Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Town Hall Estates – Hillsboro, Inc.,
(CCN: 67-6033),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-12-1265

Decision No. CR3359

Date: September 8, 2014

DECISION

Petitioner, Town Hall Estates - Hillsboro, was not in substantial compliance with program participation requirements from June 7, 2012 through July 2, 2012. There is a basis for the imposition of enforcement remedies. The following enforcement remedies are reasonable: a per-instance civil money penalty (PICMP) in the amount of $1,000 for noncompliance with 42 C.F.R. § 483.10(b)(11) [1] and a PICMP in the amount of $3,000 for noncompliance with 42 C.F.R. § 483.13(c). The determination of substandard quality of care was clearly erroneous and Petitioner remained eligible to be approved to conduct a nurse aide training and competency evaluation program (NATCEP).

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[1] Citations are to the 2011 revision of the Code of Federal Regulations (C.F.R.), unless otherwise stated.

I. Background

Petitioner is located in Hillsboro, Texas, and participates in Medicare as a skilled nursing facility (SNF) and the state Medicaid program as a nursing facility (NF). On June 7, 2012, Petitioner was surveyed by the Texas Department of Aging and Disability Services (state agency) and found not in substantial compliance with program participation requirements due to multiple regulatory violations. The Centers for Medicare & Medicaid Services (CMS) notified Petitioner by letter dated July 20, 2012, that it was imposing the following enforcement remedies: termination of Petitioner's provider agreement, unless the facility achieved substantial compliance before December 7, 2012; PICMPs in the amount of $1,000 for an alleged violation of 42 C.F.R. § 483.10(b)(11) (Tag F157) and $3,000 for an alleged violation of 42 C.F.R. § 483.13(c) (Tag F224); and a denial of payment for new admissions (DPNA) beginning July 7, 2012. CMS Exhibit (Ex.) 4 at 1-3. On August 24, 2012, CMS notified Petitioner that Petitioner returned to substantial compliance with program participation requirements on July 3, 2012, and the termination and DPNA were rescinded but the PICMPs were unchanged. CMS Ex. 5.

Petitioner requested a hearing before an administrative law judge (ALJ) on September 12, 2012. The case was assigned to me for hearing and decision on September 25, 2012, and an Acknowledgement and Prehearing Order (Prehearing Order) was issued at my direction. This case was set for hearing on July 17 and 18, 2013. On July 9, 2013, Petitioner waived an oral hearing and requested judgment on the pleadings and documentary evidence. CMS did not request an opportunity to present oral testimony and on July 15, 2013, I accepted the waiver of oral hearing and set a briefing schedule.

The parties filed opening briefs (CMS Br. and P. Br.) and reply briefs (CMS Reply and P. Reply). CMS offered CMS Exs. 1 through 17 and Petitioner offered exhibits (P. Exs.) 1 through 27.[2] No objection has been made to my consideration of CMS Exs. 1 through 15 and P. Exs. 1 through 27 and they are admitted as evidence. On August 23, 2013, Petitioner filed objections to CMS Exs. 16 and 17 that CMS filed with its opening brief on August 14, 2013. Petitioner cited multiple grounds for why CMS Exs. 16 and 17

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[2] Petitioner's exhibits were not properly marked in accordance with the Prehearing Order ¶ II.J and the Civil Remedies Division Procedures (CRDP) § 9. Petitioner numbered the pages of its 27 exhibits consecutively 1 through 82, beginning with page 1 on the first page of P. Ex. 1 and continuing through page 82 on the last page of P. Ex. 27. The Prehearing Order and CRDP require that the pages of each individual exhibit be numbered consecutively beginning with 1. The exhibits were not returned to Petitioner as the error does not pose any risk for confusion when referring to Petitioner's exhibits.

should not be admitted as evidence and should be stricken. Petitioner's objections to the admission of CMS Exs. 16 and 17 as evidence are sustained. The exhibits are not admitted as evidence but will remain part of the record.

The Secretary of the Department of Health and Human Services (the Secretary) requires that witnesses in this proceeding testify under oath or affirmation. 42 C.F.R. § 498.62. Therefore, I may not consider witness testimony, in any form, that is not sworn or affirmed. CMS Ex. 16 purports to be the declaration of Daniel J. McElroy, RN. CMS Ex. 17 purports to be the declaration of Linda McClain, RN. Neither document reflects that it was executed under oath in the presence of one authorized to administer oaths such as a notary. Therefore, CMS Exs. 16 and 17 are unsworn statements of the purported declarants. The Prehearing Order, ¶ II.L.8 provides in pertinent part:

> A written witness' statement may be submitted in lieu of live direct testimony at hearings, or in support of a motion for summary judgment, or when a hearing is waived. Written witness statements must be submitted in the form of an affidavit made under oath or as a written unsworn declaration executed in accordance with 28 U.S.C. § 1746.

The Prehearing Order clearly notified counsel for CMS that an unsworn statement must be executed in accordance with 28 U.S.C. § 1746. Congress provided an exception to the requirement that testimony be under oath or affirmation in 28 U.S.C. § 1746, as follows:

> Wherever, under any law of the United States or under any rule, regulation, order, or requirement made pursuant to law, any matter is required or permitted to be supported, evidenced, established, or proved by the sworn declaration, verification, certificate, statement, oath, or affidavit, in writing of the person making the same (other than a deposition, or an oath of office, or an oath required to be taken before a specified official other than a notary public), such matter may, with like force and effect, be supported, evidenced, established, or proved by the unsworn declaration, certificate, verification, or statement, in writing of such person which is subscribed by him, as true under penalty of perjury, and dated, in substantially the following form:
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> (1) If executed without the United States: "I declare (or certify, verify, or state) under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on (date).
>
> (Signature)".

> (2) If executed within the United States, its territories, possessions, or commonwealths: "I declare (or certify, verify, or state) under penalty of perjury that the foregoing is true and correct. Executed on (date).
>
> (Signature)".

The declarations marked as CMS Exs. 16 and 17 were not sworn or affirmed and they do not "substantially" comply with the simple requirements of 28 U.S.C. § 1746. Accordingly, CMS Exs. 16 and 17 are not admissible as witness testimony but must be excluded from consideration as substantive evidence on the merits.

II. Discussion

A. Issues

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

Whether the remedy imposed is reasonable.

B. Applicable Law

The statutory and regulatory requirements for participation of a SNF in Medicare are found at section 1819 of the Social Security Act (Act) and at 42 C.F.R. pt. 483. Section 1819(h)(2) of the Act authorizes the Secretary to impose enforcement remedies against a SNF for failure to comply substantially with the federal participation requirements established by sections 1819(b), (c), and (d) of the Act.[3] The Act requires that the Secretary terminate the Medicare participation of any SNF that does not return to substantial compliance with participation requirements within six months of being found not to be in substantial compliance. Act § 1819(h)(2)(C). The Act also requires that the Secretary deny payment of Medicare benefits for any beneficiary admitted to a SNF, if the SNF fails to return to substantial compliance with program participation requirements within three months of being found not to be in substantial compliance – commonly referred to as the mandatory or statutory DPNA. Act § 1819(h)(2)(D). The Act grants the Secretary discretionary authority to terminate a noncompliant SNF's participation in

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

Medicare, even if there has been less than 180 days of noncompliance. The Act also grants the Secretary authority to impose other enforcement remedies, including a discretionary DPNA, CMPs, appointment of temporary management, and other remedies such as a directed plan of correction. Act § 1819(h)(2)(B).

The Secretary has delegated to CMS and the states the authority to impose remedies against a long-term care facility that is not complying substantially with federal participation requirements. "*Substantial compliance* means a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm." 42 C.F.R. § 488.301 (emphasis in original). A deficiency is a violation of a participation requirement established by sections 1819(b), (c), and (d) of the Act or the Secretary's regulations at 42 C.F.R. pt. 483, subpt. B. Noncompliance refers to any deficiency that causes a facility not to be in substantial compliance. 42 C.F.R. § 488.301. State survey agencies survey facilities that participate in Medicare on behalf of CMS to determine whether the facilities are complying with federal participation requirements. 42 C.F.R. §§ 488.10-.28, 488.300-.335. The regulations specify the enforcement remedies that CMS may impose if a facility is not in substantial compliance with Medicare requirements. 42 C.F.R. § 488.406.

The regulations specify that a CMP that is imposed against a facility on a per-day basis will fall into one of two ranges of penalties. 42 C.F.R. §§ 488.408, 488.438. The upper range of a CMP, $3,050 per day to $10,000 per day, is reserved for deficiencies that pose immediate jeopardy to a facility's residents and, in some circumstances, for repeated deficiencies. 42 C.F.R. § 488.438(a)(1)(i), (d)(2). "*Immediate jeopardy* means a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301 (emphasis in original). The lower range of CMPs, $50 per day to $3,000 per day, is reserved for deficiencies that do not pose immediate jeopardy, but either cause actual harm to residents, or cause no actual harm but have the potential for causing more than minimal harm. 42 C.F.R. § 488.438(a)(1)(ii). CMS is also authorized to impose a PICMP for each instance that a facility is not in substantial compliance, whether or not the deficiency poses immediate jeopardy. 42 C.F.R. § 488.430(a). The authorized range for a PICMP is $1,000 to $10,000. 42 C.F.R. § 488.438(a)(2).

The state agency notified Petitioner by letter dated June 22, 2012, that a determination of substandard quality of care based on the alleged violation of 42 C.F.R. § 483.13 (Tag F224), triggered an extended or partial extended survey. Therefore, the state was required to withdraw approval of Petitioner to run a NATCEP. CMS Ex. 4 at 8. Pursuant to sections 1819(b)(5) and 1919(b)(5) of the Act, SNFs and NFs may only use nurse aides who have completed a training and competency evaluation program. Pursuant to sections 1819(f)(2) and 1919(f)(2) of the Act, the Secretary was tasked to develop requirements

for approval of NATCEPs and the process for review of those programs. Sections 1819(e) and 1919(e) of the Act impose upon the states the requirement to specify what NATCEPs they will approve that meet the requirements that the Secretary established and a process for reviewing and re-approving those programs using criteria the Secretary set. The Secretary promulgated regulations at 42 C.F.R. pt. 483, subpt. D. Pursuant to 42 C.F.R. § 483.151(b)(2) and (f), a state may not approve and must withdraw any prior approval of a NATCEP offered by a SNF or facility NF that has been: (1) subject to an extended or partial extended survey under sections 1819(g)(2)(B)(i) or 1919(g)(2)(B)(i) of the Act; (2) assessed a CMP of not less than $5,000; or (3) subject to termination of its participation agreement, a DPNA, or the appointment of temporary management. Extended and partial extended surveys are triggered by a finding of "substandard quality of care" during a standard or abbreviated standard survey and involve evaluating additional participation requirements. "Substandard quality of care" is identified by the situation where surveyors identify one or more deficiencies related to participation requirements established by 42 C.F.R. § 483.13 (Resident Behavior and Facility Practices), § 483.15 (Quality of Life), or § 483.25 (Quality of Care) that are found to constitute either immediate jeopardy, a pattern of or widespread actual harm that does not amount to immediate jeopardy, or a widespread potential for more than minimal harm that does not amount to immediate jeopardy and there is no actual harm. 42 C.F.R. § 488.301.

The Act and regulations make a hearing before an ALJ available to a long-term care facility against which CMS has determined to impose an enforcement remedy. Act §§ 1128A(c)(2), 1866(h); 42 C.F.R. §§ 488.408(g), 498.3(b)(13). A facility has a right to appeal a "certification of noncompliance leading to an enforcement remedy." 42 C.F.R. §§ 488.408(g)(1); 488.330(e), 498.3. However, the choice of remedies, or the factors CMS considered when choosing remedies, are not subject to review. 42 C.F.R. § 488.408(g)(2). A facility may only challenge the scope and severity level of noncompliance determined by CMS, if a successful challenge would affect the range of the CMP that may be imposed or impact the facility's authority to conduct a NATCEP. 42 C.F.R. § 498.3(b)(14), (16), (d)(10)(i). The CMS determination as to the level of noncompliance, including the finding of immediate jeopardy, "must be upheld unless it is clearly erroneous." 42 C.F.R. § 498.60(c)(2); *Woodstock Care Ctr.*, DAB No. 1726 at 9, 38 (2000), *aff'd*, 363 F.3d 583 (6th Cir. 2003). The Departmental Appeals Board (the Board) has long held that the net effect of the regulations is that a provider has no right to challenge the scope and severity level assigned to a noncompliance finding, except in the situation where that finding was the basis for an immediate jeopardy determination. *See, e.g., Ridge Terrace*, DAB No. 1834 (2002); *Koester Pavilion*, DAB No. 1750 (2000). ALJ review of a CMP is subject to 42 C.F.R. § 488.438(e).

The hearing before an ALJ is a de novo proceeding, that is, "a fresh look by a neutral decision-maker at the legal and factual basis for the deficiency findings underlying the remedies." *Life Care Ctr. of Bardstown*, DAB No. 2479 at 32 (2012) (citation omitted).

The Board has long held that the petitioner bears the burden of persuasion to show by a preponderance of the evidence that it was in substantial compliance with participation requirements or any affirmative defense. *Batavia Nursing & Convalescent Inn*, DAB No. 1911 (2004); *Batavia Nursing & Convalescent Ctr.*, DAB No. 1904, *aff'd*, *Batavia Nursing & Convalescent Ctr. v. Thompson*, 129 F. App'x 181 (6th Cir. 2005); *Emerald Oaks*, DAB No. 1800 (2001); *Cross Creek Health Care Ctr.*, DAB No. 1665 (1998); *Hillman Rehab. Ctr.*, DAB No. 1611, *aff'd*, *Hillman Rehab. Ctr. v. United States*, No. 98-3789 (GEB), 1999 WL 34813783 (D.N.J. May 13, 1999). However, only when CMS makes a prima facie showing of noncompliance, is the facility burdened to show, by a preponderance of the evidence on the record as a whole, that it was in substantial compliance or had an affirmative defense. *Evergreene Nursing Care Ctr.*, DAB No. 2069 at 4.

The standard of proof, or quantum of evidence required, is a preponderance of the evidence. CMS has the burden of coming forward with the evidence and making a prima facie showing of a basis for imposing an enforcement remedy. The Board has stated that CMS must come forward with "evidence related to disputed findings that is sufficient (together with any undisputed findings and relevant legal authority) to establish a prima facie case of noncompliance with a regulatory requirement." *Evergreene Nursing Care Ctr.*, DAB No. 2069 at 7 (2007); *Batavia Nursing & Convalescent Ctr.*, DAB No 1904. "Prima facie" means generally that the evidence is "[s]ufficient to establish a fact or raise a presumption unless disproved or rebutted." *Black's Law Dictionary* 1228 (8th ed. 2004). In *Hillman Rehab. Ctr.*, the Board described the elements of the CMS prima facie case in general terms as follows:

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

DAB No. 1611 at 8. Thus, CMS has the initial burden of coming forward with sufficient evidence to show that its decision to impose an enforcement remedy is legally sufficient under the statute and regulations. To make a prima facie case that its decision was legally sufficient, CMS must: (1) identify the statute, regulation or other legal criteria to which it seeks to hold the provider; (2) come forward with evidence upon which it relies for its factual conclusions that are disputed by Petitioner; and (3) show how the deficiencies it found amount to noncompliance that warrants an enforcement remedy, that is, that there was a risk for more than minimal harm due to the regulatory violation. In

Evergreene Nursing Care Ctr., the Board explained its "well-established framework for allocating the burden of proof on the issue of whether a SNF is out of substantial compliance" as follows:

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

DAB No. 2069 at 7. CMS makes a prima facie showing of noncompliance if the credible evidence CMS relies on is sufficient to support a decision in its favor absent an effective rebuttal. The regulation gives Petitioner notice of the criteria or elements it must meet to comply with the program participation requirement established by the regulation. 5 U.S.C. §§ 551(4), 552(a)(1). Therefore, in order to make a prima facie showing of noncompliance, CMS must show that Petitioner violated the regulation by not complying with one or more of the criteria or elements of the regulation, which is a deficiency. CMS must also show that the deficiency amounted to "noncompliance," that is, that Petitioner was not in substantial compliance because the deficiency posed a risk for more than minimal harm. *See Jennifer Matthew Nursing & Rehab. Ctr.*, DAB No. 2192 at 20 n.12 (2008). A facility can overcome CMS's prima facie case either by rebutting the evidence upon which that case rests, or by proving facts that affirmatively show substantial compliance. "An effective rebuttal of CMS's prima facie case would mean that at the close of the evidence the provider had shown that the facts on which its case depended (that is, for which it had the burden of proof) were supported by a preponderance of the evidence." *Id.* at 7-8 (citations omitted).

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

My conclusions of law are set forth in bold text followed by my findings of fact and analysis. I have carefully considered all the evidence and the arguments of both parties, though not all may be specifically discussed in this decision. I discuss in this decision the credible evidence given the greatest weight in my decision-making.[4] I also discuss any

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

evidence that I find is not credible or worthy of weight. The fact that evidence is not specifically discussed should not be considered sufficient to rebut the presumption that I considered all the evidence and assigned such weight or probative value to the credible evidence that I determined appropriate within my discretion as an ALJ. There is no requirement for me to discuss the weight given every piece of evidence considered in this case, nor would it be consistent with notions of judicial economy to do so. Charles H. Koch, Jr., *Admin. L. and Prac.* § 5:64 (3d ed. 2013).

The state agency cited Petitioner with the following deficiencies based on the survey completed on June 7, 2012: 42 C.F.R. §§ 483.10(b)(11) (Tag F157, [5] scope and severity (s/s) H[6]); 483.13(a) (Tag F221, s/s E); 483.13(c) (Tag F224, s/s H); 483.13(c)(1)(ii)-(iii), (c)(2)-(4) (Tag F225, s/s E); 483.13(c) (Tag F226, s/s E); 483.20(d) and 483.20(k)(1) (Tag F279, s/s E); 483.20(k)(3)(ii) (Tag F282, s/s E); 483.75(i) (Tag F501, s/s C); 483.75(l)(1) (Tag F514, s/s C); and 483.75(c)(1) (Tag F520, s/s C). CMS proposes to

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[5] This is a "Tag" designation as used in CMS Publication 100-07, State Operations Manual (SOM), app. PP – Guidance to Surveyors for Long Term Care Facilities (http://www.cms.hhs.gov/Manuals/IOM/list.asp). The "Tag" refers to the specific regulatory provision allegedly violated and CMS's policy guidance to surveyors. Although the SOM does not have the force and effect of law, the provisions of the Act and regulations interpreted clearly do have such force and effect. *Ind. Dept. 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.

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

impose a $1,000 PICMP for the deficiency cited as a violation of 42 C.F.R. § 483.10(b)(11) (Tag F157) and a $3,000 PICMP for the deficiency cited as a violation of 42 C.F.R. § 483.13(c)(Tag F224). The finding of substandard quality of care that caused the loss of NATCEP approval was also caused by the citation under 42 C.F.R. § 483.13(c) (Tag F224). No enforcement remedies are proposed based upon the other cited deficiencies and they are not subject to my review. 42 C.F.R. §§ 488.408(g), 498.3(b)(13)-(15).

1. Judgment on the written pleadings and documentary evidence is permissible in this case.

Pursuant to 42 C.F.R. § 498.66(a), an affected party, such as Petitioner, may waive its right to appear and present evidence at an oral hearing by filing a written waiver. When a written waiver is filed by a petitioner, an ALJ need not conduct an oral hearing except in two circumstances: the ALJ concludes witness testimony is necessary to clarify facts at issue; or CMS shows good cause for presenting oral testimony. 42 C.F.R. § 498.66(b). Petitioner waived its right to an oral hearing consistent with the requirements of 42 C.F.R. § 498.66(a). After review of the evidence and pleadings of the parties, I conclude that oral testimony is not necessary for clarification of the facts at issue. CMS has not argued that oral testimony is necessary or otherwise shown good cause to convene an oral hearing.

In accordance with 42 C.F.R. § 498.66, the record of the hearing in this case without oral testimony consists of the documentary evidence admitted and the parties' pleadings. The parties also had a reasonable opportunity for rebuttal as reflected by their various filings.

Accordingly, this decision is on the merits.

2. CMS has made a prima facie showing, which Petitioner has not rebutted, that Petitioner violated 42 C.F.R. § 483.10(b)(11) (Tag F157) and that the violation posed a risk for more than minimal harm.

a. Facts

Both alleged deficiencies subject to my review arise from the same incident involving Resident 1. The following facts are based on Resident 1's clinical records and are not disputed by Petitioner. P. Prehearing Brief at 3-5; P. Br. at 3-5; P. Reply 2-4.

Resident 1 was an 88-year-old, non-ambulatory woman, unable to bear her own weight, and she had not walked in a year. Resident 1 was receiving anticoagulant therapy using Coumadin since 2007 and was at risk for bleeding. Resident 1 suffered from thrombocytopenia (low platelet count) (P. Ex. 12 at 32, 34), anemia, cerebrovascular disease, peripheral vascular disease, osteoporosis, congestive heart failure, hypertension,

gout, chronic swelling in both feet, loss of bone density, and she was at risk for fractures. Resident 1 was cognitively impaired due to Alzheimer's disease. Resident 1 had a history of combative behavior against staff and against other residents and was easily agitated. Resident 1 had chemical restraints and had physical restraints ordered for her in the form of bedside rails. P. Ex. 10 at 25, P. Ex. 26 at 79; CMS Ex. 10 at 1, 3-8, 16-34.

Resident 1 was assessed as at risk for bleeding and bruising due to her anticoagulant therapy. She was also assessed as at risk for spontaneous fractures due her diagnosis of osteoporosis. Resident 1's care plan required Petitioner's staff to monitor her for hematomas and bruising and to ensure no falls or spontaneous fractures occurred. CMS Ex. 10 at 25, 30, 33.

On May 30 and 31, and up to June 1, 2012, at around 7:00 a.m., Resident 1 was observed as having no bruises on her left leg. P. Exs. 2 at 4; 4 at 10; 11 at 30; CMS Ex. 12 at 2-4. At about 8:45 a.m. on June 1, staffed called for the charge nurse, RN Charrie Evans, to come to Resident 1's room. RN Evans observed that Resident 1 had a bruise on her left outer ankle, approximately one centimeter in diameter, with a small tear or open area that was bleeding. Resident 1's ankles were both swollen but that was normal for her according to RN Evans. Resident 1 said "ouch" when the wound was cleaned with saline but did not otherwise complain of pain while antibiotic ointment and a dressing were applied. On June 2, 2012, RN Evans was again called to Resident 1's room to inspect the left ankle wound. RN Evans noted that the wound was still bleeding so she applied pressure for five minutes but the bleeding would not stop. RN Evans called for the weekend RN supervisor, Rebeka Calhoun. RN Calhoun entered Resident 1's room and noted that her left ankle was exposed with an old dressing with serosanguineous drainage present. She asked RN Evans whether the wound was a pressure sore or traumatic injury. RN Evans and the CNA present denied any knowledge of how the wound occurred. However, RN Evans told her that the wound was bleeding on June 1 and again on June 2, 2012. RN Calhoun described the wound as two centimeters (nickel-size), purple, on the left outer ankle, with a tiny open area in the center. The left foot was swollen and there was light purple bruising. RN Calhoun reported that when she lifted the foot she observed serosanguineous drainage coming from the tiny, open area of the wound. When RN Calhoun moved the left foot she could feel crepitus and Resident 1 complained of pain. RN Calhoun determined that further assessment of the left foot was required, and she contacted the physician and obtained an order for the resident to be sent to the emergency room. RN Calhoun contacted the Assistant Director of Nursing (ADON) Margaret Green, and reported the condition of Resident 1 and the transfer. But RN Calhoun did not contact the abuse coordinator because she assessed no evidence of abuse or neglect. P. Exs. 8 at 19; 17 at 48; 18 at 50; 22 at 71; 25 at 77; CMS Exs. 10 at 37-38; 12 at 1, 5-6. Resident 1 was transported to the emergency room. Resident 1 was admitted to the hospital for surgical repair of a tibia and fibula fracture at the level of her ankle. CMS Exs. 10 at 13, 38; 13 at 1, 5, 11; P. Exs. 7 at 16; 14 at 39-42; 23 at 72.

Resident 1's wound and bruise were not reported to her physician until 1:05 p.m. on June 2, 2012, 28 hours after the wound was first discovered at approximately 8:45 a.m. on June 1, 2012. P. Ex. 8 at 19; 25 at 77; CMS Ex. 10 at 38; CMS Ex. 12 at 1.

Petitioner's notification procedures entitled "Before calling MD/NP/PA" requires a complete evaluation of the resident documented in the clinical record prior to reporting a change in condition to a physician, nurse practitioner or physician's assistant. The notification procedures require immediate notification of the physician when the resident displays a sign or symptom of: "any suspected fracture or discoloration" (CMS Ex. 15 at 10); "any wound that will not stop bleeding OR that exposes subcutaneous tissue"(CMS Ex. 10 at 16, emphasis in original); and for "deep or open wounds, OR with more than minor bleeding" (CMS Ex. 15 at 13) (emphasis in original).

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 --
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> (A) An accident involving the resident which results in injury and has the potential for requiring physician intervention;
>
> (B) A significant change in the resident's physical, mental, or psychosocial status (i.e., a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications);
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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 Sec. 483.12(a).

42 C.F.R. § 483.10(b)(11)(i).

The regulatory language is clear but has often been misconstrued. Therefore, further analysis of the regulation and its history is appropriate not because interpretation is required but for the sake of clarity in application.

Residents in long-term care facilities have the rights enumerated in 42 C.F.R. § 483.10. Among the rights listed are the right to notice of rights and services, including the right to notice of changes in the resident's condition to the resident, the resident's physician, and

the resident's legal representative or interested family member. The language of the regulation is very specific that the facility "**must immediately inform** the resident; **consult** the physician; and . . . **notify** the legal representative or an interested family member." 42 C.F.R. § 483.10(b)(11) (emphasis added). The regulation creates a distinction between informing the resident and family and the requirement that Petitioner "**must immediately . . . consult with the resident's physician** . . . when there is a significant change in the resident's physical, mental, or psychosocial status" (meaning a deterioration in the resident's condition); an accident that may require physician intervention; a need to alter treatment; or a decision to transfer or discharge the resident to another facility or institution. *Id.* (emphasis added). It is clear from the regulatory language that the requirement to consult is not discretionary and requires more than merely informing or notifying the physician. The preamble to the final rule reflects the drafters' specific intention that the facility should "inform" the resident of the changes that have occurred but should "consult with the physician about actions that are needed." 56 Fed. Reg. 48,826 at 48,833 (Sept. 26, 1991).

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

Furthermore, if we balance the relative inconvenience to a physician and the facility staff to consult with the possibility for dire consequences to the resident if the physician is not consulted, it seems that any inconvenience certainly is inconsequential and outweighed

by the potential for significant harm if the facility fails to consult the physician. This regulation is entitled "Resident rights" and the requirements of this specific regulation provide that every resident has the right to a dignified existence and access to and communication with persons and services inside and outside the facility. Therefore, the regulatory requirements make inconsequential any inconvenience under the regulation to the resident's physician or to the facility staff when compared to the protection and facilitation of the rights of the resident. *See* 56 Fed. Reg. at 48,834. Finally, the regulation does not allow the facility to pick and choose whom to notify and whom to consult. Rather, it requires the facility to immediately inform the resident, consult the physician and notify the resident's legal representative or interested family member. The regulation also directly burdens the facility to consult and notify and does not permit a facility to rely upon a notification or consultation being accomplished by the resident or a third-party such as an emergency room.

The surveyors allege in the Statement of Deficiencies (SOD) for the survey completed on June 7, 2012, that Petitioner violated 42 C.F.R. § 483.10(b)(11) because Petitioner's staff failed to consult with Resident 1's physician when there was a need to alter treatment significantly when Resident 1 exhibited a change in condition. CMS Ex. 1 at 2. CMS also argues that Resident 1 had a significant change that triggered the requirement to immediately consult under 42 C.F.R. § 483.10(b)(11)(B). Alternatively, CMS argues that there was a need to significantly alter treatment that triggered the requirement for immediate consultation under 42 C.F.R. § 483.10(b)(11)(C). CMS Br. at 7-11; CMS Reply at 5-6. Petitioner limits its argument to whether or not there was a significant change in Resident 1's condition that triggered the immediate notification requirement of 42 C.F.R. § 483.10(b)(11)(B). P. Br. at 2-3, 7-8; P. Reply at 2-4, 5-6.

Neither party addressed either 42 C.F.R. § 483.10(b)(11)(A) and (D) or their application in this case. I am satisfied that 42 C.F.R. § 483.10(b)(11)(D) is not violated in this case as on June 2, 2012, the physician directed that Resident 1 be transferred to a hospital for care Petitioner could not deliver. 42 C.F.R. § 483.12(a)(2)(i). The evidence is not clear that Resident 1 suffered a significant change in physical condition at about 8:45 a.m. on June 1, 2012, thus, triggering the duty to immediately consult under 42 C.F.R. § 483.10(b)(11)(B). The evidence is also not clear that at 8:45 a.m. on June 1, 2012, there was a need to significantly alter Resident 1's treatment, thus, triggering the duty to immediately consult under 42 C.F.R. § 483.10(b)(11)(C). However, the evidence is clear that at 8:45 a.m. June 1, 2012, Resident 1 had a bruise, one centimeter in diameter that had a wound in the center that was bleeding. None of Petitioner's staff has admitted knowing how the resident suffered the injury to her left ankle. Therefore, on June 1, 2012, Resident 1's injury could only be attributable to an accident, that 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 (Aug. 17, 2007); *Woodstock Care Ctr.*, DAB No. 1726, at 4. Pursuant to 42 C.F.R. § 483.10(b)(11)(A), the duty to consult with the

physician is triggered whenever there is an accident involving the resident that "results in injury and has the potential for requiring physician intervention." The evidence is clear that Resident 1 was at increased risk for bleeding, bruising, and factures due to Coumadin therapy and her osteoporosis. Because staff did not know the cause of the injury, staff could not rule out that Resident 1 had suffered a traumatic accidental injury that had caused a deep puncture wound or a fracture of bones of the tarsals, the tibia, or the fibula. Therefore, the bruised area with bleeding was likely to require physician intervention and staff should have immediately consulted with Resident 1's physician and not waited to see what might develop.

Accordingly, I conclude that Petitioner violated 42 C.F.R. § 483.10(b)(11), specifically the requirement for physician consultation in the event of an accident that resulted in an injury that had the potential to require physician intervention. In reaching this conclusion, I have considered that the SOD and the CMS arguments did not specifically notify Petitioner that the violation was based on 42 C.F.R. § 483.10(b)(11)(A). I conclude that the deficiency should not be excused on a theory that Petitioner was not adequately notified of the basis for the imposition of an enforcement remedy. The surveyors correctly cited to 42 C.F.R. § 483.10(b)(11) in the SOD and they did not cite specific subsections of the regulation allegedly violated. CMS Ex. 1 at 1. Therefore, the SOD adequately notified Petitioner of the regulatory basis and the need to defend against violation of the entire regulation. The SOD also adequately notified Petitioner of the factual bases for the alleged deficiency. The failure of counsel for CMS to correctly identify the defect in the surveyors' allegations in the SOD and focus on 42 C.F.R. § 483.10(b)(11)(A) is inexplicable.[7] It is understandable that Petitioner's counsel would choose not to highlight the error of counsel for CMS, particularly where, as here, the violation of 42 C.F.R. § 483.10(b)(11)(A) is both evident and indefensible. Because Petitioner had adequate notice that the deficiency was based on violation of 42 C.F.R. § 483.10(b)(11) and the factual bases for the deficiency, I conclude that Petitioner had adequate notice of what to defend.

I also conclude that Resident 1 was at risk for more than minimal harm and suffered actual harm due to the deficiency. The surveyors specifically allege in the SOD that the failure to immediately consult the physician resulted in additional pain for Resident 1 and risked additional tissue trauma, infection, and loss of limb. The identified risk for systemic infection and amputation are supported by the medical opinions of the physicians who evaluated Resident 1 at the hospital and decided to proceed with surgery

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[7] Counsel for CMS is encouraged to exercise caution and not overstate or mischaracterize the evidence or permissible inferences to draw from the evidence. Mischaracterization may not always be excused as zealous representation, may be sanctionable, and also damages the credibility of the government case.

despite her co-morbidities. CMS Ex. 13 at 12. The evidence is undisputed that on June 2, 2012, Resident 1 complained of pain when RN Calhoun moved her left foot – pain Resident 1 would not have experienced if she had been promptly treated on June 1, 2012. However, as discussed hereafter, I conclude that surveyors' scope determination that there was a pattern of actual harm was clearly erroneous.

3. CMS has made a prima facie showing, which Petitioner has not rebutted, that Petitioner violated 42 C.F.R. § 483.13(c) (Tag F224) and that the violation posed a risk for more than minimal harm.

a. Facts

The surveyors cited Petitioner for a violation of 42 C.F.R. § 483.13(c)(Tag F224). The surveyors allege that Petitioner failed to prevent the neglect of Resident 1, based on the same facts discussed under Tag F157. [8]

b. Analysis

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 Act does not specifically address neglect. However, the Secretary requires that a facility must 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). Neglect is defined in the regulations as "failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness." 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 service 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

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[8] The SOM instructs surveyors to cite the mistreatment, neglect, or misappropriation of resident property under Tag F224. Surveyors are instructed to cite the failure to develop and implement policies and procedures prohibiting mistreatment, neglect, and abuse of residents and misappropriation of resident property under Tag F226. SOM app. PP, Tags F224 and F226 (May 21, 2004). The surveyors also cited Petitioner for deficiencies under Tag F225 for failure to investigate and report the neglect of Resident 1 and under Tag F226 based on the inadequacy and/or failure to implement its policy and procedures. Neither Tag F225 nor F226 are before me as no enforcement remedy was imposed based on either deficiency. CMS Ex. 4.

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*, No. 04-04199 (6th Cir. Dec. 14, 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. 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).

On June 1, 2012, staff identified that Resident 1 had a one centimeter diameter bruise on her left ankle with a small wound near the center that was bleeding. The evidence shows that staff applied antibiotic ointment and a dressing. There is no dispute that Resident 1 was assessed and care planned as being at risk for bruising and bleeding due to her anticoagulant therapy. There is no dispute that Resident 1 was at risk for fractures due to her osteoporosis. There is no dispute that staff admitted no knowledge of how Resident 1 suffered the injury discovered on June 1, 2012. As discussed under Tag F157, Petitioner was required by the regulations to consult with Resident 1's physician. Petitioner's failure to consult was a failure to deliver a service necessary to avoid physical harm and mental anguish. Accordingly, I conclude that Petitioner violated 42 C.F.R. § 483.13(c) because Petitioner failed to ensure that Resident 1 was not subject to neglect. I further conclude that Resident 1 suffered actual harm in the form of pain, particularly as evidenced by her complaint of pain with movement of the foot on June 2, 2012.

Petitioner argues that there is no evidence that its staff knew or should have known on June 1, 2012, that there was a possibility that Resident 1 suffered a fracture or dislocation or that her wound was "deep or open" with more than minor bleeding. P. Br. at 7. Petitioner's argument effectively admits that Resident 1 was neglected. Indeed, the evidence shows that staff did not know whether or not Resident 1 had a fracture, how

deep her wound was, or whether she had more than minor bleeding and, the fact staff did not know these facts is the crux of the problem.[9] Resident 1's records show that her care planning team assessed her as being at heightened risk for bruising and bleeding and fractures and the team developed a care plan to address those risks. However, when confronted with a wound of unknown origin that staff was apparently not qualified to completely assess, staff rendered minor first aid for this at-risk resident and failed to seek more qualified assistance to attempt to determine the severity of her accidental injury and necessary treatment. Therefore, Petitioner's staff neglected to provide Resident 1 necessary care and services.

Accordingly, I conclude that Petitioner violated 42 C.F.R. § 483.13(c) (Tag F224) and the violation cause Resident 1 to suffer actual harm.

4. The determination that the deficiency cited as a violation of 42 C.F.R. § 483.13(c) (Tag F224) constituted a pattern of noncompliance was clearly erroneous.

5. There was no substandard quality of care that triggered an extended or partial extended survey.

6. Petitioner remained eligible to conduct a NATCEP .

A facility may only challenge the level of noncompliance determined by CMS, if a successful challenge would affect the range of the CMP that may be imposed or impact the facility's authority to conduct a NATCEP. 42 C.F.R. § 498.3(b)(14), (16). Pursuant to 42 C.F.R. § 498.3(b)(16) "the finding of substandard quality of care that leads to the loss by a SNF or NF of the approval of its nurse aide training program," is an initial determination that is subject to ALJ and Board review. In a civil money penalty case, such as this case, the CMS determination of the level of noncompliance must be upheld unless it is clearly erroneous. 42 C.F.R. § 498.60(c)(2).

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[9] I am willing to assume that had staff correctly assessed the source of the wound and its severity, staff would have taken immediate action to obtain qualified assistance.

The state agency notified Petitioner by letter dated June 22, 2012, that a determination of substandard quality of care based on noncompliance under Tag F224 caused an extended or partial extended survey. Therefore, Petitioner approval to conduct a NATCEP was withdrawn and Petitioner was ineligible to conduct a NATCEP for two years.[10] CMS Ex. 4 at 6-9.

Pursuant to 42 C.F.R. § 483.151(b)(2) and (f), a state may not approve and must withdraw any prior approval of a NATCEP offered by a SNF or NF that has been: (1) subject to an extended or partial extended survey under sections 1819(g)(2)(B)(i) or 1919(g)(2)(B)(i) of the Act; (2) assessed a CMP of not less than $5,000; or (3) subject to termination of its participation agreement, a DPNA, or the appointment of temporary management. In this case the CMP proposed is not $5,000 or more and Petitioner was not subject to termination, a DPNA, or temporary management. The state agency advised Petitioner it was ineligible to offer a NATCEP because of the extended or partial extended survey. 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.

In this case, the violation of 42 C.F.R. § 483.13(c) caused actual harm and triggered the extended or partial extended survey because the surveyors also concluded that there was a pattern of actual harm. CMS Ex. 4 at 7-8. Petitioner disputed that there was actual harm, but I have resolved that issue against Petitioner. Therefore, the issue remaining is

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[10] CMS argues in a footnote that the state agency had no record that Petitioner was approved to conduct a NATCEP program and that Petitioner has no right to review of its loss of an "unsanctioned NATCEP." CMS Br. at 16, n. 5. CMS apparently overlooked the June 22, 2012, state agency notice withdrawing NATCEP approval. CMS Ex. 4 at 6-9. CMS also overlooked the statement of its witness Daniel J. McElroy, RN in which he states that the state agency withdrew Petitioner's approval to conduct a NATCEP for two years, and he opined that the withdrawal of approval to conduct a NATCEP was "required and appropriate." CMS Ex. 16 at 10 (not admitted).

whether or not Petitioner has shown that the determination that there was a pattern of actual harm was clearly erroneous. Petitioner argues that the facts show that there was only an isolated instance of actual harm involving Resident 1. I agree.

The regulation requires that in determining the seriousness of deficiencies it is necessary to consider whether the deficiencies "constitute a pattern." 42 C.F.R. § 488.404. "Pattern" is not specifically defined in the regulation. However, the drafters state in another section that "[s]ix occurrences might well be indicative of a pattern of substandard care." 42 C.F.R. § 488.110(i)(2). Furthermore, the definition of "substandard quality of care" specifically focuses upon whether there is a pattern actual of harm not just a pattern of deficiencies. The definition requires that there be "a pattern of or widespread actual harm that is not immediate jeopardy or widespread potential for more than minimal harm" for substandard quality of care to be determined. 42 C.F.R. § 488.301.

The SOM provides much more specific guidance for surveyors on how to determine if there is a "pattern":

> Scope is a pattern when more than a very limited number of residents are affected, and/or more than a very limited number of staff are involved, and/or the situation has occurred in several locations, and/or the same resident(s) have been affected by repeated occurrences of the same deficient practice. The effect of the deficient practice is not found to be pervasive throughout the facility.

SOM app. P, Task 7, § IV.C. (Apr. 24, 2009).

Applying the CMS policy set forth in the SOM to the facts before me, I conclude that the determination that the scope for the noncompliance cited under Tag F224 constituted a pattern, was clearly erroneous. Only Resident 1 was neglected. Only Resident 1 suffered actual harm. Only a few staff were involved on June 1, 2012 when the neglect occurred, a couple Certified Nurse Assistants (CNAs) and a RN. There is no evidence that neglect occurred in several locations or that the same resident experienced repeated occurrences of neglect. The evidence does not show that neglect was a pervasive problem throughout the facility.

Accordingly, I conclude that the noncompliance under Tag F224 did not meet the definition for substandard quality of care and an extended or partial extended survey should not have been determined to be necessary. Therefore, Petitioner remained eligible to be approved to conduct a NATCEP.

7. A PICMP in the amount of $1,000 is a reasonable enforcement remedy for noncompliance with 42 C.F.R. § 483.10(b)(11).

8. A PICMP of $3,000 is a reasonable enforcement for noncompliance with 42 C.F.R. § 483.13(c).

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 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 of a PICMP is $1,000 and the maximum is $10,000. 42 C.F.R. § 488.438(a)(2). CMS proposes two PICMP in this case and I must determine whether they are reasonable.

If I conclude, as I have in this case, that there is a basis for the imposition of an enforcement remedy and the remedy proposed is a CMP, my authority to review the reasonableness of the CMP is limited by 42 C.F.R. § 488.438(e). The limitations are: (1) I may not set the CMP at zero or reduce it to zero; (2) I may not review the exercise of discretion by CMS in selecting to impose a CMP; and (3) I may only consider the factors specified by 42 C.F.R. § 488.438(f) when determining the reasonableness of the CMP amount. In determining whether the amount of a CMP is reasonable, the following factors specified at 42 C.F.R. § 488.438(f) must be considered: (1) the facility's history of noncompliance, including repeated deficiencies; (2) the facility's financial condition; (3) the seriousness of the deficiencies as set forth at 42 C.F.R. § 488.404(b), the same factors CMS and/or the state were to consider when setting the CMP amount; and (4) the facility's degree of culpability, including but not limited to the facilities neglect, indifference, or disregard for resident care, comfort, and safety and the absence of culpability is not a mitigating factor. The factors that CMS and the state were required to consider when setting the CMP amount and that I am required to consider when assessing the reasonableness of the amount are set forth in 42 C.F.R. § 488.404(b): (1) whether the deficiencies caused no actual harm but had the potential for minimal harm, no actual harm with the potential for more than minimal harm, but not immediate jeopardy, actual harm that is not immediate jeopardy, or immediate jeopardy to resident health and safety; and (2) whether the deficiencies are isolated, constitute a pattern, or are widespread. My review of the reasonableness of the CMP is de novo and based upon the evidence in the record before me. I am not bound to defer to the CMS determination of the reasonable amount of the CMP to impose but my authority is limited by regulation as already explained. The Board has explained that my task is to determine whether the amount of any CMP proposed is within reasonable bounds considering the purpose of the Act and regulations. *Emerald Oaks*, DAB No. 1800, at 10 (2001); *CarePlex of Silver Spring*,

DAB No. 1683, at 14–16 (1999); *Capitol Hill Cmty. Rehab. & Specialty Care Ctr.*, DAB No. 1629 (1997). Petitioner has not argued that the proposed PICMP is unreasonable but has focused upon whether or not there is a basis for imposing such a remedy and whether the scope and severity determination for Tag F224 was erroneous.

CMS proposes a CMP of $1,000 for the noncompliance with 42 C.F.R. § 483.10(b)(11) (Tag F157). A PICMP of $1,000 is the smallest PICMP authorized by 42 C.F.R. § 488.438(a)(2). Accordingly, I conclude that the PICMP of $1,000 for 42 C.F.R. § 483.10(b)(11) (Tag F157) is reasonable.

The proposed $3,000 PICMP for noncompliance with 42 C.F.R. § 483.13(c) (Tag F224) is at the low end of the authorized range. Petitioner does not argue and has not submitted any evidence to support an argument that it is unable to pay the PICMP. CMS has offered no evidence of past noncompliance for me to consider. The deficiency is serious, caused actual harm to Resident 1, and supports the PICMP proposed. The noncompliance was isolated. Petitioner was culpable because it did not provide the care and services that Resident 1 required and delayed getting Resident 1 treatment for her bleeding wound and fracture which required surgical repair. I conclude based on my review of all the required factors, that a PICMP of $3,000 for noncompliance with the violation at 42 C.F.R. § 483.13(c) is reasonable.

III. Conclusion

For the foregoing reasons, I conclude that there is a basis for the imposition of enforcement remedies. The following enforcement remedies are reasonable: a PICMP in the amount of $1,000 for noncompliance with 42 C.F.R. § 483.10(b)(11) (Tag F157) and a PICMP in the amount of $3,000 for noncompliance with 42 C.F.R. § 483.13(c) (Tag F224). The determination of substandard quality of care was clearly erroneous and Petitioner remained eligible to be approved to conduct a NATCEP.

/s/
Keith W. Sickendick
Administrative Law Judge