514-15.

b. Analysis

The surveyors alleged a violation of 42 C.F.R. §§ 483.20(d) and 483.20(k)(1) (Tag F279) because "the facility failed to develop a plan of care related to the level of assistance needed with showers." CMS Ex. 1 at 2. The surveyors relied primarily upon the example of Resident 3, but also referred to other specific residents as examples. The surveyors alleged that "[t]he lack of a comprehensive care plan put the residents at risk for harm, injury or death resulting from accidents while in the shower." The surveyors also alleged that the violation posed immediate jeopardy, i.e., the violation caused or was likely to cause serious injury, harm, impairment, or death to a resident. CMS Ex. 1 at 2.

The surveyors alleged a violation of 42 C.F.R. § 483.20(k)(3)(i) (Tag F281) because Petitioner's failure to care plan resident needs for safe showers allowed or required that unlicensed staff make decisions regarding interventions necessary to safely shower residents in violation of the Florida "Nurse Practice Act" (Fla. Stat. §§ 464.001-.027). CMS Ex. 1 at 8-9. The parties do not dispute application of the Florida Nurse Practice Act and its requirement that the assessment of residents and care planning for their needs

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[11] The style of shower chair being used to shower Resident 3 when she fell was the subject of considerable interest for the surveyors and the parties at hearing. CNA Dyer allegedly told the surveyors that he typically used a shower chair with a bar because Resident 3 tended to lean forward, but he could not locate that chair and was using a chair with no bar at the time of the fall. Tr. 153-54. The parties believe that the chair to which CNA Dyer referred was similar to that depicted in CMS Ex. 22 at 1. Petitioner characterized the bar on the shower chair as a place where residents could rest their hands. Petitioner objects to characterization of the bar as a safety feature of the shower chair. CMS considers the bar to be a safety device. The evidence is not sufficient to determine the purpose of the bar depicted on the shower chair in CMS Ex. 22 at 1. Tr. 127-28, 144-49. Furthermore, there appears to be no disagreement among the parties that there is no standard of practice or other requirement to use a shower chair with a bar. Tr. 254, 512-14.

be performed by licensed professional nurses. Tr. 708, 820. The surveyors cited the example of Resident 3 and examples of multiple other specific residents. The surveyors also alleged that this violation posed immediate jeopardy to the residents. CMS Ex. 1 at 8.

The surveyors also alleged a violation of 42 C.F.R. § 483.25(h) (Tag F323) because Petitioner failed to provide necessary care and services, specifically supervision and assistive devices, necessary to minimize or prevent the risk for harm to residents due to accidents in the shower. The surveyors cited the example of Resident 3 and multiple other residents. The surveyors also alleged that the violation posed immediate jeopardy. CMS Ex. 1 at 12-13.

Theresa DeCanio, RN, the state agency field office manager who had oversight responsibility for the survey before me, agreed that the focus of these deficiency citations was the failure to assess and care plan for the safety needs of residents when using the shower. Tr. 509-10.

I conclude that there were deficiencies under Tags F279, F281, and F323. I conclude that the declaration of immediate jeopardy related to those deficiencies has not been shown to be clearly erroneous. I conclude that enforcement remedies proposed by CMS are reasonable for the deficiencies under Tags F279, F281, and F323. In light of the foregoing conclusions, I also conclude that it is unnecessary to consider the alleged deficiencies under Tags F465 and F490.

The analysis of the deficiencies under Tags F279, F281, and F323, must begin with a review and understanding of the regulatory scheme. The regulations that require assessment and care planning are 42 C.F.R. § 483.20(d) and (k)(1). The regulation that requires interventions to prevent accidents is 42 C.F.R. § 483.25(h). A facility "must conduct initially and periodically a comprehensive, accurate, standardized, and reproducible assessment of each resident's functional capacity." 42 C.F.R. § 483.20. The regulation requires that assessments be conducted or coordinated by an RN with the appropriate participation of other health professionals. 42 C.F.R. § 483.20(h). Pursuant to 42 C.F.R. § 483.20(d), the facility must "use the results of the assessments to develop, review, and revise the resident's comprehensive plan of care." Pursuant to 42 C.F.R. § 483.20(k)(1), the "facility must develop a comprehensive care plan for each resident that includes measurable objectives and timetables to meet a resident's medical, nursing, and mental and psychosocial needs that are identified in the comprehensive assessment." The comprehensive care plan must be prepared by an interdisciplinary team (IDT) that includes the attending physician, the RN responsible for the resident, and other appropriate staff in disciplines necessary to meet the resident's needs. 42 C.F.R. § 483.20(k)(2)(ii). The services provided or arranged by the facility must meet professional standards of quality and must be provided by qualified persons in accordance with the written plan of care. 42 C.F.R. § 483.20(k)(3). The comprehensive

care plan must describe the services that are to be furnished to assist the resident to attain or maintain his or her highest practicable physical, mental, and psychosocial well-being as required by 42 C.F.R. § 483.25. 42 C.F.R. § 483.20(k)(1)(i). Section 483.25 of 42 C.F.R. requires that Petitioner provide and ensure its residents receive the care and services necessary for the residents to attain their "highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care." Petitioner is required to ensure that: (1) "[t]he resident environment remains as free of accident hazards as possible;" and (2) "[e]ach resident receives adequate supervision and assistance devices to prevent accidents." 42 C.F.R. § 483.25(h).

Appellate panels of the Board have addressed the care planning requirements in several cases.

> The Board has explained that a comprehensive care plan "functions as a roadmap for all of the resident's caregivers, including those unfamiliar with a resident or without professional training, to provide consistent care and services tailored to 'attain or maintain the [resident's] highest practicable physical, mental and psychosocial well-being.'" *Sheridan Health Care Ctr.*, DAB No. 2178, at 37 (2008), quoting 42 C.F.R. § 483.20(k). "Accordingly, the care plan must include sufficient guidance to ensure that the services provided promote the plan's specified objectives." Id.

Deltona Health Care, DAB No. 2511, at 18 (2013) (concluding that a care plan that required monitoring but did not specify who was to monitor, how often monitoring was to occur, or how the monitoring was to be done, did not provide staff adequate guidance to ensure a resident received required care); *Brithaven of Havelock*, DAB No. 2078, at 12-14 (2007) (physician order insufficient as a care plan).

Regarding 42 C.F.R. § 483.25(h), CMS instructs its surveyors that the intent of the regulation is "to ensure the facility provides an environment that is free from accident hazards over which the facility has control and provides supervision and assistive devices to each resident to prevent avoidable accidents." The facility is expected to: identify, evaluate, and analyze hazards and risks; implement interventions to reduce hazards and risks; and monitor the effectiveness of interventions and modify them when necessary. State Operations Manual (SOM), CMS Pub. 100-07, app. PP, Guidance to Surveyors Long Term Care Facilities, F323 (Rev. 27; eff. Aug. 17, 2007). The CMS interpretation is consistent with a long-line of Board decisions.

The Board has provided interpretative guidance for adjudicating alleged violations of 42 C.F.R. § 483.25(h)(1):

> 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).

The Board has also explained the requirements of 42 C.F.R. § 483.25(h)(2) in numerous decisions. *Golden Living Ctr. – Riverchase*, DAB No. 2314, at 7-8 (2010); *Eastwood Convalescent Ctr.*, DAB No. 2088 (2007); *Century Care of Crystal Coast*, DAB No. 2076 (2007*), aff'd*, 281 F. App'x 180 (4th Cir. 2008); *Liberty Commons Nursing and Rehab. - Alamance*, DAB No. 2070 (2007); *Golden Age Skilled Nursing & Rehab. Ctr.,* DAB No. 2026 (2006); *Estes Nursing Facility Civic Ctr.,* DAB No. 2000 (2005); *Northeastern Ohio Alzheimer's Research Ctr.,* DAB No. 1935 (2004); *Woodstock Care Ctr.,* DAB No. 1726 (2000), *aff'd, Woodstock Care Ctr. v. Thompson*, 363 F.3d 583 (6th Cir. 2003). The regulation does not make a facility strictly liable for accidents that occur, but it does require that a facility take all reasonable steps to ensure that a resident receives supervision and assistance devices that meet his or her assessed needs and mitigates foreseeable risks of harm from accidents. *Woodstock Care Ctr. v. Thompson*, 363 F.3d at 589 (noting a SNF must take "all reasonable precautions against residents' accidents"). A facility is permitted the flexibility to choose the methods of supervision it uses to prevent accidents, but the chosen methods must be adequate under the circumstances. Whether supervision is "adequate" depends in part upon a resident's ability to protect him or herself from harm. *Id.* Based on the regulation and the cases in this area, CMS meets its burden to show a *prima facie* case, if the evidence demonstrates that the facility failed to provide adequate supervision and assistance devices to prevent accidents, given what was reasonably foreseeable. *Alden Town Manor Rehab. & HCC*, DAB No. 2054, at 5-6, 7-12 (2006). An "accident" is an unexpected, unintended incident which may result

in injury or illness to a resident. It does not include adverse outcomes that are a direct consequence of treatment or care provided in accordance with current standards of practice (e.g., drug side effects or reactions). SOM, app. PP, Tag F323; *Woodstock Care Ctr.*, DAB No. 1726, at 4.

> The regulation speaks in terms of ensuring that what is "practicable" and "possible" to do is done. What is thus required of facilities is not prescience but reason and professional judgment in assessing what can be done to make residents (given their special needs) safe, through removing accident hazards, providing appropriate devices, and ensuring adequate supervision.

Glenoaks Nursing Ctr., DAB No. 2522, at 8 (2013) *citing Josephine Sunset Home*, DAB No. 1908, at 14-15 (2004); *Briarwood Nursing Ctr.*, DAB No. 2115, at 11-12 (2007).

Applying the well-established law to the facts of this case reveals that Petitioner's errors and omissions are manifold.

The evidence shows that Resident 3's IDT did care plan for her to receive a shower. Evidence of that care planning is found on the Maintenance ADL & Safety Care Plan & Communication Tool (referred to by the witnesses as the KARDEX). P. Ex. 9 at 1. The care plan reflected on that KARDEX specified that Resident 3 required the assistance of one to receive a bed bath or a shower. The KARDEX does not reflect when that care plan was devised, but it shows that Resident 3 was admitted to Petitioner on August 6, 2010 and the KARDEX was last reviewed and updated on November 15, 2010, with the next review scheduled for February 14, 2011. P. Ex. 9 at 1. Petitioner submitted a second KARDEX (P. Ex. 9 at 2) which shows a change in interventions on October 4, 2011, but that change was after Resident 3's fall on September 23, 2011 and, therefore, it is not the focus of my analysis. Resident 3's "Individualized Care Plan for Fall/Fall Risk" does not specifically address interventions for the shower. CMS Ex. 15 at 24.

Petitioner does not deny that Resident 3 was assessed by occupational therapy as at risk for falling forward from her wheelchair due to her difficulty maintaining upper body positioning. CMS Ex. 15 at 44; P. Ex. 14 at 18; P. Br. at 14; P. Reply at 4. The assessment caused Resident 3's physician to issue orders on September 6 and 8, 2011, for a lap tray to be used on Resident 3's wheelchair when she was out-of-bed to help maintain a proper upper-body position. The physician ordered that the lap tray could be released when the resident had one-on-one supervision during meals, ADLs, and activities. Petitioner's staff evaluated the use of the lap tray and determined that it was a

restraint because the resident could not remove it on her own or on demand. CMS Ex. 15 at 22-23, 44; P. Ex. 10 at 17-18. The lap tray intervention and physician directions were added to Resident 3's KARDEX on September 8, 2011.[12] P. Ex. 9 at 2.

There is no question that the evidence shows that staff used a shower chair to shower Resident 3, which also required Resident 3 to sit upright. I infer, based on the fact that Resident 3 was at risk to lean forward when sitting upright in a wheelchair, that she was also at risk to lean forward when sitting upright in a shower chair. The shower chairs depicted in CMS Ex. 22 at 1 and P. Ex. 5 appear to be less substantial and less stable than the common wheelchair. Furthermore, the parties' witnesses agreed that shower rooms pose an increased risk for slips and falls. Tr. 182, 227-29, 497, 514-15, 579-80, 809. However, Petitioner offers no evidence that Resident 3's IDT ever considered those safety risks for Resident 3.

Petitioner urges me to accept that the physician's order adequately addresses the risk to Resident 3 when sitting in a shower chair because he ordered that the lap tray could be removed from the wheelchair when the resident was involved in ADLs, so long as she had one-on-one supervision. P. Reply at 5. However, Petitioner's argument is unsupported by any evidence that the physician considered the resident's needs for safety while sitting in a shower chair. The evidence shows that Resident 3's physician only addressed her sitting in a wheelchair. There is no evidence that occupational therapy or the physician ever assessed whether Resident 3 was adequately protected from the risk for accidental injury due to leaning forward while receiving a shower in a shower chair with only one-on-one supervision. There is no evidence that Resident 3's care plan for bathing or showering was reevaluated or modified due to her assessed difficulty maintaining upper-body position. CMS Ex. 15 at 25-27.

There is also no evidence that the IDT ever considered Resident 3's risk for accidental injury due to leaning forward while seated in a shower chair with no lap tray or equivalent support or restraint, while receiving a shower with only one-on-one supervision. The evidence shows that Petitioner had a policy that required staff to wear non-slip footwear. Tr. 557, 608, 779; P. Br. at 23; P. Reply at 5-6. The evidence also shows that Petitioner had a policy that required at least one-on-one supervision for a resident using a shower. Tr. 579-80; P. Br. at 14, 18; P. Reply at 9. While Petitioner's policies may be excellent safety interventions to be generally applied for all residents, Petitioner cites no authority for the proposition that such general policies adequately substitute for the individualized care planning required by the regulations. Furthermore, because the IDT did not assess and care plan to address Resident 3's tendency to lean

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[12] The order for the lap tray is not listed on the copy of Resident 3's "Individualized Care Plan for Fall/Fall Risk" that is in evidence at CMS Ex. 15 at 24.

forward when sitting upright in a shower chair and the associated risk, unlicensed staff who were not authorized under Florida law to assess and care plan were left to determine how to address the risk that Resident 3 might fall forward from the shower chair and suffer accidental injury. There is also no evidence that, as required by 42 C.F.R. § 483.20(h), an RN coordinated the assessment and interventions adopted and implemented by the unlicensed staff. Accordingly, Petitioner's care planning for Resident 3 and the development of interventions to meet Resident 3's safety needs did not meet professional standards.

In summary, Resident 3 had an assessed problem, in that she was unable to maintain her body position and tended to lean forward when sitting upright. Resident 3's physician adopted the intervention that, when Resident 3 was sitting upright in her wheelchair, a lap tray was to be used to help her maintain her position, except for specified activities during which one-on-one supervision was required. There is agreement among the parties that there is an increased safety risk for residents when using a shower room. However, there is no evidence that either the physician or the IDT specifically assessed how Resident 3's assessed problem impacted her safety while sitting upright in a shower chair while receiving a shower. There is no evidence that either the physician or the IDT specifically developed or implemented interventions to address any assessed safety risk associated with Resident 3 sitting upright in a shower chair while receiving a shower from a staff member. Because no assessment or care planning was done by the IDT, unlicensed staff was left to determine how best to handle Resident 3 if she leaned forward while sitting upright in a shower chair. Accordingly, I conclude that Petitioner failed to assess and care plan for the accident hazard that the shower room represented for Resident 3 given her assessed tendency to lean forward when sitting upright. Petitioner's delivery of care and services, therefore, failed to meet professional standards as required by state and federal law.

I conclude that the regulatory violation posed a risk for more than minimal harm. There is no dispute that showers pose an increased risk for slips and falls. Tr. 182, 227-29, 497, 514-15, 579-80, 809. There is no question that a fall may cause more than minimal harm to a resident of a long-term care facility, as evidenced by the fact that Resident 3 suffered actual harm due to her fall in the shower room on September 23, 2011.

8. Petitioner has failed to show that the declaration of immediate jeopardy based on the violations of 42 C.F.R. §§ 483.20(d) and 483.20(k)(1); 483.20(k)(3)(i); and 483.25(h), was clearly erroneous.

The surveyors concluded that the violations of 42 C.F.R. §§ 483.20(d) and 483.20(k)(1); 483.20(k)(3)(i); and 483.25(h), posed immediate jeopardy that began when Resident 3 fell on September 23, 2011. CMS Ex. 1 at 1. CMS concluded that Petitioner abated immediate jeopardy and returned to substantial compliance with program participation requirements on November 15, 2011. CMS Ex. 21. CMS proposes to impose a CMP in

the higher range of CMPs that may be imposed for immediate jeopardy for the entire 53-day period from September 23 through November 14, 2011, and that is the period of immediate jeopardy at issue before me.

The CMS determination of immediate jeopardy must be upheld, unless Petitioner shows the declaration of immediate jeopardy to be clearly erroneous. 42 C.F.R. § 498.60(c)(2). CMS's determination of immediate jeopardy is presumed to be correct, and Petitioner has a heavy burden to demonstrate clear error in that determination. *Yakima Valley Sch.,* DAB No. 2422, at 8-9 (2011); *Cal Turner Extended Care Pavilion*, DAB No. 2384, at 14 (2011); *Brian Ctr. Health and Rehab./Goldsboro,* DAB No. 2336, at 9 (2010) (*citing Barbourville Nursing Home*, DAB No. 1962, at 11 (2005)), *aff'd, Barbourville Nursing Home v. U.S. Dep't of Health & Human Srvs.,* 174 F. App'x 932 (6th Cir. 2006); *Maysville Nursing and Rehab. Facility*, DAB No. 2317, at 11 (2010); *Liberty Commons Nursing and Rehab. Ctr.– Johnston*, DAB No. 2031, at 18-19 (2006), *aff'd, Liberty Commons Nursing & Rehab. Ctr.–Johnson v. Leavitt*, 241 F. App'x 76 (4th Cir. 2007). Once CMS presents evidence supporting a finding of noncompliance, CMS does not need to offer evidence to support its determination that the noncompliance constitutes immediate jeopardy, rather, the burden is on the facility to show that that determination is clearly erroneous. *Cal Turner Extended Care Pavilion*, DAB No. 2384, at 14-15; *Liberty Commons Nursing & Rehab. Ctr.–Johnston*, 241 F. App'x 76 at 3-4.

"*Immediate jeopardy"* under the regulations refers to 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, 489.3 (emphasis in original). In the context of survey, certification, and enforcement related to SNFs and NFs under the regulations, a conclusion by the state agency and CMS that noncompliance with program participation requirements poses immediate jeopardy to facility residents triggers specific regulatory provisions that require enhanced enforcement remedies, including authority for CMS to impose a larger CMP than may be imposed when there is no declaration of immediate jeopardy. 42 C.F.R. §§ 488.408(e), 488.438(a)(1)(i), (c), and (d). The regulations also require termination of the facility's provider agreement on an expedited basis or the removal of the immediate jeopardy through appointment of temporary management. 42 C.F.R. §§ 488.410, 488.440(g), 488.456, 489.53(d)(2)(B)(ii).

Pursuant to 42 C.F.R. § 498.3(d)(10), a finding by CMS that deficiencies pose immediate jeopardy to the health or safety of a facility's residents is not an initial determination that triggers a right to request a hearing by an ALJ or that is subject to review. Rather, a finding of noncompliance that results in the imposition of an enforcement remedy, except the remedy of monitoring by the state, does trigger a right to request a hearing and is subject to review. 42 C.F.R. §§ 488.408(g); 498.3(b)(8) and (13). Furthermore, the level of noncompliance, i.e. the scope and severity, is subject to review only if a successful challenge would: (1) affect the amount of CMP that may be imposed, i.e. the higher

range of CMP authorized for immediate jeopardy; or (2) affect a finding of substandard quality of care that rendered the facility ineligible to conduct a NATCEP. 42 C.F.R. § 498.3(b)(14) and (16). Pursuant to 42 C.F.R. § 498.60(c)(2), in reviewing a CMP, the ALJ must uphold the CMS determination of the level of noncompliance (i.e., the scope and severity), unless it is clearly erroneous. The phrase "clearly erroneous" is not defined by the Secretary.

Many appellate panels of the Board have addressed "immediate jeopardy."[13] In *Mississippi Care Ctr. of Greenville*, DAB No. 2450, at 15 (2012), the Board commented:

> CMS's determination that a deficiency constitutes immediate jeopardy must be upheld unless the facility is able to prove that the determination is clearly erroneous. 42 C.F.R. § 498.60(c)(2); *Woodstock Care Center*. The "clearly erroneous" standard means that CMS's immediate jeopardy determination is presumed to be correct, and the burden of proving the determination clearly erroneous is a heavy one. *See, e.g., Maysville Nursing & Rehabilitation Facility*, DAB No. 2317 at 11 (2010); *Liberty Commons Nursing and Rehab Center — Johnston*, DAB No. 203,1 at 18 (2006), *aff'd*, *Liberty Commons Nursing and Rehab Ctr. — Johnston v. Leavitt*, 241 F. App'x 76 (4th Cir. 2007). When CMS issued the nursing facility survey, certification, and enforcement regulations, it acknowledged that "distinctions between different levels of noncompliance . . . do not represent mathematical judgments for which there are clear or objectively measured boundaries." 59 Fed. Reg. 56,116, 56,179 (Nov. 10, 1994). "This inherent imprecision is precisely why CMS's immediate jeopardy determination, a matter of professional judgment and expertise, is entitled to deference." *Daughters of Miriam Center*, DAB No. 2067, at 15 (2007).

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[13] Decisions often cited include: *Lakeport Skilled Nursing Ctr.*, DAB No. 2435, at 6 (2012); *Liberty Health & Rehab. of Indianola, LLC*, DAB No. 2434, at 13, 18-19 (2011); *Yakima Valley Sch.*, DAB No. 2422, at 8; *Lutheran Home at Trinity Oaks*, DAB No. 2111 (2007); *Daughters of Miriam Ctr.*, DAB No. 2067; *Britthaven of Havelock*, DAB No. 2078 (2007); *Koester Pavilion*, DAB No. 1750; *Woodstock Care Ctr.*, DAB No. 1726.

The Board's statement that the CMS immediate jeopardy determination is entitled to deference is subject to being misunderstood to limit ALJ and Board review of immediate jeopardy beyond what was intended by the drafters of the regulations. In the notice of final rulemaking on November 10, 1994, the drafters of 42 C.F.R. § 498.60(c)(2), discussing the merits of the reviewability of deficiency citations, selection of remedy, and scope and severity, commented:

> We believe that a provider's burden of upsetting survey findings relating to the level of noncompliance should be high, however. As we indicated in the proposed rule, distinctions between different levels of noncompliance, whether measured in terms of their frequency or seriousness, do not represent mathematical judgments for which there are clear or objectively measured boundaries. Identifying failures in a facility's obligation to provide the kind of high quality care required by the Act and the implementing regulations most often reflect judgments that will reflect a range of noncompliant behavior. Thus, in civil money penalty cases, whether deficiencies pose immediate jeopardy, or are widespread and cause actual harm that is not immediate jeopardy, or are widespread and have a potential for more than minimal harm that is not immediate jeopardy does not reflect that a precise point of noncompliance has occurred, but rather that a range of noncompliance has occurred which may vary from facility to facility. While we understand the desire of those who seek the greatest possible consistency in survey findings, an objective that we share, the answer does not lie in designing yardsticks of compliance that can be reduced to rigid and objectively calculated numbers. Survey team members and their supervisors ought to have some degree of flexibility, and deference, in applying their expertise in working with these less than perfectly precise concepts. **For these reasons, we have revised the regulations to require an administrative law judge or appellate administrative review authority to uphold State or HCFA findings on the seriousness of facility deficiencies in civil money penalty cases unless they are clearly erroneous.**

59 Fed. Reg. at 56,179 (emphasis added). It is clear from this regulatory history that the drafters of 42 C.F.R. § 498.60(c)(2) ensured that the state agency or CMS determination that there was immediate jeopardy would receive deferential consideration, by adopting the clearly erroneous standard of review. Thus, caution must be exercised to ensure that

the Board's decision in *Mississippi Care Ctr. of Greenville*, *Daughters of Miriam Ctr.,* and other decisions that have mentioned deference relative to immediate jeopardy not be read to require deference for the determination that there was immediate jeopardy beyond that imposed by adoption of the clearly erroneous standard. Giving or requiring that the immediate jeopardy determination be given deference in addition to applying the "clearly erroneous standard" would be contrary to the intent of the drafters of the regulation; would significantly limit the review of the determination by an ALJ and the Board; and would impermissibly deny an affected party the due process right to review intended by the drafters of the regulation.

In the foregoing quotation from *Mississippi Care Ctr. of Greenville,* that panel of the Board states that the clearly erroneous standard means that "the immediate jeopardy determination is presumed to be correct, and the burden of proving the determination clearly erroneous is a heavy one." *Id*. at 15. Similar formulations have been used in other Board decisions when referring to the "clearly erroneous standard." However, the Board's characterization of the "clearly erroneous standard" in *Mississippi Care Ctr.* and other cases does not define the standard. The "clearly-erroneous standard" is described in Black's Law Dictionary as a standard of appellate review applied in judging the trial court's treatment of factual issues, under which a factual determination is upheld unless the appellate court has the firm conviction that an error was committed. *Black's Law Dictionary* 269 (18th ed. 2004). The Supreme Court has addressed the "clearly erroneous standard" in the context of the Administrative Procedures Act (APA). The Court described the preponderance of the evidence standard, the most common standard, as requiring that the trier-of-fact believe that the existence of a fact is more probable than not before finding in favor of the party that had the burden to persuade the judge of the fact's existence. *In re Winship*, 397 U.S. 358, 371-72 (1970); *Concrete Pipe and Products of California, Inc. v. Construction Laborers*, 508 U.S. 602, 622 (1993). The "substantial evidence" standard considers whether a reasonable mind might accept a particular evidentiary record as adequate to support a conclusion. *Consolidated Edison*, 305 U.S. 197, 229 (1938); *Dickinson v. Zurko*, 527 U.S. 150, 162 (1999). Under the "clearly erroneous" standard a finding is clearly erroneous even though there may be some evidence to support it if, based on all the evidence, the reviewing judge or authority has a definite and firm conviction that an error has been committed. *United States v. United States Gypsum Co.*, 333 U.S. 364, 395 (1948); *Dickinson*, 527 U.S. at 162; *Concrete Pipe*, 508 U.S. at 622. The clearly erroneous standard has been characterized by the Court as being stricter than the substantial evidence test and significantly deferential. The Court stressed in discussing the clearly erroneous standard the

importance of not simply rubber-stamping agency fact-finding. The Court also commented that the APA requires meaningful review.[14] *Dickinson*, 527 U.S. at 162 (citations omitted); *Concrete Pipe*, 508 U.S. at 622-23.

Various panels of the Board have recognized other principles applicable to the review of the immediate jeopardy issue. A finding of immediate jeopardy does not require a finding of actual harm, only a likelihood of serious harm. *Dumas Nursing and Rehab., L.P.*, DAB No. 2347, at 19 (2010), *citing Life Care Ctr. of Tullahoma*, DAB No. 2304, at 58 (2010), *aff'd, Life Care Ctr. Tullahoma v. Sebelius*, 453 F. App'x 610 (2011). The definition of immediate jeopardy at 42 C.F.R. § 488.301, does not define "likelihood" or establish any temporal parameters for potential harm. *Agape Rehabilitation of Rock Hill*, DAB No. 2411, at 18-19 (2011). The duration of the period of immediate jeopardy is also subject to the clearly erroneous standard. *Brian Ctr. Health and Rehab./Goldsboro*, DAB No. 2336, at 7-8 (2010). There is a difference between "likelihood" as required by the definition of immediate jeopardy and a mere potential. The synonym for likely is probable, which suggests a greater degree of probability that an event will occur than suggested by such terms as possible or potential. *Daughters of Miriam Ctr.*, DAB No. 2067, at 10. Jeopardy generally means danger, hazard, or peril. The focus of the immediate jeopardy determination is how imminent the danger appears and how serious the potential consequences. *Woodstock Care Ctr.*, DAB No. 1726, at 39.

What is the meaning of serious injury, harm, or impairment as used in the definition of immediate jeopardy found in 42 C.F.R. § 488.301? How does serious injury, harm, or impairment compare with "actual harm?" On the first question the Board recognized in *Yakima Valley Sch.*, DAB No. 2422, at 8, that the regulations do not define or explain the meaning of the term "serious" as used in the definition of immediate jeopardy.[15] The

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[14] The Board's characterization of the clearly erroneous standard as being highly deferential to the fact-finding by the state agency surveyor and CMS, and even triggering a rebuttal presumption, is entirely consistent with the Supreme Court's characterization of the standard. However, the Court's cautions about ensuring meaningful review rather than rubber-stamping agency decisions shows it is important for the ALJ and the Board not to be tempted to simply defer to the surveyor, the state agency, or CMS on the immediate jeopardy issue.

[15] Appendix Q of the SOM also fails to provide surveyors a working definition of the term "serious" that they can use to determine whether harm, injury, or impairment is serious when deciding whether or not to declare immediate jeopardy. The Act does not define the phrase "immediately jeopardize" and does not introduce the concept of serious harm, injury, or impairment as the basis for finding immediate jeopardy. Thus, one is not in error concluding that absent a definition of the term "serious" in the Act, the
(Footnote continued next page.)

Board suggested that the definitions may be unimportant because the Board has held that, under the clearly erroneous standard, once the state agency or CMS declares immediate jeopardy there is a presumption that the actual or threatened harm was serious and the facility can only rebut the presumption of immediate jeopardy by showing that the harm or threatened harm meets no reasonable definition of the term "serious." *Id.*, *citing Daughters of Miriam Ctr.*, DAB No. 2067, at 9. In *Daughters of Miriam Ctr*, the Board discussed that the ALJ attempted to define "serious" finding meanings such as dangerous, grave, grievous, or life-threatening. The Board notes that the ALJ stated that serious harm is outside the ordinary, requiring extraordinary care, or having lasting consequences. The Board further noted that the ALJ stated that a serious injury may require hospitalization, or result in long-term impairment, or cause severe pain, as opposed to harm, injury, or impairment that is temporary, easily reversible with ordinary care, does not cause a period of incapacitation, heal without special medical intervention, or does not cause severe pain. The Board did not endorse or adopt the ALJ's definitional exercise but concluded that it was simply unnecessary in the context of that case. The Board reasoned, as already noted, that the facility bore the burden to rebut the presumption by showing that the actual or threatened harm met no reasonable definition of serious. *Daughters of Miriam Ctr.,* DAB No. 2067, at 9.

Applying the clearly erroneous standard to the record before me related to the noncompliance I have found based on the violations of 42 C.F.R. §§ 483.20(d) and 483.20(k)(1); 483.20(k)(3)(i); and 483.25(h), I have no definite and firm conviction that an error has been committed. There is no dispute that shower rooms in long-term care facilities may be hazardous. It is also not disputed that Resident 3 fell from a shower chair striking her head on a hard, tile, floor. P. Reply at 16. Petitioner has not shown that the injury suffered by Resident 3 was not serious and, in fact, the evidence supports the conclusion that her injury was indeed serious. Petitioner has not shown that slips and falls by long-term care facility residents resulting in serious injuries, harm, impairment, or death are not probable.

I conclude that Petitioner has failed to show that the declaration of immediate jeopardy based on the violations of 42 C.F.R. §§ 483.20(d) and 483.20(k)(1); 483.20(k)(3)(i); and 483.25(h) was clearly erroneous.

(Footnote continued.)

regulations, the SOM, or decisions of the Board, it is essentially up to individual surveyors, and whatever unpublished guidance they receive from their superiors or CMS officials, to exercise their individual discretion and judgment to decide that there was immediate jeopardy, which subjects a facility to the maximum imposable CMPs.

9. A CMP of $6,050 per day for the 53 days from September 23 through November 14, 2011, a total CMP of $320,650, is a reasonable enforcement remedy.

I have concluded that Petitioner violated 42 C.F.R. §§ 483.20(d) and 483.20(k)(1); 483.20(k)(3)(i); and 483.25(h); that the violations posed a risk for more than minimal harm to one or more facility residents; and that the declaration of immediate jeopardy was not clearly erroneous. If a facility is not in substantial compliance with program requirements, CMS has the authority to impose one or more of the enforcement remedies listed in 42 C.F.R. § 488.406, including a CMP. CMS is authorized to impose a per day CMP for the number of days that the facility is not in substantial compliance. 42 C.F.R. § 488.430(a). 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 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). Accordingly, a CMP of $3,050 to $10,000 per day for each day of immediate jeopardy is authorized in this case.

If I conclude, as I have in this case, that there is a basis for the imposition of an enforcement remedy and the remedy proposed is a CMP, my authority to review the reasonableness of the CMP is limited by 42 C.F.R. § 488.438(e). The limitations are: (1) I may not set the CMP at zero or reduce it to zero; (2) I may not review the exercise of discretion by CMS in selecting to impose a CMP; and (3) I may only consider the factors specified by 42 C.F.R. § 488.438(f) when determining the reasonableness of the CMP amount. In determining whether the amount of a CMP is reasonable, the following factors specified at 42 C.F.R. § 488.438(f) must be considered: (1) the facility's history of non-compliance, including repeated deficiencies; (2) the facility's financial condition; (3) the seriousness of the deficiencies as set forth at 42 C.F.R. § 488.404(b), the same factors CMS and/or the state were to consider when setting the CMP amount; and (4) the facility's degree of culpability, including but not limited to the facilities neglect, indifference, or disregard for resident care, comfort, and safety and the absence of culpability is not a mitigating factor. The factors that CMS and the state were required to consider when setting the CMP amount and that I am required to consider when assessing the reasonableness of the amount are set forth in 42 C.F.R. § 488.404(b): (1) whether the deficiencies caused no actual harm but had the potential for minimal harm, no actual harm with the potential for more than minimal harm, but not immediate jeopardy, actual harm that is not immediate jeopardy, or immediate jeopardy to resident health and safety; and (2) whether the deficiencies are isolated, constitute a pattern, or are widespread. My review of the reasonableness of the CMP is de novo and based upon the evidence in the record before me. I am not bound to defer to the CMS determination of the reasonable amount of the CMP to impose but my authority is limited by regulation as already

explained. I am to determine whether the amount of any CMP proposed is within reasonable bounds considering the purpose of the Act and regulations. *Emerald Oaks,* DAB No. 1800, at 10; *CarePlex of Silver Spring*, DAB No. 1683, at 17–18 (1999); *Capitol Hill Cmty. Rehab. & Splty. Care Ctr.*, DAB No. 1629 (1997).

I conclude, based on my review of the regulatory factors, that the CMP of $6,050 per day proposed by CMS for the 53 days of immediate jeopardy from September 23 through November 14, 2011 is reasonable in this case.

The evidence shows that Petitioner has been found not in substantial compliance on prior surveys dating to February 2007. The evidence shows one prior survey that was completed on March 1, 2011, that involved a declaration of immediate jeopardy. Petitioner returned to substantial compliance by April 1, 2011. Remedies were imposed for the immediate jeopardy level noncompliance found by the March 1, 2011 survey. There is no evidence of immediate jeopardy or of remedies being imposed for any survey other than the March 1, 2011 survey and the survey presently before me. The evidence does not reflect prior noncompliance under Tags F279, F281, or F323 or other repeated deficiencies. CMS Ex. 2. I accord this factor little weight in deciding the reasonableness of the CMP.

Petitioner has not presented evidence that it is unable to pay a total CMP of $320,650.

The noncompliance is based on three regulatory violations and is serious. The noncompliance posed immediate jeopardy for Petitioner's residents for 53 days. The surveyors found that multiple residents were subject to immediate jeopardy and concluded that there was a pattern of noncompliance. Petitioner's evidence does not rebut the surveyors' findings. Petitioner submitted the KARDEX's for the residents cited as examples in the survey in addition Resident 3. P. Ex. 14. Those KARDEX's provide little more information than the KARDEX in effect for Resident 3 at the time of her fall and the survey. The KARDEX's show whether a tub bath, bed bath, or shower was to be performed by a CNA and the number of staff required to assist. The KARDEX's do not show what further assessments were done or interventions were planned by the IDT for shower safety for the residents. While the interventions listed on the KARDEX may be adequate, Petitioner has not met its burden to present evidence to prove the interventions are adequate for the individual residents. The seriousness of Petitioner's noncompliance is also evidenced by the actual harm that Resident 3 suffered.

I also conclude that Petitioner was culpable for its noncompliance. The hazards associated with shower rooms in long-term care facilities are readily recognized by all involved in the delivery of care and services to long-term care residents. Slips and falls are a clearly foreseeable consequence of inadequate assessment and care planning to address the foreseeable risk of harm from falls in the shower. In the case of Resident 3, Petitioner's policy required that CNAs use shower chairs absent other direction. P. Br. at

14; P. Reply at 9. Resident 3 was assessed as at risk to lean forward when sitting upright, as she would be required to do in a shower chair. However, there is no evidence that Petitioner ensured that the IDT for Resident 3 assessed her and considered the risks of the shower room and her tendency to lean forward when sitting upright. There is no evidence that the IDT then devised appropriate interventions to mitigate or eliminate the accident hazard and the related risk for harm.

III. Conclusion

For the foregoing reasons, I conclude that Petitioner was not in substantial compliance with program participation requirements and a CMP of $6,050 per day for the 53 days from September 23 through November 14, 2011, a total CMP of $320,650, is a reasonable enforcement remedy. Petitioner was ineligible to be approved to conduct a NATCEP for two years based upon the CMP imposed.

/s/

Keith W. Sickendick
Administrative Law Judge