

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Sunshine Haven Lordsburg
(CCN: 32-5109),

Petitioner

v.

Centers for Medicare and Medicaid Services.

Docket Nos. C-09-442, C-09-445, C-09-446, C-09-447, C-09-498, and C-09-499

Decision No. CR2408

Date: August 5, 2011

DECISION

Petitioner, Sunshine Haven Lordsburg, was not in substantial compliance with program participation requirements from November 5, 2008 to May 6, 2009, the date on which Petitioner's provider agreement was terminated.¹ There is a basis for the imposition of enforcement remedies. Per instance civil money penalties (PICMP) totaling \$14,000 are reasonable enforcement remedies. A mandatory denial of payment for new admissions (DPNA) was triggered by failure to achieve substantial compliance within three months and is reasonable as a matter of law. Mandatory termination was triggered by failure to achieve substantial compliance within six months and is reasonable as a matter of law. Petitioner was ineligible to conduct a nurse aide training and competency evaluation program (NATCEP) for a period of two years.

¹ Counsel for Petitioner advised me that, as of the date of hearing, Petitioner was reenrolled and participating in Medicaid, but Petitioner had not yet filed an application to reenroll in Medicare. Tr. at 93.

I. Background

Petitioner is located in Lordsburg, New Mexico, and participated in Medicare as a skilled nursing facility (SNF) and the state Medicaid program as a nursing facility (NF). On November 5, 2008, November 19, 2008, January 21, 2009, February 3, 2009 (life safety code survey), February 5, 2009, April 2, 2009, and April 20, 2009, Petitioner was surveyed by the New Mexico Department of Health (state agency) and found out of compliance with program participation requirements.² Jt. Stip.; Centers for Medicare and Medicaid Services (CMS) exhibits (Exs.) 3, 11, 21, 27, 29, 39, 51. CMS notified Petitioner by letter dated March 16, 2009, that: its Medicare agreement would terminate effective April 5, 2009, unless Petitioner was in substantial compliance by that date; it was imposing PICMPs of \$5,000 for two instances of noncompliance on January 29, 2009;³ and a mandatory DPNA was triggered effective February 5, 2009, and would continue until Petitioner achieved substantial compliance or was terminated. CMS also advised Petitioner that it was not eligible to conduct a NATCEP for a period of two years. CMS Ex. 1, at 1-4. CMS notified Petitioner by letter dated April 21, 2009, that the date for termination of Petitioner's provider agreement was extended to May 6, 2009. CMS Ex. 1, at 6. CMS notified Petitioner by letter dated April 22, 2009, that a survey on April 2, 2009 concluded that Petitioner had not returned to substantial compliance; and that CMS was imposing a \$2,000 PICMP for each of two instances of noncompliance on April 2, 2009. CMS Ex. 1, at 9-11. CMS notified Petitioner by letter dated May 28, 2009, that: Petitioner's Medicare and Medicaid agreements were terminated on May 6, 2009; a DPNA was in effect from February 5, 2009 to May 6, 2009; a \$2,000 PICMP was imposed for the deficiency cited under Tag F225 by the April 2, 2009 survey; a \$2,000

² The parties stipulated that there was also a survey on January 31, 2009. Joint Stipulation of Undisputed Facts (Jt. Stip.), ¶¶ 2, 10. CMS subsequently indicated in its amended prehearing brief filed April 7, 2010, that there was no separate survey of Petitioner's facility on January 31, 2009. No Statement of Deficiencies (SOD) for a survey that ended on January 31, 2009 is in evidence. CMS does not allege that any deficiency was identified by a survey that ended on January 31, 2009 that affected either the mandatory DPNA or termination or that was the basis for an enforcement remedy. The survey actually commenced on January 26 and concluded on February 5, 2009. CMS Ex. 29, at 1; CMS Ex. 37, at 1.

³ The evidence shows that January 29, 2009, was the date on which Petitioner was advised that the surveyors declared that there was immediate jeopardy. CMS Ex. 29, at 1, 18. The survey actually commenced on January 26 and ended on February 5, 2009, and the results of the survey are reported in a Statement of Deficiencies (SOD) dated February 5, 2009. CMS Ex. 29, at 1; CMS Ex. 37, at 1.

PICMP was imposed for the deficiency cited under Tag F224 by the April 2, 2009 survey; a \$5,000 PICMP was imposed for the deficiency cited under Tag F226 by the January 29, 2009 survey; and a PICMP of \$5,000 was imposed for the deficiency cited under Tag F223 by the January 29, 2009 survey. CMS Ex. 1, at 12-14.

On May 8, 2009, Petitioner filed four hearing requests related to the surveys of November 5 and 19, 2008, January 21, 2009, February 3 and 5, 2009, and April 2, 2009. The cases were docketed as C-09-442, C-09-445, C-09-446, and C-09-447 and assigned to me for hearing and decision on May 14, 2009. Acknowledgments and Prehearing Orders were issued at my direction. I consolidated the cases under Docket No. C-09-442 on May 28, 2009. On June 4, 2009, Petitioner filed two hearing requests related to the February 3, April 2, and April 20, 2009 surveys. The cases were docketed as C-09-498 and C-09-499 and assigned to me for hearing and decision on June 10, 2009. Acknowledgments and Prehearing Orders were issued at my direction. I consolidated the cases under Docket No. C-09-442 on June 18, 2009.

On April 12 and 13, 2010, a hearing was convened in Albuquerque, New Mexico, and a transcript (Tr.) of the proceedings was prepared.⁴ CMS offered CMS Exs. 1 through 69, and all were admitted as evidence. Tr. at 28-29, 43-44. Petitioner offered Petitioner exhibits (P. Exs.) 1 through 47, and all were admitted as evidence. Tr. at 44-45. CMS called the following witnesses: Jennifer Wadley, a state agency surveyor; and Carlos Ramon Seda, a state agency surveyor. Petitioner called the following witnesses: Margaret (Peggy) Winkler, R.N., corporate director of clinical services for Cathedral Rock Management and a consultant to Petitioner; and Gregory Michael Whitaker, Petitioner's administrator beginning April 15, 2009. The parties filed post-hearing briefs (CMS Br. and P. Br.), post-hearing reply briefs (CMS Reply and P. Reply), and proposed findings of fact and conclusions of law (CMS Findings and P. Findings).

⁴ The parties advised me prior to the hearing that they intended to present evidence on only some of the surveys and deficiencies but that they would address all surveys in their post-hearing briefs. Tr. at 21-27, 51. Thus, I do not consider that the parties waived any issues or arguments by not specifically raising them at hearing.

II. Discussion

A. Issues

Whether there is a basis for the imposition of enforcement remedies?

Whether the enforcement remedies imposed are reasonable?

Whether termination of Petitioner's participation in Medicare was required?

Whether a mandatory DPNA was required?

B. Applicable Law

The statutory and regulatory requirements for participation of a SNF in Medicare are found at section 1819 of the Social Security Act (Act) and at 42 C.F.R. Part 483.⁵ Section 1819(h)(2) of the Act authorizes the Secretary of Health and Human Services (Secretary) to impose enforcement remedies against a SNF for failure to comply substantially with the federal participation requirements established by sections 1819(b), (c), and (d) of the Act.⁶ The Act requires that the Secretary terminate the Medicare participation of any SNF that does not return to substantial compliance with participation requirements within six months of being found not to be in substantial compliance. Act § 1819(h)(2)(C). The Act also requires that the Secretary deny payment of Medicare benefits for any beneficiary admitted to a SNF, if the SNF fails to return to substantial compliance with program participation requirements within three months of being found not to be in substantial compliance – commonly referred to as the mandatory or statutory DPNA. Act § 1819(h)(2)(D). The Act grants the Secretary discretionary authority to terminate a noncompliant SNF's participation in Medicare, even if there has been less than six months of noncompliance. The Act also grants the Secretary authority to impose

⁵ References are to the revision of the Code of Federal Regulations (C.F.R.) in effect at the time of survey unless otherwise indicated.

⁶ 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.

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 in substantial compliance with federal participation requirements. A facility is in “substantial compliance” so long as no identified deficiency poses a greater risk to resident health or safety than the potential for causing minimal harm. 42 C.F.R. § 488.301. “Noncompliance” is any deficiency that causes a facility to not be in substantial compliance. 42 C.F.R. § 488.301. 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. 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.

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. 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). CMS is authorized to impose a PICMP from \$1,000 to \$10,000, and that range is not affected by whether or not immediate jeopardy is identified. 42 C.F.R. § 488.438(a)(2).

Petitioner was notified in this case that any prior approval to conduct a NATCEP was withdrawn and that Petitioner was ineligible to conduct such a program for two years. Pursuant to sections 1819(b)(5) and 1919(b)(5) of the Act, SNFs and NFs may only use nurse aides who have completed a training and competency evaluation program. 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. 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. The Secretary promulgated regulations at 42 C.F.R. Part 483, subpart D. Pursuant to 42 C.F.R. § 483.151(b)(2) and (e)(1), a state may not approve, and must

withdraw, any prior approval of a NATCEP offered by a SNF or NF that has been: (1) subject to an extended or partial extended survey under sections 1819(g)(2)(B)(i) or 1919(g)(2)(B)(i) of the Act; (2) assessed a CMP of not less than \$5,000; or (3) subject to termination of its participation agreement, a DPNA, or the appointment of temporary management. Extended and partial extended surveys are triggered by a finding of “substandard quality of care” during a standard or abbreviated standard survey and involve evaluating additional participation requirements. “Substandard quality of care” is identified by the situation where surveyors identify one or more deficiencies related to participation requirements established by 42 C.F.R. § 483.13 (Resident Behavior and Facility Practices), § 483.15 (Quality of Life), or § 483.25 (Quality of Care) that are found to constitute either immediate jeopardy, a pattern of or widespread actual harm that does not amount to immediate jeopardy, or a widespread potential for more than minimal harm that does not amount to immediate jeopardy and there is no actual harm. 42 C.F.R. § 488.301.

The Act and regulations make a hearing before an 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. *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 determined by CMS if a successful challenge would affect the range of the CMP that may be imposed or impact the facility’s authority to conduct a NATCEP. 42 C.F.R. § 498.3(b)(14), (d)(10)(i). The CMS determination as to the level of noncompliance, including the finding of immediate jeopardy, “must be upheld unless it is clearly erroneous.” 42 C.F.R. § 498.60(c)(2). *Woodstock Care Ctr.*, DAB No. 1726, at 9, 38 (2000), *aff’d*, 363 F.3d 583 (6th Cir. 2003). The Departmental Appeals Board (the Board) has long held that the net effect of the regulations is that a provider has no right to challenge the scope and severity level assigned to a noncompliance finding, except in the situation where that finding was the basis for an immediate jeopardy determination. *See, e.g., Ridge Terrace*, DAB No. 1834 (2002); *Koester Pavilion*, DAB No. 1750 (2000). ALJ Review of a CMP is subject to 42 C.F.R. § 488.438(e).

The standard of proof, or quantum of evidence required, is a preponderance of the evidence. CMS has the burden of coming forward with the evidence and making a *prima facie* showing of a basis for imposition of an enforcement remedy. Petitioner bears the burden of persuasion to show by a preponderance of the evidence that it was in

substantial compliance with participation requirements or any affirmative defense. *Batavia Nursing & Convalescent Inn*, DAB No. 1911 (2004); *Batavia Nursing & Convalescent Ctr.*, DAB No. 1904 (2004), *aff'd*, *Batavia Nursing & Convalescent Ctr. v. Thompson*, 129 F. App'x 181 (6th Cir. 2005); *Emerald Oaks*, DAB No. 1800; *Cross Creek Health Care Ctr.*, DAB No. 1665 (1998); *see Hillman Rehab. Ctr.*, DAB No. 1611 (1997), *aff'd*, *Hillman Rehab. Ctr. v. U.S.*, No. 98-3789 (GEB), 1999 WL 34813783 (D.N.J. May 13, 1999).

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

My conclusions of law are set forth in bold text followed by my findings of fact and analysis. CMS alleges that Petitioner was not in substantial compliance with program participation requirements beginning November 5, 2008 and continuing through termination of Petitioner's Medicare participation on May 6, 2009. CMS relies upon deficiencies cited by surveys completed between November 5, 2008 and April 20, 2009, as evidence of Petitioner's continuing noncompliance. Petitioner argues, generally, that any noncompliance that posed a risk for more than minimal harm was corrected in less than three months, and the mandatory DPNA and termination were not triggered. Tr. at 246-48.

I conclude that: Petitioner was not in substantial compliance from November 5, 2008 through its termination on May 6, 2009; the mandatory DPNA and termination were required by the Act; and the four PICMPs are reasonable enforcement remedies. My conclusion that Petitioner was continually not in substantial compliance from November 5, 2008 through termination on May 6, 2009 is based upon the following surveys and deficiencies, which are discussed in greater detail hereafter:

SURVEY ENDED	DEFICIENCIES	EXAMPLES
November 5, 2008	42 C.F.R. § 483.25(a)(3) (Tag F312)	Residents 1, 3
November 19, 2008	42 C.F.R. § 483.13(a) (Tag F221)	Residents 1, 5
January 21, 2009	42 C.F.R. § 483.25(h) (Tag F323)	Resident 5
February 3, 2009	42 C.F.R. § 483.70(a)	Life Safety Code
February 5, 2009	42 C.F.R. § 483.13(b) (Tag F223)	Residents 6, 18, 50
	42 C.F.R. § 483.13(c) (Tag F226)	Residents 6, 18, 50
April 2, 2009	42 C.F.R. § 483.13(c) (Tag F224)	Resident 4
	42 C.F.R. § 483.13(c)(2)-(4) (Tag F225)	Residents 1, 3, 4, 5
April 20, 2009	42 C.F.R. § 483.20(b) (Tag F272)	Resident 3

I have carefully considered all the evidence and the arguments of both parties, although not all may be specifically discussed in this decision. I discuss the credible evidence

given the greatest weight in my decision-making.⁷ 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 was not in substantial compliance on November 5, 2008, due to a violation of 42 C.F.R. § 483.25(a)(3) (Tag F312) that posed a risk for more than minimal harm.

Petitioner is required to ensure that its residents receive necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being. 42 C.F.R. § 483.25. Petitioner must ensure that “[a] resident who is unable to carry out activities of daily living receives the necessary services to maintain good nutrition, grooming, and personal and oral hygiene.” 42 C.F.R. § 483.25(a)(3).

A complaint survey was conducted at Petitioner’s facility on November 5, 2008, due to a complaint by the mother of a resident that the resident and other residents were not being bathed as required. Tr. at 57-58; CMS Ex. 3, at 1. The SOD dated November 5, 2008, alleges that Petitioner failed to ensure that Residents 1, 2, and 3 received baths at least two times a week and that the violation constituted an isolated deficiency that posed no actual harm but had the potential for more than minimal harm that did not amount to immediate jeopardy. The facts related to Residents 1 and 3 are sufficient to show that there was a violation that posed more than minimal harm.

a. Facts

Petitioner had a policy and procedure that required that each resident receive a shower or bath at least two times a week and as needed. The policy also required that the shower or bath be documented in residents’ medical records. CMS Ex. 8, at 1-2. Petitioner’s charting policy and procedure required that all services provided to a resident be recorded in the resident’s medical record. CMS Ex. 8, at 3.

⁷ “Credible evidence” is evidence that is worthy of belief. *Black’s Law Dictionary* 596 (18th ed. 2004). The “weight of evidence” is the persuasiveness of some evidence compared to other evidence. *Id.* at 1625.

Resident 1's minimum data set (MDS) from August 2008 shows that she was 48 years old and totally dependent on staff for bed mobility, transfers, locomotion on and off the unit, dressing, eating, toilet use, and personal hygiene. CMS Ex. 5, at 1-2. Her care plan indicated that she needed assistance with her activities of daily living (ADLs) and required staff intervention to remain clean, neat, and free of body odors. Her care plan required that she be bathed two times a week and more often as desired. CMS Ex. 5, at 3. Petitioner's shower schedule showed that Resident 1 was to be bathed on Monday, Wednesday, and Friday. CMS Ex. 8, at 7. Petitioner's records in evidence do not show that Resident 1 received a bath or shower during the thirteen days from October 15, 2008 through October 27, 2008. CMS Ex. 5, at 4-9; Tr. at 96-101.

Resident 3's MDS from September 2008 shows that he was 82 years old and totally dependent on staff for bed mobility, transfer, locomotion on and off the unit, dressing, toilet use, and personal hygiene. CMS Ex. 7, at 2. His care plan provided that that he needed assistance to remain clean, neat, and free of body odors and stated that he was incontinent and unable to do his own ADLs. His care plan required that he be assisted with his bath or shower two to three times weekly and more often as desired. CMS Ex. 7, at 3. Petitioner's shower schedule showed that he was to be bathed on Monday, Wednesday, and Friday. CMS Ex. 8, at 7. Petitioner's records in evidence show that during the sixteen days from October 16 through October 31, 2008, Resident 3 received a bath or shower only on October 21, 2009. CMS Ex. 7, at 5-10, 12, 14-15; Tr. at 105-09.

Surveyor Wadley testified that she has been a surveyor with the state agency since August 2006, just over two years at the time of the November 5, 2008 complaint survey. She passed her surveyor minimum qualification test, and she participated in an average of two to three surveys per month. Her education and prior work experience was in criminal justice, not health care. She conducted the November 5, 2008 complaint survey, and she made the findings in the SOD for that survey. She testified that she cited Petitioner for a deficiency under Tag F312 because Petitioner could not show that residents received required baths during October 2008. Tr. at 55-59. She testified that there was a potential for more than minimal harm, as the residents who did not receive baths or showers were at increased risk for: infection; not having skin problems discovered; and not having their psychosocial needs met. Tr. at 63.

b. Analysis

Petitioner was obliged by the regulation to ensure that Residents 1 and 3 received necessary care and services, including services necessary to maintain good hygiene. Both residents were assessed as being totally dependent upon staff for being bathed or showered. Each resident's care plan required that staff provide a bath or shower at least two times each week to ensure that the resident was clean, neat, and free of body odors. Petitioner also had a policy that required that each resident receive a bath or shower at least two times per week. Petitioner's policy, absent evidence to the contrary, is good

evidence of the standard of care to be provided to Petitioner's residents. The care plan for each resident shows that the care planning team for each assessed that at least two baths or showers each week were necessary care and services for each resident.

Petitioner's records show that in October 2008, Residents 1 and 3 did not receive two showers or baths each week, as required by Petitioner's policy and as care planned for these residents. Further, the un rebutted testimony of Surveyor Wadley that the facility failed to provide the care planned baths to these residents, which failure increased their risk for infection, undetected skin problems, and psychosocial problems such as low self-esteem or embarrassment, shows that Residents 1 and 3 were at risk for more than minimal harm due to not receiving the number of baths the care planning team determined necessary. I conclude that CMS has made a *prima facie* showing that Petitioner failed to deliver care and services for Residents 1 and 3 necessary to maintain good hygiene and to attain or maintain their highest practicable physical, mental, and psychosocial well-being. CMS has made a *prima facie* showing of a deficiency under Tag F312 based on a violation of 42 C.F.R. § 483.25(a)(3) that posed a risk for more than minimal harm.

Petitioner did not present evidence to show that Residents 1 and 3 received all the showers or baths required by their care plans and Petitioner's policy. Petitioner presented no evidence to show that the care planning team did not consider a minimum of two showers or baths each week necessary care and services for these residents. Petitioner did not present evidence to rebut Surveyor Wadley's conclusion that the residents were at risk for more than minimal harm due to increased risk for infection, undetected skin problems, or psychosocial problems. Petitioner nevertheless argues that the undisputed evidence shows that it was in substantial compliance on November 5, 2008.

Petitioner argues that the Guidance to Surveyors in the State Operations Manual (SOM), app. PP, Tag⁸ F312 establishes a requirement that a surveyor must observe poor grooming or hygiene due to failure to deliver necessary services, for the surveyor to cite a deficiency under that tag. P. Br. at 4-5; P. Reply at 2-3. Petitioner argues that no deficiency should have been cited. Petitioner relies upon the testimony of Surveyor Wadley that she did not observe that Residents 1 and 3 were unkempt, dirty, or that they were suffering some negative psychosocial impact. Tr. at 109. However, Petitioner's interpretation of the SOM is in error, and there is no requirement for Surveyor Wadley to

⁸ A "Tag" is a subdivision of the SOM, app. PP, Guidance to Surveyors, which recites the specific regulatory provision and states CMS's policy guidance to surveyors related to that regulation. The SOM is CMS Publication 100-07, and it is available at <http://www.cms.hhs.gov/Manuals/IOM/list.asp>.

have observed that Resident 1 or 3 was suffering any negative outcome to cite a deficiency under Tag F312.

The SOM does not have the force and effect of law but merely provides an interpretation of the regulations and Act for the guidance of surveyors in conducting surveys. *Northwest Tissue Ctr. v. Shalala*, 1 F.3d 522 (7th Cir. 1993); *State of Ind. by the Ind. Dep't of Pub. Welfare v. Sullivan*, 934 F.2d 853 (7th Cir. 1991). The SOM does not supersede the regulations or Act. The regulation requires the delivery of necessary care and services. The necessity of goods or services is determined by the care planning team and/or standards of care. In this case, two showers or baths were required by both the care plan and the standard of care evidenced by Petitioner's policy. A deficiency exists when the regulation is violated. The violation occurred here because the necessary baths and showers were not provided. The violation amounted to noncompliance because the unrebutted evidence shows there was a risk for more than minimal harm. It is not required that a negative outcome or actual harm occur for there to be noncompliance. Petitioner cites no authority to support its interpretation of the SOM other than the language of the SOM. The plain language of the SOM when read in context, however, merely establishes a procedure for the surveyors to observe residents who are unable to do their own ADLs to identify any evidence of poor nutrition, poor grooming, or poor personal and oral hygiene. The surveyor is then to decide whether any negative observations are due to failure of the residents to receive necessary services, which necessarily requires that the surveyor review assessments, care plans, orders, and policies to learn what care and services were necessary for the individual residents. The SOM does not establish this as the only procedure that a surveyor should follow to identify a deficiency. Indeed, other Tags related to the quality of care regulation clearly show that assessing compliance with the care plan and physicians' orders are appropriate procedures for identifying deficiencies under the quality of care Tags. Petitioner's argument that there was no deficiency because no negative result or actual harm was observed by the surveyor is without merit.

Petitioner attacked the accuracy and credibility of Surveyor Wadley's allegations in the SOD (CMS Ex. 3). P. Br. at 5-6; P. Reply at 1-2. On cross-examination, Surveyor Wadley admitted that some of her findings stated in the SOD were in error. Tr. at 96-101, 105-09. Petitioner's clinical records in evidence for these residents and the entries on those records are not particularly clear and may be subject to inconsistent interpretation. Counsel's interrogation of Surveyor Wadley about the records and her interpretation of the entries caused Surveyor Wadley to admit that her prior interpretation was in error and the residents may have received more baths or showers than she initially thought. Nevertheless, Petitioner's clinical records for the residents support Surveyor Wadley's findings that Residents 1 and 3 did not receive all baths or showers required by their care plans and Petitioner's policy. Surveyor Wadley's errors in interpreting Petitioner's clinical records affected the credibility of her findings in the SOD, but not the

credibility of her testimony or conclusion that there was a risk for more than minimal harm to the residents.

Petitioner argues that Surveyor Wadley is not a medical professional and her opinions regarding potential harm should not be credited. P. Reply at 2. Petitioner also argues that CMS has not made a *prima facie* showing that there was a potential for any harm to the residents. P. Br. at 5-6; P. Reply at 2-3. While it is true that Surveyor Wadley is not a medical professional, it is un rebutted that she is a trained surveyor with survey experience. As a surveyor, she is required to make findings and conclusions as to whether a provider is in substantial compliance with program participation requirements, which requires her to conclude whether or not there is a potential for more than minimal harm. 42 C.F.R. § 488.10(a)(1). The evidence does not show that Surveyor Wadley was not competent to make the required determination. Contrary to Petitioner's arguments, Surveyor Wadley's testimony is evidence that there was a potential for more than minimal harm, and Petitioner has failed to rebut that evidence.

I conclude that Petitioner was not in substantial compliance due to a violation of 42 C.F.R. § 483.25(a)(3) that posed a risk for more than minimal harm to Residents 1 and 3. While the deficiency actually arose in October 2008, I treat the noncompliance as beginning on November 5, 2008, when the survey ended, as that is consistent with the notice provided to Petitioner by CMS and the state agency. Petitioner asserted in its plan of correction that it completed correction of the deficiency on December 5, 2008. CMS Ex. 3, at 3. Surveyor Wadley testified that Petitioner did submit a plan of correction for the November 5 survey and that she was involved in determining whether or not to accept the plan. She testified that, on December 16, 2008, the plan of correction was reviewed but no on-site revisit was actually conducted. She testified that the plan of correction was accepted as of December 16, 2008. P. Ex. 1. She could not explain why the plan of correction was not considered completed as of December 5, 2008, the date alleged in the plan of correction. CMS Ex. 3, at 3; Tr. at 109-15. Petitioner argues that its plan of correction was completed no later than December 5, 2008, and it returned to substantial compliance by that date, or at least by December 16, 2008 as the state agency found. Petitioner argues that CMS rejected the state agency finding that Petitioner returned to substantial compliance by December 16, 2008 but did not provide notice it had done so. P. Brief at 14-16; P. Findings ¶¶ 57-66. Petitioner is in error asserting that it returned to substantial compliance on December 5 or 16. Whether Petitioner corrected this deficiency on December 5 or 16, 2008, the correction of the deficiency does not mean that Petitioner returned to substantial compliance on that date. As discussed hereafter, I conclude that Petitioner continued not to be in substantial compliance due to the deficiency cited by the November 19, 2008 survey.

2. Petitioner was not in substantial compliance on November 19, 2008, due to a violation of 42 C.F.R. § 483.13(a) (Tag F221) that caused actual harm.

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.” Act § 1819(c)(1)(A)(ii). Restraints may only be imposed for the physical safety of the resident or other residents. Restraints may only be imposed based on a written physician’s order that specifies the duration and circumstances for use of the restraints, except in emergency circumstances specified by the Secretary. Act § 1819(c)(1)(A)(ii)(I), (II). The Secretary’s regulation implementing this provision of the Act is 42 C.F.R. § 483.13(a), but it does not include the requirement related to physician’s order or recognize any emergency circumstances for the imposition of restraints without a physician’s orders.⁹ The regulation provides that a “resident has the right to be free from any physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident’s medical symptoms.” 42 C.F.R. § 483.13(a).

The Board has elaborated upon the requirements of 42 C.F.R. § 483.13(a), stating:

Because section 483.13(a) is directed towards nursing facilities, the regulation imposes on the long-term care facility an independent obligation to ensure that the use of restraints, even with a doctor’s order, meets the criteria of the regulation. Further, it imposes an independent obligation to continue to assess the impact of the use of a restraint and to consult with the doctor if the nursing facility finds that use of the restraint no longer meets the criteria of the regulation. Finally, review of a facility’s compliance requires careful consideration to make sure that the facility is implementing the doctor’s restraint order pursuant to its terms. Therefore, a long-term care facility cannot rely solely on a doctor’s order to prove compliance with section 483.13(a) and must be able to show with other evidence as appropriate that the specific

⁹ Provisions related to the use of restraints in other types of facilities do not appear to be directly applicable in the case of a SNF. 42 C.F.R. §§ 418.110, 482.13, 483.350-.376, 483.450.

restraints applied were not imposed for discipline or convenience and were necessary to treat a medical symptom.

Cross Creek Health Care Ctr., DAB No. 1665, at 11; *Lakeridge Villa Health Care Ctr.*, DAB No. 1988 (2005), *aff'd*, *Lakeridge Villa Health Care Ctr. v. Leavitt*, 202 F. App'x 903 (6th Cir. 2006).

The SOM defines a physical restraint as “any manual method or physical or mechanical device, material, or equipment attached or adjacent to the resident’s body that the individual cannot remove easily which restricts freedom of movement or normal access to one’s body.” SOM app. PP, Tag F222. Physical restraints may include, among other things, side rails, lap trays, devices used in conjunction with a chair limiting movement, and soft ties or vests. SOM, app. PP, Tag F222. Alarms are not restraints unless applied in such a manner to restrict freedom of movement or normal access to one’s body, under the SOM guidance.

The state agency completed a complaint survey at Petitioner’s facility on November 19, 2008. The SOD, dated November 19, 2008, alleges that Petitioner violated 42 C.F.R. § 483.13(a) (Tag F221) by failing to follow its policies and procedures to assess, reassess, evaluate, monitor, and attempt to reduce the use of restraints for five residents, resulting in injury to Resident 1. The state agency also found that the deficient practice resulted in a decline in activities of daily living for Resident 1. Petitioner was also cited for failure to obtain physician’s orders, reflecting the medical necessity of restraint use, and failure to obtain consent to the use of restraints for the five residents. CMS Ex. 11, at 1. The examples of Residents 1 and 5 sufficiently show the deficiency.

a. Facts

Petitioner had a restraint policy that required that a resident with restraints be assessed on admission and at least quarterly by the interdisciplinary team for application, reduction, or continuation of restraints. Petitioner’s policy provided, consistent with the Act and regulations, that restraints would not be used for convenience or discipline. CMS Ex. 18, at 1. The policy required that all residents be assessed for the need for restraint and associated risk upon admission and any time that the interdisciplinary team was considering the use of a restraint or side rails. CMS Ex. 18, at 2. The policy provided that, after the restraint assessment was completed, the facility used a restraint decision tree to determine if any medical symptoms or any impact on function was identified with respect to restraint use. If a restraint was determined to be necessary, the facility required the following: (1) a physician order; (2) a care plan delineating the specific device; (3) a signed and dated consent form completed by the resident or responsible party/guardian; and (4) documentation every thirty days of physician authorization giving reasons for the restraint usage. When restraint was determined to be necessary, the physician’s order was required to specify the type of device to be used for restraint, the reason for the

device, the timeframes the device was to be used, the date of the order, and the physician's signature. The interdisciplinary team decision to use restraint was to be documented in the medical record. The specific device, reason for use, and releasing procedure was to be documented in the care plan. The facility policy also required that the restraint be released and removed every two hours for positioning, range of motion, and/or toileting and nutritional considerations. The policy required that the facility attempt to reduce restraints whenever possible through use of the facility restraint reduction team. CMS Ex. 18, at 3-4.

i. Resident 1

Resident 1 was admitted to the facility on July 12, 2006, with diagnoses including osteoarthritis involving multiple sites, persistent mental disorder, congestive heart failure, and cardiovascular disease. He was 78 at the time of the November 19, 2008 survey. CMS Ex. 13, at 1. A Physician's Orders sheet for the period October 1 through 31, 2008, lists an order from July 12, 2006, the date of admission, for top rails¹⁰ to help the resident reposition, if desired. The Physician's Orders sheet also lists an order dated February 18, 2008, for use of a seatbelt restraint or lap buddy for safety when Resident 1 was up in his wheelchair. The Physician's Orders sheet does not indicate the timeframes for use of either the top rails or the wheelchair seatbelt, *i.e.*, the frequency and duration of use is not specified. CMS Ex. 13, at 2. I have also not received evidence of physician's orders reauthorizing the restraints every thirty days as required by Petitioner's policy.

Resident 1 was assessed as at risk for falls in September, October, and November 2008. He was assessed as a high risk for falls in October 2008, but not in September or November 2008. CMS Ex. 13, at 3-4. A Side Rail Usage Assessment form dated November 12, 2008, the week prior to the survey, lists as the rationale for side rail use that the resident crawls out of bed without side rails and that there was an increased risk for injury. However, the person who completed the form also marked an "X" in the box

¹⁰ I infer based on the context that the phrase "top rail" and "side rail" both refer to hospital bed side rails. Side rails are found in various configurations, including full-length, partial length, and other designs including split rails or two-part rails with one section near the top of the bed and the other part at the lower half of the bed. It is not clear from the evidence whether the beds used for these residents had two part rails, in which case "top rail" may have referred only to the partial rail near the top half or head of the bed. In this case, the exact configuration of the side rails does not impact my decision, as I consider even a partial rail to constitute a form of restraint to the extent that it restricts a resident's freedom of movement, including free egress from his or her bed. SOM app. PP, Tag F222.

that indicates that the side rails were used as a boundary, and the resident would not be able to get out of bed on his own even if the side rails were down. The assessment form shows that Resident 1: had reduced judgment and safety awareness; had a history of falls and of falls from bed; was mobile and attempted to get out of bed and to climb over or around side rails, but that he could not get out of bed without assistance; and had been entrapped in the side rail or between the side rail and mattress with injuries. CMS Ex. 13, at 6. An undated and unsigned Restraint and Side Rail Consent form indicates that restraints were required due to falls and that use of a seat belt and side rails were discussed and rejected. CMS Ex. 13, at 29. An undated Quarterly Review for Use of Restraints/Enablers shows that a self-releasing belt was being used due to Resident 1 sliding down in his chair. The form indicates that alternatives, such as reclining his wheelchair, rehabilitation, and a personal alarm, had been attempted to reduce the need for the restraint. CMS Ex. 13, at 30.

A significant change in status MDS, with an assessment reference date of February 19, 2008, shows that: Resident 1 was severely cognitively impaired; he was easily distracted; and he had periods of altered perception or awareness, episodes of disorganized speech, periods of restlessness, periods of lethargy, and variable mental function. However, his cognitive status had not changed in the preceding ninety days. He could usually be understood, but only sometimes understood others, but there had been no change in his ability to communicate in the preceding ninety days. He engaged in wandering, verbally and physically abusive behavior, socially inappropriate behavior and/or disruptive behavior, and resisted care and his behavior had deteriorated. He required limited assistance of one-person with bed mobility, transfer, and locomotion. He required extensive assistance of one person with dressing, eating, personal hygiene, bathing, and toilet use. The assessment indicates that his ability to perform ADLs had deteriorated in the preceding ninety days, or since his last assessment. He was not assessed to have any limitations on his range of motion. His primary mode of transportation was a wheelchair pushed by someone. The page of the MDS that addresses the use of restraints is not in evidence. CMS Ex. 13, at 17-21.

A quarterly MDS with an assessment reference date of August 15, 2008, reflects no change in Resident 1's cognitive status. However, the MDS indicates that his behavioral symptoms had deteriorated in the last ninety days, or since the last assessment. Resident 1's ability to perform ADLs had also deteriorated since the February 2008 MDS, as he was assessed as totally dependent upon staff and required a two person assist with all ADLs except eating, for which he required the assistance of one person. However, the MDS indicates no change in ADL function in the last ninety days or the last assessment. I have no MDS in evidence that was completed between February 2008 and August 2008,

and cannot determine when during that six month period that Resident 1's ADLs deteriorated so significantly.¹¹ The August 2008 MDS also reflected that Resident 1 had a limitation of range of motion in all areas, a change from his February 2008 MDS. The page of the MDS that addresses the use of restraints is not in evidence. CMS Ex. 13, at 25-27.

A care plan for falls dated February 19, 2008, indicates that Resident 1 was identified as a high risk for falls related to the psychoactive drugs he was taking. One intervention required that staff check his "support/restraint" every hour, but the type of support or restraint in use was not mentioned. A handwritten entry dated May 22, 2008, shows that use of a self-release seat belt was ongoing.¹² CMS Ex. 13, at 32.

A care plan for falls dated May 25, 2008, with a review date of August 25, 2008, required that physical therapy reevaluate adaptive equipment or devices as needed for continued appropriateness and to ensure the least restrictive device or restraint was in use. A handwritten entry dated October 6, 2008, shows that Resident 1 had a problem with red marks from lying against his bed side rails. The goal was that the resident was to have no further bruising, and the intervention was to ensure that Resident 1 was correctly repositioned inside the bed rails when he was changed. CMS Ex. 13, at 34-35.

A care plan dated May 24, 2008, and reviewed on August 24, 2008, lists the problem of potential complications related to use of physical restraint, specifically the use of a seat belt. Interventions required that nursing and physical therapy evaluate restraint use per facility policy, including benefits, alternatives, need for ongoing use, and reason for ongoing use. The frequency of the evaluation is not specified. Nursing was to observe, document, and notify the physician as necessary, regarding the effectiveness of the restraint, the possibility of any less restrictive device, and any negative or adverse effects. Staff was to check the resident and release the restraint per facility protocol, to offer restraint free time and physical activity daily; to ensure that there was valid consent indicated in the chart prior to initiating restraint; and to provide meaningful activities that accommodate the use of restraints without drawing attention to the restraint and to

¹¹ A quarterly review assessment is required for each resident every three months. 42 C.F.R. § 483.20(c). Therefore, there should have been at least one additional MDS assessment between February and August 2008, which has not been offered as evidence.

¹² Petitioner's proposed Finding of Fact 94 states that this modification of the care plan reflected Resident 1's increased ability to self-release the seat belt or lap buddy on his wheelchair. Petitioner does not cite to any evidence in support of this proposed finding, and I do not accept it.

provide restraint free time during activities when supervision was adequate. CMS Ex. 13, at 36-37.

A fall care plan dated September 16, 2008, requires that nursing staff check “support/restraint” every hour. CMS Ex. 13, at 44. The type of restraint is not specified. The use of side rails is not addressed by any care plan in evidence, except the intervention that requires that staff use side rails as ordered and the handwritten entry related to bruising due to lying against the side rails and the requirement to position correctly between the side rails, both of which appears on the May 25, 2008 fall care plan. CMS Ex. 13, at 34-35.

A Monthly Summary dated November 12, 2008, indicates that during the month of October 2008 Resident 1’s mattress was removed due to his suffering a bruise on his right arm. The summary also indicates that he received a new wheel chair that prevented his head from falling back. A self-releasing restraint continued to be used when the resident was up in his wheel chair. CMS Ex. 13, at 50-51.

A Progress Notes and Observations entry (Progress Notes) dated August 17, 2008, indicates that Resident 1 opened his self-releasing seat belt three times, and each time it was replaced. An entry on August 19, 2008, indicates that Resident 1 received his new high-back wheelchair that was fitted by occupational therapy. CMS Ex. 13, at 54. An entry on August 23, 2008, indicates that the resident was sitting up straight in his new chair and not extended back as before, and another entry shows that a self-releasing abdominal restraint was being used. CMS Ex. 13, at 55. An October 1, 2008 Progress Notes entry shows that a certified nursing assistant (CNA) found Resident 1 sitting at his bed side on his buttocks. Only the top portion of the side rail was up, and the resident’s right arm was caught in the rail. There was some redness on the left arm, and there was a very red impression of the bed rail on the right arm. CMS Ex. 13, at 55. Resident 1’s February 19, 2008 fall care plan was revised on October 1, 2008 to record the fall on that date and to add interventions. Initially, the intervention was to remove the mattress; however, a line had been drawn through that intervention, and a new intervention required staff to evaluate and monitor his mattress for safety while Resident 1 was in bed and to place an alarm when he was up in a chair. CMS Ex. 13, at 32. Nursing Notes from October 6, 2008, show that Resident 1 was found lying on his right side between the side rail and the mattress with his right arm caught. The note states that the resident had red marks on his leg above the knee, on his upper arm, and on his shoulder. CMS Ex. 13, at 57. The February 19, 2008 falls care plan was modified by a handwritten entry on October 6, 2008, that lists the fall as a problem and lists as interventions removing the resident’s specialty mattress if it causes falls, observing for safety, and continuing to monitor. An entry dated October 10, 2008, indicates that the specialty mattress was discontinued. CMS Ex. 13, at 32. A Nursing Notes entry on October 12, 2008, states that Resident 1 did not get caught between the mattress and side rail after his air mattress was discontinued. CMS Ex. 13, at 56.

The surveyor that drafted the citation of deficiency under Tag F221 for the November 19, 2008 survey records in the citation that, on November 19, 2008, at 2:35 p.m., she observed Resident 1 in bed with his top rails up. She also observed that his wheelchair was equipped with an alarm and a padded belt with a Velcro® fastener. The surveyor recorded in the SOD that she interviewed the Assistant Director of Nursing (ADON) and a nurse. The surveyor states that the nurse told her the seat belt and alarm were both necessary because there was not enough staff to ensure a timely response to the alarm. The surveyor states that the ADON agreed that the seat belt in the wheelchair was probably not necessary, and the side rail was a restraint. CMS Ex. 11, at 4-5. The surveyor's allegations in the SOD are un rebutted.

ii. Resident 5

Resident 5 was admitted to the facility on June 18, 2008, with diagnoses of persistent mental disorder, dementia, anxiety, osteoarthritis, and chronic obstructive pulmonary disease (COPD), among others. He also reported a fall prior to his admission to the facility. He was 81 years old at the time of the survey. CMS Ex. 17, at 1, 4, 93. On June 19, 2008, his risk for falls was assessed, and he was not determined to be at high risk. CMS Ex. 17, at 13. A side rail usage assessment dated June 19, 2008, indicates that Resident 5 signed a form indicating he preferred side rails to permit him to self-position in bed. CMS Ex. 17, at 15.

Resident 5's MDS with an assessment reference date of June 30, 2008, shows that: his cognitive skills were moderately impaired; his vision was moderately impaired; he had some socially inappropriate or disruptive behavior; he required limited to extensive assistance with ADLs, except eating, for which he required only supervision; and no restraints were in use. CMS Ex. 17, at 65-70. His MDS, with an assessment reference date of September 16, 2008, reflects no changes except to note he had fallen within the thirty days preceding the assessment. The September 2008 MDS also indicates that no restraints were in use. CMS Ex. 17, at 71-75.

A Nursing Progress Note dated September 19, 2008, shows that staff found Resident 5 climbing out of bed without assistance and walking in the hallway all bent over. The note states the resident had no awareness of safety, and bed and chair alarms were applied. CMS Ex. 17, at 55. Nursing Progress Notes and Nursing Notes reflect that Resident 5 fell on October 4, 18, 23 or 24, 2008. CMS Ex. 17, at 35, 38, 40, 42, 78. A Nursing Notes entry at 11:30 p.m. on October 19, 2008, suggested that an abdominal self-release belt be used as a restraint while the resident was up in his wheelchair and that a wheelchair and bed alarm be implemented. CMS Ex. 17, at 42. A Nursing Progress Note dated October 26, 2008, shows that Resident 5 was found lying on his back in the hall, with his chair alarm sounding. The note indicates that Resident 5 likely released his lap belt. CMS Ex. 17, at 33, 39. Nursing Progress Notes dated November 16, 17, and 18,

2008, show that there was an alarm in the resident's wheelchair and bed to discourage him from getting up by himself, and a self-release belt in his wheelchair because he would get up by himself and he was unsteady on his feet. CMS Ex. 17, at 19, 21, 23.

A Pre-Restraining Assessment form dated June 19, 2008, does not indicate whether or not restraints were suggested, and it is not signed by a physician. CMS Ex. 17, at 57. An undated Restraint and Side Rail Consent form indicates that Resident 5 consented to having his top two side rails up, but there is no mention of use of a seat belt in his wheelchair. CMS Ex. 17, at 58-59.

A care plan for ADLs dated June 30, 2008, includes a handwritten entry dated August 29, 2008 that Resident 5 had a fall. Another entry on September 27, 2008, shows that he had another fall during a transfer. A chair alarm was implemented on September 27, 2008. CMS Ex. 17, at 77. A cognitive care plan dated June 30, 2008, includes handwritten notes that show the resident fell on October 4, 18, 23, and 26, 2008. Interventions following the falls were to: continue the chair alarm; add a self-releasing seat belt; and add a bed alarm. The date these interventions were added is not clear from the care plan. However, the context indicates that the self-releasing seat belt was added after the October 18, 2008 fall. CMS Ex. 17, at 78. Resident 5's fall care plan dated June 30, 2008, reflects no updates. CMS Ex. 17, at 81. Resident 5's fall care plan dated September 13, 2008, does not mention side rails or use of a lap belt in his wheelchair. CMS Ex. 17, at 91.

The surveyor records in the November 19, 2008 SOD, that she observed Resident 5 on November 19, 2008, at 12:01 p.m. in the dining room, with a chair alarm and a lap belt in place. CMS Ex. 11, at 18.

There is no order from Resident 5's physician for the use of a lap belt and no assessment for use of a lap belt in evidence.

b. Analysis

CMS has made a *prima facie* showing of a violation of section 1819(c)(1)(A)(ii)(I) & (II) of the Act and 42 C.F.R. § 483.13(a) (Tag F221) that caused actual harm to Resident 1. Restraints may only be imposed based on a written physician's order that specifies the duration and circumstances for use of the restraints, except in emergency circumstances specified by the Secretary. Act § 1819(c)(1)(A)(ii)(I), (II). Although 42 C.F.R. § 483.13(a) does not specifically include the requirement related to a physician's order or recognize any emergency circumstances for the imposition of restraints without a physician's order, a physician's order is clearly required under the Act. The Board has recognized in the prior decisions mentioned above that a facility must ensure it acts in accordance with a physician's order when imposing restraints. Furthermore, Petitioner's policy specifically recognizes the requirement for a physician's order to impose

restraints. Petitioner's policy also required a signed and dated consent form completed by the resident or a responsible party. CMS 18, at 3-4. Petitioner's policy is good evidence of the standard of care related to use of restraints in a long-term care facility, and this evidence is un rebutted.

It is not disputed that, during the November 19, 2008 survey, the surveyor observed Resident 1 in his bed with the side rails up and a lap belt in the resident's wheelchair. It is also not disputed that the surveyor observed Resident 5 in the dining room sitting in his wheelchair, and a lap belt was in use. The clinical records for both residents reflect that a lap belt was used in the wheelchair of each to restrict their movements, primarily as an intervention to minimize the risk for falls. CMS Ex. 13, at 6, 30, 32; CMS Ex. 17, at 19, 21, 33, 39, 78.

In the example of Resident 1, there is evidence of a physician's order, but it does not indicate the time frames or duration for use of the lap belt in the wheelchair, a violation of both the Act and the standard of care reflected by Petitioner's policy. There is also no evidence that the use of restraints, either the lap belt or the bed side rails, was reviewed and reauthorized by a physician every thirty days as required by Petitioner's policy. There is no evidence of consent by Resident 1 or a responsible party. There is no evidence that Resident 1 was reassessed to determine whether or not he had a continued need for the lap belt after receiving his new wheel chair. The evidence shows that he was sitting straighter in his new wheelchair, suggesting that the lap restraint may no longer have been necessary. There is no evidence that, after Resident 1 become entrapped in the side rails on October 1 and 6, 2008 (CMS Ex. 13, at 6, 32, 35, 51, 55), a reassessment was done to determine whether the continued use of side rails was safe and appropriate. There is no evidence that after the entrapments the interdisciplinary team evaluated whether alternatives such as use of a low bed with mats or increased supervision, for example, might be safer and more appropriate than continued use of side rails.

In the example of Resident 5 there is no evidence of a physician's order to implement the use of a lap belt, a violation of that requirement of the Act and the standard of care reflected in Petitioner's policy. There is no evidence of consent to the use of a lap belt by Resident 5 or a responsible party. There is no evidence that the interdisciplinary care planning team considered other interventions, such as increased supervision, and found alternative interventions inadequate.

I conclude that CMS has made a *prima facie* showing of a violation of the condition for participation under section 1819(c)(1)(A)(ii)(I) & (II) of the Act and 42 C.F.R. § 483.13(a) (Tag F221). I further conclude that the violation resulted in actual harm to Resident 1, as the evidence shows that he suffered bruises due to the entrapments in October 2008. CMS Ex. 13, at 32, 35, 51, 55. The burden is upon Petitioner to show by a preponderance of the evidence that it was in substantial compliance or that it has an affirmative defense.

Petitioner argues that it had a restraint policy, a fact that is undisputed, as CMS uses the policy as evidence of the standard of care related to use of restraints and alleges that Petitioner violated the standards of care evidenced by that policy. Petitioner also argues that it properly assessed and reassessed the five residents cited as examples by the surveyors. Petitioner asserts that the assessments and reassessments were consistent with its restraint policy and 42 C.F.R. § 483.13(a). Petitioner asserts that it assessed and reassessed the residents as at risk for falls and as having one or more medical symptoms warranting use of restraints. P. Br. at 8; P. Reply at 3-6. Petitioner also asserts that it: identified and described how restraints would be used to address identified medical symptoms; provided for reevaluation of continued appropriateness of restraints to ensure the use of the least restrictive restraint; and identified how the use of restraints treated medical symptoms, protected the resident, and assisted the resident in achieving the highest practicable level of physical and psychosocial well-being. P. Br. at 8-9. Petitioner reasons that it was in compliance with both the regulation and its policy regarding the use of restraints. Petitioner's reasoning is faulty.

One of Petitioner's overarching theories is that it assessed and reassessed residents at risk for falls and determined that restraints were appropriate interventions to address the risk for falls. P. Br. at 8-9. While use of restraints to reduce the risk for falls may be permissible, Petitioner must nevertheless comply with the statutory and regulatory requirements for the use of restraints. Petitioner must also use restraints consistent with the standards of care. Assessing a resident at risk for falls is an insufficient basis for imposition of restraint without assessing the appropriateness of less restrictive alternatives, such as reclining a wheelchair, using a low bed with mats, or simply providing closer supervision. As the Board indicated in the decisions discussed above, Petitioner bears the burden to show that the imposition of restraints was necessary for the treatment of a medical condition and not for discipline or convenience of staff -- that necessarily requires that Petitioner show that less restrictive interventions were not effective. Further, the use of restraints is much more regulated than many other interventions. Use of restraints, for example, always requires a very specific physician's order. Restraints may only be imposed with the consent of the resident or authorized representative, and the actual application of restraints must be limited in duration. The specific requirements for use of restraints must be satisfied even if the use of restraints is justified to minimize the risk for falls.

Petitioner argues in the case of Resident 1 that, contrary to the citation by the surveyors and arguments of CMS, the duration and circumstances for use of restraints was included in the physician's order, as the evidence shows that the order was for restraints to be applied while the resident was in his wheelchair. P. Reply at 6. This argument is not persuasive. The order to use the restraint while the resident was in his wheelchair told Petitioner when to use the lap belt restraint. The order to use the lap belt while the resident was in the wheelchair did not specify: (1) how long the lap belt could be used for any given instance of use; or (2) the physician ordered duration of the period that the

lap belt could be used, *i.e.*, a week, a month, or months. Petitioner argues that it did obtain consent to use a lap belt from the representative of a resident other than Residents 1 or 5. However, Petitioner does not assert that it obtained consent from either Resident 1 or a representative. P. Reply at 6-7; P. Findings ¶¶ 85-109. Petitioner also does not address in its pleadings the absence of evidence of consent for a lap belt by or on behalf of Resident 5. P. Reply at 6-7; P. Findings ¶¶ 176-207. I find no evidence of consent by Residents 1 or 5, or their representatives, in the records before me.

Petitioner argues that Surveyor Wadley's notes of her conversations with the ADON and nurse do not support a conclusion that Petitioner imposed restraints for the convenience of staff. P. Reply at 9. I do not disagree with Petitioner's assertion that the hearsay contained in Surveyor Wadley's notes is insufficient, standing alone, to support a conclusion that Petitioner allowed restraints to be imposed for the convenience of staff. But, Petitioner overlooks that it bears the burden to show that it was in substantial compliance once CMS makes a *prima facie* showing of a deficiency. CMS has made a *prima facie* showing in this case. Petitioner is unable to meet its burden due to missing orders and documentation necessary to show restraints were imposed for a lawful purpose and in accordance with the requirements of the Act, regulations, and standard of care reflected in Petitioner's policy.

Petitioner argues that Resident 1 did not suffer harm in the form of loss of ability to perform ADLs due to the use of restraints. Petitioner may not challenge the scope and severity determination for this deficiency as there was not a declaration of immediate jeopardy, and, thus, there would be no impact upon the amount of CMP that may be imposed. 42 C.F.R. §§ 498.3(b)(14). Petitioner may, however, attempt to rebut the element of the CMS *prima facie* case that requires a showing that there was a potential for more than minimal harm to a resident due to the statutory or regulatory violation. Petitioner argues that the evidence does not support a conclusion that Resident 1 suffered harm in the form of a decline in his ability to perform ADLs. Contrary to Petitioner's argument, the MDS assessments in February 2008 and August 2008 show that there was a significant decline in Resident 1's ability to perform ADLs during that period. CMS Ex. 13, at 20-21, 26-27. Petitioner points to some evidence that it attempted to address the decline (P. Br. at 9-10), but the evidence does not support Petitioner's position that the decline was not due to the use of restraint. Petitioner does not address the injury its records show that Resident 1 suffered due to his entrapment on October 1, 2008. CMS Ex. 13, at 32, 51, 55. Petitioner does not deny that Resident 1 was injured due to the entrapment on October 6, 2008. Petitioner argues that Resident 1's injury was not due to any failure to assess or monitor side rail use. Petitioner's argument is based on its reassessment, monitoring, and interventions after the October 6, 2008 entrapment. P. Br. at 10-11. Petitioner's argument is not persuasive, however, as Petitioner fails to address any monitoring or reassessment of the use of restraint after the October 1, 2008 entrapment. The October 1, 2008 entrapment demonstrated that there was a risk for entrapment, and the evidence does not show that Petitioner reassessed the appropriateness

of continued use of restraints in light of that risk. Furthermore, Petitioner's actions after the injury on October 6, 2008 do not negate the impact of the October 1 injury or its value as evidence that there was a risk for more than minimal harm due to the use of the restraint. I conclude that Petitioner has failed to rebut the evidence that shows that there was a risk for more than minimal harm, and, in fact, the evidence shows there was actual harm.

Petitioner's plan of correction for this deficiency, dated February 5, 2009, states that Petitioner completed all necessary corrective actions not later than December 19, 2008. CMS Ex. 11, at 3.¹³ The state agency found that Petitioner corrected the deficiency under section 1819(c)(1)(A)(ii)(I) & (II) of the Act and 42 C.F.R. § 483.13(a) (Tag F221), but not until January 31, 2009. P. Ex. 4. Petitioner may attempt to show that it returned to substantial compliance on a date earlier than that found by the state agency and CMS. However, the facility bears the burden to show by a preponderance of the evidence the date on which it corrected deficiencies and returned to substantial compliance. *Omni Manor Nursing Home*, DAB No. 2374, at 8 (2011). The mere representation in the plan of correction that it was completed by a certain date is insufficient to establish correction or a return to substantial compliance as verification by revisit or document review is required by 42 C.F.R. § 488.454(a). *Texan Nursing & Rehab. of Amarillo, LLC*, DAB No. 2323, at 19-20 (2010).

Petitioner argues that it timely submitted its plan of correction for the November 19 survey and that the plan was accepted by the state agency. Petitioner presents no evidence in support of its argument that it completed all elements of the plan of correction other than a letter from the state agency dated March 5, 2009. The state agency letter shows that the state accepted the plan of correction and also found that Petitioner had corrected the deficiencies identified by the November 19, 2008 survey as of January 31, 2009. P. Ex. 4. Petitioner suggests that the March 5, 2009 letter is evidence that the state also accepted Petitioner's representation that correction actually occurred by December 19, 2008, but there is nothing on the face of the letter or other evidence to support Petitioner's suggestion. To satisfy its burden, Petitioner needed to

¹³ The copy of the plan of correction introduced as evidence by Petitioner, dated January 28, 2009, indicates that Petitioner did not expect to complete its plan of correction until February 19, 2009. P. Ex. 3, at 3. Why the plan of correction dated February 5, 2009 has a completion date of December 19, 2008, and the plan of correction dated January 28, 2009 has a completion date of February 19, 2009, is not clear from the record. Petitioner does not address this inconsistency. I would expect, however, that when the Administrator signed the plan dated January 28, 2009, he should have known whether the plan had been fully implemented more than a month before.

present some affirmative evidence that it completed all elements of its plan prior to the date on which the state agency accepted the plan and found that correction occurred. Petitioner has not presented the required evidence.

Petitioner also asserts that the state agency certified by its letter dated March 5, 2009 that Petitioner returned to substantial compliance as of January 31, 2009, and that the state agency subsequently improperly rescinded that certification. P. Br. at 17-18. Petitioner's argument attempts to capitalize on the poorly drafted state notice that includes the sentence: "[y]our facility was found to be in compliance with the Standards of Participation based on the health revisit conducted on **January 31, 2009.**" CMS Ex. 4 (emphasis in original). Despite the state agency's unfortunate phraseology, the letter clearly advised in the note following the confusing language that the "notice of clearance is limited only to the survey mentioned above." CMS Ex. 4. The only survey referred to by the letter was the November 19, 2008 survey. Petitioner cannot feign confusion, as Petitioner was well aware that the January 21, 2009 survey, which identified that Petitioner was not in substantial compliance, had already occurred. Petitioner was advised that another deficiency had been found that caused Petitioner not to be in substantial compliance (CMS Ex. 26) prior to the state agency review on January 31. Further, by the time the state agency issued the March 5, 2009 letter, the February 3 and 5, 2009 surveys had occurred, and Petitioner had again been found not to be in substantial compliance.

I conclude that Petitioner has failed to show that it corrected the deficiency before January 31, 2009. I further conclude that Petitioner did not return to substantial compliance with program participation requirements on January 31, 2009, due to the deficiency found by the survey completed on January 21, 2009, as discussed hereafter.

Accordingly, I conclude that Petitioner was not in substantial compliance with program participation requirements due to a violation of section 1819(c)(1)(A)(ii)(I) & (II) of the Act and 42 C.F.R. § 483.13(a) (Tag F221) from November 19, 2008 through January 30, 2009, and that the violation caused actual harm to Resident 1. Petitioner did not return to substantial compliance on January 31, 2009, due to the findings and conclusions of the survey completed on January 21, 2009.

3. Petitioner was not in substantial compliance on January 21, 2009, due to a violation of 42 C.F.R. § 483.25(h) (Tag F323), that posed a risk for more than minimal harm.

The general quality of care regulation, 42 C.F.R. § 483.25, requires that a facility ensure that each resident receives 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 instructs surveyors that the intent of 42 C.F.R. § 483.25(h)(1) and (h)(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, Tag F323.

The Board has provided interpretative guidance for adjudicating alleged violations of 42 C.F.R. § 483.25(h)(1), stating that the standard in the regulation:

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 . . . Where a facility alleges (or shows) that it did not know that a hazard existed, the facility cannot prevail if it could have reasonably foreseen that an endangering condition existed either generally or for a particular resident or residents.

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

The Board has also explained the requirements of 42 C.F.R. § 483.25(h)(2) in numerous decisions. *Golden Living Ctr. – Riverchase*, DAB No. 2314, at 7-8 (2010); *Eastwood Convalescent Ctr.*, DAB No. 2088 (2007); *Century Care of Crystal Coast*, DAB No. 2076 (2007), *aff'd*, *Century Care of Crystal Coast*, 281 F. App'x 180 (4th Cir. 2008); *Liberty Commons Nursing and Rehab - Alamance*, DAB No. 2070 (2007); *Golden Age Skilled Nursing & Rehab. Ctr.*, DAB No. 2026 (2006); *Northeastern Ohio Alzheimer's Research Ctr.*, DAB No. 1935 (2004); *Woodstock Care Ctr.*, DAB No. 1726 (2000), *aff'd*, *Woodstock Care Ctr. v. Thompson*, 363 F.3d 583 (6th Cir. 2003). Section 483.25(h)(2) does not make a facility strictly liable for accidents that occur, but it does

require that a facility take all reasonable steps to ensure that a resident receives supervision and assistance devices that meet his or her assessed needs and mitigate foreseeable risks of harm from accidents. *Woodstock Care Ctr. v. Thompson*, 363 F.3d at 589 (holding a SNF must take “all reasonable precautions against residents’ accidents”). A facility is permitted the flexibility to choose the methods of supervision it uses to prevent accidents, but the chosen methods must be adequate under the circumstances. Whether supervision is “adequate” depends in part upon a resident’s ability to protect him or herself from harm. *Id.* Based on the regulation and the cases in this area, CMS meets its burden to make a *prima facie* showing 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.

The state agency completed a complaint survey at Petitioner’s facility on January 21, 2009. CMS Ex. 21. The SOD alleged that Petitioner failed to ensure that a CNA used proper transfer techniques to avoid injury to Resident 5. This failure resulted in bruising of Resident 5’s arms and pain. The surveyors concluded that the violation was an isolated deficiency that caused no actual harm but had the potential for more than minimal harm that is not immediate jeopardy. However, the evidence shows the resident sustained actual harm.

a. Facts

Resident 5¹⁴ was 93 years old when she was admitted to Petitioner’s facility on March 26, 2006. Her admitting diagnoses included osteoarthritis, contracture of the hand joint, persistent mental disorder, depression, diabetes with neuropathy, and congestive heart failure, among others. CMS Ex. 23, at 1.

Resident 5’s ADL care plan dated May 24, 2008, was updated with additional problems on August 30, September 27, and December 2, 2008. The September 27 entry listed as a problem pain in the left shoulder from a transfer. The December 2 addition related to an incident on November 26, 2008 that caused bruising on the left forearm and upper arm of the resident. Goals on the care plan were updated through February 27, 2009. The first page of the care plan includes an undated, handwritten intervention that required staff to

¹⁴ Resident 5 in the January 21, 2009 survey is not the same Resident 5 involved in the November 19, 2008 survey.

use a Hoyer lift for safe transfers. On the second page, a handwritten intervention dated September 27, 2008, required transfer training for the resident, use of a gait belt, and use of two people for transfers or a Hoyer lift. Interventions listed on December 2, 2008, included padding the wheelchair with sheepskin to prevent further trauma, and the instruction to use care when using the Hoyer lift. CMS Ex. 23, at 12-13.

Resident 5 was assessed to require the total assistance of two or three staff or the use of a Hoyer for transfers throughout December 2008 and January 2009. CMS Ex. 23, at 5-6, 10-11. An Interdisciplinary Communication Memo dated December 4, 2008, from Physical Therapy to Nursing, advised that the resident had been screened for transfers, and it was determined that she required total assistance and should be transferred by two people or with a Hoyer lift. CMS Ex. 23, at 11. ADL Performance and Support Flow Sheets for December 2008 and January 2009, however, show that a three person assist was required for transfers. CMS Ex. 23, at 5-6.

The November 26, 2008 incident referred to in the care plan actually occurred on November 25, 2008, according to Petitioner's Incident Report dated November 26. The Incident Report states that a CNA reported to a nurse that Resident 5 had two hematomas on her left arm of unknown origin. The resident was assessed, and the nurse concluded that the resident had bruises rather than hematomas. Another CNA reported that the bruises were actually first noticed on November 25, 2008. CMS Ex. 23, at 3, 17. A Nursing Notes entry dated November 26, 2008, indicates that the incident was discussed in the fall committee and that it was determined that the bruising occurred during a transfer with the Hoyer lift. CMS Ex. 23, at 17. A Nursing Notes entry dated December 1, 2008, indicates that CNA Mike Hayes notified a nurse that a large dark purple bruise on the resident's left elbow occurred when the resident's arm was trapped next to the wheelchair side rail when he was putting the resident in her wheelchair. The nurse's note indicates that Resident 5 had limited movement and weakness in her left arm and could not move it out of the way. The note does not state the date the accident reported by CNA Hayes occurred. However, based on the clinical record, I find that the accident occurred on or about November 25 and was first reported on November 26, 2008, as I see no evidence of a second occurrence of bruising between November 25 and December 1, 2008. The nursing note also indicates that restorative nursing and the physician were contacted, and a sheepskin was placed over the left side rail of the wheelchair. A note dated December 3, 2008, indicates that a bariatric chair and mechanical lift were considered but rejected because they were thought to cause a dignity problem. CMS Ex. 23, at 18. A note dated December 4, 2008, states that Resident 5 was very heavy to lift, and that sheepskin remained on the wheelchair arm to prevent arm scraping. A subsequent note dated December 4, 2008, indicates that physical therapy evaluated the resident for transfers, and an order was received for a two person assist or use of a mechanical lift. CMS Ex. 23, at 19. A Nursing Notes entry dated December 23, 2008, states that Resident 5 is a two or three person assist, as she is dead weight and cannot assist at all. The note states that the resident should be "considered for a Hoyer Lift for

transfers before staff gets injured.” CMS Ex. 23, at 23. Bath/Shower Completion Forms dated December 29, 2008 and January 2, 2009, show that Resident 5 had the old bruise on her left arm and also bruises on her right upper arm and right lower leg. CMS Ex. 23, at 15.

The SOD states that the surveyor observed Resident 5 on January 21, 2009, and the resident had bruises on her left arm at the elbow and above the left wrist and on her right arm at the elbow. CMS Ex. 21, at 1.

b. Analysis

CMS has made a *prima facie* showing of a violation of 42 C.F.R. § 483.25(h) that caused actual harm to Resident 5.

The resident’s care plan shows that her left shoulder was injured during a transfer in September 2008. The interventions adopted in September 2008 to address the problem of injury during transfers were: transfer training; use of a gait belt; and two person transfers or the use of a Hoyer lift. CMS Ex. 23, at 13. It is not disputed that the resident was injured again on or? about November 25, 2008 during a transfer causing the bruises on her left arm near the elbow. Interventions to address the problem of injury during transfer were: padding the wheelchair arm; and advising staff to take care when using the Hoyer lift. CMS Ex. 23, at 13.

It is not disputed that the surveyor observed bruises on the left and right arms of Resident 5 during the survey on January 21, 2009. The evidence supports a finding that the bruises on the left arm observed by the surveyor were those that occurred on November 25, 2008, during a transfer to the wheelchair by CNA Hayes. Petitioner’s records show that Resident 5 also suffered a bruise on her right arm near the elbow on December 29, 2008. The clinical evidence does not state the cause for the right arm bruise. However, Resident 5 could not perform her own ADLs or transfers. Therefore, given the similarity of the right arm injury to the left arm injury and the fact that the resident could not transfer herself or perform ADLs, I infer her right arm bruise also resulted from a transfer. The inference that the bruise on the right arm was caused by a transfer to the wheelchair is supported by, and corroborates, CNA Montano’s admission to the surveyor that she injured the resident’s right arm during a transfer. CMS Ex. 21, at 1-2; CMS Ex. 25, at 2.

The surveyor alleged in the SOD that Petitioner failed to ensure that a CNA used proper transfer technique to avoid injuring Resident 5, which resulted in bruising and pain. CMS Ex. 21, at 1. The allegations of the SOD may be read as focusing upon the conduct of a single CNA, CNA Montano. The SOD indicates that CNA Montano told the surveyor that she had been accused of hurting Resident 5 during a transfer with a Hoyer, and she admitted to causing bruising on the resident’s right arm, but she denied

knowledge of the bruising on the left arm. CMS Ex. 21, at 1-2; CMS Ex. 25, at 2. In fact, the evidence shows that CNA Montano was counseled on December 5, 2008 for being rough at the bedside, during transfers, and when verbally redirecting a resident. However, the counseling does not mention Resident 5 or any injury caused Resident 5, and I conclude that the counseling is not evidence that CNA Montano caused the bruising on Resident 5's left arm on November 25, 2008. Rather, the clinical evidence shows that the left arm bruising that occurred around November 25, 2008 was, more likely than not, caused by CNA Hayes when he was transferring Resident 5 and her left arm was trapped by the wheelchair arm. CMS Ex. 23, at 18. I infer CNA Montano's admission of bruising Resident 5's right arm relates to the bruising of her right arm reflected in the documents dated December 29, 2008 and January 2, 2009. CMS Ex. 23, at 15. Thus, the evidence shows three instances of accidental injury of Resident 5 during transfers involving at least two different CNAs. The September accident caused pain, and the November and December accidents caused bruising. CMS 23, at 13, 15. The evidence shows that the requirement to use a Hoyer lift was in effect prior to the September injury. CMS Ex. 23, at 12. The interventions added after the September injury were for the staff to use a gait belt and transfer training. The evidence does not show how the September injury occurred, so it is not possible to determine whether the two new interventions were planned or intended to address some problem identified by the care planning team. Following the December injury, the new interventions were to pad the left wheelchair arm and to take care using the Hoyer. No modifications of the care plan are reflected by the evidence following the right arm bruising in late December 2008.

The evidence presented by CMS shows that, by September 2008, it was foreseeable that Resident 5 was subject to accidental injury of her arms during transfers. After the November accidental injury, it was foreseeable that Resident 5 was subject to accidental injury during transfers using the Hoyer lift. Petitioner's clinical records do not show that Resident 5's interdisciplinary team took action, after either the September 2008 or the November 2008 accidental injuries to Resident 5's arms, to: identify, evaluate, and analyze hazards and risks related to transfers of Resident 5; implement adequate interventions to reduce hazards and risks; or monitor the effectiveness of interventions and modify them when necessary. SOM, app. PP, Tag F323. Petitioner's clinical records for Resident 5 show that it was not clear whether Resident 5 was to have the assistance of two or three staff. CMS 23, at 5-6, 10-11. The records also show confusion as to whether or not a Hoyer lift was to be used. The use of a Hoyer lift was listed on the care plan before September 2008, according to the order in which it was added to the care plan. CMS Ex. 23, at 12-13. A Nursing Notes entry on December 3, 2008, indicates that a bariatric chair (an extra-wide chair for the obese) and a mechanical lift were discussed but rejected due to a possible dignity issue. CMS Ex. 23, at 18. But the care plan clearly shows that use of a Hoyer had been listed as an intervention since before September 2008. CMS Ex. 23, at 12. The evidence does not reflect that the interdisciplinary team ever considered the use of a bariatric or extra-wide chair to avoid the problem of Resident 5 injuring her arms on the arms of the wheelchair during transfer. A physical therapy

evaluation on December 4, 2008 is the first documentation in evidence of an assessment that either a two person assist or Hoyer lift should be used for transfers of Resident 5. CMS Ex. 23, at 11, 19. The evidence does not show that the interdisciplinary team ever considered ordering a two person assist using the Hoyer lift for transfers with special attention to preventing the resident's arms from contacting the wheelchair arms. A Nursing Notes entry on December 23, 2008, reflects that some staff may not have been aware that use of a Hoyer was authorized as the nurse complained that the resident was dead weight, and she should be considered for use of a Hoyer lift before staff was injured. CMS Ex. 23, at 23. After the November 25, 2008 injury, the left arm of the wheelchair was padded but not the right, and there is no evidence that the interdisciplinary care planning team considered whether or not the right arm should also be padded. CMS Ex. 23, at 12-13, 18. I conclude that Petitioner did not take reasonable steps to eliminate or minimize the foreseeable risk for accidental injury of Resident 5 during transfers, which is shown by the fact Resident 5's arm was again injured during a transfer on about December 29, 2008.

Because CMS has made a *prima facie* showing, the burden is upon Petitioner to rebut the *prima facie* showing or to establish an affirmative defense. Petitioner fails to meet its burden.

Petitioner asserts that it took all steps required to assess and implement interventions. Petitioner argues it provided training to staff to ensure they were competent for two person transfers, use of a gait belt, and use of Hoyer lifts. Petitioner notes it placed sheepskin on Resident 5's wheelchair to help prevent bruising on her arms, but Petitioner does not explain why its records show the sheepskin was only placed on the left arm. Petitioner argues: it completed an incident report on November 26, 2008 regarding the bruising; it undertook an investigation of the bruising; and a CNA was counseled as a result of that investigation. Petitioner contends that no evidence exists that improper hand placement, or other improper technique, caused any bruising for Resident 5. Petitioner asserts that no credible evidence exists that the bruises resulted during a transfer as opposed to during a shower. P. Br. at 19-20; P. Reply at 11-12. Again, Petitioner misunderstands that it bears the burden to show by competent evidence that Resident 5's interdisciplinary care planning team assessed Resident 5's needs with regard to safe transfers, developed interventions effective to address those needs, ensured the interventions were implemented, and then reassessed the effectiveness of the interventions, adopting new interventions as needed. Petitioner has not come forward with evidence that shows it ensured that adequate supervision and assistance devices were provided to Resident 5 to mitigate or eliminate the risk of foreseeable accidental injury to her arms during transfers, no matter what transfer technique may have been used.

Based upon Petitioner's clinical evidence, and with no reliance upon the potentially inconsistent statements of the resident to the surveyor, I have found it more likely than

not that there were three instances of injury to Resident 5 during transfers. Petitioner's argument that there is no credible evidence to show that Resident 5 suffered the bruises during transfers is unfounded. Petitioner's problem is that documentation of its assessments, care planning, and implementation of interventions, and its investigations of the causes of accidental injury, are inadequate to permit it to meet its burden of proof.

Accordingly, I conclude that Petitioner was in violation of 42 C.F.R. § 483.25(h) (Tag F323), and that violation resulted in actual harm to Resident 5. Although not specifically alleged by the surveyors or CMS, this violation began as early as November 25, 2008, due to the failure of the interdisciplinary team to assess the effectiveness of existing interventions and to adopt new appropriate interventions intended to minimize or eliminate the foreseeable risk that Resident 5's arms would be injured during transfers. Petitioner states in its plan of correction dated February 19, 2009, that it completed correction of the deficiency on February 21, 2009. CMS Ex. 21, at 2. However, even if Petitioner corrected the deficiency on February 21, 2009, it did not return to substantial compliance due to deficiencies identified by the surveys on February 3 and 5, 2009.

4. Petitioner was not in substantial compliance from February 3, 2009 to May 6, 2009 due to violation of 42 C.F.R. § 483.70(a), resulting from Life Safety Code violations that posed a risk for more than minimal harm.

A long-term care "facility must be designed, constructed, equipped, and maintained to protect the health and safety of residents, personnel and the public." 42 C.F.R. § 483.70. The regulation requires that a facility must meet the applicable provisions of the 2000 edition of the Life Safety Code published by the National Fire Protection Association. 42 C.F.R. § 483.70(a)(1). CMS may waive specific provisions of the Life Safety Code after consideration of the state agency findings, if the rigid application of the Code requirement would result in unreasonable hardship upon the facility, but only if such a waiver does not adversely affect the health and safety of any resident. 42 C.F.R. § 483.70(a)(2); SOM chap. 7, ¶ 7410.6; SOM app. PP, Tag F454.

The Life Safety Code survey was completed at Petitioner's facility on February 3, 2009. The SOD for the Life Safety Code alleged nine violations that posed a risk for more than minimal harm, in violation of the participation requirement at 42 C.F.R. § 483.70(a). CMS Ex. 27. Petitioner does not dispute that it violated eight of the nine life safety code

(LSC) deficiencies alleged in SOD,¹⁵ or that there was a risk for more than minimal harm. P. Br. at 22; P. Findings 249-50; Tr. at 317-34. Petitioner alleged in its plan of correction that it would complete all corrections by April 1, 2009. Before me, Petitioner asserts that it corrected all its LSC deficiencies prior to May 6, 2009, the date of termination. P. Br. at 23-26; P. Finding 252. Petitioner's arguments are not persuasive.

Petitioner's Administrator, Gregory Whitaker, testified that correction of the various deficiencies was done, or he had executed contracts or purchase orders to correct deficiencies prior to the May 6, 2009 termination date. Tr. at 317-32. Administrator Whitaker testified that he was told by the surveyor that so long as he had a receipt showing the required materials were purchased or ordered or that he had a contract for the work to be done, the surveyor would consider the facility in "compliance." Tr. at 323-26, 328-30; P. Br. at 23-24. However, Petitioner's November 4, 2009 letter to the state agency effectively rebuts the testimony of the Administrator. The letter states that the Life Safety Code surveyor only verbally approved Petitioner's plan of correction. The letter further shows that when a relicensing survey was done on November 2, 2009, it was found that Petitioner had not yet corrected two of the deficiencies from the February 3, 2009 Life Safety Code survey. P. Ex. 6, at 1-2; Tr. at 333-34. The evidence shows, contrary to the testimony of the Administrator, that the surveyor did not represent that execution of a contract or a purchase order for repairs was a sufficient basis for a finding that Petitioner had returned to compliance with participation requirements. Rather, the surveyor told Petitioner, according to Petitioner's own letter and the Administrator's testimony, that the plan to correct the deficiencies was approved by the surveyor based upon Petitioner having evidence in the form of contracts or purchase orders showing that corrections would be made. The surveyor's Fire Safety Report dated February 3, 2009, block 7, reflects that he accepted the plan of correction, not that he found compliance with all Life Safety Code provisions. CMS Ex. 28. Petitioner does not deny that the November 2, 2009 relicensing survey correctly determined that it had not corrected two Life Safety Code violations from the February 3 survey and that it requested a waiver of the deficiencies to obtain its license. P. Ex. 6; Tr. at 334.

Administrator Whitaker also admitted in testimony that, while he had ordered supplies or contracted for work, actual corrections did not occur until after the date of termination. For example, he testified he ordered fire rated ceiling tile on April 27, 2009, but they

¹⁵ Petitioner argues that it was not in violation of Tag K046, which is related to a requirement for emergency lighting. I need not resolve this dispute, as the other Life Safety Code violations are adequate bases for concluding that there was a violation of 42 C.F.R. § 483.70(a).

were not received and installed until two weeks later, on about May 11, 2009, after the date of mandatory termination. Tr. at 323-26; P. Br. at 24.

Petitioner argues that the Life Safety Code deficiencies were not the basis for the imposition of remedies and did not cause termination of Petitioner's provider agreement, and those deficiencies are not properly before me. P. Br. at 21. Contrary to Petitioner's argument, eight of the nine deficiencies were not contested, they posed a risk for more than minimal harm, and they amounted to noncompliance. At least four of the deficiencies, K021, K029, K051, and K056, were not actually corrected prior to May 6, 2009. Tr. at 322-29; P. Ex. 6, at 4-5; P. Br. at 23-25. The uncorrected Life Safety Code deficiencies, standing alone, would have caused termination because Petitioner was not in substantial compliance due to those deficiencies. Therefore, the Life Safety Code deficiencies are properly before me.

Accordingly, I conclude that, from February 3, 2009 to termination on May 6, 2009, Petitioner was not in substantial compliance with 42 C.F.R. § 483.70(a) due to violations of the Life Safety Code that posed a risk for more than minimal harm.

5. Petitioner was not in substantial compliance on February 5, 2009 due to a violation of 42 C.F.R. § 483.13(b) and (c)(1)(i) (Tag F223)¹⁶ that posed immediate jeopardy to resident health and safety.

6. Petitioner was not in substantial compliance on February 5, 2009 due to a violation of 42 C.F.R. § 483.13(c) (Tag F226) that posed immediate jeopardy to resident health and safety.

The state agency entered the facility again on January 26, 2009, to conduct an extended annual certification survey and complaint investigation that concluded on February 5, 2009. CMS Ex. 29, at 1; CMS Ex. 37, at 1. The survey included investigation of three complaints. A complaint that alleged neglect of residents was found by the state agency to be unsubstantiated. Two complaints that alleged a male resident abused two female

¹⁶ The SOD cites 42 C.F.R. § 483.13(b)(1)(i), but this is obviously an error as there is no such subsection. The surveyors recite the language of 42 C.F.R. § 483.13(c)(1)(i) in the SOD under Tag F223, and I recognize that the surveyors' reference to 42 C.F.R. § 483.13(b)(1)(i) was a clerical error. The erroneous citation caused no prejudice to Petitioner, as the language of the correct subsection is recited in the SOD and Petitioner clearly recognized the error. P. Br. at 28 n.1. All references in this decision to Tag F223, as cited by the SOD dated February 5, 2009, refer to 42 C.F.R. § 483.13(b) and (c)(1)(i).

residents were found to be substantiated. CMS Ex. 67, at 10-14; CMS Ex. 29, at 1. CMS imposed PICMPs for the two substantiated complaints: a \$5,000 PICMP for a violation of 42 C.F.R. § 483.13(b) and (c)(1)(i) (Tag F223, Abuse) and a \$5,000 PICMP for a violation of 42 C.F.R. § 483.13(c) (Tag F226, Staff Treatment of Residents), both of which allegedly posed immediate jeopardy. CMS Ex. 1, at 1-2.

The state agency also alleged violations of the following regulations that posed a risk for more than minimal harm and Petitioner does not dispute these deficiencies: 42 C.F.R. §§ 483.15(g)(1) (Tag F250); 483.45(a) (Tag F406); 483.13(c)(1)(ii)-(iii), (c)(2)-(4) (Tag F225); 483.25(i) (Tag F325); 483.30(b) (Tag F354); and 483.35(i) (Tag F371). P. Br. at 27. Thus, Petitioner admits that it was not in substantial compliance with these regulatory requirements. Petitioner asserts that the deficiencies were corrected no later than April 19, 2009. CMS does not dispute that Petitioner corrected these deficiencies and the other deficiencies alleged by this survey not later than April 20, 2009.¹⁷ Tr. at 136-39. Petitioner contests all other deficiencies alleged in the February 5, 2009 SOD, including the alleged violations of 42 C.F.R. §§ 483.13(b) and (c), 483.15(f)(1), 483.20(b), (d), (k)(1), (k)(3)(ii), 483.75, 483.75(d)(1)-(2), and 483.75(h). I discuss only the two deficiencies cited as the bases for the PICMPs.

The surveyors cited the two deficiencies based on the same facts, and, for that reason, the deficiencies are discussed together. The surveyors alleged a violation of 42 C.F.R. §483.13(b) and (c)(1)(i) (Tag F223) based on Petitioner's failure to implement its care plan to monitor Resident 50 every thirty minutes and to document that monitoring to limit or control his interactions with vulnerable residents, after Resident 50 physically abused Resident 18 and sexually assaulted Resident 6. CMS Ex. 29, at 1-2. The surveyors alleged a violation of 42 C.F.R. § 483.13(c), as the facts allegedly show that Petitioner failed to develop and implement its policies and procedures to protect residents after incidents of physical and sexual abuse. CMS Ex. 29, at 17-18. The surveyors concluded

¹⁷ Thus, CMS concedes that the deficiencies from this survey did not cause termination on May 6, 2009. Whether Petitioner corrected some deficiencies earlier than April 19, 2009 need not be resolved as that issue does not impact the PICMPs imposed. The correction of deficiencies from the February 5 survey also does not impact the running of the mandatory DPNA as the Life Safety Code violations continued to termination on May 6, 2009.

that the deficiencies presented immediate jeopardy to Petitioner's residents.¹⁸

a. Facts

The deficiencies involve three residents, 50, 18, and 6. Resident 50 was admitted to the facility on June 10, 2008, when he was 81 years old. CMS Ex. 34, at 1. Resident 50 did not have a diagnosis of dementia when admitted, but he was noted to have another persistent mental disorder. He also suffered COPD. His competency was assessed as "moderate." CMS Ex. 34, at 1, 2, 15. His diagnoses at transfer to another facility on February 5, 2009, included COPD and dementia. CMS Ex. 34, at 43. Resident 18 was admitted to the facility on April 1, 2007, when she was 92 years old. Her diagnoses included pneumonia, emphysema, peripheral neuropathy, transient cerebral ischemia, depression, arthritis, and senile dementia. CMS Ex. 33, at 1, 11. Her competency was assessed as "moderate." CMS Ex. 33, at 3. Resident 6 was admitted to the facility on October 22, 2007, when she was 80 years old. Her diagnoses included anxiety, generalized pain, muscle weakness, convulsions, and senile dementia. CMS Ex. 32, at 1, 7. Her "consumer competency level" was rated "low." She was non-verbal. CMS Ex. 32, at 2, 5.

Residents 18 and 50 resided across the hall from each other and spent time with each other. Resident 18 referred to Resident 50 as her "boyfriend," and her care plan of December 8, 2008, recognized her right to have consensual sexual encounters. CMS Ex. 33, at 7, 24, 27-28; CMS Ex. 34, at 11, 22, 35. On January 2, 2009, Resident 18 reported to facility staff that Resident 50 had beaten her in her room. Staff assessed the resident to have a "slight bloody nose," and her shirt had been pulled and stretched. CMS Ex. 33, at 4, 7-9, 14, 25, 27; CMS Ex. 34, at 11, 21; P. Ex. 8. Facility staff contacted law enforcement and completed an incident report following the incident. No "Resident Protection Investigation Path" form, a form required by Petitioner's abuse policy, is in evidence. CMS Ex. 33, at 3-7; CMS Ex. 34, at 2-5.

After the reported battery of Resident 18 by Resident 50, Petitioner's interventions were to move Resident 18 to a new room on a different hallway and to schedule a psychiatric

¹⁸ The surveyors alleged under Tag F223 an example involving Residents 30 and 38 (CMS Ex. 29, at 7-10), but I conclude it is not necessary to discuss this example as the deficiency is adequately shown by the example involving Residents 50, 18, and 6. The surveyors also allege under Tag F226 an example involving alleged neglect of Resident 59. CMS Ex. 29, at 28-32. I conclude it is unnecessary to discuss the example of Resident 59, as the deficiency under Tag F226 is amply illustrated by the example discussed.

consult for her. CMS Ex. 33, at 5-7, 14, 25. Resident 18 was not happy about being moved and informed a nurse that she felt like she was being punished. CMS Ex. 33, at 14, 25. She also expressed to her physician that she was not afraid of Resident 50. CMS Ex. 33, at 27.

Resident 50's records show that he was also to be moved to a new room on a different hallway. CMS Ex. 34, at 5, 9. However, a Social Service Progress Notes entry dated January 2, 2009, states that he refused to move, which is why Resident 18 was moved. CMS Ex. 34, at 35. Resident-to-resident abuse was added to Resident 50's care plan as a problem on January 2, 2009. Interventions were to move him, to monitor him to ensure he stayed away from Resident 18, and to make frequent checks. A subsequent note on the care plan indicates Resident 50 refused to move, and Resident 18 was moved. CMS Ex. 34, at 46.

On January 4, 2009, two days after he battered Resident 18, Resident 50 was observed in the hallway kissing Resident 6 and fondling her breasts. Petitioner indicates in its report to the state agency that Resident 6 is non-verbal and cannot ask for sexual contact. I infer that she also cannot consent to sexual contact based upon her low competency. CMS Ex. 32, at 2, 5-6; CMS Ex. 34, at 6-8, 10, 11. No "Resident Protection Investigation Path" form, a form required by Petitioner's abuse policy, is in evidence. CMS Ex. 32, at 2-3. A Nursing Notes entry on January 4, 2009, states that when staff spoke with Resident 50 about the incident with Resident 6, he denied doing anything wrong and then became angry and aggressive with staff. CMS Ex. 34, at 23. Petitioner's incident report to the state indicates that the residents were separated and interviewed to ascertain what happened. Resident 50 was counseled about being respectful to female residents. The police were called to assist with the resident, and the Ombudsman was called. The report indicates that Resident 50 was moved to another hallway, and police advised him that he could be charged with felony assault and that he should become a gentleman and leave the ladies alone. CMS Ex. 34, at 6-8. Petitioner subsequently provided conflicting reports to the state agency in two different letters both dated January 12, 2009. One letter stated that Resident 50 was on fifteen-minute checks, and the other letter stated that he was on thirty-minute checks. CMS Ex. 32, at 5; CMS Ex. 34, at 10. An incident report states that the resident was being monitored closely, and he had been instructed not to invite female residents to his room. CMS Ex. 34, at 12.

Resident 50's physician stated in a progress note dated January 5, 2009, that he was concerned about the two incidents, and he felt the resident was no longer safe in the facility and should be sent home as there was not another facility with an available room that could handle him. The physician noted that, pending release, Resident 50 had been moved away from the residents he assaulted, and he was being monitored closely day and night to ensure he did not enter the women's rooms or engage in further misconduct. CMS Ex. 34, at 13, 24. A Nursing Notes entry dated January 5, 2009, shows that, after

the incident with Resident 6, Resident 50 was moved from room 102 to room 301 and that thirty-minute checks were to be done. CMS Ex. 34, at 24, 36-37.

A Nursing Notes entry on January 13, 2009, indicates Resident 50 was in the hall looking for his girlfriend. CMS Ex. 34, at 27. Entries dated January 15, 17, and 18, 2009, indicate no verbal or sexual advances toward other residents or staff. CMS Ex. 34, at 27. Nursing Notes entries show contact, including touching and kissing, between Residents 18 and 50 on January 20, 21, 23, 28, and 29, 2009, and staff separated them. CMS Ex. 33, at 17, 19, 21; CMS Ex. 34, at 28-31. A Nursing Notes entry dated January 29, 2009, at 4:30 p.m., indicates that Resident 50 was receiving one-on-one supervision with staff present at all times. But an entry on January 30, 2009, at 5:15 a.m., indicates that fifteen-minute checks continued. An entry at 10:00 a.m. on January 30 indicates one-on-one supervision with staff present at all times. One-on-one supervision is noted in the remaining Nursing Notes, until Resident 50's transfer to another facility on February 5, 2009. CMS Ex. 34, at 31-34, 48-52.

The clinical records in evidence for Resident 50 include forms titled "15 Minute Check Sheet" that show fifteen-minute checks were done from 12:15 p.m. on January 29, 2009 to 12:30 p.m. on January 30, 2009. CMS Ex. 34, at 41-42.

Resident 50's care plan was updated on January 4, 2009, with the problem of sexual touching of a demented resident. The interventions were to move him to another room, to continue thirty-minute checks, and to start discharge planning. CMS Ex. 34, at 46.

It is not disputed that on January 27, 2009, a surveyor observed Residents 18 and 50 unsupervised and touching in the hallway. On January 29, 2009, the surveyor observed them unsupervised and kissing in the hallway. CMS Ex. 29, at 3.

Petitioner's abuse policy prohibits mistreatment, neglect, or abuse of its residents by anyone. CMS Ex. 36, at 1. The policy requires that staff report signs and symptoms of mistreatment, neglect, or abuse to their supervisor, DON, or Administrator immediately so that the allegations can be investigated. CMS Ex. 36, at 22-23. The policy requires the Administrator or DON to initiate an investigation of, and report any allegation of, abuse. The policy requires in the case of an allegation of resident to resident abuse that steps be taken to protect residents from the abuser. CMS Ex. 36, at 24, 33. The policy also requires that the Administrator or DON use a tool referred to as the "Resident Protection Investigation Path" form appropriate to the type of alleged abuse. CMS Ex. 36, at 24, 27, 29, 31. It appears from the face of the forms that their purpose was to ensure that no steps were missed in dealing with an allegation of abuse.

b. Analysis

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." Act § 1819(c)(1)(A)(ii). The Secretary has provided that a "resident has the right to be free from verbal, sexual, physical, and mental abuse, corporal punishment, and involuntary seclusion" and that a "facility must develop and implement written policies and procedures that prohibit mistreatment, neglect, and abuse of residents and misappropriation of resident property." 42 C.F.R. § 483.13(b), (c). Subsection 483.13(c)(1)(i) specifies that a facility must "not use verbal, mental, sexual, or physical abuse, corporal punishment, or involuntary seclusion." The regulations define "abuse" to be "the willful infliction of injury, unreasonable confinement, intimidation, or punishment with resulting physical harm, pain or mental anguish." 42 C.F.R. § 488.301.

The surveyors' allegations are precisely focused. The surveyors allege that Petitioner violated 42 C.F.R. § 483.13(b) and (c)(1)(i) (Tag F223) because Petitioner failed to follow its care plan to check Resident 50 every thirty minutes and to document those checks, and, as a result, Petitioner failed to protect its residents after physical or sexual abuse had occurred. CMS Ex. 29, at 1. The surveyors allege that Petitioner violated 42 C.F.R. § 483.13(c), because Petitioner failed to develop and implement its policies and procedures to protect residents after incidents of physical and sexual abuse. CMS Ex. 29, at 17-18. I conclude that CMS has made a *prima facie* showing of a violation of both regulations.

The facts are clear and undisputed. Petitioner reported to the state agency that Resident 50 battered Resident 18. Petitioner recognized and reported the incident as abuse. CMS Ex. 33, at 3-7; CMS Ex. 34, at 2-5, 9. Petitioner's interventions were to: move Resident 50 to another room, and, when he would not move, Resident 18 was moved; monitor Resident 50 to ensure that he stayed away from Resident 18; and perform frequent checks on Resident 50, but no frequency was specified for the checks. CMS Ex. 34, at 46. Two days later, staff discovered Resident 50 fondling and kissing Resident 6 who was unable to resist. Staff redirected Resident 50 who became aggressive with staff. CMS Ex. 34, at 23. Petitioner recognized and reported the incident as abuse. CMS Ex. 32, at 2-5; CMS Ex. 34, at 6-8, 10. Petitioner's interventions added to Resident 50's care plan on January 4, 2009, were to move Resident 50 to another room, to continue thirty-minute checks, and to start discharge planning. CMS Ex. 34, at 46. Petitioner reported to the state agency on January 12, 2009, that it was conducting fifteen-minute checks on Resident 50. CMS Ex. 32, at 5. Petitioner also reported to the state agency on January 12, 2009, that it was conducting thirty-minute checks on Resident 50. CMS Ex. 34, at 10. Petitioner's abuse policy required that, in the case of an allegation of resident to resident abuse, steps be taken to protect residents from the abuser. CMS Ex. 36, at 24, 33. The policy also required that the Administrator or DON use a tool referred to as the "Resident Protection Investigation Path" form appropriate to the type of alleged abuse. CMS Ex. 36, at 24, 27, 29, 31.

The evidence shows that Petitioner's interventions were ineffective to prevent Resident 50 from abusing Resident 6 and to prevent several subsequent instances of Resident 50 having contact with Resident 18, including touching and kissing. P. Findings 306, 318-325. The clinical records refer to thirty-minute checks but do not include documentation that such checks were actually done. The records show that fifteen-minute checks are documented for one twenty-four hour period only from January 29 to 30, 2009. CMS Ex. 34, at 41-42. The records reflect that Petitioner then increased Resident 50's supervision to one-on-one on January 30, 2009, and that continued until his discharge on February 5, 2009. CMS Ex. 34, at 31-34, 48-52. The need for fifteen-minute checks and one-on-one supervision was recognized when Resident 50 became more aggressive with staff, but I recognize that the closer supervision had the ancillary effect of protecting residents. P. Finding 314. There is also no evidence that Petitioner's Administrator or DON used the "Resident Protection Investigation Path" form as required by its policy. The evidence shows that Petitioner failed to protect its residents from abuse by Resident 50, after Resident 50 abused Resident 18, a violation of 42 C.F.R. § 483.13(b) and (c)(1)(i) (Tag F223). The evidence also shows that Petitioner failed to implement its abuse policy in violation of 42 C.F.R. § 483.13(c), because it failed to protect its residents from further abuse and because its Administrator and DON failed to follow the requirements of Petitioner's policy by using the prescribed form.

Petitioner advances several arguments, all of which are without merit. Petitioner argues that it was not foreseeable that Resident 50 would commit a battery of Resident 18. Petitioner does not suggest, however, that, after Resident 50 hit Resident 18, it was not foreseeable that he might commit further abuse. Rather, Petitioner argues that, as soon as Resident 50 struck Resident 18, Petitioner took appropriate action. P. Br. at 30-31. Petitioner does not acknowledge that the interventions adopted were not effective or not effectively implemented to prevent the sexual assault of Resident 6. Petitioner alleges regarding the further contacts between Resident 18 and Resident 50, that it could not prevent such contacts without violating resident rights. Petitioner also argues that, because there were no further allegations of abuse after the incident with Resident 6, its interventions were effective. P. Br. at 31-32. Petitioner's arguments are not persuasive. Petitioner bears the burden to rebut the CMS *prima facie* showing, and Petitioner has not presented evidence that it actually implemented the intervention of frequently checking Resident 50 after he battered Resident 18. Petitioner also has not shown that the thirty-minute checks were actually done after Resident 50 sexually assaulted Resident 6 and prior to the implementation of fifteen-minute checks on January 29, 2009. Petitioner's argument that it could not prevent contacts between Resident 50 and Resident 18 without violating resident rights is not persuasive. Petitioner has presented no evidence that Petitioner's interdisciplinary care planning team actually considered that issue. There is also no evidence that the care planning team attempted to devise an intervention, such as one-on-one supervision, intended to balance the need to protect residents from potential abuse by Resident 50 and the right of Resident 18 to have access to him. Petitioner asserts that the evidence shows that staff did observe many contacts between Resident 50

and Resident 18. P. Br. at 31. However, a chance observation of a contact by staff is not the same as staff supervising the contact to ensure no opportunity for abuse occurred. Petitioner does not address the failure of its Administrator and DON to follow the procedures specified by its abuse policy and does not rebut CMS's *prima facie* showing of a violation of 42 C.F.R. § 483.13(c).

Petitioner does not argue or point to any evidence that its residents were not at risk for more than minimal harm from Resident 50. In fact, Resident 50 inflicted actual harm upon Resident 18, demonstrating that he had the potential to do so if not properly supervised. Petitioner does argue that the declaration of immediate jeopardy was clearly erroneous. P. Br. at 32. The issue of whether the declaration of immediate jeopardy related to the deficiencies under Tags F223 and F226 is not before me. CMS imposed PICMPs based on these deficiencies. The regulations provide that a facility may only challenge the scope and severity of the level of noncompliance if it would affect the range of the CMP. Because there is a single range for PICMPs, my review of immediate jeopardy would not affect the amount of the PICMP authorized. Therefore, immediate jeopardy is not at issue or subject to my review. 42 C.F.R. § 498.3(b)(14), (d)(10)(i).

I conclude that: Petitioner violated 42 C.F.R. § 483.13(b), (c)(1)(i), and 483.13(c) ; the violations posed a risk for more than minimal harm to Petitioner's residents; and the violations provide bases for the imposition of PICMPs.

7. Petitioner was not in substantial compliance on April 2, 2009, due to a violations of 42 C.F.R. §§ 483.13(c) (Tag F224) that caused actual harm.

8. Petitioner was not in substantial compliance on April 2, 2009, due to a violation of 42 C.F.R. § 483.13(c)(2)-(4) (Tag F225) that caused actual harm.

The surveyors completed another complaint survey at Petitioner's facility on April 2, 2009. The complaint survey was triggered by four complaints, two of which were found substantiated and two unsubstantiated. The surveyors allege in the SOD that Petitioner violated: 42 C.F.R. § 483.13(c) (Tag F224), and the violation resulted in an isolated instance of actual harm; 42 C.F.R. § 483.13(c)(1)(ii)-(iii) and (c)(2)-(4) (Tag F225) and the violation caused an isolated instance of actual harm; 42 C.F.R. § 483.20(b) (Tag F272), and the violation posed a risk for more than minimal harm; and 42 C.F.R. § 483.20(k)(3)(ii) (Tag F282), and the violation posed a risk for more than minimal harm. Petitioner states in its plan of correction that it completed correction of each of these alleged deficiencies on April 19, 2009. CMS Ex. 39. CMS agreed at hearing that the alleged deficiencies were corrected by April 20, 2009 and, implicitly, that these deficiencies did not cause termination on May 6, 2009. Tr. at 136-39. CMS notified Petitioner that it was imposing a \$2,000 PICMP each for the deficiencies cited under

Tags F224 and F225. CMS Ex. 1, at 9-14. As already discussed, the mandatory DPNA continued to termination on May 6, 2009, due to the Life Safety Code deficiencies. Thus, I conclude that it is necessary to discuss only the deficiencies under Tags F224 and F225 as they are the bases for the imposition of the PICMPs.

a. Facts – Tag F224

The surveyor alleges in the SOD that, during the survey on April 1, 2009, she observed Resident 4 in the dining room with a red hard cast on her right foot and ankle. CMS Ex. 39, at 1. Resident 4 was 95 years old when she was observed by the surveyor. She was admitted to Petitioner on February 25, 2005. CMS Ex. 45, at 52-53. Her MDS, with an assessment reference date of September 22, 2008, assessed her as moderately impaired cognitively, but she usually understood and could be understood. She required limited assistance of one person for locomotion, which was primarily by wheelchair. Her diagnoses included congestive heart failure, depression, and emphysema or COPD. CMS Ex. 45, at 52-58.

An incident report dated March 18, 2009, at 7:30 a.m., states that Resident 4 was walking to the dining room and turned her ankle; the report shows a bruise on the right heel; and the report indicates the nurse was immediately notified, the resident was returned to her wheelchair and taken to the dining room. The report does not show that any notifications were made. The report is signed by a CNA. CMS Ex. 45, at 1. A subsequent Nursing Notes entry dated March 18, 2009, shows that the resident complained of pain in her right foot and refused to stand at bed time. CMS Ex. 45, at 4. A Nursing Notes entry on March 19, 2009, states that a purple area was noted on Resident 4's right heel and she complained her heel hurt. CMS Ex. 45, at 19. Neither nursing note indicates any assessment was done to assess the complaint of pain or the bruising.

A second incident report dated March 19, 2009, at 6:40 p.m., more than thirty-five hours after the first incident report, indicates that Resident 4 suffered an injury of unknown origin that was unwitnessed and involved bruising and swelling of the right ankle. The ankle was warm to the touch. Resident 4 could not bear weight on the right ankle, and Resident 4 complained of severe pain on light touch or movement. The report shows that the physician and responsible party were notified about 7:00 p.m. on March 19, and the resident was taken to the hospital. The report is signed by a nurse. CMS Ex. 45, at 2. The substance of the second incident report, including assessment and follow-up, is also contained in Nursing Notes entries on March 19, 2009 at 6:40 p.m. CMS Ex. 45, at 19, 22. An x-ray showed that the resident had a fracture of the right calcaneous, the bone in the right heel. CMS Ex. 45, at 7.

b. Analysis – Tag F224

The deficiency citation is not artfully drafted. However, the gist of the citation is clear from reading the entire citation. Petitioner allegedly violated the regulation in two ways. Resident 4 was neglected in violation of Petitioner’s policy prohibiting neglect because, at 7:30 a.m. the morning of March 18, 2009, the CNA reported to nursing staff that Resident 4 had turned her ankle while being walked to breakfast and there was bruising, but no assessment of the ankle was done until 6:40 p.m. on March 19, 2009, more than thirty-five hours later. The surveyor also alleges that Petitioner’s abuse policy required an investigation in the case of an unexplained injury (CMS Ex. 36) as was reported by the nurse in the second incident report dated March 19, but there is no evidence of an investigation.¹⁹ CMS Ex. 39, at 1-10. Resident 4’s complaints of pain from the ankle are established by the record, and I accept pain to be actual harm. I conclude that CMS has established a *prima facie* showing of a violation of 42 C.F.R. § 483.13(c) that caused actual harm.

Petitioner does not deny the facts or the conclusions of the surveyor. Rather, Petitioner argues that Tag F224 alleges identical noncompliance as the deficiency cited by the February 5, 2009 survey. Petitioner argues that the deficiency under Tag F224 cited by the February 5, 2009 survey was the subject of a plan of correction that had been approved and was not required to be complete until April 19, 2009. Petitioner asserts, without citation to authority,²⁰ that the state agency should not have cited Petitioner with a deficiency under Tag F224 while Petitioner was working to implement its plan of correction. P. Br. at 35-36; P. Reply at 19-20. Petitioner’s argument is without merit.

A deficiency is a violation of, or a failure to meet, a participation requirement. 42 C.F.R. § 488.301. The violation of a participation requirement is of necessity identified by the facts alleged to cause the violation. The deficiency cited under Tag F224 by the survey completed on April 2, 2009, is not the same deficiency as that cited by the survey completed on February 5, 2009. The two deficiency citations involve different residents, and events that occurred on different dates. Furthermore, Petitioner’s theory that it

¹⁹ The surveyor included an allegation that the facility failed to properly assess the appropriateness of Restorative Therapy provided the resident. CMS Ex. 39, at 1. I conclude it is not necessary to address that allegation, as the deficiency is established by the facts discussed.

²⁰ Petitioner cites “SOM App. PP.” The SOM is a CMS policy document of over 600 pages that provides guidance to surveyors for conducting surveys. My review of the SOM reveals no provision that supports Petitioner’s argument in this case.

cannot be cited for violation of the same participation requirement while it is attempting to correct a prior violation has been rejected by the Board. *Lakeridge Villa Health Care Ctr.*, DAB No. 1988, at 7-10 (2005). Although not binding precedent, I find persuasive the Board's analysis in *Lakeridge* that no regulation prevents the imposition of a CMP based on a continuing deficiency cited based upon different facts, even before a facility has an opportunity to correct the deficiency pursuant to a plan of correction that the state agency has approved. As the Board recognized in *Lakeridge*, the purpose for imposing enforcement remedies is to encourage a facility to return to compliance. It is consistent with that purpose to cite Petitioner for continuing noncompliance based on different facts, particularly when, as here, the new deficiency arose during the period of attempted correction.

I conclude that Petitioner has not rebutted the CMS *prima facie* showing of a violation of 42 C.F.R. § 483.13(c) that caused actual harm to Resident 4. This deficiency is a basis for the imposition of an enforcement remedy. The fact that this deficiency was corrected on or before April 20, 2009 is not disputed by CMS.

c. Facts and Analysis – Tag F225

The surveyor alleged that Petitioner violated 42 C.F.R. § 483.13(c)(1)(ii)-(iii) and (c)(2)-(4), because Petitioner did not have evidence that it thoroughly investigated four incidents in February and March 2009, including: an injury of unknown origin reported on February 16, 2009; a head injury reported on February 24, 2009; an unwitnessed fall reported on March 4, 2009; and the fractured ankle of Resident 4 discussed under Tag F224 for this survey. Petitioner does not dispute the facts or deny the alleged deficiency in its post-hearing briefing (P. Br. at 35-36; P. Reply at 19-20) or in its prehearing brief (Petitioner's Prehearing Brief at 19-21).

Accordingly, I conclude that CMS has made a *prima facie* showing of a violation that caused actual harm. I conclude that Petitioner has not rebutted the *prima facie* showing. The deficiency is a basis for the imposition of an enforcement remedy. The fact that this deficiency was corrected on or before April 20, 2009 is not disputed by CMS.

9. Petitioner was not in substantial compliance on April 20, 2009, due to violations of 42 C.F.R. § 483.20 and 483.20(b) (Tag F272), which caused actual harm.

The state agency conducted a final revisit survey at the facility on April 20, 2009, to evaluate the facility's plans of correction for the surveys completed on November 19, 2008, January 21, 2009, February 5, 2009, and April 2, 2009. The surveyors concluded that, while Petitioner had corrected previously cited deficiencies, Petitioner had not returned to substantial compliance with program participation requirements due to four deficiencies: 42 C.F.R. §§ 483.20 and 483.20(b) (Tag F272) with actual harm;

483.20(d)(3) and 483.10(k)(2) (Tag F280) with a potential for more than minimal harm; 483.20(k)(3)(ii) (Tag F282) with a potential for more than minimal harm; and 483.25(h) (Tag F323) with a potential for more than minimal harm. CMS Ex. 51. The alleged violation of 42 C.F.R. § 483.20 and 483.20(b) (Tag F272), resulting in actual harm to Resident 3, establishes that Petitioner was not in substantial compliance on April 20, 2009, and it is not necessary to discuss all the alleged deficiencies.

The surveyor alleged in the SOD dated April 20, 2009, that Petitioner failed to do a pain assessment for Resident 3, after he reported on April 18, 2009, that he was experiencing pain at a level of four on a scale of one to ten. The surveyor characterized the deficiency as isolated with actual harm. CMS Ex. 51, at 2-3; Tr. at 65-71, 118-51.

a. Facts

Resident 3 was admitted to the facility on June 20, 2008. He was 83 years old at the time of the survey. CMS Ex. 55, at 5-6. His MDS, with an assessment reference date of July 3, 2008, reflects moderately impaired cognitive ability, he usually understood others, he had highly impaired vision, he wandered, he was totally dependent upon staff for ADLs, he used a wheelchair for locomotion, and he was incontinent of bowel and bladder and had a catheter. CMS Ex. 55, at 6-9. The diagnoses listed on his MDS were diabetes mellitus, antibiotic resistant infection, urinary tract infection within the past thirty days, urinary tract calculus, adult failure to thrive, and generalized pain. CMS Ex. 55, at 9. The MDS indicated that he displayed symptoms of mild joint pain less than daily. CMS Ex. 55, at 10. An MDS from December 2008 indicates Resident 3's pain symptoms worsened and that he suffered pain daily and at a moderate level. P. Ex. 21, at 28. A quarterly review MDS, with an assessment reference date of March 12, 2009, indicates that he only sometimes understood others and that he displayed physically abusive behaviors, which are changes from the prior MDS. However, he had improved to the extent that he could eat with staff assistance. CMS Ex. 55, at 13-14. The MDS shows that he continued to have daily complaints of moderate pain. CMS Ex. 55, at 15.

Resident 3's comprehensive plan of care, dated March 29, 2009, listed as a problem or need that he needed pain management and monitoring related to pain from a wound on his heel, back pain, and a history of neuropathy. Goals listed were to maintain an adequate level of comfort with no signs or symptoms of unrelieved pain or distress and verbalization of level of comfort within one hour of receiving pain meds or treatment. Interventions included, among others, to: administer pain medications as ordered; monitor and record effectiveness and side effects as necessary; assess/record/report to physician as necessary any signs and symptoms of distress or pain unrelieved by medication and treatment; provide alternative comfort measures; and distract from pain. CMS Ex. 55, at 35; P. Ex. 21, at 31.

A Medication Record listed a requirement that staff conduct a pain assessment every shift. The assessment for the 6:00 a.m. to 6:00 p.m. shift on April 18, 2009 shows that Resident 3 complained of pain at a level of four on a scale of one to ten, which is moderate pain according to Petitioner's scale. CMS Ex. 55, at 40. The surveyor cited the deficiency because no other clinical record addressing the complaint of pain, assessment of the pain, and treatment of the pain could be located. Surveyor Wadley also testified that Resident 3's pain was actual harm. CMS Ex. 51, at 4-5; Tr. at 65-71, 118-51.

Petitioner's pain management policy, which bears no effective date, required that residents be evaluated and treated for pain. Pain was to be assessed and recorded on a Pain Assessment Form NUR-063a upon admission, quarterly, and whenever a resident expressed a complaint of pain or appeared to be in pain. After the pain was assessed, interventions were to be used to reduce or alleviate the pain. Use of pain medications that were authorized to be used on an as needed basis had to be documented on the back of the MAR. Use of routine pain medication was to be documented on the front of the MAR. CMS Ex. 47, at 20.

b. Analysis

A long-term care facility must conduct, initially and periodically, a comprehensive, accurate, standardized, and reproducible assessment of a resident's functional capacity. 42 C.F.R. § 483.20. The SOM states that the intent of the regulation is "[t]o provide the facility with ongoing assessment information necessary to develop a care plan, to provide the appropriate care and services for each resident, and to modify the care plan and care/services based on the resident's status." SOM, app. PP, Tag F272. A facility is required to use a "resident assessment instrument" (RAI) specified by the state, and the RAI must include the minimum areas for assessment specified. 42 C.F.R. § 483.20(b)(1). The regulation requires that the comprehensive assessment be done within fourteen days after admission or significant change in condition, and not less often than once every twelve months thereafter. 42 C.F.R. § 483.20(b)(2). However, the facility is responsible for assessing all a resident's needs, whether or not listed on the RAI or the MDS based on the RAI, and delivering care and services to meet those needs. SOM, app. PP, Tag F272; *Maine Veterans' Home – Scarborough*, DAB No. 1975 (2005). The surveyor's citation of a deficiency under Tag F272 is not based on a failure to properly use the RAI and MDS for the comprehensive assessments specified by the regulation. Rather, the cited deficiency is based upon Petitioner's failure of its general obligation to comprehensively assess a resident's needs, in this case Resident 3's need for treatment of signs and symptoms of pain.

Petitioner's clinical record for Resident 3 shows that on April 18, 2009, he complained of moderate pain. The requirement to provide further assessment of a complaint of pain is found in the regulation, in Petitioner's policy, and in Resident 3's care plan. Petitioner's clinical for Resident 3 in evidence does not reflect any further assessment of the

complaint of pain. I conclude that CMS has made a *prima facie* showing of a violation of 42 C.F.R. § 483.20. There is no evidence that the pain of which Resident 3 complained was treated at the time, and I further conclude untreated pain is actual harm. Petitioner has presented no evidence to show that there was a further assessment of Resident 3 when he complained of pain. Petitioner has also failed to present any evidence that any interventions from Resident 3's plan of care were selected and implemented based on any assessment of Resident 3 when he complained of pain. I conclude that Petitioner has failed to rebut the CMS *prima facie* case.

Petitioner argues that, because Resident 3 did not complain of more than moderate pain, his complaint on April 18, 2009 should not have triggered or required any additional assessment under his plan of care or the physician's order. P. Br. at 37; Tr. at 262. This argument is contrary to the resident's care plan and Petitioner's policy. One of the goals listed on Resident 3's care plan was for him to have no signs or symptoms of unrelieved pain or distress. CMS Ex. 55, at 35; P. Ex. 21, at 31. The care plan did not suggest that a moderate level of pain was acceptable. There is no physician's order in evidence that states that a moderate level of pain was acceptable and required no treatment. Furthermore, Petitioner's pain policy required assessment based on any complaint of pain and required treatment to mitigate or alleviate the pain. CMS Ex. 47, at 20.

Petitioner argues that Surveyor Wadley was not qualified to diagnose Resident 3's pain as breakthrough pain. P. Br. at 38. There is no assessment in Petitioner's records to identify the location of the pain or possible cause of the pain Resident 3 was experiencing between 6:00 a.m. and 6:00 p.m. on April 18, 2009, and it is not possible to characterize the pain as breakthrough pain. But under Petitioner's policy and Resident 3's care plan and orders, it is the complaint of pain that triggers the need for further assessment and treatment. Whether or not Resident 3's pain may properly be labeled "breakthrough pain" does not affect my decision as the undisputed fact, established by Petitioner's own records, that Resident 3 was suffering pain, which required assessment and treatment.

Petitioner argues that, on April 18, 2009, it was still in the process of implementing its plan of correction for a previously cited violation of 42 C.F.R. § 483.20 (Tag F272), and it should be deemed to be in substantial compliance. P. Br. at 38. To the extent that Petitioner's argument is that it cannot be cited for violation of a participation requirement while it is working on a plan of correction from a prior survey, I reject that argument for reasons already discussed under Tag F224 from the April 2, 2009 survey. If Petitioner's argument is supposed to be that the pain policy in evidence was not yet in effect, I note that the requirement for assessment of Resident 3's pain was not based only upon Petitioner's policy but also upon the regulation and the resident's care plan. However, Petitioner never specifically alleges that the pain policy in evidence was not in effect prior to April 18, 2009.

Petitioner also argues that it should not be cited for failure to complete the pain assessment form that the surveyor found in the file, because it was a new form not yet implemented on April 18, 2009. P. Br. at 38-39. This deficiency is not based upon Petitioner's failure to use a specific form. It is clear from both the deficiency as alleged in the SOD and Surveyor Wadley's testimony, that the deficiency was based upon the complete absence of any documentation, in any form, of an assessment of Resident 3's complaint of pain on April 18, 2009, other than the notation that the pain was a level of four, which Petitioner's witness, RN Winkler, testified was not a thorough assessment. Tr. at 257. RN Winkler testified that, prior to the implementation of the new form, pain assessments should have been included in nurse's notes, on the back of MARs or on narcotic sheets. Tr. at 257-58. The clinical records in evidence do not contain a more detailed assessment of Resident 3's pain. Petitioner also argues that is unfair to infer that no pain assessment was completed after the surveyors left the facility on April 20, 2009. Petitioner has not presented evidence that Resident 3's complaint of pain on April 18, 2009 was assessed other than the notation that it was at a level of four.

Accordingly, I conclude that Petitioner was not in substantial compliance on April 20, 2009, due to violations of 42 C.F.R. § 483.20 and 483.20(b) (Tag F272) that caused actual harm to Resident 3. The state refused to accept a plan of correction for the deficiencies identified by the April 20 revisit survey, due to the pending termination of Petitioner's participation. P. Ex. 18. Petitioner submitted as evidence its draft plan of correction, which indicates that Petitioner did not expect completion of its plan of correction for this deficiency until May 14, 2009, after the date for mandatory termination of its provider agreement. P. Ex. 20, at 6. Petitioner did not present evidence that shows that this deficiency was corrected prior to termination. Therefore, I conclude that Petitioner did not correct this deficiency prior to termination.

10. Petitioner was not in substantial compliance with participation requirements for the entire period November 5, 2008 to May 6, 2009.

11. A mandatory DPNA was triggered effective February 5, 2009 and continued to termination on May 6, 2009.

12. Termination of Petitioner's provider agreement and participation in Medicare on May 6, 2009, was required by the Act.

13. Petitioner was ineligible to be approved to conduct a NATCEP due to the termination of its provider agreement.

14. The PICMPs totaling \$14,000 are reasonable enforcement remedies.

Petitioner was not in substantial compliance with program participation requirements on November 5, 2008. Petitioner did not return to substantial compliance with program participation requirements before February 5, 2009. The Act 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. Act § 1819(h)(2)(D). The mandatory DPNA was triggered in this case on February 5, 2009, after three months of noncompliance. The mandatory DPNA is required by the Act, and it is a reasonable enforcement remedy as a matter of law.

Petitioner failed to return to substantial compliance between November 5, 2008 and May 6, 2009. 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 termination of Petitioner's provider agreement and participation in Medicare was mandated by the Act after six months and one day of noncompliance. Termination is required by law, and there is no issue as to its reasonableness as an enforcement remedy.

Pursuant to 42 C.F.R. § 483.151(b)(2) and (e)(1), a state may not approve, and must withdraw, any prior approval of a NATCEP offered by a SNF 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, Petitioner's provider agreement and participation in Medicare were terminated; Petitioner was subject to a mandatory DPNA; and CMPs of not less than \$5,000 have been imposed. Accordingly, Petitioner was ineligible to be approved to conduct a NATCEP for two years.

CMS advised Petitioner by letters dated March 16, April 22, and May 28, 2009, that it was proposing the following PICMPs totaling \$14,000: a \$2,000 PICMP for a deficiency cited under Tag F225 (42 C.F.R. § 483.13(c)(1)(ii)-(iii) and (c)(2)-(4)) for the instance on April 2, 2009, that resulted in actual harm of a resident; a \$2,000 PICMP for the deficiency cited under Tag F224 (42 C.F.R. § 483.13(c)) for the instance on April 2, 2009, that resulted in actual harm of a resident; a \$5,000 PICMP for the deficiency cited under Tag F226 (42 C.F.R. § 483.13(c)) for the instance on January 29, 2009, that posed immediate jeopardy; and a PICMP of \$5,000 for the deficiency cited under Tag F223 (42 C.F.R. § 483.13(b) and (c)(1)(i)) for the instance on January 29, 2009, that posed

immediate jeopardy.²¹ I concluded that the cited deficiencies provided basis for the imposition of the proposed enforcement remedies.

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 substantial 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).

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

²¹ The January 29, 2009 instances are cited in the SOD for the survey that ended on February 5, 2009. CMS Ex. 29, at 1, 17. The April 2, 2009 instances are cited in the SOD for the survey that ended on April 2, 2009. CMS Ex. 39, at 1, 11.

DAB No. 1800, at 10; *CarePlex of Silver Spring*, DAB No. 1683, at 14–16 (1999); *Capitol Hill Cmty. Rehab. & Specialty Care Ctr.*, DAB No. 1629 (1997).

I find that the deficiencies cited as the bases for imposition of PICMPs were serious, as they caused actual harm or posed immediate jeopardy, contrary to Petitioner's assertions (P. Br. at 47). The evidence shows that the deficiencies under Tags F223 and F226 from the survey completed on February 5, 2009, constituted a pattern of noncompliance, involving multiple residents and incidents, and Petitioner has not rebutted that showing. The instances cited by the survey concluded on April 2, 2009, Tags F224 and F225, were isolated instances of actual harm. The survey history before me is the survey cycle from November 5, 2008 to May 6, 2009. Petitioner has not alleged an inability to pay the \$14,000 of PICMPs or presented evidence to support such an allegation. The evidence supports a conclusion that Petitioner was culpable. Despite having an extensive policy regarding the prevention, investigation, and reporting of abuse, neglect, maltreatment, and misappropriation, Petitioner failed to implement that policy on multiple occasions. I conclude, based upon my consideration of the required factors, that PICMPs are not unreasonable.

Petitioner filed a motion for summary judgment on December 7, 2009 (P. MSJ). I deferred ruling on the motion until the decision on the merits and stated in a February 2, 2009 Notice that the parties could address the issues further in post-hearing briefing. Petitioner argues in its motion for summary judgment and its post-hearing brief, that it did not receive adequate notice from the state and CMS and that it did not have an adequate opportunity to correct its deficiencies. Petitioner argues that notices were so defective that, as a matter of law, I should strike the mandatory DPNA and the termination. P. MSJ at 12, 14-16, 17-20; P. Br. at 17-18. Contrary to Petitioner's arguments, the notices in evidence are adequate in their content and timing. Petitioner had six months to return to substantial compliance and failed to demonstrate that it had done so. Petitioner has now had the opportunity to show me on *de novo* review that it returned to substantial compliance during the six month survey cycle, and it has failed to do so. The fault here is not the adequacy of the notices, but Petitioner's inability to show compliance.

Petitioner also argued in its motion for summary judgment (P. MSJ at 16-20), and renewed the argument in its post-hearing brief (P. Br. at 48), that termination of its provider agreement was improper because the state agency and CMS failed comply with the: (1) public notice requirement; and (2) resident transfer requirement. The regulations require that CMS and the state provide notice to the facility and the public at least fifteen days prior to termination. 42 C.F.R. § 488.456(c)(2). The regulations also require that the state agency must arrange for the safe and orderly transfer of all residents to another facility, when CMS terminates a facility's participation. 42 C.F.R. § 488.426(b). Petitioner argues that no public notice was published and no residents were transferred, and, therefore, there was no termination of Petitioner's participation. CMS does not deny

that the notice was not published and that the residents were not transferred. CMS' Response to Petitioner's Motion for Summary Judgment at 10. However, the failure of the state agency and CMS to comply with the Secretary's regulations does not avoid the mandate of Congress that the Secretary not permit Petitioner to participate in Medicare following six months of noncompliance with the conditions for participation. *See Beechwood Sanitarium*, DAB No. 1824 (2002). Termination was required despite any failure of the state agency or CMS to comply with a regulation.

15. The evidence is not in equipoise, and the allocation or the burden of persuasion did not affect the decision in this case.

Petitioner argued that the allocation of the burden of persuasion in this case, according to the rationale of the Board in the prior decisions cited above, violates the Administrative Procedures Act (APA), 5 U.S.C. § 551 *et. seq.*, specifically 5 U.S.C. § 556(d). P. Brief at 4. Pursuant to the scheme for the allocation of burdens adopted by the Board in its prior cases, CMS bears the burden to come forward with the evidence and to establish a *prima facie* showing of the alleged regulatory violations in this case by a preponderance of the evidence. If CMS makes its *prima facie* showing, Petitioner has the burden of coming forward with any evidence in rebuttal and the burden of showing by a preponderance of the evidence that it was in substantial compliance with program participation requirements. Petitioner also bears the burden to establish by a preponderance of the evidence any affirmative defense. The allocation of burdens suggested by the Board is not inconsistent with the requirements of 5 U.S.C. § 556(d), as CMS is required to come forward with the evidence that establishes its *prima facie* case by a preponderance of the evidence. Petitioner did not describe for me an allocation that it believes comports with the requirements of the APA. Furthermore, the evidence is not in equipoise, the burden of persuasion did not affect my decision, and Petitioner suffered no prejudice.

III. Conclusion

For the foregoing reasons, I conclude that Petitioner was not in substantial compliance with program participation requirements from November 5, 2008 to May 6, 2009. Reasonable enforcement remedies are PICMPs totaling \$14,000, a DPNA beginning February 5, 2009, and termination of Petitioner's participation agreement on May 6, 2009. Petitioner is also ineligible to conduct a NATCEP for a two-year period.

/s/
Keith W. Sickendick
Administrative Law Judge