Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Caretel Inns of Brighton
(CCN: 23-5615),

Petitioner,

v.

Centers for Medicare and Medicaid Services.

Docket No. C-11-375

Decision No. CR2643

Date: October 12, 2012

Petitioner, Caretel Inns of Brighton, was not in substantial compliance with program participation requirements from November 2 through December 21, 2010, due to violations of 42 C.F.R. §§ 483.13(c)(2), 483.20(k)(3)(i), and 483.25(m)(2). There is a basis for the imposition of enforcement remedies. A civil money penalty (CMP) of $4,500 per day for the period November 2 through 23, 2010, and $200 per day from November 24 through December 21, 2010 is reasonable. Petitioner was ineligible to conduct a Nurse Aide Training and Competency Evaluation Program (NATCEP) for two years.

I. Background

Petitioner is located in Brighton, Michigan, and participates in Medicare as a skilled nursing facility (SNF) and the state Medicaid program as a nursing facility (NF). From November 18 through December 8, 2010, Petitioner was surveyed by the Michigan Department of Community Health (state agency) and found not in substantial compliance with program participation requirements. Joint Stipulation of Fact (Jt. Stip.) ¶ 2. A revisit survey completed on January 10, 2011, concluded that Petitioner returned to substantial compliance effective December 22, 2010. Jt. Stip. ¶ 9. The Centers for Medicare and Medicaid Services (CMS) notified Petitioner by letter dated February 1, 2011, that it was imposing a CMP of $4,500 per day from November 2 through 23, 2010,

and $200 per day from November 24 through December 21, 2010. CMS also notified Petitioner that it was ineligible to be approved to conduct a NATCEP. Jt. Stip. ¶ 10; CMS Ex. 1.

Petitioner requested a hearing before an administrative law judge (ALJ) on March 30, 2011. The case was assigned to me for hearing and decision on April 5, 2011, and an Acknowledgement and Prehearing Order (Prehearing Order) was issued at my direction. On January 17, 18, and 19, 2012, a hearing was convened in Detroit, Michigan, and a transcript (Tr.) of the proceedings was prepared. CMS offered CMS exhibits (CMS Exs.) 1 through 21, 23 and 24, and 26 through 35 that were admitted as evidence. Tr. 46. CMS withdrew its previously exchanged CMS Exs. 22 and 25. Tr. 44. Petitioner's exhibits (P. Exs.) 1 through 17, page 1 of P. Ex. 18 (Tr. 461-76); pages 2, 3, and 4 of P. Ex. 19 and P. Exs. 20 through 29 (Tr. 627, 672, 709-16); P. Exs. 30 and 31 (Tr. 494); P. Exs. 32 through 47 (Tr. 730-46); P. Exs. 54 through 60 (Tr. 749-50)[1]; P. Ex. 62 (Tr. 754); P. Exs. 63 through 66 (Tr. 50-51); P. Exs. 71 and 72 (Tr. 765-66); and P. Ex. 77 (Tr. 771-72) were admitted as evidence. Pages 2 through 7 of P. Ex. 18 (Tr. 476); pages 1, 5, and 6 of P. Ex. 19 (Tr. 716); P. Exs. 48 through 53 (Tr. 746); P. Ex. 61 (Tr. 753); and P. Exs. 67 through 70 were not admitted (Tr. 760-61). P. Ex. 73 was withdrawn and remarked and admitted as Court exhibit (Ct. Ex.) 1. Tr. 321-25, 766. P. Exs. 74, 75, and 76 were withdrawn. Tr. 766-69.

On April 24, 2012, CMS filed a document entitled "CMS's Post-Hearing Status Report Regarding Exhibits Admitted Into Evidence" (Exhibit Status Report). In footnote 3 of its Exhibit Status Report, CMS states that P. Exs. 54 through 58 are the written opinion of Diane Brown and related documents. CMS notes that Diane Brown was not called to testify by Petitioner. CMS does not specifically move to strike the documents, but states that the exhibits were admitted with the understanding that Diane Brown would be produced and that CMS would have the opportunity for cross-examination. Tr. 749-50. CMS did specifically object several times at hearing to the admission of prior statements on grounds that the declarant would not be available for cross-examination. Tr. 471-76; 709-16; 746-47. The parties were advised by paragraph II.12.h of the Prehearing Order that a party must produce at hearing for cross-examination any witness whose written direct testimony is offered as evidence. The parties were further advised that if the witness was not produced at hearing the written statement would be stricken upon the motion of the opposing party. I conclude that it is appropriate to strike and not consider P. Exs. 54 through 58 in deciding this case.

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[1] Petitioner offered P. Ex. 55. CMS had no objection. I failed to specifically state on the record that P. Ex. 55 was admitted. Tr. 749-50. P. Ex. 55 is admitted as evidence.

Petitioner filed with its post-hearing brief documents marked as "Petitioner Attachment A" (Pet. Att. A). Pages 1 and 2 of P. Att. A appear to be a printed copy of a Michigan Department of Licensing and Regulatory Affairs webpage with a training outline titled "Spring 2012 Joint Provider/Surveyor Outline and Objectives." Some of the "objectives" listed on the page refer to medication errors. The remaining 12 pages of Pet. Att. A are printed presentation slides. The text on the slides is mostly unreadable. Petitioner argues in its post-hearing brief that P. Att. A reflects that the state agency has adopted a particular position or philosophy regarding medication errors in long-term care facilities. It is apparent that Petitioner offers Pet. Att. A to bolster the testimony of its witness Kyle Hultgren, Pharm.D.; or as substantive evidence in support of Petitioner's theory. P. Br. at 19. CMS objects to my consideration of Pet. Att. A on grounds that it has not been properly offered as evidence and the text of the document is mostly illegible. CMS Reply Br. at 21-22. The CMS objection is sustained on the grounds cited by CMS and P. Att. A is not considered for any purpose.

CMS called the following witnesses: Surveyor Lorraine Barba, RN, and Robert Lash, MD. Petitioner called the following witnesses: Jerome Wilborn, MD; Mary Gorman, RN and Nurse Practitioner (NP); Deborah Durham, Vice President of Petitioner's management company; Stephanie Hildebrant, Director of Compliance and Guest Relations for Petitioner's management company; Kristin Wrubel, RN; Annette (Annie) Taylor, RN; Michelle Benedict, RN, NP; John H. Fullerton, MD; and Kyle Hultgren, Pharm.D.

On April 2, 2012, Petitioner filed a motion to reopen the record to receive additional evidence, the testimony of Mark McQuillan, MD. Petitioner filed its opening post-hearing brief on April 23, 2012 (P. Br.). CMS filed its opening post-hearing brief on April 24, 2012 (CMS Br.). On April 20, 2012, CMS filed its opposition to Petitioner's motion to reopen the record. I granted Petitioner's motion on April 30, 2012 and ordered that the parties file a joint status report advising me how they wished to proceed. The parties advised me by their joint status report filed May 24, 2012, that they offered the deposition of Dr. McQuillan taken in a civil proceeding in lieu of live testimony. On June 4, 2012, I issued a ruling admitting the deposition of Dr. McQuillan as P. Ex. 78. Petitioner filed a supplemental post-hearing brief on June 12, 2012 (P. Supp.). On June 14, 2012, CMS waived the opportunity to supplement it post-hearing brief. The parties filed their post-hearing reply briefs on July 16, 2012 (CMS Reply and P. Reply, respectively).

II. Discussion

A. Issues

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

Whether the remedy imposed is reasonable.

B. Applicable Law

The statutory and regulatory requirements for participation of a SNF in Medicare are found at section 1819 of the Social Security Act (Act) and at 42 C.F.R. Part 483.[2] Section 1819(h)(2) of the Act authorizes the Secretary of Health and Human Services (Secretary) to impose enforcement remedies against a SNF for failure to comply substantially with the federal participation requirements established by sections 1819(b), (c), and (d) of the Act.[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 denial of payments for new admissions (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, civil money penalties (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

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[2] References are to the version of the Code of Federal Regulations (C.F.R.) at the time of the survey, unless otherwise indicated.

[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.

regulations at 42 C.F.R. Part 483, subpart 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.

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).

Petitioner was notified in this case that it was ineligible to conduct a NATCEP for two years due to the imposition of a CMP of $5,000 or more. However, the notice also advised Petitioner that there was a partial extended survey conducted due to the conclusion that there was also substandard quality of care, which is also a basis for ineligibility to conduct a NATCEP. CMS Ex. 1 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. Part 483, subpart D. Pursuant to 42 C.F.R. § 483.151(b)(2) and (e)(1), a state may not approve and must withdraw any prior approval of a NATCEP offered by a 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); 42 C.F.R. §§ 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, 38 (2000), *aff'd, Woodstock Care Ctr. v. Thompson*, 363 F.3d 583 (6th Cir. 2003). The Departmental Appeals Board (the Board) has long held that the net effect of the regulations is that a provider has no right to challenge the scope and severity level assigned to a noncompliance finding, except in the situation where that finding was the basis for an immediate jeopardy determination. *See, e.g., Ridge Terrace*, DAB No. 1834 (2002); *Koester Pavilion*, DAB No. 1750 (2000). ALJ review of a CMP is subject to 42 C.F.R. § 488.438(e).

The standard of proof, or quantum of evidence required, is a preponderance of the evidence. CMS has the burden of coming forward with the evidence and making a prima facie showing of a basis for imposition of an enforcement remedy. Petitioner bears the burden of persuasion to show by a preponderance of the evidence that it was in substantial compliance with participation requirements or any affirmative defense. *Batavia Nursing & Convalescent Inn*, DAB No. 1911 (2004); *Batavia Nursing & Convalescent Ctr.*, DAB No. 1904 (2004), *aff'd, Batavia Nursing & Convalescent Ctr. v. Thompson*, 129 F. App'x 181 (6th Cir. 2005); *Emerald Oaks*, DAB No. 1800; *Cross Creek Health Care Ctr.*, DAB No. 1665 (1998); *Hillman Rehab. Ctr.*, DAB No. 1611 (1997), *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 bold text 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 and explain why I determined some evidence was not credible or entitled to weight.[4] 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.

The survey that ended on December 8, 2010, cited Petitioner for the following deficiencies: 42 C.F.R. §§ 483.13(c)(1)(ii)-(iii) and (c)(2)-(4) (Tag F225) at a scope and severity (s/s) of D[5]; 483.20(k)(3)(i) (Tag F281, s/s J); 483.25(m)(2) (Tag F333, s/s J); 483.75(e)(8) (Tag F497, s/s E); and 483.75(i) (Tag F501, s/s F). CMS Ex. 8. CMS has elected not to proceed on the alleged noncompliance under Tag F501, cited as a violation of 42 C.F.R. § 483.75(i). CMS Br. at 3 n. 1.

1. **Petitioner violated 42 C.F.R. § 483.25(m)(2) (Tag F333).**

2. **Petitioner violated 42 C.F.R. § 483.20(k)(3)(i) (Tag F281).**

3. **Petitioner violated 42 C.F.R. § 483.13(c)(2).**

The surveyor alleged in the Statement of Deficiencies (SOD) for the survey that concluded on December 8, 2010, that Resident 105 was given Glyburide, a drug used for the treatment of diabetes, on October 27, 2010 at about 3:40 p.m. Resident 105 was not diagnosed as suffering from diabetes and Glyburide had not been prescribed for her.

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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.

[5] The scope and severity of D, E, and F, reflects the determination that the alleged deficiency posed a risk for more than minimal harm without actual harm. A scope and severity of J reflects the determination that the alleged deficiencies posed an isolated instance of immediate jeopardy for Petitioner's residents.

Based on the alleged medication error, the surveyor charged Petitioner with violation of 42 C.F.R. § 483.25(m)(2), which requires that Petitioner ensure that there are no significant medication errors. The surveyor concluded that the medication error posed immediate jeopardy to the health and safety of Petitioner's residents. CMS Ex. 8 at 11. The surveyor charged Petitioner with failure to report to the state agency an injury of unknown origin to Resident 105 in violation of 42 C.F.R. § 483.13(c)(2)-(4), and that the violation posed a risk for more than minimal harm to Petitioner's residents. CMS Ex. 8 at 2. The surveyor also charged Petitioner with a violation of 42 C.F.R. § 483.20(k)(3)(i) based on her conclusion that Petitioner's services to Resident 105 did not meet professional standards of quality. The surveyor concluded that the violation of 42 C.F.R. § 483.20(k)(3)(i) posed immediate jeopardy to Petitioner's residents. CMS Ex 8 at 5. The following factual findings relate to all three of these alleged violations.

a. Facts

Resident 105 was a 99-year-old female admitted to Petitioner on October 5, 2010, for rehabilitation of a fractured left humerous (the long bone from the shoulder to the elbow) that she suffered due to a fall in her home. Prior to her fall and admission to Petitioner, Resident 105 resided in an assisted living facility, she was independent in her activities of daily living, and she walked with a four-wheel walker. Resident 105's diagnoses included: atrial fibrillation, peripheral vascular disease, history of a cerebrovascular accident (CVA or stroke), a small frontal sub-acute subdural hematoma due to her fall, asthma, hypertension, hyperlipidemia, muscle weakness, and difficulty walking.[6] There is no dispute that Resident 105 had not been diagnosed as suffering from diabetes. There is also no dispute that she had no prescription for Glyburide, which is generally prescribed for the treatment of diabetes. Resident 105 did have prescriptions for Albuterol and Advair. There is no dispute that Resident 105 was alert and oriented and could communicate. The goal throughout her stay with Petitioner was for Resident 105 to complete her rehabilitation and return home where she would live independently as she had prior to her fall. Daily progress notes reflect good progress with her rehabilitation to October 28, 2010. Except, a progress note dated October 19, 2010, shows that an antibiotic, Bactrim DS, was ordered for a urinary tract infection. CMS Ex. 19 at 5-15, 78, 80, 84, 86, 88, 90, 92, 96, 98, 106, 108, 110, 112, 114, 116, 120, 122, 167-69, 174, 178. A progress note dated October 28, 2012, shows that Resident 105 suffered an episode of

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[6] Resident 105 had a care plan for chronic renal failure. CMS Ex. 19 at 156-57. However, there is no other indication of such a diagnosis in the medical evidence before me. Dr. Lash testified that a person of Resident 105's age would have markedly reduced kidney function. Tr. 62.

hypoglycemia or low blood sugar that caused her to be nonresponsive and she was given glucagon by injection. She subsequently became responsive, took her medications, ate a meal, and received a tube of glucagon gel. CMS Ex. 19 at 124, 126, 128-29. Progress notes from October 29, 2010, at 6:15 a.m., show that Resident 105 was only responsive to pain, she was given an injection of glucagon, and she was transported to the University of Michigan Hospital emergency room at 6:00 a.m. and was subsequently admitted to the hospital. CMS Ex. 19 at 128. Resident 105 was discharged from the University of Michigan Hospital on November 2, 2010. CMS Ex. 17. Resident 105 died on November 16, 2010. P. Ex. 3.

The parties stipulated to the following prior to hearing:

> 12. A medication error occurred regarding R105 . . . .
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> 13. On October 29, 2010, R105 was transported to the University of Michigan Hospital. A blood sample was taken from R105 at the hospital and forwarded to the Mayo Clinic in Rochester, Minnesota for a Hypoglycemic Agent Screen. The laboratory report from the Mayo Clinic[7] shows the presence of Glyburide in R105's blood.
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> 14. Glyburide is a hypoglycemic agent (i.e. it lowers blood sugar) that is used to treat diabetes mellitus.
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> 15. R105 was given Glyburide while she was a resident at Caretel.

Jt. Stip. ¶¶ 12-15; Tr. 279-86; CMS Ex. 17 at 42-43. Petitioner clarified the stipulation at hearing. Petitioner concedes that two medication errors occurred on October 27, 2010 at about 3:40 p.m.: (1) LPN Emerson gave Resident 104 (Resident 105's roommate) only three of four prescribed pills; and (2) LPN Emerson documented that she gave Resident 105 her inhaler, but she did not administer the medication. Tr. 281-83. Petitioner did not stipulate that Resident 105 was given Glyburide on October 27, 2010. Tr. 285. Petitioner did concede and stipulated that: (1) laboratory tests show Resident 105 had Glyburide in her system; and (2) she received the Glyburide while she was under Petitioner's care and treatment. However, Petitioner alleges to have no idea and declined

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[7] The actual quantitative blood analysis was done by MEDTOX. CMS Ex. 17 at 43; Tr. 96.

to stipulate or concede how, when, or by whom Resident 105 was given Glyburide. Tr. 286.

Resident 104, Resident 105's roommate, was diabetic and had prescriptions for both Glyburide and Metformin, also a drug generally only used for the treatment of diabetes. CMS Ex. 18 at 5, 7, 22.

Administration of Glyburide to one without diabetes may cause hypoglycemia with potential discomfort, including sweating and lowered body temperature, or more serious harm such as brain damage if the hypoglycemia is prolonged. Tr. 67-68, 73-74, 92-94, 121, 972, 978-79, 981, 986; P. Ex. 59.

b. Analysis related to 42 C.F.R. § 483.25(m)(2) (Tag F333)

Long-term care facilities participating in Medicare must ensure that each resident is provided and receives "the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the [resident's] comprehensive assessment and plan of care." 42 C.F.R. § 483.25. Regarding medication errors, the quality of care regulations require that the facility must ensure that:

> (1) It is free of medication error rates of five percent or greater; and
> (2) Residents are free of any significant medication errors.

42 C.F.R. § 483.25(m).

According to the State Operations Manual (SOM),[8] app. PP, Tags F332 and F333, a medication error is the "observed preparation or administration of drugs or biologicals" not in accordance with: physician's orders, manufacturer's specification, or accepted professional standards and principles applicable to the professional preparing or administering the drug or biological. The SOM instructs surveyors that a significant medication error is one that causes a resident discomfort or jeopardizes his or her health

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[8] 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. *State of Indiana by the Indiana 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.

or safety. The term "jeopardizes" is not defined in the SOM. The common meaning of "jeopardize" is "to expose to danger or risk" or to "imperil."[9] The Board has stated that it is not necessary for CMS to show that there was any actual harm to support a conclusion that a medication error is significant. Rather, a medication error may be significant if there is a potential danger or risk to a resident's health and safety. *Life Care Ctr. of Tullahoma*, DAB No. 2304 at 35 (2010), *aff'd, Life Care Ctr. of Tullahoma v. Sebelius*, 453 F. App'x 610 (6th Cir. 2011). Discomfort may depend upon the individual resident. The relative significance of medication errors is a matter of professional judgment that considers three factors: (1) resident condition; (2) drug category; and (3) frequency of the error. The SOM includes a list of medication errors and characterizes them as significant or non-significant. Glyburide and Resident 105's inhaled medications (Albuterol and Advair) are not listed. Thus, there is no presumption that a medication error related to the administration of Glyburide or the failure to administer Albuterol and Advair are either significant or non-significant. SOM, app. PP, Tags F332 and 333.

Surveyor Barba alleged in the SOD and CMS charges that Petitioner violated 42 C.F.R. § 483.25(m)(2) and that the violation posed immediate jeopardy. The elements of the CMS prima facie case under 42 C.F.R. § 483.25(m)(2) are that: (1) a medication error occurred; (2) the medication error was significant; and (3) the error had the potential for causing more than minimal harm. Petitioner has stipulated that there were three medication errors: (1) on October 27, 2010, at about 3:40 p.m., LPN Emerson failed to administer to Resident 104 one of her prescribed medications of unknown type; (2) on October 27, 2010, at about 3:40 p.m., LPN Emerson failed to administer Advair for Resident 105; and (3) on an unknown date and time Resident 105 received Glyburide from an unknown source.[10] Petitioner has not stipulated that Resident 105 received the

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[9] Merriam-Webster, www.m-w.com.

[10] The surveyor charged in the SOD that Petitioner failed to protect Resident 105 from a significant medication error and that there was immediate jeopardy because Resident 105 suffered severe hypoglycemia, irreversible brain damage due to hypoglycemia, and death on November 16, 2010. CMS Ex. 8 at 11. The surveyor did not allege a deficiency based upon failure to administer a medication to Resident 104 or failure to give Resident 105 her inhaled medication. CMS did not cite the failure to administer a medication to Resident 104 or the failure to provide Resident 105 her inhaled medication as the bases for a violation of 42 C.F.R. § 483.25(m) or the imposition of an enforcement remedy in either its February 1, 2011 notice (CMS Ex. 1) or in its prehearing brief (CMS Prehearing Brief at 5-20). Accordingly, Petitioner was not on notice to defend and I do not consider further the failure to administer a medication to Resident 104 or the failure to give Resident 105 her inhaled medication on October 27, 2010.

Glyburide from its staff, only that Resident 105 received the Glyburide while she was under Petitioner's care and treatment. The fact that Resident 105 was under Petitioner's care and treatment at the time she received the Glyburide is sufficient to support an inference that the Glyburide was administered by Petitioner's staff, or, at the very least, that it was from the supply of medications that Petitioner was obliged to maintain and secure to ensure no misuse by residents or erroneous administration, accidental or intentional. Petitioner has presented no evidence that the Glyburide was from another source. Thus, the preponderance of the evidence supports a finding that Petitioner's staff committed a medication error that resulted in Resident 105 receiving the Glyburide. Petitioner has not conceded that the medication error was significant or that it had the potential for causing more than minimal harm, and it is necessary to consider those elements of the CMS prima facie case in more detail.[11]

A significant medication error is one that causes a resident discomfort or jeopardizes his or her health or safety. SOM, app. PP, Tags F332 and F333. There is little question that the administration of Glyburide to one without diabetes may cause hypoglycemia. There is also no real dispute that hypoglycemia causes discomfort and may jeopardize one's health and safety. Robert Lash, MD, an endocrinologist and professor of internal medicine at the University of Michigan Health System (Tr. 53-54), was called as a witness by CMS and testified that when Resident 105 arrived at the University of Michigan Hospital on October 29, 2010, her blood sugar level was normal. Tr. 60, 67. However, she was unresponsive and he diagnosed her unresponsiveness as being due to prolonged hypoglycemia, i.e. low blood sugar for more than 20 minutes. He testified that prolonged hypoglycemia can cause brain damage, which is often irreparable. Tr. 67-68. Dr. Lash testified that Glyburide is a drug that causes blood sugars to be reduced and it is prescribed to treat diabetes. Glyburide would have a more significant and longer effect in a person without diabetes. The drug would also have more significant effect in the elderly, particularly those with reduced renal function such as Resident 105. Tr. 71-73. Dr. Lash testified that administering Glyburide to one without diabetes carries a very high risk of causing severe, prolonged hypoglycemia and related complications, more so in the elderly with reduced renal function than in younger individuals. He testified that Metformin generally does not cause hypoglycemia. Tr. 73-74, 76, 92-94. Dr. Lash testified that Glyburide is well known to cause prolonged hypoglycemia more than 24 hours after ingestion. Tr. 121.

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[11] Whether or not the medication error posed immediate jeopardy is not an element of the CMS prima facie case and is discussed separately hereafter.

Based upon the testimony of Dr. Lash regarding the effect of the administration of Glyburide to a person without diabetes, and the fact that Resident 105 clearly suffered an episode of hypoglycemia on October 28 and another on October 29, I have no difficulty concluding that CMS has satisfied the last two elements of its prima face case. The CMS evidence shows it is more likely than not that Resident 105 ingested Glyburide, which caused the hypoglycemic events on October 28 and 29, 2010, with discomfort and/or jeopardy to Resident 105's health and safety. Both Resident 105's condition, and the effects of Glyburide as described by Dr. Lash, weigh in favor of a conclusion that the error was significant. The evidence also shows that there was a potential for more than minimal harm. Accordingly, I conclude that CMS has made its prima facie showing of noncompliance under Tag F333.

I conclude that Petitioner failed to rebut the CMS prima facie case. Petitioner argues that CMS failed to show that Resident 105 suffered discomfort or that her health or safety was jeopardized by her admitted ingestion of Glyburide at Petitioner's facility. P. Br. at 2-14. Petitioner is correct that as part of its prima facie case CMS must show that the medication error caused discomfort or jeopardized the health or safety of Resident 105. For reasons already discussed, I conclude that the evidence adduced by CMS shows it is more likely than not that Resident 105 suffered discomfort or her health and safety were jeopardized by the ingestion of Glyburide. Petitioner offers alternate theories for the cause of Resident 105's hypoglycemic episodes, but the alternative theories do not rule out the likely cause was the ingestion of Glyburide.

Petitioner's expert, John Fullerton, MD, testified that he is board certified in internal medicine, geriatrics, and hospice and palliative care. Tr. 927; P. Ex. 33. He testified that there is no evidence that Resident 105 experienced any discomfort or harm as a result of ingesting Glyburide. Tr. 959, 973. I do not accept that opinion as credible, as the weight of the evidence does not support his opinion and he did not otherwise state an adequate basis for the opinion. He testified in response to my questioning that hypoglycemia is a potential side effect of Glyburide. He agreed that hypoglycemia may be a serious medical condition. Tr. 972. He testified on cross-examination that Glyburide administered to a non-diabetic may have a bigger impact. Tr. 977-79, 981. He agreed that based upon the positive blood test for the presence of Glyburide from a blood sample drawn on October 29, 2010, that it was possible Resident 105 received Glyburide approximately 46 hours earlier on October 27, 2010, though he qualified his response stating that he could not make that conclusion with a reasonable degree of medical certainty. Tr. 974-75. He opined that while Resident 105 may have received Glyburide at Petitioner, based on the blood test result, it would not have been in a clinically significant dosage to produce a clinically significant hypoglycemia. Tr. 977. He testified that the timing of the hypoglycemic symptoms suffered by Resident 105 was inconsistent with her having received Glyburide around 3:45 p.m. on October 27, 2010, and it is more likely she would have suffered hypoglycemia around dinner-time on October 27, 2010. Tr. 983. Dr. Fullerton testified on cross-examination that he would expect that a non-

diabetic given Glyburide would experience some signs and symptoms, possibly sweating and lowered body temperature causing them to feel cold and clammy, which is consistent with a conclusion that Resident 105 experienced discomfort due to ingestion of Glyburide. Tr. 986.

The manufacturer's insert for Glyburide cautions that the drug is capable of producing severe hypoglycemia and that renal insufficiency may cause elevated drug levels of Glyburide, increasing the risk for serious hypoglycemic reactions. P. Ex. 59 at 1.

The testimony of Dr. Fullerton and the manufacturer's insert for Glyburide support a finding that the ingestion of Glyburide by a non-diabetic has the potential to cause a serious hypoglycemic reaction. The testimony of Dr. Lash that a serious hypoglycemic reaction can cause serious injury in the form of brain damage is unrebutted. Petitioner has not rebutted that: Resident 105 received Glyburide while she was in Petitioner's care and treatment, a medication error; the ingestion of Glyburide by Resident 105 more likely than not caused discomfort or jeopardized her health and safety, which constitutes a significant medication error; or that the significant medication error had the potential for causing more than minimal harm to Resident 105. The fact that Resident 105 had a detectible amount of Glyburide in her blood supports the parties' stipulation that she ingested Glyburide. Petitioner has not presented sufficient evidence that the test results reflected a false positive result for Glyburide, which would at any rate be inconsistent with Petitioner's admission that Resident 105 ingested Glyburide while subject to Petitioner's care. Petitioner argues that Resident 105's hypoglycemic episodes occurred outside the window of clinical effectiveness of Glyburide, but Petitioner did not show when the admitted ingestion of Glyburide occurred. Petitioner has also presented no evidence or argument in the nature of an affirmative defense to excuse its failure to prevent this significant medication error.

It is not necessary for me to make further findings related to whether the significant medication error caused or contributed to Resident 105's hospitalization and, ultimately, her death. I conclude that Petitioner violated 42 C.F.R. § 483.25(m)(2), the violation posed a risk for more than minimal harm, and the violation amounted to noncompliance under Tag F333.

Petitioner argues that it should not be charged for any medication error prior to November 23, 2010. P. Br. at 24-27. This argument strains credibility as Resident 105 departed the facility on October 29, 2010, and never returned prior to her death on November 16, 2010. Given the facts before me, it is factually impossible for Petitioner to have committed a medication error related to Resident 105 between October 29 and November 23, 2010. The gist of Petitioner's argument is that it was only on November 23, 2010 that it received the laboratory report showing evidence of Glyburide in Resident 105's blood, and only then was Petitioner aware of the true nature of the noncompliance so that it could respond and take corrective action. Petitioner reasons that immediate

jeopardy was abated on November 24, 2010, and, therefore, Petitioner should only be subject to an enhanced CMP for immediate jeopardy on one day. These arguments are without merit. Petitioner is obliged as a condition of participation to maintain substantial compliance with program participation requirements. 42 C.F.R. §§ 483.1, 488.301. The Secretary and CMS have discretion to impose enforcement remedies whenever a SNF or NF is not in substantial compliance to ensure prompt return to substantial compliance. 42 C.F.R. § 488.400. The admitted medication error occurred in this case sometime prior to Resident 105's departure to the hospital on October 29, 2010. Also, Petitioner's staff received an allegation of neglect on October 30, 2010, when the University of Michigan Hospital contacted Petitioner, that Petitioner failed to report to the state agency. Petitioner was not in substantial compliance on October 29, 2010, but CMS proposes an enforcement remedy only on and after November 2, 2010, which is well within the authority and discretion of CMS under the Act and regulations.

c. Analysis related to 42 C.F.R. § 483.20(k)(3)(i) (Tag F281)

The regulation requires that "services provided or arranged by the facility must – . . . [m]eet professional standards of quality." 42 C.F.R. § 483.20(k)(3)(i). The regulation does not define the phrase "professional standards of quality" but CMS explains to surveyors in the SOM, app. PP, Tag F281 that the phrase means that services are provided according to accepted standards of clinical practice which may be found in various sources. CMS also advises surveyors that if there is a negative resident outcome due to failure to meet professional standards of quality, the deficiency should be cited under the appropriate quality of care or other relevant requirement. The SOM states that actual medication errors should be cited under 42 C.F.R. § 483.25(m). SOM, app. PP, Tag F281.

The service that is at issue under this citation of noncompliance is the administration of medication to Resident 105. The applicable standard of quality is established by 42 C.F.R. § 483.25(m)(2), i.e., a facility must ensure that its residents are free of any significant medication errors. Because I have concluded that there was a significant medication error, in that Resident 105 ingested Glyburide, it follows that there is also a violation of 42 C.F.R. § 483.20(k)(3)(i) (Tag F281) as the failure to ensure that Resident 105 was free of any significant medication error was a violation of the professional standard of quality in the administration of medications. Furthermore, Petitioner's failure to ensure that Resident 105 was free of any significant medication error posed a risk for more than minimal harm for the reasons already discussed in the analysis under Tag F333. Accordingly, I conclude that CMS has made a prima facie showing of noncompliance under Tag F281. I further conclude that Petitioner has failed to rebut the noncompliance or establish an affirmative defense.

Petitioner argues that it was not the intent of the drafters of 42 C.F.R. § 483.20(k)(3)(i) and the drafters of the SOM for a single medication error to be a violation. Petitioner asserts that the proper focus of the regulation is "whether and how a facility plans and trains to avoid medication errors, whether and how it reacts to them, and whether and how it adheres to accepted professional standards that address their inevitable occurrence." P. Br. at 15-16. Petitioner cites no authority for its interpretation other than the context of the regulation. I am not persuaded. The plain language of the regulation leaves little room for interpretation: "services provided or arranged by the facility must – . . . [m]eet professional standards of quality." 42 C.F.R. § 483.20(k)(3)(i). If the services do not meet professional standards of quality, clearly there is a violation of the regulation. The question is, really, what are the applicable professional standards of quality. The SOM, app. PP, F281, suggests possible sources. However, in this case the regulation at 42 C.F.R. § 483.25(m)(2) establishes the standard of quality, supplanting any lesser standard, by requiring that residents must be free of any significant medication error. The application of any lesser standard from another source would constitute a failure to follow the Secretary's regulations, which I am not permitted to do.

Petitioner elicited testimony from Kyle Hultgren, Pharm.D. (P. Ex. 42; Tr. 873). Dr. Hultgren opined that Petitioner did a good job with its investigations (P. Exs. 14, 16) and addressing the medication error. Tr. 885-87. He opined that Petitioner's action related to the investigations and punishment of LPN Emerson comported with professional standards of quality. Tr. 896-97; P. Ex. 41. Petitioner's expert, John Fullerton, MD, also opined that Petitioner's investigations of the incident involving Resident 105 met professional standards of quality related to the investigation of medication errors. Tr. 961; P. Ex. 32 at 3-4. However, it is the medication error and not Petitioner's response to the medication error that is at issue. Petitioner's failure to ensure that its resident did not ingest improper or incorrect medication that could result in discomfort or jeopardize the resident's health is the focus of the deficiency citation. P. Br. at 17-19; P. Reply at 14-16.

d. Analysis related to 42 C.F.R. § 483.13(c)(2)

Section 1819(c)(1)(A)(ii) of the Act requires that a SNF protect its residents and promote their "right to be free from physical or mental abuse, corporal punishment, involuntary seclusion, and any physical or chemical restraints imposed for purposes of discipline or convenience and not required to treat the resident's medical symptoms." The Secretary has provided by regulation that a "resident has the right to be free from verbal, sexual, physical, and mental abuse, corporal punishment, and involuntary seclusion." 42 C.F.R. § 483.13(b). The regulations require that a facility develop and implement written policies and procedures prohibiting mistreatment, neglect, and abuse of residents and the misappropriation of residents' property. 42 C.F.R. § 483.13(c). The facility must "[n]ot use verbal, mental, sexual, or physical abuse, corporal punishment, or involuntary seclusion." 42 C.F.R. § 483.13(c)(1)(i). The facility "must ensure that all alleged violations involving mistreatment, neglect, or abuse . . . are reported immediately to the

administrator of the facility and to other officials in accordance with State law." 42 C.F.R. § 483.13(c)(2). The facility "must have evidence that all alleged violations are thoroughly investigated, and must prevent further potential abuse" during the investigation. 42 C.F.R. § 483.13(c)(3). The facility must ensure that the results of all investigations are "reported to the administrator or his designated representative and to other officials in accordance with State law . . . within 5 working days of the incident." 42 C.F.R. § 483.13(c)(4).

"Abuse" is "the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish." 42 C.F.R. § 488.301. The regulatory definition of "neglect" includes two elements: (1) any "failure to provide goods and services" and (2) the goods and services are "necessary to avoid physical harm, mental anguish, or mental illness." 42 C.F.R. § 488.301. The definition of neglect does not include an element of knowledge or notice, and the definition of neglect may be satisfied whether or not staff was aware that the resident was in need of goods and services to avoid physical harm, mental anguish, or mental illness. The definition of neglect does not consider the intent of Petitioner's staff. Neglect may occur even if the failure to deliver necessary goods and services was unintended. Under a strict application of the definition of neglect, neglect is complete the instant that staff fails to deliver care or services necessary to avoid physical harm, mental anguish, or mental illness. The definition of neglect does not specifically permit a period for a facility to assess and intervene to meet the need for goods and services. However, it has been noted by the Board in a number of different SNF enforcement cases that SNFs are generally not treated as being "strictly liable" for violations of statutory and regulatory requirements for participation. *See e.g. Tri-County Extended Care Ctr.*, DAB No. 1936 at 7 (2004), *aff'd, Tri-County Extended Care Ctr. v. Leavitt*, 157 F. App'x (6th Cir. 2005); *Cherrywood Nursing and Living Ctr.*, DAB No. 1845 (2002). A limited number of defenses have been recognized for specific noncompliance, such as unavoidability, unforeseeability, and reasonableness. The Board has recognized, based mostly on interpretation of the regulations, that SNFs are not subject to enforcement remedies for unavoidable negative outcomes, or unforeseen or unpreventable circumstances that produce a risk for or an actual negative outcome. *Tri-County Extended Care Ctr.*, DAB No. 1936 at 7; *Woodstock Care Ctr.*, DAB No. 1726 at 21, 25, 40, *aff'd, Woodstock Care Ctr. v. Thompson*, 363 F.3d 583. Furthermore, not all regulatory or statutory violations, including instances of neglect, are subject to the imposition of enforcement remedies by CMS. Noncompliance occurs, and CMS is authorized to impose an enforcement remedy, only if a statutory or regulatory violation poses a risk for more than minimal harm. 42 C.F.R. §§ 488.301, 488.402(b).

The issues to be resolved under this deficiency citation are: whether there was an allegation of neglect that triggered the requirements of 42 C.F.R. § 483.13(c) to report, protect, and investigate; and when was the allegation made to Petitioner's staff. The Board has addressed the standard to be applied to determine whether an allegation

amounts to an allegation of abuse or neglect that triggers the requirements of 42 C.F.R. § 483.13(c)(2)-(4). The Board has stated that it is not necessary for a person who reports an incident or situation to specifically characterize the incident as being abuse or neglect. Rather, the test to be applied is whether a reasonable person would regard the allegations as involving neglect or abuse or, alternatively, whether one could reasonably conclude that the alleged facts involved neglect or abuse. *Illinois Knights Templar Home*, DAB No. 2369 at 10-11 (2011) (*citing Grace Healthcare of Benton*, DAB No. 2189 at 6 (2008), *rev'd on other grounds, Grace Healthcare of Benton v. U.S. Dep't of Health & Human Servs., Ctrs. for Medicare & Medicaid Servs.*, 589 F.3d 926 (8th Cir. 2009), *modified on reh'g*, 603 F.3d 412 (8th Cir. 2010), (the "broad language" of section 483.13(c) "encompasses not only a direct allegation that the resident has been abused, but also an allegation of facts from which one could reasonably conclude that the resident has been abused.")); *Dumas Nursing and Rehab., L.P.*, DAB No. 2347 at 13 (2010) ("allegations that a reasonable person would regard as involving possible neglect"). The Board has not adopted a "reasonable surveyor" or "reasonable administrator or director of nursing" test for determining whether an allegation is an allegation of neglect or abuse for purposes of triggering the requirements of 42 C.F.R. § 483.13(c)(2)-(4). The standard or test to apply is whether a reasonable person could construe a verbal or written statement as alleging neglect or abuse of a resident.

The surveyor alleges that Petitioner failed to report the alleged medication error involving Resident 105 to the state as an allegation of neglect. CMS Ex. 8 at 2-3. The surveyor did not allege that Petitioner's subsequent investigation and report of investigation were insufficient or that Petitioner failed to protect its residents during its investigation, as required by 42 C.F.R. § 483.13(c).

The evidence shows that on October 30, 2010, staff at the University of Michigan Hospital called Petitioner's staff and requested a list of the medications prescribed for Resident 105's roommate because staff at the University of Michigan Hospital were "looking into" whether Resident 105 was possibly exposed to her roommate's medications. RN Taylor was advised of the inquiry on November 1, 2010; she advised the Director of Health Services; an investigation was commenced to determine whether there was a medication error; although no medication error was discovered, a corrective action plan was initiated; and a medication count was done by RN Taylor and Petitioner's pharmacy. CMS Ex. 24 at 9-10; P. Ex. 14 at 2, 98-99, 117-18; Tr. 796-801, 1027-33. There is no dispute that Petitioner did not report the contact from the University of Michigan Hospital to the state agency as an allegation of neglect.

Neglect is simply the failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness. 42 C.F.R. § 488.301. The definition is broad enough to include the failure to protect a resident from ingesting incorrectly administered medication. Petitioner's staff clearly did not take any action to report or investigate a possible medication error on October 30, 2010, when the call was received from the

University of Michigan Hospital. On November 1, 2010, RN Taylor learned of the October 30, 2010 telephone call from the University of Michigan Hospital. Clearly, RN Taylor recognized that the inquiry from the University of Michigan Hospital showed that university staff was inquiring regarding the possibility that Resident 105 received Resident 104's medication. Petitioner's staff immediately began an investigation to determine whether there was neglect in the form of a medication error. P. Ex. 14. RN Taylor conducted a medication count on November 1, 2010. P. Ex. 14 at 99. However, RN Taylor and Petitioner's director of nursing and administrator did not report the incident to the state on November 1, 2010. Using RN Taylor as the reasonable person, it is clear that on November 1, 2010 she construed the October 30, 2010 inquiry from the University of Michigan Hospital as an allegation of neglect of Resident 105 in the form of a medication error. The staff member who received the telephone call on October 30, 2010, should have recognized that the inquiry amounted to an allegation that Resident 105 may have been given incorrect medication by Petitioner, which amounts to an allegation of neglect. Accordingly, the requirement to report to the state agency under 42 C.F.R. § 483.13(c)(2) was triggered on October 30, 2010.

Petitioner argues that it had no reasonable cause to believe that it had to address alleged neglect of Resident 105. Petitioner argues that RN Taylor had done a count of Resident 104's medications and found no anomaly. Petitioner argues, generally, that its duty to report to the state was not triggered as Petitioner had no evidence of neglect. P. Br. at 21-24. Petitioner's arguments are without merit. There is no reasonable cause standard applicable. Under current interpretation of the regulation, Petitioner is not permitted a period to assess the validity of the allegation of neglect before reporting to the state agency. It is the allegation of neglect, recognizable as such by a reasonable person, that triggers the duty to report to the state agency.

Petitioner argues that Surveyor Barba testified that she actually cited Petitioner for noncompliance under Tag F225 because Petitioner failed to report an injury of unknown source and not for Petitioner's failure to report neglect. Petitioner asserts that CMS should be bound to its theory and that Resident 105's hypoglycemia was not an injury of unknown source. P. Reply at 19-20; Tr. 336-37. It is not necessary to attempt to dissect Petitioner's argument. The issue is whether or not Petitioner was on notice by the allegations of the SOD that it was being cited for failure to report to the state agency as required by 42 C.F.R. § 483.13(c)(2). The deficiency citation in the SOD sets forth the regulatory language which requires reporting of a list of possible allegations, including mistreatment, neglect, abuse, injuries of unknown source, and misappropriation of resident property. The SOD alleges that the facility failed to report to the state in this case. In the SOD, Surveyor Barba describes the situation involving Resident 105 without specifically characterizing the situation using any of the regulatory phrases. I conclude that the citation of the regulatory language and the general description of the situation involving Resident 105 were sufficiently precise to give Petitioner adequate notice to

defend an allegation that it failed to report anything to the state when the regulatory requirement to report was triggered.

Petitioner argues that it attempted to obtain clarification from the state agency in 2011, regarding whether all medication errors must be reported. P. Reply at 21. Petitioner made the request by letter dated October 11, 2011, and the state agency responded by letter dated October 19, 2011. P. Exs. 71, 72. The state agency responded that not all medication errors need to be reported to the state. However, the state agency advised Petitioner that a facility must ensure that all allegations involving mistreatment, neglect, or abuse, including injuries of unknown source and misappropriation of resident property must be reported immediately to the administrator and the state agency. The state agency interpretation of the regulations is consistent with my own, i.e., there is no requirement to report medication errors unless it is alleged that the error amounted to abuse or neglect, as in this case. Accordingly, I conclude that the state agency's October 19, 2011 response to Petitioner provides no defense for Petitioner.

The surveyor alleged that the deficiency posed a risk for more than minimal harm, thus, the deficiency amounted to noncompliance. In *Dumas Nursing and Rehab., L.P.*, DAB No. 2347 at 15, an appellate panel of the Board commented in considering a deficiency under 42 C.F.R. § 483.13(c)(2)-(4), that "[t]he potential for significant harm from these types of reporting and investigatory failures is manifest because residents may be exposed to a continuing risk of neglect based on a failure to understand and correct deficient practices." Furthermore, scope and severity is not subject to challenge or review in this circumstance, as such review, if favorable to Petitioner, would have no impact upon the amount of the CMP that CMS may impose or Petitioner's eligibility to conduct a NATCEP. 42 C.F.R. § 498.3(b)(14), (d)(10)(i); *Plott Nursing Home*, DAB No. 2426 at 11 (2011).

Accordingly, I conclude that Petitioner violated 42 C.F.R. § 483.13(c)(2) on October 30, 2010, and the violation posed a risk for more than minimal harm.

4. Petitioner has not established by a preponderance of the evidence that it returned to substantial compliance prior to December 22, 2010.

The parties stipulated that the state agency conducted a revisit survey on January 10, 2011 and determined that Petitioner returned to substantial compliance effective December 22, 2010. CMS seeks to impose a CMP through December 21, 2010. Jt. Stip. ¶¶ 9, 10. Petitioner states in its plan of correction that it completed corrective action related to the deficiencies alleged under Tags F225, F281, and F333 on December 22, 2010. CMS Ex. 9 at 3, 5, 12; P. Ex. 11 at 3, 5, 12. Petitioner's plan of correction states under F225 that the Administrator and Director of Health Services did not receive in-service training on reporting and investigative requirements until December 22, 2010. CMS Ex. 9 at 4; P. Ex. 11 at 4. Under Tag F281, Petitioner states that the all nurses had

received medication pass education as of December 3, 2010. CMS Ex. 9 at 7; P. Ex. 11 at 7. Petitioner also planned to have its director of health services perform weekly audits of medication administration, but Petitioner specified no time frame other than stating that the corrective action under the deficiency citation was completed by December 22, 2010. CMS Ex. 9 at 5, 8; P. Ex. 11 at 5, 8. Petitioner's plan of correction under Tag F333 alleges essentially the same facts regarding completion as under Tag F281. CMS Ex. 9 at 12-15; P. Ex. 11 at 12-15.

Petitioner has not met its burden to show by a preponderance of the evidence that it returned to substantial compliance prior to December 22, 2010. *Rosewood Care Ctr. of Rockford*, DAB No. 2466 at 10 (2012); *Sunshine Haven Lordsburg*, DAB No. 2456 at 2 (2012).

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

The surveyor concluded that the violations of 42 C.F.R. §§ 483.20(k)(3)(i) and 483.25(m)(2) posed immediate jeopardy beginning on October 27, 2010. CMS Ex. 8 at 10, 18. The surveyor concluded that immediate jeopardy was abated on November 24, 2010. CMS Ex. 8 at 11, 19. CMS proposes to impose a CMP in the higher range of CMPs that may be imposed for immediate jeopardy only for the period November 2 through 23, 2010 (CMS Ex. 1 at 2) 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 the 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. 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. 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."[12] Recently, in *Mississippi Care Ctr. of Greenville*, DAB No. 2450 at 14 (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

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[12] 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.

> 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, 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 14. 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.[13] *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, *citing Life Care Ctr. of Tullahoma*, DAB No. 2304 at 58, *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 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. 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

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[13] 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.

determination is how imminent the danger appears and how serious the potential consequences. *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.[14] 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 Daugthers 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.

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[14] Appendix Q of the State Operations Manual (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.

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(k)(3)(i) and 483.25(m)(2), I have no definite and firm conviction that an error has been committed. I conclude that Petitioner has failed to show that Resident 105's ingestion of Glyburide was not likely to cause her serious injury, harm, impairment, or death. The testimony of Dr. Fullerton and the manufacturer's insert for Glyburide support a finding that the ingestion of Glyburide by a non-diabetic has the potential to cause a serious hypoglycemic reaction. The testimony of Dr. Lash that a serious hypoglycemic reaction may result in serious injury in the form of brain damage is unrebutted.

Petitioner argues that "[t]he maximum IJ status for which CMS was entitled to penalize Petitioner was one day." P. Br. at 27; P. Reply at 24-25. Petitioner argues that Surveyor Barba did not identify immediate jeopardy until November 22, 2010, when she reviewed the laboratory report indicating the presence of Glyburide in Resident 105's blood. Tr. 587-88. Petitioner did not receive the laboratory report until November 23, 2010, when it was advised of the immediate jeopardy. Petitioner reasons it should only be held accountable for one day of immediate jeopardy on November 23, 2010, because it could not have known about the Glyburide prior to receiving the report, just as Surveyor Barba could not determine there was immediate jeopardy until she saw the report on November 22, 2010. P. Br. at 27. Petitioner's argument is without merit. "*Immediate jeopardy*" exists when the facility'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). The existence of immediate jeopardy is not dependent upon when it is identified and declared by a surveyor or CMS. It is Petitioner's obligation to ensure that it maintains substantial compliance with program participation requirements so that there is no risk for more than minimal harm to its residents and no immediate jeopardy. Contrary to the Petitioner's assertion, I see no procedural due process issue to address. It is Petitioner's burden before me to show that the conclusion there was immediate jeopardy during the period alleged was clearly erroneous. Petitioner has not met its burden.

Petitioner's legal arguments raised in its post-hearing reply brief also do not satisfy its burden. P. Reply at 16-19. Petitioner's argument that CMS is barred from advancing the theory that immediate jeopardy may be based on potential for serious injury, harm, impairment, or death because the SOD alleges that the determination of immediate jeopardy was based on actual injury to Resident 105, is in error. P. Reply at 17. The SOD may be read to allege that immediate jeopardy was declared based on actual harm to Resident 105. CMS Ex. 8 at 10, 18. However, Petitioner cannot avoid -- based on an inartfully drafted allegation in the SOD -- the long-standing interpretation of the regulation that immediate jeopardy does not require proof of an actual injury. Petitioner was clearly on notice that CMS alleged immediate jeopardy based on the violations of 42

C.F.R. §§ 483.20(k)(3)(i) and 483.25(m)(2) and Petitioner had adequate notice and opportunity to meet its burden to show that the declaration of immediate jeopardy was clearly erroneous.

6. Petitioner did not violate 42 C.F.R. § 483.75(e)(8) (Tag F497).

The regulation requires:

> A facility must be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.
>
> * * * *
>
> (8) *Regular in-service education*. The facility must complete a performance review of every nurse aide at least once every 12 months, and must provide regular in-service education based on the outcome of these reviews. The in-service training must-
>
> (i) Be sufficient to ensure the continuing competence of nurse aides, but must be no less than 12 hours per year;
>
> (ii) Address areas of weakness as determined in nurse aides' performance reviews and may address the special needs of residents as determined by the facility staff; and
>
> (iii) For nurse aides providing services to individuals with cognitive impairments, also address the care of the cognitively impaired.

42 C.F.R. § 483.75(e)(8).

Surveyor Barba cited the deficiency because Petitioner could not produce documentation showing that 7 of its 29 nurse aides received the full 12 hours of in-service training. CMS Ex. 8 at 19-20; Tr. 360. Petitioner does not deny that it did not provide the documentation. Petitioner stipulated at hearing that it was not documented that seven nurse aides received 12 hours of in-service training. However, Petitioner does not concede the training did not occur. Tr. 361-63; P. Br. at 27-28; P. Reply at 23-24. Petitioner presented the testimony of RN Taylor to rebut any inference that the training was not provided. RN Taylor testified that she determined that Human Resources, which was responsible for documenting in-service training attendance, had failed to document all reported attendance. She testified that she was satisfied that more than the required number of hours of training was provided based upon her participation in training and that all CNAs received more than 12 hours. Tr. 786-92, 1033-39. Surveyor Barba agreed that no deficiency was identified that reflected that CNAs were not fully trained and

competent. Although CMS presented a prima facie showing of the deficiency, I conclude that Petitioner has successfully rebutted it by showing through the unrebutted testimony of RN Taylor, that this was merely a documentation error and that there was not even a risk for minimal harm.

Accordingly, I conclude that Petitioner did not violate 42 C.F.R. § 483.75(e)(8).

7. The enforcement remedy of a CMP of $4,500 per day for the period November 2 through 23, 2010, and $200 per day from November 24 through December 21, 2010 is reasonable.

8. Petitioner was ineligible to be approved to conduct a NATCEP for two years by operation of law.

I have concluded that Petitioner violated 42 C.F.R. §§ 483.13(c)(2), 483.20(k)(3)(i), and 483.25(m)(2); that the violations amounted to noncompliance because they posed a risk for more than minimal harm to one or more facility residents; and that Petitioner has failed to prove that the declaration of immediate jeopardy related to the violations of 42 C.F.R. §§ 483.20(k)(3)(i) and 483.25(m)(2) was clearly erroneous. 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). I conclude that there is a basis for the imposition of an enforcement remedy, specifically a CMP, 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 facility's neglect, indifference, or disregard for resident care, comfort, and safety. 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 (2001); *CarePlex of Silver Spring*, DAB No. 1683 at 14-16 (1999); *Capitol Hill Comm. Rehab. and Specialty Care Ctr.*, DAB No. 1629 (1997).

CMS proposes a CMP of $4,500 for the period of immediate jeopardy from November 2 through 23, 2010. CMS Ex. 1 at 2. During a period of immediate jeopardy the range authorized for a per day CMP is $3,050 per day to $10,000 per day. 42 C.F.R. § 488.438(a)(1)(i), (d)(2). The daily CMP proposed by CMS during the period of immediate jeopardy falls in the lower quarter of authorized CMPs. CMS proposes a CMP of $200 per day for the period November 24 through December 21, 2010, after immediate jeopardy was abated and before Petitioner returned to substantial compliance, when there remained a risk for more than minimal harm but no actual harm or immediate jeopardy. CMS Ex. 1 at 2; CMS Ex. 8 at 11, 19. Authorized CMPs for the period range from $50 per day to $3,000 per day. 42 C.F.R. § 488.438(a)(1)(ii). The proposed CMP of $200 per day falls in the lowest quarter of the authorized range.

The factors that must be considered under 42 C.F.R. § 488.404(b) are the scope and severity of the deficiencies. The surveyor alleged in the SOD that the noncompliance under Tags F225, F281, and F333 was isolated. CMS Ex. 8 at 1, 4, 11. I agree that the noncompliance I have found was isolated. I concluded that Petitioner has failed to show that the determination that the noncompliance under Tags F281 and F333 posed immediate jeopardy was clearly erroneous. The fact Tags F281 and F333 were found by the surveyor and CMS to pose immediate jeopardy during the period November 2 through 23, is an indication of the seriousness of the noncompliance. In concluding that the noncompliance was extremely serious, I also considered the evidence presented by both parties that the ingestion of Glyburide by a non-diabetic may result in serious hypoglycemia and the testimony of Dr. Lash that serious hypoglycemia causes irreversible brain damage.

The remaining factors I must consider that are specified by 42 C.F.R. § 488.438(f) are the facility's history of noncompliance; the facility's financial condition, and the facility's degree of culpability. CMS presented evidence that Petitioner was previously cited for noncompliance under Tag F333 in 2006. CMS Ex. 4 at 6. The CMS evidence shows that the 2006 survey and another survey in 2009 resulted in enforcement remedies. CMS Ex. 4 at 4, 6. I have no details regarding the scope and severity of the prior noncompliance

under Tag F333 or the 2009 survey, and I give little weight to Petitioner's history of noncompliance. CMS presented some financial data for Petitioner (CMS Ex. 5), but Petitioner does not argue that it is unable to pay the CMP proposed by CMS (P. Reply at 25-26). The final factor is Petitioner's culpability. The regulation specifies that the concept of "culpability" includes but is not limited to the facility's neglect, indifference, or disregard for resident care, comfort, or safety. The regulation also specifies that the absence of culpability is not a mitigating factor. 42 C.F.R. § 488.438(f)(4). I conclude that Petitioner's culpability is minimal based on the evidence in this case. Petitioner stipulated that Resident 105 ingested Glyburide while she was in Petitioner's care. The evidence is insufficient to show by a preponderance of the evidence how Resident 105 received the Glyburide to ingest. However, the evidence shows that on November 1, 2010, when RN Taylor became aware that the University of Michigan Hospital inquired about the medications Resident 105 and her roommate, Resident 104, were taking, Petitioner's staff began an immediate investigation and began to take corrective actions.

Based primarily upon the seriousness of the noncompliance under Tags F281 and F333, I conclude that the CMP proposed by CMS is a reasonable enforcement remedy.

Pursuant to 42 C.F.R. § 483.151(b)(2) and (e)(1), Petitioner was rendered ineligible to conduct a NATCEP for a period of two years based on the CMP and the partial extended survey triggered by findings of substandard quality of care.

III. Conclusion

For the foregoing reasons, Petitioner was not in substantial compliance with program participation requirements from November 2 through December 21, 2010. A CMP of $4,500 per day for the period of immediate jeopardy from November 2 through November 23, 2010, and $200 per day from November 24 through December 21, 2010 is reasonable. Petitioner was ineligible to conduct a NATCEP for two years.

/s/
Keith W. Sickendick
Administrative Law Judge