Department of Health and Human Service

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
Brian Center Health and Rehabilitation/Goldsboro (CCN: 34-5343),	)	Date: February 05, 2010
Petitioner,	)	Docket No. C-08-422
	)	Decision No. CR2063
v.	)	
Centers for Medicare & Medicaid Services.	)	

DECISION

Petitioner, Brian Center Health and Rehabilitation/Goldsboro, was not in substantial compliance with program participation requirements from December 6, 2007 through March 24, 2008. A civil money penalty (CMP) of $3050 per day effective December 6, 2007 through February 4, 2008, and $200 per day from February 5 through March 24, 2008, a total CMP of $195,850, is reasonable. Petitioner's authority to conduct a Nurse Aide Training and Competency Evaluation Program (NATCEP) was required to be withdrawn for the two-year period effective February 5, 2008 through February 4, 2010.

I. Background

Petitioner, located in Goldsboro, North Carolina, is authorized to participate in Medicare as a skilled nursing facility (SNF) and in the Medicaid program as a nursing facility (NF). Petitioner was subject to a survey by the North Carolina Department of Health and Human Services, Division of Health Service Regulation, Nursing Home Licensure and Certification Section (the state agency) that was completed on February 5, 2008. The Centers for Medicare and Medicaid Services (CMS) notified Petitioner by letter dated March 5, 2008, that based on regulatory violations, i.e. deficiencies, found during the February 2008 survey, CMS was imposing a CMP of $4550 per day effective December 6, 2007 through February 4, 2008 and $200 per day beginning February 5, 2008 and

continuing until Petitioner returned to substantial compliance; a denial of payment for new admissions (DPNA) beginning on May 5, 2008 and continuing until Petitioner returned to substantial compliance; termination of Petitioner's provider agreement on August 5, 2008, if Petitioner did not return to substantial compliance before that date; and that Petitioner's authority to conduct a NATCEP was withdrawn. Petitioner was found to have returned to substantial compliance on March 25, 2008, based upon a revisit survey completed on that date. The termination and DPNA remedies were rescinded, and the CMP proposed by CMS is $4550 per day from December 6, 2007 through February 4, 2008, and $200 per day from February 5 through March 24, 2008. Joint Stipulation and Statement of Issues filed July 22, 2008 (Jt. Stip.); CMS exhibits (CMS Ex.) 1, 7, 8, 10.

Petitioner timely requested a hearing by letter dated May 2, 2008. On May 8, 2008, the request for hearing was docketed and assigned to me for hearing and decision and a Notice of Case Assignment and Prehearing Case Development Order was issued at my direction.

A hearing was convened in Raleigh, North Carolina on November 18, 2008 and a 230-page transcript (Tr.) was prepared. CMS offered, and I admitted, CMS Exs. 1 through 54. Tr. 14. Petitioner offered Petitioner exhibits (P. Ex.) 1 through 25. CMS objections to P. Exs. 12 and 13 were overruled and P. Exs. 1 through 25 were admitted. Tr. 15-22. CMS called Surveyors Ann Modlin and Teresa Radcliffe as witnesses. Petitioner called employees Bindy Powell, Registered Nurse (RN), and Karla Minyard, Licensed Practical Nurse (LPN), as witnesses.

The parties filed post-hearing briefs[1] (CMS Brief and P. Brief) on February 9, 2009. CMS filed its post-hearing reply brief (CMS Reply) on March 11, 2009. Petitioner filed its post-hearing reply brief (P. Reply) on March 10, 2009.

II. Discussion

A. Issues

The issues in this case are:

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

[1] CMS requested leave to exceed by five pages, the 30-page limitation that I set for post-hearing briefs. Petitioner did not oppose the request. The CMS post-hearing brief is accepted.

Whether the remedy imposed is reasonable.

B. Applicable Law

The statutory and regulatory requirements for participation by a long-term care facility are found at sections 1819 (SNF) and 1919 (NF) of the Act and at 42 C.F.R. Part 483.[2] Section 1819(h)(2) of the Act vests the Secretary of the Department of Health and Human Services (Secretary) with authority to impose enforcement remedies against a SNF for failure to comply substantially with the federal participation requirements established by sections 1819(b), (c), and (d) of the Act.[3] Pursuant to 1819(h)(2)(C), the Secretary may continue Medicare payments to a SNF not longer than six months after the date the facility is first found not in compliance with participation requirements. Pursuant to 1819(h)(2)(D), if a SNF does not return to compliance with participation requirements within three months, the Secretary must deny payments for all individuals admitted to the facility after that date – commonly referred to as the mandatory or statutory DPNA. In addition to the authority to terminate a noncompliant SNF's participation in Medicare, the Act grants the Secretary authority to impose other enforcement remedies, including a discretionary DPNA, CMPs, appointment of temporary management, and other remedies such as a directed plan of correction. Act § 1819(h)(2)(B).

The Secretary has delegated to CMS and the states the authority to impose remedies against a long-term care facility that is not complying substantially with federal participation requirements. "*Substantial compliance* means a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm." 42 C.F.R. § 488.301 (emphasis in original). A deficiency is a violation of a participation requirement established by sections 1819(b), (c), and (d) of the Act or the Secretary's regulations at 42 C.F.R. Part 483, subpart B. Facilities that participate in Medicare may be surveyed on behalf of CMS by state survey agencies in order to determine whether the facilities are complying with federal participation requirements. 42 C.F.R. §§ 488.10-488.28, 488.300-488.335. 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.

---

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

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

Scope and severity levels are used by CMS and a state when selecting remedies. The scope and severity level is designated by an alpha character, A through L, selected by CMS or the state agency from the scope and severity matrix published in the State Operations Manual (SOM)[4], Chapter (Ch.) 7, section 7400E. A scope and severity level of A, B, or C indicates a deficiency that presents no actual harm but has the potential for minimal harm, which is an insufficient basis for imposing an enforcement remedy. Facilities with deficiencies of a level no greater than C remain in substantial compliance. 42 C.F.R. § 488.301. A scope and severity level of D, E, or F indicates a deficiency that presents no actual harm but has the potential for more than minimal harm that does not amount to immediate jeopardy. A scope and severity level of G, H, or I indicates a deficiency that involves actual harm that does not amount to immediate jeopardy. Scope and severity levels J, K, and L are deficiencies that constitute immediate jeopardy to resident health or safety. The matrix, which is based on 42 C.F.R. § 488.408, specifies which remedies are required and optional at each level based upon the frequency of the deficiency. *See* SOM, Ch. 7, § 7400E.

The regulations specify that a CMP that is imposed against a facility on a per day basis will fall into one of two ranges of penalties. 42 C.F.R. §§ 488.408, 488.438. The upper range of CMPs, $3050 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). Pursuant to 42 C.F.R. § 488.301, "*[i]mmediate 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." (Emphasis in original.) The lower range of CMPs, $50 per day to $3000 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).

---

[4] The SOM is not a substantive regulation promulgated pursuant to the Administrative Procedure Act (APA) (5 U.S.C. § 500 *et. seq.*) and the provisions of the SOM are not enforceable as law. Rather, SOM provisions reflect the CMS interpretation of the Act and regulations implementing the Act and provide policy guidance for surveyors. Although SOM provisions are not enforceable as law, the provisions of the Act and the Secretary's regulations they interpret are. *See Vencor Nursing Centers, L.P. v. Shalala*, 63 F. Supp. 2d. 1, 11-12 (D.D.C. 1999); *Beverly Health & Rehabilitation Services, Inc., et al. v. Thompson*, 223 F. Supp. 2d 73, 98-103 (D.D.C. 2002); *Cal Turner Extended Care Pavilion*, DAB No. 2030 (2006); *see also State of Indiana by the Indiana Department of Public Welfare v. Sullivan*, 934 F.2d 853 (7th Cir. 1991); *cf. Northwest Tissue Center v. Shalala*, 1 F.3d 522 (7th Cir. 1993).

In this case, the state agency was required to withdraw Petitioner's approval to conduct a NATCEP. Pursuant to sections 1819(b)(5) and 1919(b)(5) of the Act, SNFs and NFs may only use nurse aides who have taken 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 established by the Secretary and a process for reviewing and reapproving those programs using criteria set by the Secretary. Pursuant to sections 1819(f)(2) and 1919(f)(2) the Secretary was tasked to develop requirements for approval of NATCEPs and the process for review of those programs. The Secretary promulgated regulations at 42 C.F.R. Part 483, subpart D. Pursuant to 42 C.F.R. § 483.151(b)(2) and (e)(1) of the regulations, a state may not approve and must withdraw any prior approval of a NATCEP offered by a SNF or NF that: (1) has been subject to an extended or partial extended survey under sections 1819(g)(2)(B)(i) or 1919(g)(2)(B)(i) of the Act; (2) has been assessed a CMP of not less than $5000; or (3) that has been subject to termination of its participation agreement, a DPNA, or the appointment of temporary management. Extended and partial extended surveys are triggered by a finding of "substandard quality of care" during a standard or abbreviated standard survey and involve evaluating additional participation requirements. "*Substandard quality of care*" is identified by the situation where surveyors identify one or more deficiencies related to participation requirements established by 42 C.F.R. §§ 483.13 (Resident Behavior and Facility Practices), 483.15 (Quality of Life), or 483.25 (Quality of Care) that are found to constitute either immediate jeopardy, a pattern of or widespread actual harm that does not amount to immediate jeopardy, or a widespread potential for more than minimal harm that does not amount to immediate jeopardy and there is no actual harm. 42 C.F.R. § 488.301 (emphasis in original).

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) and 1866(h); 42 C.F.R. §§ 488.408(g) and 498.3(b)(13). The hearing before an ALJ is a *de novo* proceeding. *Anesthesiologists Affiliated, et al*, DAB CR65 (1990), *aff'd*, 941 F.2d 678 (8th Cir. 1991); *Emerald Oaks*, DAB No. 1800, at 11 (2001); *Beechwood Sanitarium*, DAB No. 1906 (2004); *Cal Turner Extended Care Pavilion*, DAB No. 2030 (2006)*; The Residence at Salem Woods*, DAB No. 2052 (2006). A facility has a right to appeal a "certification of noncompliance leading to an enforcement remedy." 42 C.F.R. § 488.408(g)(1); *see also* 42 C.F.R. §§ 488.330(e), 498.3. However, the choice of remedies by CMS or the factors CMS considered when choosing remedies are not subject to review. 42 C.F.R. § 488.408(g)(2). A facility may only challenge the scope and severity level of noncompliance found by CMS if a successful challenge would affect the range of the CMP that could be imposed by CMS or impact the facility's authority to conduct a nurse aide training and competency evaluation program. 42 C.F.R. § 498.3(b)(14)(i) and (ii). The CMS determination as to the level of noncompliance "must be upheld unless it is clearly erroneous" (42 C.F.R. § 498.60(c)(2)), including the finding of immediate jeopardy. *Woodstock Care Center*, DAB No. 1726, at 9, 38 (2000), *aff'd, Woodstock*

Care Center v. Thompson, 363 F.3d 583 (6th Cir. 2003). The Departmental Appeals Board (the Board) has long held that the net effect of the regulations is that a provider has no right to challenge the scope and severity level assigned to a noncompliance finding, except in the situation where that finding was the basis for an immediate jeopardy determination. *See, e.g.*, *Ridge Terrace*, DAB No. 1834 (2002); *Koester Pavilion*, DAB No. 1750 (2000). Review of a CMP by an ALJ 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. *See Hillman Rehabilitation Center*, DAB No. 1611 (1997), *aff'd, Hillman Rehabilitation Ctr. v. United States Dep't of Health and Human Services, Health Care Fin. Admin.*, No. 98-3789 (GEB), slip op. at 25 (D.N.J. May 13, 1999); *Cross Creek Health Care Center*, DAB No. 1665 (1998); *Emerald Oaks*, DAB No. 1800; *Batavia Nursing and Convalescent Center*, DAB No. 1904 (2004), *aff'd, Batavia Nursing & Convalescent Ctr. v. Thompson*, 129 F. App'x 181 (6th Cir. 2005); *Batavia Nursing and Convalescent Inn*, DAB No. 1911 (2004).

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.

The survey at issue, a scheduled recertification and complaint survey related to the incident involving Resident 23 began on January 13 and continued through January 16, 2008. As of January 16, 2008, the surveyors had found deficiencies related to the incident involving Resident 23, but concluded that the deficiency was an instance of past noncompliance that had been corrected and that immediate jeopardy was not present. However, subsequent review and consultation with CMS led to a determination that the incident involving Resident 23 showed that immediate jeopardy was posed to Petitioner's residents. Therefore, the surveyors returned to the facility on February 4, 2008, to collect additional information and to complete an extended survey that ended on February 5, when they concluded that immediate jeopardy was abated. Tr. 38-47, 64-65, 76-77.

CMS alleges before me that Petitioner was not in substantial compliance with program participation requirements from December 6, 2007 through March 24, 2008, based upon the following violations cited in the Statement of Deficiencies (SOD) dated February 5,

2008: 42 C.F.R. §§ 483.13(c) (Tag F224,[5] scope and severity (s/s) J); 483.15(f)(1) (Tag F248, s/s D); 483.20(k)(3)(i) (Tag F281, s/s D); 483.25 (Tag F309, s/s J); 483.25(a)(3) (Tag F312, s/s D); 483.25(c) (Tag F314, s/s G); 483.25(d) (Tag F315, s/s D); 483.25(l) (Tag F329, s/s D); 483.30(a) (Tag 353, s/s G); and 483.60(c) (Tag F428, s/s E). The parties requested at hearing that I issue a decision based on the documentary evidence for all the deficiencies that were not alleged to pose immediate jeopardy and they agreed that the testimony at hearing would focus upon the two deficiencies alleged to have posed immediate jeopardy – the alleged violations of 42 C.F.R. §§ 483.13(c) (Tag F224) and 483.25 (Tag F309). Tr. 23-29. The parties further agreed that the citation of immediate jeopardy for both Tag F224 and Tag F309 was based upon an alleged failure of Petitioner's staff to adequately deliver cardiopulmonary resuscitation (CPR) for Resident 23 on December 6, 2007, rather than the other alleged failures cited in those two deficiency citations. Tr. 29-31.

1. The incident related to Resident 23 on December 6, 2007, was not a violation of 42 C.F.R. § 483.13(c) (Tag F224).

2. Petitioner violated 42 C.F.R. § 483.25 (Tag F309) as a result of the incident related to Resident 23 on December 6, 2007.

3. Petitioner has not shown that the determination that immediate jeopardy was posed to Petitioner's residents from December 6, 2007 through February 4, 2008, was clearly erroneous.

The surveyors allege as a violation of 42 C.F.R. § 483.13(c) (Tag F224) that: (1) Petitioner failed to initiate immediate CPR for Resident 23; and (2) Petitioner failed to provide wound care as ordered by the physician for Residents 7, 8, 19, and 25. CMS Ex. 2, at 1. The surveyors allege as violations of 42 C.F.R. § 483.25 (Tag F309) that: (1) Petitioner failed to initiate immediate CPR for Resident 23; and (2) Petitioner failed to provide wound treatment as ordered by the physician for Residents 19 and 25. CMS Ex. 2, at 48. The alleged failure to initiate CPR for Resident 23 is alleged by the surveyors to have posed immediate jeopardy to Petitioner's residents from December 6, 2007 through February 4, 2008. The alleged failure to provide wound treatment was not the basis for the allegation of immediate jeopardy. CMS Ex. 2, at 1, 48; Tr. 28-31.

[5] This is a "Tag" designation as used in the SOM, Appendix PP – Guidance to Surveyors for Long Term Care Facilities. The "Tag" refers to the specific regulatory provision allegedly violated and CMS's guidance to surveyors.

To the extent that the alleged violations of 42 C.F.R. §§ 483.13(c) and 483.25 are based upon the same incident involving Resident 23, they are discussed together here for convenience. The alleged violation of the regulations based upon failure to provide wound care is discussed under 42 C.F.R. § 483.25(c) (Tag F314).

(a) Facts Related to the Incident on December 6, 2007.

There is little dispute as to the incident involving Resident 23 on December 6, 2007. Petitioner does not dispute that CPR was not performed for Resident 23 on December 6, 2007. Tr. 31-32.

Resident 23 was a 50-year-old male when the events that gave rise to the deficiency occurred. Resident 23 was initially admitted from his home to Petitioner's facility on November 2, 2007, and following a short hospital stay from November 4 to November 8, 2007 due to acute esophagitis, he was readmitted to Petitioner's facility on November 8, 2007. His diagnoses included a history of cerebrovascular accident, peripheral vascular disease, coronary artery disease, acute esophagitis, diabetes, anemia, and end stage renal disease. CMS Ex. 34, at 37, 59-60, 69. On November 2, 2007, Resident 23's representative signed a form titled *Advance Directives/Medical Treatment Decisions Acknowledgement of Receipt* indicating that the decision was made that Resident 23 was "full-code," i.e. all possible measures were to be taken to revive him and sustain life. CMS Ex. 34, at 9. His admission orders dated November 8, 2007 show his code status as "RESUSCITATE." CMS Ex. 34, at 45. The fact that Resident 23 was a "full-code" and had orders that he be resuscitated is not disputed by Petitioner.

The incident on December 6, 2007 is reflected by the nurses' entries on a "Nurse's Notes" form dated December 6, 2007. An entry at 4:15 a.m. on December 6 indicates that a Certified Nursing Assistant (CNA) called to RN Waters to come to Resident 23's room because the resident was not responsive. RN Waters reports in her nurse's note that she went to Resident 23's room, found him not responsive and she was unable to rouse him; but he had a carotid pulse and shallow respirations; he was drooling; and his skin was warm and dry. RN Waters recorded that she went to get a glucometer, a device to determine Resident 23's blood sugar, and that it registered low. RN Waters asked another nurse to check Resident 23's vital signs and she went to call for emergency medical services (EMS) and the resident's physician. RN Waters added a second nurse's note at 4:25 a.m. on December 6, which states that she tried to start an intravenous line (IV) to give Resident 23 medication to reverse severe hypoglycemia as ordered by the physician; the paramedics arrived; Resident 23 had no pulse or respiration; and the paramedics took over. RN Waters' note at 4:30 a.m. on December 6, 2007 states that Resident 23 had no vital signs; EMS left; and post-mortem care was provided. A Nurse's Notes entry at 6:00 a.m. on December 6, 2007 by LPN Hilda Hill states that she was called to Resident 23's room by a CNA because the resident did not appear to be breathing; that she checked for breath sounds and none could be heard or felt; EMS

checked and found no breath sounds or pulse; and the resident expired at 4:30 a.m. LPN Hill's note does not indicate when she was called to Resident 23's room. CMS Ex. 34, at 48, 61-62.

Petitioner's Regional Clinical Director, Bindy Powell, RN, testified that she gave direction to LPN Karla Minyard who conducted the investigation related to Resident 23's death and she developed the corrective or remedial measures to be implemented. Tr. 145-46. She testified that LPN Hilda Hill was terminated due to her failure to initiate CPR for Resident 23. Tr. 147-48. She testified as to the remedial measures taken by Petitioner, including: in-service training of Petitioner's licensed nurses (P. Ex. 24; CMS Ex. 48, at 10-12), chart audits to verify code status, color-coding of charts to reflect code status, and an audit of crash cart equipment. Tr. 145, 150-54, 172-73. She testified that during the January survey, the surveyors examined the remedial measures taken after the incident involving Resident 23 and the surveyors did not mention any deficiency in the remedial actions or suggest that Petitioner would be cited for immediate jeopardy. Tr. 156-58. However, when the surveyors came back in February, they expressed concern that CNAs had not been included in the in-service training. Tr. 159. In response to my questioning, RN Powell testified that she concluded based on the investigation that the CNA told both RN Waters and LPN Hill that Resident 23 was found unresponsive. Both went to Resident 23's room and RN Waters determined that the resident had a carotid pulse and shallow respirations. RN Waters then left the resident's room and went to phone the physician for directions. RN Waters was not found at fault for failure to initiate CPR. Tr. 164-65.

The EMS report shows that EMS was contacted at 4:30 a.m. on December 6, 2007 and arrived at the facility at 4:38 a.m. EMS personnel reported that Resident 23 had no pulse, no respirations, no cardiac sounds, and his skin was cool; that staff had found him that way; that no CPR was in progress; and that Resident 23 was dead when they arrived. CMS Ex. 34, at 6.

A "Disciplinary Action Record" dated December 6, 2007, signed by LPN Karla Minyard indicates that LPN Hilda Hill was suspended on December 6, 2007 pending investigation. The form indicated that LPN Hill's employment with Petitioner was terminated on December 14, 2007, because she neglected Resident 23 by failing to initiate CPR on December 6 and failed to follow a doctor's order to send the resident to the emergency room. CMS Ex. 34, at 66; P. Exs. 7, 10, 14. An undated statement signed by LPN Minyard indicates that at 7:30 a.m., apparently on December 6, 2007, she was notified of Resident 23's death. She interviewed Nurse Edna Hamilton who advised her that she had been in Resident 23's room with RN Waters and LPN Hill. Nurse Hamilton stated that between 4:15 and 4:25 a.m. the resident was found unresponsive but with pulse and respirations; his blood sugar was low; RN Waters notified the physician who gave orders to transport the resident to the emergency room and to give an ampoule of D50 for low blood sugar. EMS arrived at 4:30 a.m., but told the nurses Resident 23 had expired, and

they left the facility without transporting the resident. LPN Minyard also interviewed LPN Hill, Resident 23's assigned nurse at the time, and she stated that the resident was dead and she saw no need to do CPR. LPN Hill was then suspended and subsequently terminated. CMS Ex. 34, at 26; P. Ex. 12; Tr. 203-05.

Petitioner's policy prohibiting abuse and neglect of residents dated April 2005 was admitted as CMS Ex. 34, at 88-91. Petitioner's policy defines neglect as the "failure to provide goods and services necessary to avoid physical harm, mental anguish, or mental illness." CMS Ex. 34, at 88. Petitioner reported the incident involving Resident 23 to the state agency and conducted an investigation and there is no allegation that the reporting and investigation did not comply with state and federal requirements. P. Ex. 6, 7, 12, 13, 14; Tr. 51-55, 87, 144-48, 204-05, 211, 214.

Petitioner's plan of correction for the deficiency cited under Tag F309 reflects that elements of the plan, discussed more fully in the analysis section, were not completely implemented until February 4, 5, and 19, 2008. CMS Ex. 2, at 51-57; Tr. 126-28, 182-87, 205-07, 216-18.

(b) Analysis.

(i) 42 C.F.R. § 483.13(c) (Tag F224)

I conclude that there was no violation of 42 C.F.R. § 483.13(c). Long-term care facilities that participate in Medicare or Medicaid are required to "protect and promote the rights of each resident, including . . . [t]he 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) (SNFs) and 1919(c)(1)(a)(ii) (NFs). The Secretary has provided by regulation:

> (c) Staff treatment of residents. The facility must develop and implement written policies and procedures that prohibit mistreatment, neglect, and abuse of residents and misappropriation of resident property.
>
> (1) The facility must –
>
> (i) Not use verbal, mental, sexual, or physical abuse, corporal punishment, or involuntary seclusion;
>
> (ii) Not employ individuals who have been--
>
> (A) Found guilty of abusing, neglecting, or mistreating residents by a court of law; or

> (B) Have had a finding entered into the State nurse aide registry concerning abuse, neglect, mistreatment of residents or misappropriation of their property; and
>
> (iii) Report any knowledge it has of actions by a court of law against an employee, which would indicate unfitness for service as a nurse aide or other facility staff to the State nurse aide registry or licensing authorities.
>
> (2) The facility must ensure that all alleged violations involving mistreatment, neglect, or abuse, including injuries of unknown source, and misappropriation of resident property are reported immediately to the administrator of the facility and to other officials in accordance with State law through established procedures (including to the State survey and certification agency).
>
> (3) The facility must have evidence that all alleged violations are thoroughly investigated, and must prevent further potential abuse while the investigation is in progress.
>
> (4) The results of all investigations must be reported to the administrator or his designated representative and to other officials in accordance with State law (including to the State survey and certification agency) within 5 working days of the incident, and if the alleged violation is verified appropriate corrective action must be taken.

42 C.F.R. § 483.13(c). The plain language of 42 C.F.R. § 483.13(c) requires that a facility such as Petitioner develop and implement policies and procedures that satisfy the requirements of its four subsections.

The allegations are that a nurse failed to deliver a necessary service to Resident 23, i.e., CPR. There is no allegation that Petitioner failed to have the required policy and the evidence shows that Petitioner did have the required policy. I will not infer from the single incident cited by the surveyors that Petitioner failed to implement its policy prohibiting neglect. To the contrary, the evidence shows that Petitioner complied with its policy by promptly investigating the incident and taking action to dismiss the employee it

found neglected Resident 23. Any failure to provide necessary care or treatment arguably could be charged as neglect. However, it is not necessary to charge every failure as a violation of 42 C.F.R. § 483.13(c) particularly where, as here, an appropriate charge is made under 42 C.F.R. § 483.25 (Tag F309).

(ii) 42 C.F.R. § 483.25 (Tag F309).

The quality of care regulation requires that each resident receive, and that the participating facility provide the necessary care and services to attain or maintain a resident's highest practicable physical, mental, and psychosocial well-being, in accordance with the resident's comprehensive assessment and plan of care. 42 C.F.R. § 483.25. The surveyors allege that Petitioner violated 42 C.F.R. § 483.25 in the example of Resident 23 because staff failed to immediately initiate CPR for Resident 23 who experienced cardiopulmonary failure and had an order that efforts be made to resuscitate him. CMS Ex. 2, at 48; P. Ex. 1, at 48-74. Petitioner does not deny that CPR was not initiated for Resident 23. Petitioner does not deny that CPR should have been initiated. Tr. 31. Petitioner also does not argue that there was no deficiency or that the deficiency is not properly cited as a violation of 42 C.F.R. § 483.25 (Tag F309). P. Brief at 1, 6-7, 16; P. Reply at 3, 7. I conclude that Petitioner failed to provide Resident 23 the necessary service of CPR in violation of 42 C.F.R. § 483.25.[6]

Petitioner's argument is that, though there was a deficiency due to the failure to initiate CPR for Resident 23, the deficiency was corrected and any immediate jeopardy was abated not later than December 6, 2007, by Petitioner's swift corrective action. Petitioner describes the corrective or remedial action completed by December 6, 2007 as follows:

- Petitioner comprehensively reviewed its CPR policies and procedures;
- The code status of each resident was updated and full-code status was indentified on medical records with a white label;
- The staff Development Coordinator audited all licensed nurses to ensure current CPR certification;
- The Assistant Director of Nursing (ADON) audited the emergency or crash cart to ensure equipment was available and working;

[6] Because I find Petitioner violated 42 C.F.R. § 483.25 based on the CPR incident, I conclude it is unnecessary to consider the examples cited by the surveyors under this Tag related to wound care for Residents 19 and 25.

- A system was implemented to ensure that all nurses have current CPR certification; and

- A new policy was adopted that required the Director of Nursing (DON) to review employee files every three months to verify current CPR certification for all nurses.

P. Brief at 6-7; P. Reply at 3-4; P. Exs. 3, 8-11, 14-24; CMS Ex. 48; Tr. 150-54, 206-08. Petitioner asserts that by December 10, 2007, all licensed nurses had received in-service training regarding emergency management policies, code policies, location of crash carts, daily checks of crash carts, and when to initiate CPR. Petitioner asserts that after the incident on December 6, 2007, no nurse was permitted to return to work with residents until they received the in-service training. P. Brief at 7; P. Reply at 4; P. Exs. 3, 8, 24; CMS Ex. 48; Tr. 169, 172-74, 181-82. RN Powell, Regional Clinical Director with Petitioner's owner/operator, testified that there were two incidents between December 6 and February 4, 2008, when CPR was performed. Tr. 162-63. Petitioner points to this unrebutted evidence as proof of the effectiveness of the corrective action it implemented on December 6 following the incident with Resident 23. P. Brief at 16; P. Reply at 5.

CMS does not dispute that Petitioner devised and implemented corrective actions described above by December 10, 2007. CMS Reply at 2-5. CMS did not rebut Petitioner's evidence that CPR was properly initiated in two cases at Petitioner's facility after December 6, 2007 and before February 4, 2008. CMS also does not deny Petitioner's allegation that the surveyors who conducted the initial survey from January 13 through 16, 2008, concluded that the incident involving Resident 23 was an incident of past noncompliance that Petitioner had corrected. Tr. 25-27. Surveyor Ann Modlin, the survey team leader for the January 13 through 16 survey, testified that the surveyors decided on January 16 that the incident involving Resident 23 was an instance of past noncompliance that the facility had corrected and that would be cited under Tag F698; that the team left the facility on January 16 without identifying immediate jeopardy; and that a quality control person, a supervisor, or CMS reviewed the draft report of survey and decided that immediate jeopardy was present, which caused the survey team to return to Petitioner for an extended survey. Tr. 39, 57-68, 76-77. Surveyor Teresa Radcliffe, who also participated in the survey on January 13 through 16, testified that the report of survey was prepared with the surveyors' recommendations; the report was submitted for quality review and then to CMS; and CMS determined that immediate jeopardy was present, which resulted in the surveyors returning to Petitioner for an extended survey and to address questions raised by CMS. She testified that after questioning staff and reviewing in-service training materials the survey team concluded in January that the incident involving Resident 23 was past noncompliance. Tr. 87-89, 119-24. Surveyor Radcliffe testified in response to my questions that Petitioner's corrective action in December 2007 was subsequently found inadequate because in-service training did not include the CNAs; further training for assessing carotid pulse and low blood sugar was

deemed necessary; and Petitioner needed to do further review and revision of policy and protocol related to actions by a CNA in an incident similar to that involving Resident 23. Tr. 125-30.

The SOD reflects both the remedial action that Petitioner implemented December 6 through 10, 2008, and the additional remedial actions the surveyors deemed necessary and appropriate before they were willing to find immediate jeopardy was abated on February 5, 2008. The SOD under Tag F309 (CMS Ex. 2, at 61-65; P. Ex. 1, at 61-65),[7] states that Petitioner's Administrator was notified of the immediate jeopardy determination at 4:50 p.m. on February 4, 2008, and that at 6:45 p.m. on February 5, 2008, Petitioner presented a credible allegation of compliance to remove the immediate jeopardy. The credible allegation of compliance is set forth in the SOD and reflects the following remedial actions by Petitioner on February 4 and 5, 2008:

- Licensed nurses were re-educated and their competency was validated in the assessment of carotid pulse; documentation of vital signs in the clinical record; and competency in clearing an airway, assessing carotid pulse, and performing CPR was demonstrated to the Staff Development Coordinator and DON;

- Licensed nurses were re-educated regarding facility policy for diabetic management including interventions if blood sugar is below 70 and a requirement to educate newly hired licensed nurses on the policy was adopted;

- CNAs were educated on what to do in the event of an emergency and actions to take to ensure appropriate and immediate response using a calling tree to contact staff on the assigned hall, and if no action, the charge nurse and DON;[8]

- The admissions coordinator was given responsibility to ensure that code status was determined on admission and the Director of Social Services was to conduct monthly sample audits to verify resident code status and report the results of her audit to the quality assurance committee;

---

[7] Similar text appears under Tag F224. CMS Ex. 2, at 14-18; P. Ex. 1, at 14-18.

[8] Petitioner's plan of correction reflects that implementation of this intervention was not complete until February 19, 2008. CMS Ex. 2, at 52; P. Ex. 1, at 52. However, the fact that this remedial action was not fully implemented did not prevent the surveyors from concluding that immediate jeopardy was abated on February 5, 2008.

- The ADON was to do a daily review of the crash cart checklist during the week and the weekend manager was to do the review on the weekend; and

- The quality assurance committee, with the Regional Clinical Director attending, was to meet weekly for four weeks and monthly thereafter to ensure all the remedial measures were implemented

CMS Ex. 2, at 14-18; P. Ex. 1, at 14-18. The SOD also indicates that an in-service training of all staff on the emergency management policy of Petitioner was completed by the Staff Development Coordinator on January 31, 2008 and would be continued on an ongoing basis. CMS Ex. 2, at 16; P. Ex. 1, at 16.

Petitioner argues that the additional remedial actions required by the surveyors were unnecessary to abate immediate jeopardy. RN Powell testified that in her opinion the CNA involved acted appropriately in response to the incident involving Resident 23, she advised her supervisory nurse, an LPN, and then went to the RN.[9] Tr. 154-55, 161. She testified that during the survey in January 2008, they explained their remedial measures to the surveyors who tested the plan and indicated that it was a good plan and that staff had acted appropriately to remedy the deficiency. Tr. 156. She testified that if the surveyors had indicated in January that immediate jeopardy was present, staff would have worked with the surveyors to remedy the situation immediately. Tr. 157. RN Powell reviewed the plan to lift immediate jeopardy set forth in the SOD (CMS Ex. 2, at 14-18; P. Ex. 1, at 14-18) with me at hearing. RN Powell testified that Petitioner had not assessed licensed nurses' ability to assess carotid pulse; document vital signs in the clinical record; and their competency in clearing an airway, assessing carotid pulse, and performing CPR as part of its remedial measures following the December 6 incident, as those things are learned in nursing school and there appeared to have been no error in that regard during the incident with Resident 23. RN Powell testified that during the February survey, Petitioner's staff resisted adding a requirement related to CNAs because they perceived what the survey team desired was out of the scope of practice for CNAs. However, Petitioner ultimately added the intervention of educating the CNAs on what to do in the event of an emergency including use of the calling-tree approach to ensure appropriate emergency response occurred. RN Powell testified that prior to the February survey Petitioner was monitoring code status but that specific requirement was added in writing to ensure the plan was completely stated to get immediate jeopardy lifted and the surveyors would not treat it as implemented prior to receiving it in writing. RN Powell testified that the quality assurance committee was being informed prior to the February

---

[9] Karla Minyard also testified that in her opinion the CNA involved on December 6, 2007 acted appropriately. Tr. 208.

survey. She testified that the requirement for the quality assurance committee to meet weekly for four weeks to oversee the remedial actions was a new intervention implemented during the February survey. Tr. 178-91.

I conclude that Petitioner has not shown that CMS's determination that immediate jeopardy continued from December 6, 2007 through February 4, 2008, was clearly erroneous. Immediate jeopardy is defined as a situation in which a facility's "noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301. The CMS determination as to the level of noncompliance "must be upheld unless it is clearly erroneous" (42 C.F.R. § 498.60(c)(2)), including the finding of immediate jeopardy. *Woodstock Care Center*, DAB No. 1726, at 9, 38 (2000), *aff'd, Woodstock Care Center v. Thompson*, 363 F.3d 583 (6th Cir. 2003).

The evidence before me supports CMS's finding of immediate jeopardy based on staff's failure to immediately initiate CPR for Resident 23 who was a full code and experiencing cardiopulmonary failure, and I find that Petitioner failed to carry its heavy burden of showing clear error in CMS's immediate jeopardy finding. Although it is undisputed that Petitioner took immediate action to remedy staff's failure to implement its emergency policy on December 6, 2007, Petitioner did not abate its immediate jeopardy until verification was obtained that its nurses, RNs and LPNs, were properly in-serviced on timely and appropriate interventions that should be rendered during a medical emergency, including CPR, and until their ability to do proper assessments and implement emergency procedures was actually demonstrated. The fact that a nurse may be trained in nurses' training or CPR class to assess a need for and then initiate CPR as argued by Petitioner, is not a sufficient response as is clearly demonstrated by the nurse who was terminated for failing to initiate CPR for Resident 23 on December 6, 2007. Further, there is no dispute by Petitioner that when licensed nurses were trained in December, CNAs were not included in the training. Petitioner argues that there was no deficient performance or errors committed by a CNA cited in the SOD and, therefore, no further training for CNAs was necessary to abate the immediate jeopardy. P. Brief at 6, 14-15. Whether or not the CNA acted appropriately on December 6, 2007, is not the issue. It is clearly reasonable to ensure that all CNAs are trained to address a situation such as that which occurred on December 6, 2007, and to verify that all CNAs understand the actions they are authorized and required to take. Petitioner's concern that the surveyors were suggesting a corrective action that would be outside the scope of duties of a CNA was proved unfounded by the survey team's acceptance of corrective action that involved creation of a decision-tree that instructed and clearly authorized CNAs to alert the entire nursing chain-of-command if they believed appropriate emergency actions were not taken. Petitioner does not dispute that the additional corrective actions devised during the February survey in response to the declaration of immediate jeopardy were not completed until February 5, 2008. The weight of the evidence supports the CMS position that the state agency and CMS were unable to verify that Petitioner's plan of correction abated immediate jeopardy

prior to February 5, 2008. Accordingly, I conclude that Petitioner has not shown that the CMS determination that immediate jeopardy commenced on December 6, 2007 and was not abated until February 5, 2008, was clearly erroneous.

4. Petitioner violated 42 C.F.R. § 483.20(k)(3)(i) (Tag F281) and the violation posed more than minimal harm.

Petitioner is required by regulation to conduct "initially and periodically a comprehensive, accurate, standardized, reproducible assessment of each resident's functional capacity." 42 C.F.R. § 483.20. Based upon the comprehensive assessment, Petitioner "must develop a comprehensive care plan for each resident . . . to meet a resident's medical, nursing, mental and psychosocial needs" as identified by the comprehensive assessment. 42 C.F.R. § 483.20(k)(1). The services for a resident provided by or arranged by Petitioner must "[m]"eet professional standards of quality; . . . ." 42 C.F.R. § 483.20(k)(3)(i). The SOM defines "professional standards of quality" as:

> "Professional standards of quality" means services that are provided according to accepted standards of clinical practice. Standards may apply to care provided by a particular clinical discipline or in a specific clinical situation or setting. Standards regarding quality care practices may be published by a professional organization, licensing board, accreditation body or other regulatory agency. Recommended practices to achieve desired resident outcomes may also be found in clinical literature.

SOM, App. PP, Tag F281. The SOM instructs surveyors that if a negative resident outcome is determined to be related to failure to meet professional standards and the survey team determines a deficiency has occurred, the deficiency should be cited under the appropriate quality of care or other requirement. Further, surveyors are to question only practices that have a negative outcome or the potential for such outcome.

The surveyors allege that Petitioner violated the regulation because Petitioner failed to follow physician orders for vital sign monitoring for Resident 4 and failed to obtain a physician-ordered laboratory test for Resident 7. CMS Ex. 2, at 44; P. Ex. 1, at 44. More specifically, the surveyors allege that Resident 4 had a physician's order dated June 28, 2007 that directed that her blood pressure and pulse be checked weekly. Petitioner did not produce documentation that monitoring was done November 27 to 30, 2007, in December 2007, or up to the date of the January 2008 survey. CMS Ex. 2, at 45-46; P. Ex. 1, at 45-46. The surveyors allege that Resident 7's records contained a physician's order dated December 29, 2007 for a complete metabolic panel to be done on December 31, 2007. Staff could not produce evidence that the laboratory test was done as ordered.

CMS Ex. 2, at 47. The surveyors cited the deficiency at a scope and severity of D, which indicates isolated incidents with no actual harm with the potential for more than minimal harm that is not immediate jeopardy. SOM, Ch. 7, § 7400E.

The SOD does not specify what potential harm could occur if monitoring of blood pressure and pulse or laboratory testing was not done as ordered. The parties did not present evidence on this deficiency at hearing. CMS simply restates the allegation from the SOD in its brief and provides no clarification of the potential for harm to either resident involved in this deficiency. CMS Brief at 16. Petitioner does not dispute that the monitoring of Resident 4's vital signs and the laboratory tests for Resident 7 were not done as alleged by the surveyors. Rather, Petitioner argues that there is no evidence that there was a potential for more than minimal harm and, therefore, though there may have been a regulatory violation or deficiency, it did not amount to substantial noncompliance. Tr. 32-33; P. Brief at 18.

Despite the dearth of evidence illuminating what potential harm confronted Resident 4 and 7, the surveyors' citation of the admitted deficiency at a scope and severity of D is some evidence that qualified individuals[10] concluded that the potential for more than minimal harm arose due to the deficiency. Both surveyors were experienced nurses and surveyors. Tr. 37, 80; CMS Ex. 51, 54. I conclude that the evidence is sufficient to put Petitioner to its proof and Petitioner's mere denial was not sufficient to rebut the surveyors' conclusion that the deficiency posed more than minimal harm.

Accordingly, I conclude that Petitioner violated 42 C.F.R. § 483.20(k)(3)(i) (Tag F281) and the violation posed more than minimal harm to its residents.

5. Petitioner violated 42 C.F.R. § 483.25(c) (Tag F314) and the deficiency resulted in actual harm to two residents.

The surveyors cited wound care examples under the alleged violation of 42 C.F.R. §§ 483.13(c) (Tag F224) (Residents 7, 8, 19, and 25) and 483.25 (Tag F309) (Residents 19 and 25). I concluded that Petitioner did not violate 42 C.F.R. § 483.13(c) for reasons already discussed and my rationale in that regard is unchanged by consideration of the wound care examples cited by the surveyors. The surveyors cited the wound care examples of Residents 19 and 25 under Tag F309, apparently because the wounds were considered by the surveyors not to be pressure ulcers. CMS Ex. 2, at 48; P. Ex. 1, at 48. I concluded that it was unnecessary for me to consider the wound care examples cited under Tag F309 as I found 42 C.F.R. § 483.25 violated based upon the CPR incident

[10] Surveyors are presumptively professionals tasked with using their judgment and federal forms and procedures to determine compliance with program participation requirements. 42 C.F.R. § 488.26(c)(3). The presumption was not rebutted in this case.

which posed immediate jeopardy. The surveyors only cite the examples of Residents 7 and 8 under Tag F314 and I conclude that those examples show a violation of the regulation that caused actual harm.

The quality of care regulation, 42 C.F.R. § 483.25, includes the requirement that a facility ensure that a resident who enters the facility without a pressure sore does not develop one unless clinically unavoidable, and that a resident entering with a pressure sore receives care and services necessary for healing, to prevent infection, and to prevent other sores from developing. 42 C.F.R. § 483.25(c).

The application of this regulation is well-established by decisions of various appellate panels of the Board. *Koester Pavilion*, DAB No. 1750 and *Cross Creek Health Care Center*, DAB No. 1665 are leading decisions in this area. The Board has noted that the pressure sore regulation contains two prongs: (1) a facility must ensure a resident who enters the facility without sores does not develop sores unless the resident's clinical condition demonstrates that pressure sores are unavoidable; and (2) a resident with pressure sores must receive necessary treatment and services to promote healing, prevent infection and prevent new sores. With respect to prevention and treatment of pressure sores, the Board has concluded that a facility bears a duty to "go beyond merely what seems reasonable to, instead, always furnish what is necessary to prevent new sores unless clinically unavoidable, and to treat existing ones as needed." *Koester Pavilion*, DAB No. 1750, at 32; *see also Meadow Wood Nursing Home*, DAB No. 1841 (2002) (loose dressing contaminated with fecal matter constitutes violation); *Ridge Terrace*, DAB No. 1834, at 15-16 (2002) (a single observation by a surveyor of a nurse aide cleaning an open sore area with a stool-stained washcloth was sufficient to sustain a deficiency finding under this Tag); *Clermont Nursing and Convalescent Center*, DAB No. 1923, at 9-10 (2004), *aff'd, Clermont Nursing and Convalescent Center v. Leavitt*, 142 F. App'x 900 (6th Cir. 2005); *Woodland Village Nursing Center*, DAB No. 2172, at 12-14 (2008).

The survey team alleged that Petitioner violated 42 C.F.R. § 483.25(c) because Petitioner failed to provide treatments as ordered by the residents' physicians and that the failure to provide treatments resulted in actual harm as indicated by the scope and severity citation of G. CMS Ex. 2, at 79; P. Ex. 1, at 79. The surveyors allege regarding the example of Resident 8, that she had a pressure ulcer; that Petitioner did not have documentation that treatment was done on multiple days in October, November, and December 2007 and January 2008 as ordered by the resident's physician; and that the ulcer worsened during that period. CMS Ex. 2, at 79-88; P. Ex. 1, at 79-88. The surveyors allege regarding the example of Resident 7, that Petitioner failed to document physician-ordered treatment of a pressure ulcer on several days in December 2007, and that the wound worsened. CMS Ex. 2, at 88-91; P. Ex. 1, at 88-91.

Petitioner does not deny the violation related to the treatment of the pressure ulcers of Residents 7 and 8 or that they suffered actual harm as a result. Petitioner argues that the CMP based on this deficiency should not begin before February 5, 2008. P. Brief at 17, 23-24. I conclude that Petitioner violated 42 C.F.R. § 483.25(c) based on the examples of Residents 7 and 8 and that the violation resulted in actual harm to the residents. Petitioner's argument regarding the duration of the CMP is without merit as I conclude, considering all the deficiencies discussed in this decision that Petitioner was not in substantial compliance with program participation requirements beginning December 6, 2007 as alleged by CMS and that there was a basis for the imposition of a CMP from December 6, 2007 through March 24, 2008.

6. Petitioner violated 42 C.F.R. § 483.60(c) (Tag F428) and the violation had the potential for more than minimal harm.

The regulation requires that the drug regimen of each resident be reviewed "at least once a month by a licensed pharmacist" who "must report any irregularities to the attending physician and the director of nursing, and [the reported irregularities] must be acted upon." 42 C.F.R. § 483.60(c).

The surveyors allege that the regulation was violated based on the following examples:

> 1. Petitioner's consultant pharmacist failed to notify the attending physician and DON of irregularities including continuation of medication without assessment of continued need for Resident 13;
>
> 2. Petitioner's consultant pharmacist failed to notify the attending physician and DON of irregularities including continuation of medication identified as high risk in the elderly without assessment of risk and benefit to Resident 12;
>
> 3. Petitioner's consultant pharmacist failed to notify the attending physician and DON of irregularities including continuation of medication without assessment of continued need for Resident 8; and
>
> 4. Petitioner failed to ensure monthly licensed pharmacist medicine regime reviews for Residents 1, 4, 5, 6, 7, 8, 10, 11, 13, 15, 16, 18, 19, 20, and 22 from May 30, 2007 to August 21, 2007.

CMS Ex. 2, at 123-50; P. Ex. 1, at 123-50.

Petitioner argues regarding Resident 13, citing the allegation from the SOD,[11] that Petitioner's consulting pharmacist appropriately notified the resident's physician but the physician declined the pharmacist recommendation to reevaluate the need for continued antidepressant therapy. P. Brief at 22-23. Petitioner does not dispute that the pharmacist review and recommendation to the physician and the physician's decision to continue Zoloft (the antidepressant medication) occurred in February 2007 nearly a year prior to the survey and before Resident 13's symptoms of Alzheimer's disease worsened and she had stopped expressing any clear emotions. CMS Ex. 2, at 124-29; P. Ex. 1, at 124-29. Petitioner also does not dispute that after February 2007, there is no evidence that the pharmacist raised any question about the continued need for antidepressant therapy for Resident 13.

Petitioner does not dispute that its consultant pharmacist failed to: notify the attending physician and DON of continuation of medication identified as high risk in the elderly without assessment of risk and benefit to Resident 12; failed to notify the attending physician and DON of the continuation of medication without assessment of continued need for Resident 8; and failed to conduct medicine regime reviews for Residents 1, 4, 5, 6, 7, 8, 10, 11, 13, 15, 16, 18, 19, 20, and 22 from May 30, 2007 to August 21, 2007. Rather, Petitioner argues that the surveyors' findings do not support a determination that there was a possibility for more than minimal harm to any resident due to the deficiency and the deficiency is not a basis for the imposition of any enforcement remedy. P. Brief at 22-23.

The surveyors do not specifically state what harm confronted the residents discussed under this Tag. However, the surveyor's citation of the deficiency at a scope and severity of E is some evidence that qualified individuals concluded that the potential for more than minimal harm arose due to the deficiency. Both surveyors were experienced nurses and surveyors. Tr. 37, 80; CMS Ex. 51, 54. I conclude that the evidence is sufficient to put Petitioner to its proof and Petitioner's mere denial was not sufficient to rebut the surveyors' conclusion that the deficiency posed more than minimal harm.

---

[11] Petitioner cites P. Ex. 1, at 99. The discussion on that page relates to Tag F329 and not F428. However, it is stated on that page that on February 16, 2007, Resident 13's physician declined the pharmacist's recommendation with the specific note that the resident was stable then on the present dose of Zoloft. The same facts are alleged under Tag F428 at CMS Ex. 2, at 124-25; P. Ex. 1, at 124-25. The allegations in the SOD are consistent with the evidence from the resident's clinical record. CMS Ex. 26, at 7; CMS Ex. 26, at 5.

Accordingly, I conclude that Petitioner violated 42 C.F.R. § 483.60(c) (Tag F428) and the violation posed more than minimal harm to its residents.

7. Petitioner's challenges to the survey process are without merit or not subject to my review.

Petitioner raised several issues in its request for hearing and post-hearing brief challenging the lawfulness of the survey process. Petitioner specifically recognizes that these issues are not within my authority to review but states the intent to preserve the issues for appeal. P. Brief at 25. The issues raised challenge the lawfulness of CMS regulations as being inconsistent with the Administrative Procedure Act (5 U.S.C. §§ 551-99), the Social Security Act, and/or in violation of the U.S. Constitution. I agree with Petitioner that all but one of its challenges to the survey process on statutory or Constitutional grounds are not within my authority to adjudicate and I find it unnecessary to comment further on those issues. *Northern Montana Care Center*, DAB No. 1930 (2004); *Wisteria Care Center*, DAB No. 1892 (2003); *Hermina Traeye Memorial Nursing Home*, DAB No. 1810, at 22-23 (2002), *aff'd, Sea Island Comprehensive Healthcare Corp., d/b/a Hermina Traeye Memorial Nursing Home v. Dep't of Health & Human Servs.*, No. 02-2076 (4th Cir. Oct. 29, 2003); *Sentinel Medical Laboratories, Inc.*, DAB No. 1762 (2001).

The one issue that I find appropriate to address relates to the sufficiency of the CMS notice of imposition of enforcement remedies. Petitioner argues that 42 C.F.R. § 488.434(a)(2) prescribes the content of a CMS notice to a provider that it intends to impose a remedy. Petitioner argues the CMS notice in this case did not comply with the regulation and because the notice was insufficient the CMP may not be imposed in this case. More specifically, Petitioner argues that the CMS notice failed "to include the nature of the noncompliance factors considered when determining the amount of the penalty." P. Brief at 27. This argument is without merit.

The requirements for notice are set forth at 42 C.F.R. § 488.434, which provides in pertinent part:

> (a) CMS notice of penalty.
>
> (1) CMS sends a written notice of the penalty to the facility for all facilities except non-State operated NFs when the State is imposing the penalty.
>
> (2) Content of notice. The notice that CMS sends includes--
>
> (i) The nature of the noncompliance;
>
> (ii) The statutory basis for the penalty;

> (iii) The amount of penalty per day of noncompliance or the amount of the penalty per instance of noncompliance;
> (iv) Any factors specified in Sec. 488.438(f) that were considered when determining the amount of the penalty;
> (v) The date of the instance of noncompliance or the date on which the penalty begins to accrue;
> (vi) When the penalty stops accruing, if applicable;
> (vii) When the penalty is collected; and
> (viii) Instructions for responding to the notice, including a statement of the facility's right to a hearing, and the implication of waiving a hearing, as provided in Sec. 488.436.

Section 488.438(f) of Title 42 provides:

> (f) Factors affecting the amount of penalty. In determining the amount of penalty, CMS does or the State must take into account the following factors:
>
> (1) The facility's history of noncompliance, including repeated deficiencies.
> (2) The facility's financial condition.
> (3) The factors specified in Sec. 488.404.
> (4) The facility's degree of culpability. Culpability for purposes of this paragraph includes, but is not limited to, neglect, indifference, or disregard for resident care, comfort or safety. The absence of culpability is not a mitigating circumstance in reducing the amount of the penalty.

The CMS notice letter dated March 5, 2008, states in relevant part, "[w]e considered factors identified at 42 CFR 488.438(f) in setting the amount of the CMP being imposed for each day of noncompliance." CMS Ex. 7, at 2. Contrary to what Petitioner argues, however, this notice letter complies with the regulatory requirement. In *Hermina Traeye*, the Board rejected a similar argument, holding that there is no statutory or regulatory requirement for CMS to explain how it weighed the 42 C.F.R. § 488.438(f) factors. *Hermina Traeye Memorial Nursing Home*, DAB No. 1810, at 16-17, citing *CarePlex of Silver Spring*, DAB No. 1683 (1999) and *Emerald Oaks*, DAB No. 1800. The Board also found the facility was not prejudiced because CMS failed to more specifically explain how the regulatory factors were weighed. The Board noted that any arguable due process claim *Hermina* might have incurred from a "faulty" CMS notice letter was effectively cured by the hearing. *Hermina Traeye* at 17-18. In this case, Petitioner neither asserts

nor points to any evidence that the alleged defect in CMS's notice resulted in any prejudice to Petitioner. Furthermore, Petitioner's assertion that the CMS notice left me guessing as to how CMS considered the regulatory factors (P. Brief at 27) does not reflect prejudice to Petitioner. I am obliged to do a *de novo* review of the factors and how CMS may have weighed those factors is not binding on me. Further, because evidence of how CMS weighed the regulatory factors may be persuasive in some cases, the fact that CMS does not offer such evidence is certainly not prejudicial to Petitioner.

8. A CMP of $4550 per day for the period of immediate jeopardy from December 6, 2007 through February 4, 2008 is not reasonable.

9. A CMP of $3050 per day for the period of immediate jeopardy from December 6, 2007 through February 4, 2008, and $200 per day from February 5 through March 24, 2008, a total CMP of $195,850, is reasonable.

I have concluded that Petitioner was in violation of 42 C.F.R. § 483.25 (Tag F309) from December 6, 2007 through February 4, 2008, and that the violation posed immediate jeopardy to Petitioner's residents during that period. The surveyors concluded that after immediate jeopardy was abated on February 5, 2008, the deficiency continued at a scope and severity of D, i.e., an isolated instance with no actual harm but the potential for more than minimal harm that was not immediate jeopardy. I have also concluded that Petitioner was in violation of 42 C.F.R. §§ 483.20(k)(3)(i) (Tag F281, s/s D), 483.25(c) (Tag F314, s/s G), and 483.60(c) (Tag F 428, s/s E) and not in substantial compliance based upon these violations as of February 4, 2008. The evidence does not show that Petitioner returned to substantial compliance with program participation requirements before March 25, 2008. Jt. Stip. 1f; CMS Ex. 8; P. Ex. 5. I have concluded that Petitioner did not violate 42 C.F.R. § 483.13(c) (Tag F224 s/s J) as alleged by CMS. I do not address the alleged violations of 42 C.F.R. §§ 483.15(f)(1) (Tag F248 s/s D), 483.25(a)(3) (Tag F312 s/s D), 483.25(d) (Tag F315 s/s D), 483.25(l) (Tag F329 s/s D), and 483.30(a) (Tag F353 s/s G) in the interest of judicial economy, as the violations I do discuss establish that Petitioner was not in substantial compliance for the period December 6, 2007 through March 24, 2008 and those violations are a sufficient basis for the imposition of the CMP that I approve. Withdrawal of Petitioner's approval to conduct a NATCEP for two years from February 5, 2008 through February 4, 2010, was required based upon the amount of the CMP and the fact an extended survey was conducted. 42 C.F.R. § 483.151(b)(2) and (e)(1).

If a facility is not in substantial compliance with program participation requirements, CMS has the authority to impose one or more of the enforcement remedies listed in 42 C.F.R. § 488.406, including a CMP. CMS may impose a CMP for the number of days that the facility is not in compliance or for each instance that a facility is not in substantial compliance. 42 C.F.R. § 488.430(a). There are two ranges for per day CMPs.

42 C.F.R. §§ 488.408, 488.438. The upper range of CMPs of $3050 to $10,000 per day is reserved for deficiencies that constitute immediate jeopardy to a facility's residents, and, in some circumstances, for repeated deficiencies. 42 C.F.R. §§ 488.438(a)(1)(i), (d)(2). The lower range of CMPs of $50 per day to $3000 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). In this case, CMS proposed a CMP of $4550 per day for the period of immediate jeopardy from December 6, 2007 through February 4, 2008, and a CMP of $200 per day from February 5 through March 24, 2008. CMS Ex. 7, at 2.

Pursuant to 42 C.F.R. § 488.438(e) and (f), my authority on review of the reasonableness of the CMP is limited: (1) I may not set the penalty at or reduce it to zero; (2) I may not review the CMS or state decision to use a CMP as an enforcement remedy; and (3) I may only consider the factors specified at 42 C.F.R. § 488.438(f). I review the reasonableness of the enforcement remedy *de novo* applying the regulatory factors at 42 C.F.R. § 488.438(f), which include: (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; and (4) the facility's degree of culpability.

There is no evidence that Petitioner has a history of noncompliance. Petitioner has not presented evidence that it is unable to pay the CMP proposed by CMS. Accordingly, I conclude that the amount of the reduced CMP that I approve will not cause a substantial financial burden to Petitioner, and Petitioner does not assert that the obligation to pay will put it out of business. *Crestview Parke Care Center v. Thompson*, 373 F.3d 743,756 (6th Cir. 2004). The deficiencies cited were serious. Whether or not initiation of CPR may have saved Resident 23 is not the issue. Petitioner's policy required that CPR be initiated and Resident 23 or his responsible parties specifically elected that all reasonable measures be taken to resuscitate in case of an event such as occurred on December 6, 2007. Petitioner's obligation under 42 C.F.R. § 483.25 was to ensure that CPR was initiated for Resident 23, and Petitioner cannot escape that obligation by blaming the failure on the nurse. However, I do not approve the CMP proposed by CMS for the period of immediate jeopardy. The surveyors cited immediate jeopardy for violations of Tags F224 and F309 and CMS presumably considered both violations when proposing the $4550 per day CMP. Because I concluded there was no deficiency under Tag F224, I conclude that a reduction of the daily CMP for the period of immediate jeopardy is appropriate. Furthermore, there is no dispute that Petitioner took significant remedial action immediately from December 6 through 10, 2007, in a good faith effort to ensure that no similar incidents would occur. I also note that Petitioner's violation of Tag F314 caused actual harm to two residents. I conclude after weighing all the factors that a per day CMP of $4550 for the period of immediate jeopardy is not reasonable. I further conclude that a CMP of $3050, the lowest authorized CMP for immediate jeopardy, is

reasonable on the facts of this case. I further conclude that a CMP of $200 per day for the period of noncompliance from February 5, 2008 through March 24, 2008, is reasonable based on my assessment of the regulatory factors.

III. Conclusion

For the foregoing reasons I conclude that Petitioner was not in substantial compliance with program participation requirements from December 6, 2007 through March 24, 2008. A CMP of $3050 per day effective December 6, 2007 through February 4, 2008, and $200 per day from February 5 through March 24, 2008, a total CMP of $195,850, is reasonable. Petitioner's authority to conduct a NATCEP was required to be withdrawn for the two-year period of from February 5, 2008 through February 4, 2010.

/s/
Keith W. Sickendick
Administrative Law Judge