Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Lake County Nursing & Rehabilitation Center,
(CCN: 15-5653),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-13-1399

Decision No. CR3804

Date: April 21, 2015

DECISION

Petitioner, Lake County Nursing & Rehabilitation Center, was not in substantial compliance with program participation requirements from July 20, 2013 through August 19, 2013, based on violations of 42 C.F.R. §§ 483.10(b)(11) and 483.25(l).[1] There is a basis for the imposition of enforcement remedies. The following enforcement remedies are reasonable: a civil money penalty (CMP) of $3,650 per day for 12 days of immediate jeopardy and a CMP of $100 per day for 19 days of noncompliance that did not pose immediate jeopardy but posed a risk for more than minimal harm without actual injury, a total CMP of $45,700.

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[1] Citations are to the 2012 revision of the Code of Federal Regulations (C.F.R.), unless otherwise stated.

I. Background

Petitioner is located in East Chicago, Indiana and participates in Medicare as a skilled nursing facility (SNF) and the state Medicaid program as a nursing facility (NF). On July 31 and August 1, 2013, Petitioner was surveyed by the Indiana State Department of Health (state agency) and found not in substantial compliance with program participation requirements due to two regulatory violations. Joint Stipulation of Facts (Jt. Stip.) ¶¶ 1-7.

The Centers for Medicare & Medicaid Services (CMS) notified Petitioner on August 16, 2013, that it was imposing the following enforcement remedies: termination of Petitioner's provider agreement, unless the facility achieved substantial compliance before February 1, 2014; CMPs in the amount of $3,650 per day for 12 days beginning July 20, 2013 and continuing through July 31, 2013 and $100 per day beginning August 1, 2013 and continuing until Petitioner returned to substantial compliance or was terminated; and a denial of payment for new admissions (DPNA) beginning November 1, 2013. Petitioner was also advised that it was prohibited from offering a nurse aide training and competency evaluation program (NATCEP) for a period of two years beginning August 1, 2013, because a partial extended survey was conducted. CMS Exhibit (Ex.) 4 at 1-4. Petitioner returned to substantial compliance with program participation requirements on August 19, 2013, and the termination and DPNA were not effectuated. CMS Ex. 46.

Petitioner requested a hearing before an administrative law judge (ALJ) on September 25, 2013. The case was assigned to me for hearing and decision on September 30, 2013, and an Acknowledgement and Prehearing Order (Prehearing Order) was issued at my direction. A hearing was convened on June 24, 2014, and a transcript (Tr.) was prepared. CMS called Surveyor Lara Richards, RN to testify. Tr. 73; CMS Ex. 55. CMS offered and I admitted CMS Exs. 1 through 30, 32 through 49, and 51 through 56. Tr. 32-54, 156. Petitioner offered and I admitted Petitioner's exhibits (P. Exs.) 1 through 10. Tr. 55-58. The parties filed post-hearing briefs (CMS Br. and P. Br.) and reply briefs (CMS Reply and P. Reply).

II. Discussion

A. Issues

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

Whether the remedy imposed is reasonable.

B. Applicable Law

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

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

The 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, $3,050 per day to $10,000 per day, is reserved for deficiencies that pose immediate jeopardy to a facility's residents and, in some circumstances, for repeated deficiencies. 42 C.F.R. § 488.438(a)(1)(i), (d)(2). "*Immediate jeopardy* means a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301 (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). CMS is also authorized to impose a per instance CMP for each instance that a facility is not in substantial compliance, whether or not the deficiency poses immediate jeopardy. 42 C.F.R. § 488.430(a). The authorized range for a per instance CMP is $1,000 to $10,000. 42 C.F.R. § 488.438(a)(2).

CMS notified Petitioner in its letter dated August 16, 2013, that Petitioner was ineligible to be approved to conduct a NATCEP for two years because a partial extended survey was conducted. CMS Ex. 4 at 4. 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 SNF or NF that has been: (1) subject to an extended or partial extended survey under sections 1819(g)(2)(B)(i) or 1919(g)(2)(B)(i) of the Act; (2) assessed a CMP of not less than $5,000; or (3) subject to termination of its participation agreement, a DPNA, or the appointment of temporary management. Extended and partial extended surveys are triggered by a finding of "substandard quality of care" during a standard or abbreviated standard survey and involve evaluating additional participation requirements. "Substandard quality of care" is identified by the situation where surveyors identify one or more deficiencies related to participation requirements established by 42 C.F.R. §§ 483.13 (Resident Behavior and Facility Practices), § 483.15 (Quality of Life), or § 483.25 (Quality of Care) that are found to constitute either immediate jeopardy, a pattern of or widespread actual harm that does not amount to immediate jeopardy, or a widespread potential for more than minimal harm that does not amount to immediate jeopardy and there is no actual harm. 42 C.F.R. § 488.301.

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). 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), (16), (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 hearing before an ALJ is a de novo proceeding, that is, "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 Board has long held that the 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, *aff'd*, *Batavia Nursing & Convalescent Ctr. v. Thompson*, 129 F. App'x 181 (6th Cir. 2005); *Emerald Oaks*, DAB No. 1800 (2001); *Cross Creek Health Care Ctr.*, DAB No. 1665 (1998); *Hillman Rehab. Ctr.*, DAB No. 1611 (1997) (remand to ALJ), DAB No. 1663 (1998) (after remand), *aff'd*, *Hillman Rehab. Ctr. v. United States*, No. 98-3789 (GEB), 1999 WL 34813783 (D.N.J. May 13, 1999). However, only when CMS makes a prima facie showing of noncompliance, is the facility burdened to show, by a preponderance of the evidence on the record as a whole, that it was in substantial compliance or had an affirmative defense. *Evergreene Nursing Care Ctr.*, DAB No. 2069 at 4 (2007).

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 imposing an enforcement remedy. The Board has stated that CMS must come forward with "evidence related to disputed findings that is sufficient (together with any undisputed findings and relevant legal authority) to establish a prima facie case of noncompliance with a regulatory requirement." *Evergreene Nursing Care Ctr.*, DAB No. 2069 at 7; *Batavia Nursing & Convalescent Ctr.*, DAB No 1904. "Prima facie" means generally that the evidence is "[s]ufficient to establish a fact or raise a

presumption unless disproved or rebutted." *Black's Law Dictionary* 1228 (8th ed. 2004). In *Hillman Rehab. Ctr.*, the Board described the elements of the CMS prima facie case in general terms as follows:

> HCFA [now known as CMS] must identify the legal criteria to which it seeks to hold a provider. Moreover, to the extent that a provider challenges HCFA's findings, HCFA must come forward with evidence of the basis for its determination, including the factual findings on which HCFA is relying and, if HCFA has determined that a condition of participation was not met, HCFA's evaluation that the deficiencies found meet the regulatory standard for a condition-level deficiency.

DAB No. 1611 at 8. Thus, CMS has the initial burden of coming forward with sufficient evidence to show that its decision to impose an enforcement remedy is legally sufficient under the statute and regulations. To make a prima facie case that its decision was legally sufficient, CMS must: (1) identify the statute, regulation or other legal criteria to which it seeks to hold the petitioner; (2) come forward with evidence upon which it relies for its factual conclusions that are disputed by the petitioner; and (3) show how the deficiencies it found amount to noncompliance that warrants an enforcement remedy; that is, that there was a risk for more than minimal harm due to the regulatory violation. In *Evergreene Nursing Care Ctr.*, the Board explained its "well-established framework for allocating the burden of proof on the issue of whether a SNF is out of substantial compliance" as follows:

> CMS has the burden of coming forward with evidence related to disputed findings that is sufficient (together with any undisputed findings and relevant legal authority) to establish a prima facie case of noncompliance with a regulatory requirement. If CMS makes this prima facie showing, then the SNF must carry its ultimate burden of persuasion by showing, by a preponderance of the evidence, on the record as a whole, that it was in substantial compliance during the relevant period.

DAB No. 2069 at 7. CMS makes a prima facie showing of noncompliance if the credible evidence CMS relies on is sufficient to support a decision in its favor absent an effective rebuttal. The regulation gives Petitioner notice of the criteria or elements it must meet to comply with the program participation requirement established by the regulation. 5 U.S.C. §§ 551(4), 552(a)(1). Therefore, in order to make a prima facie showing of noncompliance, CMS must show that Petitioner violated the regulation by not complying with one or more of the criteria or elements of the regulation, which is a deficiency. CMS must also show that the deficiency amounted to "noncompliance," that

is, that Petitioner was not in substantial compliance because the deficiency posed a risk for more than minimal harm. *See Jennifer Matthew Nursing & Rehab. Ctr.*, DAB No. 2192 at 20 n.12 (2008). A facility can overcome CMS's prima facie case either by rebutting the evidence upon which that case rests, or by proving facts that affirmatively show substantial compliance. "An effective rebuttal of CMS's prima facie case would mean that at the close of the evidence the provider had shown that the facts on which its case depended (that is, for which it had the burden of proof) were supported by a preponderance of the evidence." *Evergreene Nursing Care Ctr.*, DAB No. 2069 at 7-8 (citations omitted).

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

My conclusions of law are set forth in bold text followed by my findings of fact and analysis. I have carefully considered all the evidence and the arguments of both parties, though not all may be specifically discussed in this decision. I discuss in this decision the credible evidence given the greatest weight in my decision-making.[3] I also discuss any evidence that I find is not credible or worthy of weight. The fact that 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. Charles H. Koch, Jr., *Admin. L. and Prac.* § 5:64 (3d ed. 2013).

The state agency cited Petitioner with the following deficiencies based on the complaint survey completed on August 1, 2013: 42 C.F.R. §§ 483.10(b)(11) (Tag F157,[4] scope and

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[3] "Credible evidence" is evidence that is worthy of belief. *Black's Law Dictionary* 596 (8th ed. 2004). The "weight of evidence" is the persuasiveness of some evidence compared to other evidence. *Id*. at 1625.

[4] This is a "Tag" designation as used in CMS Publication 100-07, State Operations Manual (SOM), app. PP – Guidance to Surveyors for Long Term Care Facilities (http://www.cms.hhs.gov/Manuals/IOM/list.asp). The "Tag" refers to the specific regulatory provision allegedly violated and CMS's policy guidance to surveyors. Although the SOM does not have the force and effect of law, the provisions of the Act and regulations interpreted clearly do have such force and effect. *Ind. Dep't of Pub. Welfare v. Sullivan*, 934 F.2d 853 (7th Cir. 1991); *Northwest Tissue Ctr. v. Shalala*, 1 F.3d 522 (7th Cir. 1993). Thus, while the Secretary may not seek to enforce the provisions of the SOM, she may seek to enforce the provisions of the Act or regulations as interpreted by the SOM.

severity level (s/s) D[5]); and 483.25(l) (Tag F329, s/s J). CMS Exs. 1 - 2. CMS proposes a per-day CMP of $3,650 for 12 days of immediate jeopardy and a per-day CMP in the amount of $100 for 19 days of noncompliance that did not pose immediate jeopardy, a total CMP of $45,700. The finding of substandard quality of care that triggered the partial extended survey and the ineligibility to conduct a NATCEP was the noncompliance under 42 C.F.R. § 483.25(l) (Tag F329), which the surveyors concluded posed immediate jeopardy.

1. CMS has made a prima facie showing that Petitioner violated 42 C.F.R. § 483.10(b)(11) (Tag F157).

2. The violation of 42 C.F.R. § 483.10(b)(11) posed a risk for more than minimal harm and amounted to noncompliance.

3. Petitioner has failed to rebut the prima facie showing of noncompliance or establish an affirmative defense.

a. Facts

The deficiency cited under Tag F157 cites examples related to both Resident B and Resident H. The deficiency cited under Tag F329, cites only the example of Resident B.

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[5] Scope and severity levels are used by CMS and a state when selecting remedies. The scope and severity level is designated by an alpha character, A through L, selected by CMS or the state agency from the scope and severity matrix published in the SOM, chap. 7, § 7400.5 (Sep. 10, 2010). A scope and severity level of A, B, or C indicates a deficiency that presents no actual harm but has the potential for minimal harm, which is an insufficient basis for imposing an enforcement remedy. Facilities with deficiencies of a level no greater than C remain in substantial compliance. 42 C.F.R. § 488.301. A scope and severity level of D, E, or F indicates a deficiency that presents no actual harm but has the potential for more than minimal harm that does not amount to immediate jeopardy. A scope and severity level of G, H, or I indicates a deficiency that involves actual harm that does not amount to immediate jeopardy. Scope and severity levels J, K, or L indicate deficiencies that constitute immediate jeopardy to resident health or safety. The matrix, which is based on 42 C.F.R. § 488.408, specifies which remedies are required and optional at each level based upon the frequency of the deficiency.

(i.) Resident B.

The survey was triggered by the July 25, 2013 complaint of Resident B's father to the state agency. Resident B's father complained that Resident B's peripherally inserted central catheter (PICC or PICC line) started bleeding sometime during the afternoon on July 19, 2013; the dressing on the PICC line site was changed twice and subsequently wrapped with a towel; bleeding continued through the night; Resident B was finally sent to the emergency room on July 20, 2013, where she required a blood transfusion because she had bled so much; and Resident B's call light was not answered for as long as one and one-half hours. CMS Ex. 16.

Surveyor Richards identified progress notes for Resident B obtained from Petitioner during the survey and admitted at hearing without objection as CMS Ex. 19. Tr. 89, 91-92. A progress note at 12:30 a.m. on July 20, 2013, by RN Thomas Arnett, indicates that the pressure dressing on Resident B's PICC line site had to be changed due to continued bleeding. The note states 10 to 15 milliliters of blood were noted. It was also concluded based on observation of over a minute that the bleeding had stopped. Roughly three hours later, at 3:30 a.m., a progress note entered by Morgan Goldman, states that Resident B called the nurse to her room and pointed out bleeding at the PICC line site. The nurse recorded that there was a moderate amount of blood; she applied pressure, cleaned the site, and applied a new pressure dressing. Nurse Goldman checked the resident at about 3:44 a.m. and observed the dressing to the PICC line site was intact with no drainage. CMS Ex. 19 at 2; P. Ex. 7 at 23. A progress note at 4:31 a.m. on July 20, 2013, by Nurse Goldman indicates that the dressing was intact with no drainage. However, a note at 6:34 a.m. on July 20, 2013, indicates Resident B again called Nurse Goldman to her room, and the nurse observed a moderate amount of blood from the resident's PICC site. Pressure was applied, the site cleaned; a new pressure dressing was applied. A note at 7:20 a.m. indicates that during the report meeting between the day nurse, Nicole Coley, LPN, and the night nurse, the midnight nurse reported that Resident B had saturated three PICC site dressings; the resident was on Coumadin®; and the resident had a critical hemoglobin approximately two weeks prior. The note states that the nurse attempted to call Dr. Desal, but there was no answer and so she called and texted Dr. Sarma. A note at 7:35 a.m. indicates that LPN Coley observed another nurse remove an old saturated dressing from Resident B and that the resident did not complain of fatigue or lightheadedness. LPN Coley's note at 7:47 a.m. states she noted a small amount of blood coming through the pressure dressing. LPN Coley either called Dr. Patel or was called by Dr. Patel (the note is not clear on this point), and he ordered that Resident B be sent to the emergency room. A subsequent progress note at 10:39 a.m. states that Resident B was admitted to the hospital for a critical "PT/INR" and "critical hemoglobin." A note at 3:41 p.m. indicates that Resident B had received two bags of blood. CMS Ex. 19 at 1; P. Ex. 7 at 22. Progress notes for Resident B placed in evidence by Petitioner show that bleeding from the PICC line site was observed on July 19, 2013 and reported at 10:45 p.m. on July 19, 2013. P. Ex. 4 at 1.

There is no dispute that at the time of the bleeding from the PICC site on July 19 and 20, 2013, Resident B had orders to receive 12 milligrams (mg.) of Coumadin® every evening and one 81 mg. tablet of aspirin each day. CMS Ex. 20 at 1-2. Emergency room records from July 20, 2013, show that Resident B was assessed as suffering from coagulopathy due to long-term anticoagulant therapy, Coumadin® toxicity, and anemia due to blood loss. CMS Ex. 23 at 5-6.

Surveyor Richards identified her notes that she prepared based on her review of Resident B's clinical records, which were admitted without objection as CMS Ex. 18. Tr. 89. She testified based on her notes that Resident B's physician had ordered PT/INR testing to be done monthly on the first Monday of the month. She testified the purpose of PT/INR testing is to monitor the ability of blood to clot. Tr. 99-101. Her testimony is consistent with the order for PT/INR testing placed in evidence by Petitioner. P. Ex. 7 at 9. Surveyor Richards testified that she cited Petitioner for failure to have PT/INR testing done as ordered because the last evidence of testing was May 31, 2013, and there was no evidence of testing between May 31, 2013 and when the bleeding from the PICC line site was observed on July 19, 2013, except for testing by the physician on July 10, 2013. She testified that because Resident B's dosage of Coumadin® was increased on June 5, 2013, there was an increased risk for bleeding if her Coumadin® level was not within the therapeutic range. Tr. 102-04. She testified that she was given a document showing that a PT/INR was done at the physician's office on July 10, 2013. CMS Ex. 24; Tr. 153. Surveyor Richards testified that the citation under Tag F157 for failure to consult the physician was based on the failure to contact Resident B's physician between 10:45 p.m. on July 19 and 7:20 a.m. on July 20, 2013. Tr. 123-24. Petitioner concedes that no PT/INR testing was done on July 1, 2013. P. Br. at 2.

I advised the parties at hearing that I took judicial notice of the 2013 calendar, specifically noting that May 31, 2013 was Friday, and June 3 and July 1, 2013 were first Mondays of those months. Tr. 163. Surveyor Richards testified that she did not see any laboratory requisition for Resident B for June 3 or July 1, 2013. Tr. 164-66.

Petitioner offered as evidence a letter dated August 19, 2013, from Surendra J. Shah, M.D. The copies of the letter offered were marked as P. Ex. 2 and P. Ex. 7 at 25. CMS did not object to the admissibility of the copies of the document on grounds that they were unsworn or that Dr. Shah was not available for cross-examination. Both copies of the document were admitted as evidence. Dr. Shah states he was Resident B's primary physician. He opines that the bleeding at Resident B's PICC line site on July 19 and 20, 2013, was not the reason she needed two units of blood when she was admitted to the hospital on July 20. Dr. Shah states that Resident B had "multiple morbidities," including chronic anemia due to uterine fibroids. Dr. Shah reveals that Resident B was admitted to the hospital in August 2013, and the problem of the uterine fibroids was addressed. P. Ex. 2; P. Ex. 7 at 25. I do not accord weight to Dr. Shah's opinion that the PICC line site bleeding was not the reason, or at least a contributing factor, to Resident

B's need for a blood transfusion in July 2013. Dr. Shah does not explain the basis for his opinion. He did not testify; thus, he was not subject to examination at the hearing where the basis for his opinion could have been revealed and tested. Dr. Shah mentions that Resident B had chronic anemia due to uterine fibroids. However, he does not explain the connection between the diagnoses of anemia and uterine fibroids and how those diagnoses may have caused the resident to require a blood transfusion. Medical diagnoses are matters for medical professionals. I am not a medical expert, and I am not qualified to draw any inferences based on the diagnoses Dr. Shah mentions. The attorneys for the parties, who are not witnesses and not qualified as medical experts, are similarly unqualified to draw inferences based on the medical diagnoses. However, even if I accept that Dr. Shah was suggesting that the diagnoses of uterine fibroids and chronic anemia support an inference or is evidence that Resident B also had uterine bleeding, Dr. Shah does not explain why he completely discounted the PICC line site bleeding as the cause or contributing factor for the need for the blood transfusion. The records do not show, and Dr. Shah does not state that he even examined the resident during her hospitalization on July 20, 2013. The only hospital records in evidence for the July 20, 2013 admission list K. Patel, M.D. as the physician attending to Resident B. CMS Ex. 23 at 1, 6. The hospital record shows an assessment of anemia due to acute blood loss (CMS Ex. 23 at 5), but the hospital records do not mention uterine fibroids or link the acute blood loss to uterine fibroids (CMS Ex. 23 at 5-6).

Petitioner offered as evidence a hospital record dated May 15, 2013, which shows that Resident B was admitted for a high fever and assessed as having a large pressure ulcer on her coccyx, as being anemic, and in need of a blood transfusion. The record indicates that Resident B had multiple comorbidities, but there is no mention of uterine fibroids or other cause for Resident B's anemia. P. Ex. 7 at 11-14.

Petitioner presented evidence that Resident B was again admitted to the hospital on July 30, 2013, which was the day prior to the survey. Hospital records for her admission on July 30, 2013, show that she was admitted for complaints of dark stool and vomiting. Her stool tested positive for the presence of blood. P. Ex. 7 at 18. On July 31, 2013, Resident B was assessed as having an acute GI bleed, diabetes mellitus, cardiomyopathy, a history of a cerebral vascular accident, and a chronic pressure ulcer on her coccyx. P. Ex. 7 at 20. On August 1, 2013, the resident had a transabdominal and transvaginal pelvic ultrasound with findings that she had several small fibroids. P. Ex. 7 at 19-20. An Internal Medicine Progress Note dated August 4, 2013, which appears to be part of a longer note, indicates that Resident B and her father were advised by Dr. Shah in detail about the resident's large fibroid and heavy menstrual bleeding. The note further indicates that Resident B was scheduled for embolization of her uterine artery. P. Ex. 7 at 16. On August 5, 2013, Resident B had a left uterine artery embolization. P. Ex. 7 at 17. The records from Resident B's hospitalization in late July and early August 2013 show that she was assessed as suffering a GI bleed, uterine fibroids, and having a history

of heavy menstrual bleeding. However, those records do not support an inference that the need for the transfusion on July 20, 2013, was due to a GI bleed, uterine fibroids, or heavy menstrual bleeding, rather than the bleeding from the PICC line site.

(ii.) Resident H

Surveyor Yolanda Love who conducted the review related to Resident H was not called to testify at hearing by CMS. CMS Ex. 28. CMS presented no testimony related to the example of Resident H alleged under Tag F157. However, documentary evidence from Petitioner's clinical records for Resident H was presented. Resident H had an order dated June 4, 2013, for warfarin, the generic form of Coumadin®, 4 mg. per day. CMS Ex. 29 at 4. She also had an order for PT/INR testing every Monday due to her long-term anticoagulant use. CMS Ex. 44. A medication flow sheet for Resident H records an order for the period June 24, 2013 to July 1, 2013, which states that the resident had long-term use of coagulants; her Coumadin® was to be held for one week; and her PT/INR test was to be repeated on Monday, July 1, 2013. CMS Ex. 29 at 1. The order is also noted on a laboratory report for PT/INR dated June 24, 2013. CMS Ex. 30 at 7. A laboratory report dated July 1, 2013, reflects the physician's order to resume Coumadin® at 4 mg. CMS Ex. 30 at 8-9. A laboratory report dated July 9, 2013, reflects an order to hold Coumadin® for three days and then repeat the PT/INR test. The PT/INR was done on July 12, 2013, and the laboratory report reflects that both the PT and INR were reported low, that is, below the laboratory reference range. A notation on the report indicates that the physician noted the report on July 15, 2013, at which time he ordered that Coumadin® 4 mg. be restarted. CMS Ex. 30 at 11. PT/INR testing was also reported on July 15, 2013, with the PT and INR both below the laboratory reference ranges and lower than reported on July 12, 2013. A notation on the laboratory report also indicates that the physician noted this report on July 15, 2013, and ordered resumption of Coumadin® at 4 mg. CMS Ex. 30 at 12.

b. Analysis

Following the presentation of the CMS case, Petitioner moved for a judgment, similar to a motion for judgment on partial findings such as authorized under Fed. R. Civ. Pro. 52(c). Petitioner cited as grounds that CMS failed to make a prima facie showing of noncompliance and the scope and severity alleged. I deferred a ruling until such time as the parties could file proposed findings of fact and conclusions of law and their briefs, and I could issue written findings and conclusions as required by 5 U.S.C. § 557(c) and 42 C.F.R. § 498.74(a). Tr. 170-76. Petitioner's motion is denied for the reasons discussed hereafter.

Petitioner also renewed an objection to my consideration of CMS Exs. 51 through 54. Tr. 41-51, 173. The documents are all printed from internet resources. There is no real challenge to the authenticity of the documents, and they are what they appear to be.

There is also no challenge to the relevance of the documents. Because the documents are relevant and authentic, they may be admitted as evidence. However, I give the documents no weight in deciding this case as competent expert medical testimony would be necessary for me to assess the appropriate weight of the scientific evidence.

I conclude that CMS made a prima facie showing that Petitioner violated 42 C.F.R. § 483.10(b)(11) in the cases of Residents B and H. and that the violation posed a risk for more than minimal harm. I further conclude that Petitioner failed to rebut the prima facie showing.

A long-term care facility is required to recognize certain resident rights specified by the Act and the Secretary's regulations. Section 483.10(b)(11)(i) of 42 C.F.R. entitled "Resident rights" requires:

> (11) Notification of changes. (i) A facility must immediately inform the resident; consult with the resident's physician; and if known, notify the resident's legal respresentative (sic) or an interested family member when there is –
>
> (A) An accident involving the resident which results in injury and has the potential for requiring physician intervention;
>
> (B) A significant change in the resident's physical, mental, or psychosocial status (i.e., a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications);
>
> (C) A need to alter treatment significantly (i.e., a need to discontinue an existing form of treatment due to adverse consequences, or to commence a new form of treatment); or
>
> (D) A decision to transfer or discharge the resident from the facility as specified in Sec. 483.12(a).

42 C.F.R. § 483.10(b)(11)(i). The language of the regulation is very specific that the facility "**must immediately inform** the resident; **consult** with the resident's physician; and . . . **notify** the resident's legal respresentative (sic) or an interested family member." 42 C.F.R. § 483.10(b)(11)(i) (emphasis added). The regulation creates a distinction between informing the resident and family and the requirement that Petitioner "**must immediately . . . consult with the resident's physician**" when there is: a significant change in the resident's physical, mental, or psychosocial status (meaning a deterioration

in the resident's condition); an accident that may require physician intervention; a need to alter treatment; or a decision to transfer or discharge the resident to another facility or institution. *Id.* (emphasis added). It is clear from the regulatory language that the requirement to consult is not discretionary and requires more than merely informing or notifying the physician. The preamble to the final rule reflects the drafters' specific intention that the facility should "inform" the resident of the changes that have occurred but should "consult with the physician about actions that are needed." 56 Fed. Reg. 48,826, 48,833 (Sept. 26, 1991).

Thus, it is clear from the language of the regulation and its history that the requirement of the regulation to consult with the physician means more than to simply notify the physician. Consultation implies the requirement for a dialogue with and a responsive directive from the resident's physician as to what actions are needed; it is not enough to merely notify the physician. Nor is it enough to leave a message for the physician. The regulation also requires notification and consultation "immediately" upon perceiving a change in condition of the resident, the occurrence of an accident that may require physician intervention, or the occurrence of any of the other triggers in the regulation. The use of the term "immediately" in the regulatory requirement indicates that consultation is expected to be done as soon as the change is detected, without any intervening interval of time. It does not mean that the facility can wait hours or days before notification of the resident and his or her representative and consultation with the physician. The preamble to the final rule indicates that originally the proposed rule granted the facility up to 24 hours in which to consult with the resident's physician and to notify the legal representative or family. However, after the receipt of comments that time is of the essence in such circumstances, the final rule amended that provision to require that the physician be consulted and the legal representative or family be notified immediately. 56 Fed. Reg. 48,826, 48,833 (Sept. 26, 1991). The point of using the word "immediately" is to recognize that in such situations, a delay could result in a situation where a resident is beyond recovery or dies. The Board has been consistent in its interpretation of the regulation that consultation with a physician must occur immediately, that is, without delay, after a significant change is detected or observed. *Magnolia Estates Skilled Care*, DAB No. 2228 at 9 (2009).

Furthermore, if we balance the relative inconvenience to a physician and the facility staff to consult with the possibility for dire consequences to the resident if the physician is not consulted, it seems that any inconvenience certainly is inconsequential and outweighed by the potential for significant harm if the facility fails to consult the physician. The regulation is entitled "Resident rights," and the requirements of this specific regulation provide that every resident has the right to a dignified existence and access to and communication with persons and services inside and outside the facility. Therefore, the regulatory requirements make inconsequential any inconvenience under the regulation to the resident's physician or the facility staff when compared to the protection and facilitation of the rights of the resident. *See* 56 Fed. Reg. 48,826, 48,834. Finally, the

regulation does not allow the facility to pick and choose whom to notify and whom to consult. Rather, it requires the facility to immediately inform the resident, consult the physician, and notify the resident's legal representative or interested family member. The regulation also directly burdens the facility to consult and notify and does not permit a facility to rely upon a notification or consultation being accomplished by the resident or a third party such as an emergency room.

The surveyors allege in the Statement of Deficiencies (SOD) for the survey completed on August 1, 2013, that Petitioner violated 42 C.F.R. § 483.10(b)(11) because Petitioner's staff failed to consult Resident B's physician "following a change in condition related to bleeding from a peripherally inserted central catheter (PICC) line." CMS Ex. 2 at 3-4. The surveyors also allege that staff failed to ensure that Resident H's physician was timely notified of PT/INR test results. CMS Ex. 2 at 4.

The evidence shows that on July 19 and 20, 2013, Resident B was receiving blood thinner, which affected the ability of her blood to clot. CMS Ex. 20 at 1-2; Tr. 99-101. On July 19, 2013 at about 10:45 p.m., staff discovered bleeding from the site on Resident B's arm where her PICC line was inserted. Bleeding was observed at about 12:30 a.m. on July 20, 2013, that caused staff to change the pressure dressing on the PICC line site. Approximately three hours later, bleeding was observed again and a new pressure dressing was applied. At about 6:54 a.m. on July 20, 2013, bleeding was observed again and a third new dressing was applied to the PICC line site. CMS Ex. 19 at 1-2. It is undisputed that there is no evidence that staff attempted to consult with Resident B's physician about the bleeding from the PICC line site before 7:20 a.m. on July 20, 2013, despite bleeding of such quantity to require repeated dressing changes between 10:45 p.m. on July 19 and 6:54 a.m. on July 20, 2013. It is undisputed that at about 7:20 a.m. on July 20, 2013, during the shift change report between the day and night nurses, it was reported to the day nurse that Resident B had saturated three dressings on the PICC line site, the resident was on Coumadin®, and the resident had a critical hemoglobin approximately two weeks prior. The day nurse promptly attempted to contact two different physicians. The day nurse then observed a dressing change at about 7:35 a.m. and described the old dressing as saturated. At 7:47 a.m., the day nurse observed the dressing and noted a small amount of blood seeping through. At an unspecified time following her 7:47 a.m. observation, the day nurse finally consulted with a third physician who ordered that Resident B be sent to the emergency room. CMS Ex. 19 at 1. Hospital records show that Resident B was assessed as suffering from coagulopathy (that is, her blood would not clot), and anemia due to blood loss. Resident B required a blood transfusion. CMS Ex. 19 at 1; CMS Ex. 23 at 5-6.

I conclude that the undisputed facts and the CMS evidence are sufficient for a prima facie showing of noncompliance based on a violation of 42 C.F.R. § 483.10(b)(11) and the resulting risk for more than minimal harm due to the violation.[6] Both 42 C.F.R. § 483.10(b)(11)(i)(B) and (C) are violated in this case.

Consultation with a physician is required under 42 C.F.R. § 483.10(b)(11)(i)(B) when there is a significant change in the resident's physical status. The regulation provides examples, which include deterioration in health with life-threatening conditions or clinical complications. It is clear that the day nurse recognized that she needed to consult with a physician about Resident B's continued bleeding from her PICC site, even though it took 27 minutes for her to find a physician to consult with. It does not take a medical expert to appreciate that bleeding over an extended period can have significant adverse health consequences including death, particularly when bleeding is of sufficient quantity to require repeated dressing changes and caused a nurse to characterize a dressing as being saturated. Further, the night nurse advised the day nurse that Resident B had a critical hemoglobin event approximately two weeks prior, which shows the night nurse appreciated that Resident B's continued bleeding posed some risk for another critical hemoglobin event. Based on the facts, it was clear that a physician should have been consulted immediately when continued bleeding was observed, at least after bleeding occurred again following the first attempt to stop the bleeding at about 10:45 p.m. on July 19, 2013 and before the day nurse finally consulted a physician on July 20, 2013 at about 7:47 a.m. The night nurse was clearly aware that Resident B was on anticoagulant therapy and had a prior critical hemoglobin test. The night nurse should have recognized, based on facts she knew, that continued bleeding represented a deterioration that posed a life-threatening condition or a clinical complication due to the presence of the PICC line and continued anticoagulant therapy.

Even if one accepted Petitioner's position that the facts did not amount to a significant change in the resident's condition, 42 C.F.R. § 483.10(b)(11)(i)(C) requires consultation if there is a need to alter treatment significantly. Failure to stop bleeding, particularly in a resident with a prior critical hemoglobin test and on anticoagulant therapy, should have

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[6] The surveyors alleged in the SOD a scope and severity level of D for Tag F157; that is, there was a risk for more than minimal harm without actual harm or immediate jeopardy. The facts support a finding that Resident B suffered actual harm and was subject to immediate jeopardy due to blood loss that was sufficient to require a transfusion. However, it is not necessary for me to conclude that there was either actual harm or immediate jeopardy to conclude that there was noncompliance it is enough for me to conclude that there was a risk for more than minimal harm. The actual harm suffered by Resident B is, however, a fact considered in assessing the reasonableness of the enforcement remedy.

alerted staff to the possible need to alter treatment by discontinuing the current treatment of the resident and commencing a new treatment to stop the bleeding. The need to address Resident B's continued bleeding, in light of the other facts, should have been sufficient to cause the night nurse to immediately consult with a physician, rather than waiting several hours to convey the information to the day nurse.

The evidence shows no consultation occurred between 10:45 p.m. on July 19, 2013 and 7:47 a.m. on July 20, 2013. P. Ex. 7 at 22-23. The evidence shows that, under the regulation, consultation should have occurred. Accordingly, I conclude that CMS made a prima facie showing of a violation of 42 C.F.R. § 483.10(b)(11). I further conclude that CMS made a prima facie showing of a risk for more than minimal harm due to the regulatory violation, based on evidence that Resident B had to be hospitalized and treated for coagulopathy and transfused due to blood loss. CMS Ex. 23.

CMS has also made a prima facie showing of a violation of 42 C.F.R. § 483.10(b)(11) based on the documentary evidence related to Resident H that was obtained from Petitioner's clinical records during the survey. The evidence shows that Resident H was on anticoagulant therapy, specifically, warfarin. CMS Ex. 29 at 4. Resident H was to be tested every Monday to determine the ability of her blood to clot. CMS Ex. 44. The documents, specifically laboratory reports, contain notations that show that Resident H's physician was promptly reviewing the weekly laboratory reports and starting or stopping the resident's anticoagulant therapy. I infer that the physician took these actions to adjust the effect of the therapy. On July 12, 2013, the laboratory report showed that the anticoagulant result was low. However, it was not until July 15, 2013, that there is evidence that the physician was consulted about whether to restart the anticoagulant which the physician had ordered held on July 9, 2013. CMS Ex. 30 at 7-12. Based on the fact that the physician was closely monitoring and starting or stopping Resident H's anticoagulant, I conclude that the low test results on July 12, 2013, reflected a significant change in Resident H's condition that should have triggered an immediate consult with the resident's physician. There is no dispute that the consultation did not occur until July 15, 2013, after another blood test showed even lower results which resulted in an order to resume the anticoagulant. I also conclude that, as demonstrated by the facts related to Resident B, the failure to consult with the physician posed a risk for more than minimal harm to Resident H due to the risk for uncontrollable bleeding. I conclude, based on the example of Resident H, that CMS made a prima facie showing of a violation of 42 C.F.R. § 483.10(b)(11)(i)(B) and (C) that posed a risk for more than minimal harm.

I further conclude that Petitioner failed to rebut the prima facie showing based on the examples of either Resident B or Resident H. Petitioner presented no evidence related to Resident H. The evidence presented by Petitioner related to Resident B does not show the absence of a significant change or that there was no need to significantly alter her treatment. In fact, the evidence presented by Petitioner supports my findings that Resident B was on long-term anticoagulant therapy, she previously required a blood

transfusion, and she was at risk for harm due to uncontrolled bleeding. Petitioner's evidence further shows that at the time of the survey, Resident B was hospitalized for an acute GI bleed. P. Ex. 7 at 20. Dr. Shah's revelation that Resident B was also at risk for bleeding due to uterine fibroids shows that Resident B was at an even higher risk for injury from blood loss than that posed by her bleeding PICC line site alone. Therefore, based on the evidence presented by Petitioner, it is apparent that staff should have recognized that any bleeding by Resident B was cause for an immediate consult with the physician to address a likely significant change or need to alter treatment.

4. CMS has made a prima facie showing that Petitioner violated 42 C.F.R. § 483.25(l).

5. The violation of 42 C.F.R. § 483.25(l) posed a risk for more than minimal harm and amounted to noncompliance.

6. Petitioner has failed to rebut the prima facie showing of noncompliance under Tag F329 or establish an affirmative defense.

7. Petitioner has failed to show that the declaration of immediate jeopardy was clearly erroneous.

a. Facts

This deficiency is cited based on the facts already set forth related to Resident B. This deficiency citation is specifically based on the fact that the resident had an order for PT/INR testing on the first Monday of each month, but the records produced by Petitioner's staff do not show testing was done as ordered on either the first Monday of June 2013 or the first Monday of July 2013. Tr. 99-104.

b. Analysis

Petitioner is required to ensure that each resident's drug regime is free of any unnecessary drugs. The regulation defines unnecessary drugs as drugs received in excessive dose, for excessive duration, without adequate monitoring, without adequate indications for use, in the presence of adverse consequences that indicate the dose of the drug should be reduced or discontinued, or for any combination of these reasons. 42 C.F.R. § 483.25(l)(1).

The surveyors allege in the SOD that Petitioner violated the regulatory requirement to ensure Resident B was free of unnecessary drugs because its staff failed to adequately monitor Resident B's blood thinner, specifically its anticoagulant effect, using PT/INR testing. CMS Ex. 2 at 10-18. The resident's physician ordered PT/INR testing the first Monday of each month. The physician's order is evidence that the physician determined that such monitoring of the anticoagulant effect of the resident's blood thinner therapy

was necessary. No laboratory reports reflecting PT/INR testing on June 3, 2013 or July 1, 2013, the first Mondays of those months, were produced during the survey, and none have been presented to me. Accordingly, I find that Petitioner failed to ensure that Resident B's blood thinner was monitored as ordered by her physician to ensure she was not receiving an unnecessary drug. I conclude that Petitioner violated 42 C.F.R. § 483.25(l)(1). I also conclude that the failure to conduct PT/INR testing as ordered posed a risk for more than minimal harm. Tr. 102-04.

There is evidence that Resident B's PT/INR was tested on May 31, 2013 and again on July 10, 2013. Tr. 102-04, 153; CMS Ex. 24. However, there is no evidence of the reason for those off-schedule tests or that they showed that the physician determined that they were adequate monitoring in lieu of the monitoring he ordered to occur on the first Monday of each month.

The surveyor alleged that the failure to monitor Resident B's PT/INR as ordered posed immediate jeopardy. CMS Ex. 2 at 10. 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 & 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. – Johnston 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 constituted immediate jeopardy. Rather, the burden is on the facility to show that that determination is clearly erroneous. *Cal Turner*, DAB No. 2384 at 14-15; *Liberty Commons Nursing & Rehab. Ctr. – Johnston*, 241 F. App'x 76 at 3-4.

Many appellate panels of the Board have addressed "immediate jeopardy."[7] In *Mississippi Care Ctr. of Greenville*, DAB No. 2450 at 15 (2012), the Board commented:

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[7] 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 (2007); *Britthaven of Havelock*, DAB

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> 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. 2031 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).

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,

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(Continued from preceding page.)

No. 2078 (2007); *Koester Pavilion*, DAB No. 1750; *Woodstock Care Ctr.*, DAB No. 1726 .

> 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. 56,116, 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 decisions in *Mississippi Care Ctr. of Greenville, Daughters of Miriam Ctr.*, and other cases 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." *Miss. Care Ctr. of Greenville,* DAB No. 2450 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 Procedure 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 Prods. of Cal., Inc. v. Constr. Laborers Pension Trust*, 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. *Consol. Edison v. NLRB*, 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.[8] *Dickinson*, 527 U.S. at 162 (citations omitted); *Concrete Pipe*, 508 U.S. at 622-23.

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[8] The Board's characterization of the clearly erroneous standard as being highly deferential to the fact-finding by the state agency surveyors 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.

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. of Tullahoma v. Sebelius*, 453 F. App'x 610. 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 Rehab. 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. 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 may be. *Woodstock Care Ctr.*, DAB No. 1726.

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.[9] The 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" and associated it with meanings

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[9] 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 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.

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, heals 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.

In the present case, Petitioner clearly failed to meet its heavy burden to show that the immediate jeopardy determination was clearly erroneous because Petitioner presented no evidence on the issue. Furthermore, applying the clearly erroneous standard to the record before me related to the noncompliance I have found based on the violation of 42 C.F.R. § 483.25(l), I have no definite and firm conviction that an error was committed in the determination that immediate jeopardy existed.

8. A CMP of $3,650 per day is a reasonable enforcement remedy for the period July 20 through July 31, 2013, during which noncompliance under Tag F329 posed immediate jeopardy.

9. A CMP of $100 per day is a reasonable enforcement for the period August 1 through August 19, 2013, for noncompliance under Tags F157 and F329 that did not pose immediate jeopardy but posed a risk for more than minimal harm without actual harm.

If a facility is not in substantial compliance with program participation 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 may impose a per-day CMP for the number of days that the facility is not in compliance or a per instance CMP for each instance that a facility is not in substantial compliance, whether or not the deficiencies pose immediate jeopardy. 42 C.F.R. § 488.430(a). A CMP that is imposed against a facility on a per-day basis falls into one of two ranges of penalties. 42 C.F.R. §§ 488.408, 488.438. The upper range, $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). 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).

CMS proposes a CMP of $3,650 for each of the 12 days of immediate jeopardy from July 20 through July 31, 2013. CMS proposes a CMP of $100 per day for each day after immediate jeopardy was abated to the date on which Petitioner returned to substantial compliance, August 1 through 19, 2013. The total CMP proposed is $45,700. I must determine whether the CMPs are reasonable. I note that both proposed CMPs are near the low end of the range of authorized CMPs.

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 noncompliance, 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 facility's 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. The Board has explained that my task is 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 (2001); *CarePlex of Silver Spring*, DAB No. 1683 at 14–16 (1999); *Capitol Hill Cmty. Rehab. & Specialty Care Ctr.*, DAB No. 1629 (1997). Petitioner has not argued that the proposed CMPs are unreasonable but has focused upon whether or not there is a basis for imposing such an enforcement remedy and whether the declaration of immediate jeopardy was erroneous.

I have considered Petitioner's history of compliance reflected in CMS Exs. 6 and 7, and note prior noncompliance under Tag F157. Petitioner does not argue that it is unable to pay the proposed CMP nor has it submitted any financial information for my consideration. The noncompliance under Tags F157 and F329 cited by the survey that ended on August 1, 2013, was cited as isolated. The noncompliance under both Tags

F157 and F329 was serious. Resident B suffered actual harm in the form of blood loss that required a transfusion. Petitioner was culpable in failing to ensure that its staff promptly consulted with the resident's physician and followed physician orders for laboratory testing of the ability of the resident's blood to clot when the resident was receiving blood thinner. Considering that both proposed CMPs are at the low end of the authorized range and also considering the regulatory factors, I conclude that the proposed CMPs are reasonable enforcement remedies.

III. Conclusion

For the foregoing reasons, I conclude that there is a basis for the imposition of enforcement remedies. The following enforcement remedies are reasonable: a CMP in the amount of $3,650 per day for 12 days of noncompliance that posed immediate jeopardy and a CMP of $100 per day for 19 days of noncompliance that did not pose immediate jeopardy but posed a risk for more than minimal harm without actual injury, a total CMP of $45,700.

/s/
Keith W. Sickendick
Administrative Law Judge