Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

St. Joseph Villa Nursing Center
(CCN: 28-5078),

Petitioner

v.

Centers for Medicare and Medicaid Services.

Docket No. C-09-127

Decision No. CR2288

Date: November 29, 2010

DECISION

Petitioner, St. Joseph Villa Nursing Center, was not in substantial compliance with program participation requirements as alleged by the survey completed on May 3, 2007, due to violations of 42 C.F.R. §§ 483.10(b)(11)(Tag F157) and 483.25(h)(2)(Tag F324). There is a basis for the imposition of an enforcement remedy. A per instance civil money penalty (PICMP) of $8,000 is not reasonable. A PICMP of $4,000 is reasonable.

I. Background

Petitioner, located in Omaha, Nebraska, is authorized to participate in Medicare as a skilled nursing facility (SNF) and in the Medicaid program as a nursing facility (NF). The Nebraska Department of Health and Human Services System, Department of Regulation and Licensure, Section for Long Term Care and Assisted Living Facilities (the state agency), conducted a survey of Petitioner that was completed on May 3, 2007.

The Centers for Medicare and Medicaid Services (CMS) notified Petitioner by letter dated June 6, 2007, that based on deficiencies found by the May 3, 2007 survey, CMS was imposing: a PICMP of $8,000; a denial of payment for new admissions (DPNA) beginning on June 21, 2007 and continuing until Petitioner returned to substantial

compliance; termination of Petitioner's provider agreement on November 3, 2007, if Petitioner did not return to substantial compliance before that date; and withdrawal of Petitioner's authority to conduct a Nurse Aide Training and Competency Evaluation Program (NATCEP). Request for Hearing (RFH) at 1-2; RFH Exhibit (RFH Ex.) A; CMS Exhibit (CMS Ex.) 1, at 12. The state agency conducted a revisit survey in July 2007 and determined that Petitioner returned to substantial compliance as of May 30, 2007. RFH at 2; RFH Ex. C; CMS Ex. 1, at 16. The DPNA and termination remedies were never effectuated.

Petitioner requested a hearing on August 2, 2007. The request for hearing was assigned to me on August 7, 2007. A hearing was convened in this case on April 1, 2008, in Omaha, Nebraska. Petitioner appeared represented by counsel. No representative for CMS appeared. Petitioner's exhibits (P. Ex.) 1 through 39 were admitted without objection. Transcript (Tr.) at 27. On June 6, 2008, I issued a decision concluding that CMS had failed to make a *prima facie* showing that Petitioner was not in substantial compliance with program participation requirements and that no basis existed to impose an enforcement remedy. An appellate panel of the Departmental Appeals Board (the Board) issued a decision on December 8, 2008, reversing my decision. The Board remanded the case to me with directions to receive the CMS exhibits not offered at the prior hearing and for other appropriate action.

A second hearing was held in this case on May 19 and 20, 2009, in Omaha, Nebraska. CMS offered CMS exhibits 1 through 16. CMS exhibits 1, 2, 3 (except page 15), 6 (except pages 1-4, 27-28, 38-39, 107-18), 7, 8, 9 (except pages 1-3, 15-16, 20-21), 10, 11 (except page 1), 12 (except page 1), 13 (except page 1), 14 (except page 1), and 16 were admitted. Tr. at 66-68. CMS called Surveyor Ron Chase, Registered Nurse (RN) as a witness. Petitioner called the following witnesses: Donald R. Frey, MD; Tiffany Harrahill, a Licensed Registered Occupational Therapist (OTR/L); Jennifer O'Neil, OTR/L; Nicole Halski, Licensed Practical Nurse (LPN); Hector Lequillow, LPN; and Mary Malone, RN. The parties filed post-hearing briefs (CMS Br. and P. Br.) and post-hearing reply briefs (CMS Reply and P. Reply).

II. Discussion

A. Issues

The issues in this case are:

Whether there is a basis to impose an enforcement remedy; and

Whether the proposed enforcement remedy is reasonable.

B. Applicable Law

The statutory and regulatory requirements for participation by a long-term care facility are found at sections 1819 (SNF) and 1919 (NF) of the Social Security Act (Act) and at 42 C.F.R. Part 483.[1] Section 1819(h)(2) of the Act vests the Secretary of Health and Human Services (Secretary) with authority to impose enforcement remedies against a SNF for failure to comply substantially with the federal participation requirements established by sections 1819(b), (c), and (d) of the Act.[2] Pursuant to 1819(h)(2)(C), the Secretary may continue Medicare payments to a SNF not longer than six months after the date the facility is first found not in compliance with participation requirements. Pursuant to 1819(h)(2)(D), if a SNF does not return to compliance with participation requirements within three months, the Secretary must deny payments for all individuals admitted to the facility after that date – commonly referred to as the mandatory or statutory DPNA. In addition to the authority to terminate a noncompliant SNF's participation in Medicare, the Act grants the Secretary authority to impose other enforcement remedies, including a discretionary DPNA, civil money penalties (CMP), 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. Part 483, subpart B. State survey agencies on behalf of CMS may survey facilities that participate in Medicare 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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[1] All references are to the 2006 version of the Code of Federal Regulations (C.F.R.), which was in effect at the time of the survey, unless otherwise indicated.

[2] Section 1919(h)(2) of the Act gives similar enforcement authority to the states to ensure that NFs comply with their participation requirements established by sections 1919(b), (c), and (d) of the Act.

CMS may impose a CMP for the number of days a facility is not in substantial compliance or for each instance of noncompliance. 42 C.F.R. § 488.430(a). The regulations specify that a CMP that is imposed against a facility on a per day basis will fall into one of two ranges of penalties. 42 C.F.R. §§ 488.408, 488.438. The upper range of 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 a CMP, $50 per day to $3,000 per day, is reserved for deficiencies that do not constitute immediate jeopardy but either cause actual harm to residents, or cause no actual harm but have the potential for causing more than minimal harm. 42 C.F.R. § 488.438(a)(1)(ii). A PICMP may range from $1,000 to $10,000, and the range is not affected by the presence of immediate jeopardy. 42 C.F.R. § 488.438(a)(2).

Petitioner was notified in this case that the state agency could not approve and withdrew any prior approval of Petitioner to conduct a NATCEP. Petitioner advised me at hearing that, while it did not have a NATCEP, it desired to have such a program in the future. Although the two year ban had already elapsed by the time of the second hearing, Petitioner wanted to preserve its right to review of the deficiencies upon which the ban was based. Tr. at 5-7. Pursuant to sections 1819(b)(5) and 1919(b)(5) of the Act, SNFs and NFs may only use nurse aides who have completed a training and competency evaluation program. Sections 1819(e) and 1919(e) of the Act impose upon the states the requirement to specify what NATCEPs they will approve that meet the requirements that the Secretary established and a process for reviewing and re-approving those programs using criteria that the Secretary set. Pursuant to sections 1819(f)(2) and 1919(f)(2), the Secretary was tasked to develop requirements for approval of NATCEPs and the process for review of those programs. The Secretary promulgated regulations at 42 C.F.R. Part 483, subpart D. Pursuant to 42 C.F.R. § 483.151(b)(2) and (e)(1), a state may not approve and must withdraw any prior approval of a NATCEP that a SNF or NF offered that: (1) has been 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) has been assessed a CMP of not less than $5,000; or (3) has been 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 administrative law judge (ALJ) available to a long-term care facility against which CMS has determined to impose an enforcement remedy. Act §§ 1128A(c)(2), 1866(h); 42 C.F.R. §§ 488.408(g), 498.3(b)(13). The hearing before an ALJ is a *de novo* proceeding. *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, is not subject to review. 42 C.F.R. § 488.408(g)(2). A facility may only challenge the scope and severity level of noncompliance that CMS determined, if a successful challenge would affect the range of the CMP that may be imposed or impact the facility's authority to conduct a NATCEP. 42 C.F.R. § 498.3(b)(14), (d)(10)(i). The CMS determination as to the level of noncompliance, including the finding of immediate jeopardy, "must be upheld unless it is clearly erroneous." 42 C.F.R. § 498.60(c)(2); *Woodstock Care Ctr.*, DAB No. 1726, at 9, 38 (2000), *aff'd,* 363 F.3d 583 (6th Cir. 2003). The 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 Ctr.*, DAB No. 1904 (2004)*, aff'd,* 129 F. App'x. 181 (6th Cir. 2005); *Batavia Nursing & Convalescent Inn*, DAB No. 1911 (2004); *Emerald Oaks*, DAB No. 1800; *Cross Creek Health Care Ctr.*, DAB No. 1665 (1998); *see Hillman Rehab. Ctr.*, DAB No. 1611 (1997), *aff'd,* No. 98-3789, 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 followed by my findings of fact and analysis. The survey that was completed on May 3, 2007, cited Petitioner for the following deficiencies: 42 C.F.R. §§ 483.10(b)(11) (Tag F157, scope and severity (s/s) J (immediate jeopardy)); 483.20(d)(3) and 483.10(k)(2) (Tag F280, s/s D (potential for

more than minimal harm)); 483.25 (Tag F309, s/s G (actual harm)); and 483.25(h)(2) (Tag F324,[3] s/s K (immediate jeopardy)). CMS Ex. 2. CMS imposed the $8,000 PICMP based upon Tags F157 and F324, the tags cited as posing immediate jeopardy. CMS Ex. 1, at 12. The only remedy at issue before me is the proposed $8,000 PICMP. No remedy was imposed based upon Tag F280 or Tag F309 and those deficiencies are not subject to my review.[4] 42 C.F.R. §§ 488.408(g)(i); 498.3(b)(13).

CMS argues that Petitioner violated 42 C.F.R. §§ 483.10(b)(11) (Tag F157) and 483.25(h)(2) (Tag F324). CMS only discusses in its briefs the examples from the Statement of Deficiencies related to Resident 1. I do not apply the doctrine of waiver against CMS but consider each alleged example under both deficiency citations as discussed hereafter. I have carefully considered all the evidence, including the documents and the testimony at hearing and the arguments of both parties, though not all may be specifically discussed in this decision.[5] I discuss in this decision the credible

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[3] CMS amended the State Operations Manual (SOM), app. PP and deleted Tag F324 effective August 17, 2007. Violations of 42 C.F.R. § 483.25(h)(1) and (2) are both covered by SOM, app. PP, Tag F323. However, Tag F324 is used in this decision as the version of the SOM in effect at that time of the survey included Tag F324. 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 Public 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 the SOM interprets.

[4] The ban on approval to conduct a NATCEP was triggered by the $8,000 PICMP in this case, as there was no extended or partial extended survey based upon a finding of substandard quality of care (Tr. at 114), the DPNA was not effectuated, termination was not effectuated, and temporary management was not imposed. Thus, the ban on NATCEP approval does not trigger my jurisdiction to review Tags F280 and F309, neither of which is cited as a basis for the PICMP or amounted to substandard quality of care that would have triggered an extended or partial extended survey.

[5] Petitioner includes in its Prehearing Brief a laundry list of twenty-three arguments attacking the constitutionality of the statutes, regulations, and procedures that are the survey, certification, and enforcement process. Petitioner's Prehearing Brief at 35-40; P. Br. at 30. My jurisdiction is limited to the issues discussed in this decision, and I do not address the issues raised by Petitioner over which I have no authority.

evidence given the greatest weight in my decision-making.[6] 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.

1. Petitioner violated 42 C.F.R. § 483.10(b)(11) (Tag F157).

The surveyors allege in the SOD that Petitioner violated 42 C.F.R. § 483.10(b)(11), because Petitioner failed to notify the physicians for Resident 1 and Resident 4 that they had a change in condition related to skin burns from spilled hot liquid. CMS Ex. 2, at 2. I conclude that Petitioner violated the regulation by failing to immediately consult Resident 1's physician on April 14, 2007, when the burn blister was observed to be open, the area around the open blister was observed to be reddened, and the resident made repeated complaints of pain that required administration of pain medication. I do not find a violation in the case of Resident 4.

(a) Facts.

Resident 1, a female, was 76 years old at the time of the survey. Her Minimum Data Set (MDS) with an assessment reference date of March 29, 2007, lists diagnoses of chronic obstructive pulmonary disease (COPD) or emphysema, hypothyroidism, cardiac dysrhythmias, congestive heart failure, osteoporosis, paroxysmal atrial fibrillation, gastroesophageal reflux disease, depression, anemia, atrophy and muscle wasting, and abnormal gait. CMS Ex. 6, at 59. The MDS reflects that Resident 1 was cognitively intact and independent for daily decision-making and she could speak, understand others, and be understood. CMS Ex. 6, at 57. She had no negative behavioral symptoms and was well-adapted to her environment emotionally. She required supervision and set-up assistance for eating. CMS Ex. 6, at 58. The MDS shows that she was assessed as having no limitation of range of motion in her neck, arms, or hands. CMS Ex. 6, at 59. The MDS assesses Resident 1's skin as being "desensitized to pain or pressure." CMS Ex. 6, at 60.

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[6] "Credible evidence' is evidence that is worthy of belief. *Blacks Law Dictionary* 596 (18th ed. 2004). The "weight of evidence" is the persuasiveness of some evidence compared to other evidence. *Id*. at 1625. Evidence that is not credible generally has no probative value or weight. Evidence that is credible may or may not be given probative value or weight based upon its comparison with other evidence of record.

An occupational therapist (OT) evaluated Resident 1 on March 26, 2007, and she was not identified as at risk for handling hot liquids. CMS Ex. 6, at 29; Tr. at 232-33. Resident 1's care plan, dated March 29, 2007, lists as a problem that she had activity of daily living deficits due to a fractured foot, back pain, and muscle wasting. The care plan states that she was capable of feeding herself with staff assistance for setup. An undated, handwritten note on the care plan states that the resident wants drinks in Styrofoam cups and that she sometimes wants staff to fill two cups with coffee. P. Ex. 32 at 21; CMS Ex. 6 at 5, 83. The care plan does not list an intervention to address a request by the resident for more than one cup of coffee or other hot liquid. P. Ex. 32, at 22-3; CMS Ex. 6, at 6-7, 84-5.

It is undisputed that on April 8, 2007, Resident 1 had a Styrofoam cup of hot water and, when she attempted to pour the water on her cereal, she spilled the water on her left leg and abdomen. The record shows that ice was applied and the resident's physician was immediately called. He ordered that ice be continued for twenty-four hours. The evidence shows that Resident 1's husband was also called. Blisters subsequently formed. The physician was called about the blisters, and the evidence shows that at 3:00 p.m. on April 9, 2007, staff was waiting for a call-back from the physician for a treatment order for the blisters. The husband was called again. The evidence shows that at 3:40 p.m. on April 11, 2007, orders were received from the physician to apply Silvadene cream twice per day to the blisters on her abdomen and thigh. The husband was again notified. On April 12, 2007, the physician ordered that the Silvadene be discontinued due to allergies and that ice be used as necessary. Nurse's notes for April 14, 2007 show that a blister had opened. On April 15, 2007, a new order was received for Bactroban three times per day for seven days, and the physician was scheduled to see the resident in his office. Resident 1 went to the physician's office on April 16, 2007, and he sent the resident to the hospital for possible cellulitis related to the blisters on her abdomen. CMS Ex. 6, at 19-21, 24, 36, 40, 48, 73-76; P. Ex. 32, at 34-36, 47-48, 64, 77-78, 84, 86-88. Resident 1 was discharged from the hospital on May 3, 2007. The discharge summary reflects final diagnoses that include first and second degree burns to the lower abdominal wall and left thigh with secondary cellulitis, a bacterial infection of the skin.[7] P. Ex. 32, at 29-32.

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[7] Donald R. Frey, MD, opined that there was no evidence of cellulitis. His opinion is outweighed by the discharge summary. Resident 1 was not his patient, and the evidence shows that he did not examine the resident at the pertinent time. Tr. at 126-33, 157. Petitioner's wound care expert, Mary Malone, RN, also opined that she observed no cellulitis when she examined the wounds on April 16, 2007. Tr. at 306-21. I do not find that opinion weighty considering my discussion with RN Malone on the record at hearing. I find more weighty the discharge summary.

Resident 4, a female, was 82 years old at the time of the survey. P. Ex. 33, at 1. Resident 4's MDS, with an assessment reference date of January 22, 2007, lists the following diagnoses: diabetes; hypothyroidism; arthritis; osteoporosis; seizure disorder; depression; cataracts; glaucoma; allergies; and polyuria. In addition, she had a colostomy. The MDS reflects that Resident 4 had visual limitations, as she could read large print but not regular printing in books and newspapers. She did not wear glasses[8] and had modified independence for daily decision-making. She usually understood others and could be understood, and she displayed some symptoms of depression, but her mood could be easily altered. She had some socially inappropriate behaviors, but she was adapted to her environment. She was assessed as independent for eating but required set-up from staff. She had no limitations in her range of motion, and her skin was assessed as being desensitized to pain or pressure. P. Ex. 33, at 16-19, 30.

There is no dispute that on February 7, 2007, at about 6:30 p.m., Resident 4 spilled coffee on her right arm. A nurse's note states that the resident's right arm was red, there were no blisters or open areas, the resident denied any pain, and staff would monitor her for the next seventy-two hours. P. Ex. 33, at 54, 90; CMS Ex. 9, at 4. An incident report dated February 7, 2007 by the person preparing the report and signed by the DON on February 10, 2007, states that the physician was contacted at 10:30 p.m. on February 7, 2007 by facsimile and that a message was left for the resident's family member at 6:50 p.m. CMS Ex. 9, at 14. The next nurse's note is dated February 10, 2007 at 9:15 a.m. The nurse's note states that the resident complained of pain on her right arm, and a one centimeter by one centimeter scabbed wound with red area around the wound was observed on her right arm. The nurse's note states that the resident's physician was informed of the wound, and a telephone order was received for triple antibiotic ointment with covering for protection. The note states that the resident's grandson was called and that staff would continue to monitor the resident. CMS Ex. 9, at 14; P. Ex. 33, at 54. The physician's order in evidence is actually dated February 11, 2007. CMS Ex. 9, at 7-8, 36; P. Ex. 33, at 62, 83, 87. A weekly wound assessment dated February 14, 2007, indicates that the wound was healing. The assessment characterized the wound as a burn on the right wrist but indicates that it was acquired on February 11, 2007. P. Ex. 33, at 84. The wound was characterized as healed by March 3, 2007. CMS Ex. 9, at 8.

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[8] A Resident Assessment Protocol (RAP) worksheet for visual function dated January 22, 2007 and the resident's care plan dated January 22, 2007, show that Resident 4 did have and used glasses. P. Ex. 33, at 39, 44; CMS Ex. 9, at 13.

(b) Analysis.

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;
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> > (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);
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> > (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 § 483.12(a).

The regulation does not allow a facility to pick and choose whom to notify and whom to consult. Rather, it requires that the facility immediately inform the resident, consult the physician, and notify the resident's legal representative or interested family member. The regulatory requirement is clearly stated – a facility "**must immediately** . . . **consult with the resident's physician"** when any of the four triggering events occur. 42 C.F.R. § 483.10(b)(11) (emphasis added). The requirement is not discretionary, and it requires more than merely informing or notifying the physician. The preamble to the final rule indicates 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, the requirement of the regulation to consult means more than to simply notify. Consultation requires a dialogue with the resident's physician as to what actions are needed. It is not enough to merely notify the physician of the resident's change in condition, nor is it enough to leave just a message for the physician. The facility must provide the physician with all the information necessary to properly assess any changes to the resident's condition and what course of action is necessary.

The regulation also requires consultation "immediately" upon discernment of a change in condition of the resident. The use of the term "immediately" in the regulatory requirement indicates that consultation is expected as soon as the change is detected. It does not mean that the facility can wait hours or days before consulting with the physician. The preamble to the final rule indicates that the proposed rule originally granted the facility up to twenty-four hours in which to notify the resident's physician and 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 and legal representative or family be consulted and notified immediately. 56 *Fed. Reg.* at 48,833. The word "immediately" recognizes that a delay in such situations could result in a situation where a resident is beyond recovery or dies. *Magnolia Estates Skilled Care*, DAB No. 2228, at 8 (2009). In balancing the relative inconvenience to a physician and the facility staff to consult about a resident's change in condition with the possibility for dire consequences to the resident if the physician is not consulted, any inconvenience certainly is inconsequential and outweighed by the potential for resident harm. Therefore, the regulatory requirements make inconsequential any inconvenience to the resident's physician or to the facility staff when compared to the protection and facilitation of the rights of the resident. 56 *Fed. Reg.* at 48,834.

I conclude based upon the evidence before me that, on April 14, 2007, Petitioner's staff failed to consult with the treating physician for Resident 1, immediately after discovering that the blisters had opened with discharge and that there was reddening of the skin, indicating that a change of treatment might be required.

The evidence shows that Resident 1 spilled a cup of hot water on her left leg and abdomen on April 8, 2007. Ice was applied to the burns. Her physician was called, and he ordered application of ice for twenty-four hours. CMS Ex. 6, at 20, 73-74. A nurse's note at 2:45 a.m. on April 9, 2007, shows that blisters on the abdomen and thigh had formed. A nurse's note at 3:00 p.m. on April 9, 2007 shows that staff was waiting for the physician to call with new orders. The time the physician was called is not indicated. A nurse's note dated April 11, 2007 at 3:40 p.m. shows that the physician called back with orders to apply Silvadene cream to the blisters twice per day. However, the Silvadene was discontinued on April 12 at 1:00 p.m. due to a possible allergy. The nurse's note at 1:15 p.m. on April 12 shows that the blisters were still closed, there was no reddening around the site, there was tenderness to touch, and the resident's pain medication was effective. CMS Ex. 6, at 74-75; Tr. at 247-48. These facts show no violation of 42 C.F.R. § 483.10(b)(11)(i).

The evidence shows however, that at 8:00 a.m. on April 14, 2007, Resident 1 complained of pain, and she was given pain medication. At 9:30 a.m. on April 14, staff noted a 3.7 centimeter open blister, with redness around the blister. At 3:00 p.m. on April 14, the resident was given more pain medication. Resident 1 expressed concern about her skirt sticking to the blisters on her thigh. A Telfa non-stick dressing was applied. The

blistered areas were noted to be red in color with no drainage, but an old drainage stain was found on a pillow case. At 9:00 p.m. on April 14, the resident was given another pain pill. Not until 1:30 p.m. April 15, 2007 is there a note that staff received orders to use an antibiotic ointment for seven days and that the physician directed that the resident be brought to his office for examination. The note also indicates that the blister on the abdomen was bigger and that there was dead tissue from the wound. CMS Ex. 6, at 75-76. The complaint of pain requiring administration of pain medication and the redness around the open blister at 9:30 a.m. on April 14 indicated that there was a potential need for a significant change of treatment within the meaning of 42 C.F.R. § 483.10(b)(11)(i)(C) that triggered the obligation to immediately consult with the physician. According to Petitioner's own records, the consultation did not occur until 1:30 p.m. on April 15, 2007, more than twenty-four hours later. I conclude that the consultation was not immediate.[9] Petitioner has not rebutted the inference triggered by its records that no immediate consultation was accomplished. Accordingly, I conclude that Petitioner violated 42 C.F.R. § 483.10(b)(11)(i) in the case of Resident 1. The evidence shows that Resident 1 suffered actual harm in the form cellulitis to the abdomen with pain. CMS Ex. 6, at 76; P. Ex. 32, at 29-32.

I do not find a violation occurred in the case of Resident 4. The resident spilled coffee on her right arm on February 7, 2007 sometime around 6:00 p.m. with redness observed but no blisters or complaints of pain. P. Ex. 33, at 54; CMS Ex. 9, at 4. The evidence does not show that at that time there was a potential for physician intervention, a significant change in the resident's condition, or a need to significantly alter treatment. Accordingly, the regulatory requirement to immediately consult the physician was not triggered. On February 10, 2007 at about 9:15 a.m., the resident complained of pain on her right arm, and a scab with a surrounding red area was observed. The evidence shows the physician was immediately called, and a new order was subsequently documented. P. Ex. 33, at 54; CMS Ex. 9, at 4. Based upon the evidence before me, the regulatory requirement to immediately consult the physician was satisfied in the case of Resident 4. Accordingly, I conclude that there was no violation related to Resident 4.

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[9] Dr. Frey opined that staff timely and appropriately contacted Resident 1's physician. Tr. at 133. I do not consider that opinion weighty with respect to the issue of whether or not the consultation by staff with physician satisfied the requirements of the regulation. Dr. Frey was not qualified to render legal opinions, and the ultimate issue is for me, not an expert witness, to decide.

2. Petitioner violated 42 C.F.R. § 483.25(h)(2) (Tag F324).

The surveyors allege in the SOD that Petitioner violated 42 C.F.R. § 483.25(h)(2), because Petitioner failed to: (1) evaluate resident safety following repeated occurrences of resident burns from hot liquids involving Residents 1, 3, and 4; (2) evaluate for safety with hot liquids, Residents 6, 7, 8, and 9, who consumed fluids independently or with supervision; and (3) implement interventions to prevent skin tears for Resident 5. CMS Ex. 2, at 21.

(a) Facts.

(i) Residents 1, 3, and 4 suffered burns from spilled hot liquids.

There is no dispute that all three residents spilled hot liquid on themselves while using Styrofoam cups. The facts related to the burns suffered by Residents 1 and 4 are discussed under Tag F157. The SOD alleges that Resident 3 suffered a burn when she poured hot tea onto her left thigh while in the main dining room of the facility. CMS Ex. 2, at 32. The evidence shows that the resident spilled hot tea from a Styrofoam cup onto her left thigh while in the dining room for dinner at about 6:30 p.m. on April 8, 2007. CMS Ex. 8, at 30, 32. Staff documented that the spill caused some redness but no pain, and the next day the redness was gone, there was no pain or discomfort, and staff decided to stop charting the incident. CMS Ex. 8, at 24, 30, 33.

(ii) Residents 6, 7, 8 and 9 did not suffer burns, but surveyors observed that the residents used Styrofoam cups.

The SOD alleges that on May 2, 2007, a surveyor observed that Resident 6 was given a Styrofoam cup from which she drank. The surveyor also observed that Resident 6 had several adaptive cups with lids on the bedside table. Resident 6 had physician orders dated February 26, 2007 and April 16, 2007, that required that she use a cup with handle, lid, and straw at meals. CMS Ex. 2, at 26-27; CMS Ex. 11, at 3; P. Ex. 35, at 4, 11. Nutrition Assessments dated October 27, 2006, February 5, 2007, and April 17, 2007, assessed the resident as requiring cups with handles, lids, and straws for feeding. CMS Ex. 11, at 7. Her nutrition care plan, dated March 11, 2007, required the use of cups with handles, lids, and straws. CMS Ex. 11, at 16-17.

Resident 7 was assessed as requiring setup help from staff and supervision while eating. P. Ex. 36, at 4. The SOD alleges that the surveyor observed a family member of Resident 7 obtain a Styrofoam cup of coffee, and, ten minutes later, the surveyor observed that Resident 7 had the cup of coffee and no staff or family member was present. CMS Ex. 2, at 28-29.

The SOD alleges that a surveyor observed Resident 8 on May 2, 2007 with coffee in a Styrofoam cup, and no staff member was present. CMS Ex. 2, at 29. The SOD alleges that Resident 8's care plan required that Resident 8 have assistance with eating. However, I find no evidence that the resident's requirement for assistance with feeding was actually documented in a care plan. CMS Ex. 2, at 29; CMS Ex. 13, at 5; P. Ex. 37, at 21. Resident 8's MDS assessments with reference dates of March 18, 2007 and April 3, 2007, assessed her as requiring limited physical assistance of one staff member for eating. P. Ex. 37, at 6-7, 15-16.

A surveyor observed Resident 9 at 11:42 a.m. on May 2, 2007, with coffee in a Styrofoam cup, while an unused coffee mug sat on the table. No staff member was with Resident 9, and Resident 9 reported that staff gave him the coffee in the Styrofoam cup. CMS Ex. 2, at 3. Resident 9's MDS with an assessment reference date of March 31, 2007, shows that he was assessed as independent for eating with setup assistance from staff. P. Ex. 38, at 1-2.

(iii) Resident 5 was observed without her care-planned Geri Sleeves.

The SOD alleges that, at 10:30 a.m. on May 3, 2007, the surveyor observed Resident 5 without Geri Sleeves on her arms. The surveyor observed the resident again at 11:15 a.m. on May 3, 2007, and the resident was not wearing Geri Sleeves. CMS Ex. 2, at 34; Tr. at 86-87. Resident 5 was assessed in October 2006 as needing to wear Geri Sleeves at all times to prevent skin tears. CMS Ex. 10, at 28, 39. Resident 5's skin care plan dated October 8, 2007, as updated through April 5, 2007, included an intervention for the resident to wear Geri Sleeves at all times to prevent skin tears. CMS Ex. 10, at 36. On March 4, 2007, Resident 5 experienced a skin tear on her left forearm while she was not wearing her Geri Sleeves. CMS Ex. 10, at 40-42. A nurse's note dated February 4, 2007, also shows that the resident suffered a skin tear, but the location of the tear and whether or not the resident was wearing Geri Sleeves is not shown by the evidence before me. P. Ex. 39, at 22. Petitioner does not dispute that Resident 5 did not have Geri Sleeves on her arms when the surveyor observed her. P. Br. at 22-23.

(b) Analysis.

The general quality of care regulation, 42 C.F.R. § 483.25, requires that a facility ensure that each resident receives the necessary care and services to attain or maintain the resident's highest practicable physical, mental, and psychosocial well-being, in accordance with the resident's comprehensive assessment and plan of care that the resident's care planning team developed in accordance with 42 C.F.R. § 483.20. The quality of care regulations impose specific obligations upon a facility related to accident hazards and accidents.

> The facility must ensure that—
>
> (1) The resident environment remains as free of accident hazards as is possible; and
>
> (2) Each resident receives adequate supervision and assistance devices to prevent accidents.

42 C.F.R. § 483.25(h). The SOM, as amended in August 2007, instructs surveyors that the intent of 42 C.F.R. § 483.25(h)(1) and (2) is "to ensure the facility provides an environment that is free from accident hazards over which the facility has control and provides supervision and assistive devices to each resident to prevent avoidable accidents." The facility is expected to: identify, evaluate, and analyze hazards and risks; implement interventions to reduce hazards and risks; and monitor the effectiveness of interventions and modify them when necessary. SOM, app. PP, Guidance to Surveyors for Long Term Care Facilities, F323, Quality of Care (Rev. 27; eff. Aug. 17, 2007).

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

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

Maine Veterans' Home – Scarborough, DAB No. 1975, at 6-7 (2005) (emphasis added).

The Board has also explained the requirements of 42 C.F.R. § 483.25(h)(2) in numerous decisions. *Golden Living Ctr. – Riverchase*, DAB No. 2314, at 7-8 (2010); *Eastwood Convalescent Ctr.*, DAB No. 2088 (2007); *Liberty Commons Nursing and Rehab* -

Alamance, DAB No. 2070 (2007); *Century Care of Crystal Coast*, DAB No. 2076 (2007), *aff'd,* 281 F. App'x 180 (4th Cir. 2008); *Golden Age Skilled Nursing & Rehab. Ctr.*, DAB No. 2026 (2006); *Estes Nursing Facility Civic Ctr.*, DAB No. 2000 (2005); *Northeastern Ohio Alzheimer's Research Ctr.*, DAB No. 1935 (2004); *Woodstock Care Ctr.*, DAB No. 1726 (2000), *aff'd*, 363 F.3d 583 (6th Cir. 2003). Section 483.25(h)(2) does not make a facility strictly liable for accidents that occur; however, it does require that a facility take all reasonable steps to ensure that a resident receives supervision and assistance devices that meet his or her assessed needs and mitigate foreseeable risks of harm from accidents. *Woodstock Care Ctr. v. Thompson*, 363 F.3d at 589 ([A] SNF must take "all reasonable precautions against residents' accidents."). A facility is permitted the flexibility to choose the methods of supervision it uses to prevent accidents, but the chosen methods must be adequate under the circumstances. Whether supervision is "adequate" depends in part upon the resident's ability to protect himself or herself from harm. *Id*. Based on the regulation and the cases in this area, CMS meets its burden to show a *prima facie* case if the evidence demonstrates that the facility failed to provide adequate supervision and assistance devices to prevent accidents, given what was reasonably foreseeable. *Alden Town Manor Rehab. & HCC*, DAB No. 2054, at 5-6, 7-12 (2006). An "accident" is an unexpected, unintended event that can cause a resident bodily injury, excluding adverse outcomes associated as a direct consequence of treatment or care (e.g., drug side effects or reactions). SOM, app. PP, Tag F323; *Woodstock Care Ctr.*, DAB No. 1726, at 4.

I conclude that Petitioner violated 42 C.F.R. § 483.25(h)(2) by failing to provide Residents 5 and 6 with care planned assistive devices and by failing to provide Residents 7 and 8 with supervision or assistance that they were assessed to require.

There is no dispute that Resident 5 was assessed in October 2006 to need Geri Sleeves at all times to prevent skin tears and that her care plan required that she wear Geri Sleeves at all times. CMS Ex. 10, at 28, 36, 39. Petitioner's clinical records for Resident 5 clearly show that when she was not wearing her Geri Sleeves on March 4, 2007, she suffered a skin tear on her left forearm. CMS Ex. 10, at 40-42. Petitioner cannot credibly argue in the face of this evidence that it was not foreseeable that if Resident 5 did not wear Geri Sleeves she was at risk for an accidental skin tear. Petitioner assessed and care planned the resident for Geri Sleeves, an assistive device, to prevent accidental skin tears, and the surveyor's observations that the resident was not wearing the Geri Sleeves is a *prima facie* showing of a violation of 42 C.F.R. § 483.25(h)(2). A skin tear is clearly actual harm. The evidence does not show that Resident 5 suffered actual harm due to the absence of Geri Sleeves on May 3, 2007, and CMS does not charge Petitioner for a violation based on the March 4, 2007 skin tear. The evidence is sufficient to show, however, that Resident 5 was clearly at risk for more than minimal harm due to the increased risk for accidental skin tears when she was not wearing the Geri Sleeves. Petitioner has not rebutted the *prima facie* showing.

There is no dispute that Resident 6 had a physician's orders that required that she use a cup with handle, lid, and straw. CMS Ex. 2, at 26-27; CMS Ex. 11, at 3; P. Ex. 35, at 4, 11. Furthermore, she was assessed as requiring cups with handles, lids, and straws for feeding. CMS Ex. 11, at 7. Resident 6's nutrition care plan, dated March 11, 2007, required the use of cups with handles, lids, and straws. CMS Ex. 11, at 16-17. Nevertheless, it is undisputed that, on May 2, 2007, a surveyor observed Resident 6 drinking from a Styrofoam cup while several assistive devices, adaptive cups with lids, sat on the bedside table. The failure to comply with Resident 6's care plan placed the resident at risk for an accidental injury due to a spill of hot liquid from a cup without a lid, handles, and straw. The evidence shows that other residents did suffer burns from hot liquids spilled for Styrofoam cups, which were commonly used throughout the facility. A burn, first, second, or third degree, is actual harm. Tr. at 135-36. Resident 6 is not alleged to have suffered actual harm on May 2, 2007, but I find the evidence shows that she was at risk for more than minimal harm. I conclude that the example of Resident 6 is a *prima facie* showing of a violation of 42 C.F.R. § 483.25(h)(2) that Petitioner has failed to rebut.

There is no dispute that Resident 7 was assessed as requiring setup help from staff and supervision while eating. P. Ex. 36, at 4. However, the surveyor observed a family member of Resident 7 obtain a Styrofoam cup of coffee, and, ten minutes later, the surveyor observed that Resident 7 had the cup of coffee and no staff or family member was present to provide supervision. CMS Ex. 2, at 28-29. Thus, I find that Resident 7 did not receive the supervision that he required, which placed him at risk for an accidental burn from hot coffee spilled from the Styrofoam cup. The evidence shows that three residents suffered burns from spills of hot liquid from Styrofoam cups and burns are actual harm. Thus, I find that Resident 7 was a risk for more than minimal harm though there was no actual harm. I conclude that there is a *prima facie* showing of a violation of 42 C.F.R. § 483.25(h)(2) that Petitioner has failed to rebut.

Resident 8's MDS's with assessment reference dates of March 18, 2007 and April 3, 2007, assessed her as requiring limited physical assistance of one staff member for eating. P. Ex. 37, at 6-7, 15-16. I do not have evidence that Petitioner ever adopted a care planned intervention to address Resident 8's need for physical assistance with eating. The SOD alleges that Resident 8 was observed by a surveyor on May 2, 2007 with coffee in a Styrofoam cup and no staff member was present. CMS Ex. 2, at 29. I find that Resident 8 was not receiving the assessed assistance and/or supervision necessary while drinking from a Styrofoam cup. I find that there was a risk for more than minimal harm without actual harm for the reasons already discussed. I conclude that the evidence related to Resident 8 amounts to a *prima facia* showing of a violation of 42 C.F.R. § 483.25(h)(2) that Petitioner has failed to rebut.

I conclude, based upon my application of the law to the facts, that the examples cited in the SOD related to Residents 1, 3, 4, and 9 do amount to violations of 42 C.F.R. § 483.25(h)(2).

Resident 9 was assessed as independent for eating with setup assistance from staff. P. Ex. 38, at 1-2. There is no evidence that the use of a Styrofoam cup for hot liquids by a resident is inherently dangerous. The evidence does not show that Resident 9 was at risk to spill a hot liquid from a cup due to some impairment or defect that he suffered. The mere fact that Resident 9 was observed by a surveyor with coffee in a Styrofoam cup, an unused coffee mug on the table, with no staff member present (CMS Ex. 2, at 30), does not amount to a *prima facie* showing that Resident 9 was not receiving necessary supervision or assistance.

Resident 4 experienced a minor burn due to a spill from a Styrofoam cup on February 7, 2007. I have no evidence of any prior instance of accidental spills from Styrofoam or other types of cups that caused harm or posed harm to any resident. Thus, I have no basis to infer that Petitioner was on notice, or should have foreseen, that hot liquids in Styrofoam cups posed a risk for accidental injury to residents who were assessed as able to eat independently, with or without setup assistance. There is no evidence that shows, or from which I may infer, that the assistance and supervision provided to residents was not sufficient to protect them from accidental injury even when using a Styrofoam cup for hot liquids. Resident 1 and 3 experienced spills on the same day, April 8, 2007. For the reasons already stated for Resident 4, I conclude that, on April 8, 2007, the evidence does not show that Petitioner knew or should have foreseen that there was a risk for accidental injury from serving residents hot liquids in Styrofoam cups if they were otherwise assessed as able to eat independently. However, when the spills occurred on April 8, 2007, I conclude that Petitioner could not ignore or overlook that there was some potential for accidental injury due to the use of Styrofoam cups or other open cups for hot liquids, at least with some residents. As of April 8, 2007, Petitioner should have: foreseen the risk for accidental injury; undertaken to assess which residents were susceptible; implemented interventions to mitigate or eliminate the risk; and assessed the effectiveness of its interventions and implemented new more effective interventions if necessary. The evidence before me shows that, between April 8, 2007 and the date of the survey, Petitioner did not take reasonable steps to mitigate or eliminate the risk for accidental injury to its residents from the use of Styrofoam or other cups without lids, by supervision, assistance devices, or other appropriate interventions. Tr. at 202-03; 238-39; 294.

3. There is a basis for the imposition of an enforcement remedy.

4. The immediate jeopardy determination is not subject to review in this case, as the amount of PICMP is not affected by whether or not there is immediate jeopardy.

5. The scope and severity assessed by the surveyors is not subject to review.

6. Whether or not a violation of a statutory or regulatory participation requirement poses more than minimal harm must be determined as part of deciding whether CMS has made a *prima facie* showing that Petitioner was not in substantial compliance with program participation requirements.

7. It is my duty to make a de novo determination of a reasonable enforcement remedy to be applied within the parameters established by the regulations.

8. A PICMP of $8,000 is not reasonable, but a PICMP of $4,000 is reasonable.

I have already acknowledged the regulatory provisions that limit my authority to review the determination that there was immediate jeopardy or the scope and severity determination of the agency. In this case, the only enforcement remedy at issue is the $8,000 PICMP. The regulations establish only a single range for PICMPs. The presence or absence of immediate jeopardy does not automatically escalate the amount of PICMP as it does in the case of CMP imposed for a period of days. The scope and severity determination does not affect the limitation on authority to conduct a NATCEP or the amount of the CMP imposed in this case. Accordingly, the scope and severity determination and declaration of immediate jeopardy are not reviewable. However, it is necessary for me to review and determine whether or not any of the deficiencies posed more than minimal harm for purposes of deciding whether CMS has shown Petitioner was not in substantial compliance. My determinations in that regard were discussed in the analysis of each deficiency subject to my review in this case. As discussed hereafter, it is also necessary for me to consider the severity of each deficiency in assessing a reasonable enforcement remedy.

I have concluded that Petitioner violated 42 C.F.R. §§ 483.10(b)(11) (Tag F157) and 483.25(h)(2) (Tag F324). I have also concluded that each violation posed a risk for more than minimal harm to facility residents. Thus, I conclude that Petitioner was not in substantial compliance with program participation requirements, and there is a basis for the imposition of an enforcement remedy. If a facility is not in substantial compliance with program requirements, CMS has the authority to impose one or more of the enforcement remedies listed in 42 C.F.R. § 488.406, including a CMP. CMS may impose a per day CMP for the number of days that the facility is not in compliance or a PICMP 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). The minimum amount

for a PICMP is $1,000 and the maximum is $10,000. 42 C.F.R. § 488.438(a)(2). CMS elected to impose a PICMP in this case.

When I conclude 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 electing 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. Therefore, 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 based upon the factors 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 set forth in 42 C.F.R. § 488.404(b) include: (1) whether the deficiencies caused ─ (a) no actual harm but had the potential for minimal harm, (b) no actual harm with the potential for more than minimal harm, but not immediate jeopardy, (c) actual harm that is not immediate jeopardy, or (d) 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 Community Rehab. & Specialty Care Ctr.*, DAB No. 1629 (1997).

There is no evidence that Petitioner had a history of noncompliance. Petitioner has not alleged to me that it cannot pay the PICMP and has presented no evidence of its financial condition. Based upon the facts discussed above, I find that the deficiencies were serious in that they posed a risk for actual harm. I am not persuaded that either of the deficiencies posed a risk for serious harm or death considering the nature and extent of the injuries suffered by Residents 1 and 4 and assuming that any burns caused by spilled liquids from a Styrofoam or other uncovered cup were promptly and properly treated. Petitioner is culpable for failing to recognize the risk for accidental injury to its residents and to implement interventions to provide necessary assistance and supervision to mitigate or eliminate the risk for accidental injury from spills of hot liquids from uncovered cups.

Based upon my *de novo* review of the required regulatory factors, I conclude that a PICMP of $8,000 is not reasonable. I conclude that a PICMP of $4,000 is a sufficient

enforcement remedy to encourage Petitioner to achieve and maintain substantial compliance. Indeed, the evidence before me is undisputed that even during the survey Petitioner was taking significant steps to perform assessments to identify residents at risk for accidental injuries and to implement interventions to minimize or eliminate the risk, including removing Styrofoam cups from the facility and prohibiting their use for residents.

III. Conclusion

For the foregoing reasons, I conclude that Petitioner was not in substantial compliance with program participation requirements due to violations of 42 C.F.R. §§ 483.10(b)(11) (Tag F157) and 483.25(h)(2) (Tag F324). There is a basis for the imposition of an enforcement remedy. A PICMP of $8,000 is not a reasonable enforcement remedy, but a $4,000 PICMP is reasonable.

/s/
Keith W. Sickendick
Administrative Law Judge