Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Golden Living Center – Mountain View,
(CCN: 44-5145),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-14-1369

Decision No. CR4842

Date: May 8, 2017

DECISION

Petitioner, Golden Living Center – Mountain View, was not in substantial compliance with program participation requirements from January 13, 2014 through June 10, 2014, based on violations of 42 C.F.R. §§ 483.20(d)(3)[1] and 483.10(k)(2) (Tag F280[2]);

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[1] References are to the 2013 revision of the Code of Federal Regulations (C.F.R.), unless otherwise indicated.

[2] This is a "Tag" designation as used in CMS Pub. 100-07, State Operations Manual (SOM), Appendix PP – Guidance to Surveyors for Long Term Care Facilities (http://www.cms.hhs.gov/Manuals/IOM/list.asp). The "Tag" refers to the specific regulatory provision allegedly violated and policy guidance to surveyors from the Centers for Medicare & Medicaid Services (CMS). Although the SOM does not have the force and effect of law, the provisions of the Act and regulations as interpreted in the SOM clearly do have such force and effect. *Ind. Dep't of Pub. Welfare v. Sullivan*, 934 F.2d 853 (7th Cir. 1991); *NW Tissue Ctr. v. Shalala*, 1 F.3d 522 (7th Cir. 1993). Thus, while the Secretary of Health and Human Services (Secretary) may not seek to enforce the
(*Footnote continued next page.*)

483.25(h) (Tag F323); 483.30(a) (Tag F353); 483.75 (Tag F490); 483.75(i) (Tag F501); and 483.75(o)(1) (Tag F520). A civil money penalty (CMP) of $5,800 per day from January 13, 2014 through April 28, 2014, and $150 per day from April 29, 2014 through June 10, 2014, a total CMP of $621,250, and a denial of payment for new admissions (DPNA) from April 25, 2014 through June 10, 2014,[3] are reasonable enforcement remedies.

I. Background

Petitioner is located in Winchester, Tennessee. Petitioner participates in Medicare as a skilled nursing facility (SNF) and Medicaid as a nursing facility (NF). Jt. Stip. ¶ 1.

On April 11, 2014, the Tennessee State Survey Agency (state agency), completed a survey of Petitioner's facility. The surveyors alleged in the Statement of Deficiencies (SOD) for the April 11, 2014 survey that Petitioner was not in substantial compliance with 42 C.F.R. §§ 483.20(d)(3) and 483.10(k)(2) (Tag F280); 483.25(h) (Tag F323); 483.30(a) (Tag F353); 483.75 (Tag F490); 483.75(i) (Tag F501); and 483.75(o)(1) (Tag F520). The surveyors allege in the SOD that each of the alleged deficiencies posed

(*Footnote continued.*)

provisions of the SOM, he may seek to enforce the provisions of the Act or regulations as interpreted by the SOM.

[3] The parties stipulated that a revisit survey was completed on June 11, 2014, and it was determined that Petitioner returned to substantial compliance. Joint Stipulations of Undisputed Fact (Jt. Stip.) ¶ 10. The parties did not stipulate to the date on which Petitioner returned to substantial compliance and no notice letter from CMS discussing the date on which Petitioner returned to substantial compliance is in evidence. Based on the parties' stipulation, I infer Petitioner returned to substantial compliance on June 11, 2014. Because Petitioner returned to substantial compliance on June 11, 2014, the CMP only accrued through June 10, 2014, the last day of noncompliance. 42 C.F.R. § 488.440(b) (CMP computed and collectible for number of days of noncompliance). Therefore, the CMP of $5,800 per day was in effect for 106 days and the $150 per day CMP was in effect for 43 days, yielding a total CMP of $621,250. The parties stipulated that the DPNA was in effect from April 25, 2014 through June 11, 2014. Jt. Stip. ¶ 10. Pursuant to 42 C.F.R. § 488.417(c) and (d), payments are resumed on the date a facility achieves substantial compliance, in this case June 11. Therefore, the parties' stipulation that the DPNA continued through June 11, 2014, is erroneous as a matter of law and unacceptable.

immediate jeopardy at a scope and severity rating of K.[4] Petitioner did not request ALJ review of other deficiency citations that were not alleged to pose immediate jeopardy. Jt. Stip. ¶¶ 2-4; CMS Exhibit (Ex.) 1; Request for Hearing dated June 20, 2014 (RFH). CMS notified Petitioner by letter dated April 23, 2014, that it was imposing the following enforcement remedies based on the noncompliance found by the state agency: a CMP of $5,800 per day effective January 13, 2014, and continuing until Petitioner returned to substantial compliance or its participation in Medicare was terminated, and a discretionary DPNA effective April 25, 2014. CMS advised Petitioner that its provider agreement and enrollment in Medicare would be terminated on May 4, 2014, if Petitioner did not return to substantial compliance before that date. CMS also advised Petitioner that it was ineligible to conduct a Nurse Aide Training and Competency Evaluation Program (NATCEP) for two years.[5] Jt. Stip. ¶¶ 5-7; CMS Ex. 2.

A revisit survey conducted on May 1, 2014, determined that Petitioner abated immediate jeopardy as of April 29, 2014, but that noncompliance at a lesser scope and severity continued. CMS advised Petitioner by letter dated May 9, 2014, that the CMP of $5,800 ran from January 13, 2014 through April 28, 2014, and that the CMP was reduced to $150 per day effective April 29, 2014, and would continue to accrue at that rate until Petitioner returned to substantial compliance. CMS advised Petitioner that mandatory termination would occur on October 11, 2014, if Petitioner did not return to substantial compliance before that date. The DPNA remained in effect. Jt. Stip. ¶¶ 8-9; CMS Ex. 3.

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[4] Scope and severity levels are used by CMS and a state when selecting remedies. The scope and severity level is designated by an alpha character, A through L, selected by CMS or the state agency from the scope and severity matrix published in the SOM, Chap. 7, § 7400.5.1 (eff. Sep. 23, 2016). 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.

[5] Petitioner was notified in this case that it was ineligible to conduct a NATCEP for two years. But the parties stipulated and agreed that Petitioner was not operating a NATCEP and there is no issue for me to decide in that regard. Jt. Stip. ¶ 7.

I infer, based on the proposed CMP that ended on June 10, 2014, that CMS determined that Petitioner returned to substantial compliance effective June 11, 2014, based on a revisit survey completed on that date. The $5,800 per day CMP was in effect from January 13, 2014 through April 28, 2014, and the $150 per day CMP was in effect from April 29, 2014 through June 10, 2014, a total CMP of $621,250. The DPNA was in effect from April 25, 2014 through June 10, 2014. Termination of Petitioner's provider agreement did not occur and is not at issue in this case. Jt. Stip. ¶ 10.

Petitioner requested a hearing before an administrative law judge (ALJ) by letter dated June 20, 2014. Petitioner only requested review of the deficiencies for which the surveyors alleged immediate jeopardy and of the enforcement remedies related thereto. RFH at 1, 2 n.1. On June 27, 2014, the case was assigned to me for hearing and decision and an Acknowledgement and Prehearing Order (Prehearing Order) was issued.

A hearing was convened by video teleconference from April 21 through 24, 2015 and on June 15, 2015. A transcript of the proceedings was prepared.[6] CMS offered CMS Exs. 1 through 40, all of which were admitted as evidence except CMS Ex. 40. Tr. Vol. 1 at 31-52; Tr. Vol. 3 at 159; Tr. Vol. 4 at 234-41. Petitioner offered Petitioner exhibits (P. Exs.) 1 through 36 that were admitted as evidence. Tr. Vol. 1 at 56. CMS called the following witnesses: Surveyor Sheila Varner, R.N., and Surveyor Betty Jo Skidmore, R.N. Petitioner called the following witnesses: Donald Vollmer, M.D., Petitioner's Medical

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[6] The first four volumes of the transcript are incorrectly dated April 21, 2014, April 22, 2014, April 23, 2014, and April 24, 2014, even though it is clearly stated in each that the year is 2015. A separate volume of the transcript was prepared for each day the hearing was in session. Rather than number all pages consecutively across all five volumes of the transcript – the usual practice – the court reporting firm began the numbering of the pages of each volume of the transcript with the number 1. Therefore, to avoid potential confusion, references to the transcript must be by volume and page. The transcript for April 21 is referred to as "Tr. Vol. 1" followed by the page number. The transcripts for April 22, 23, 24, and June 15 are referred to as "Tr. Vol. 2," "Tr. Vol. 3," Tr. Vol. 4," and "Tr. Vol. 5," respectively. The transcript includes many reporter notes indicating that the recording from which the transcript was prepared was inaudible due to poor audio quality. The quality of the audio did not impair my ability to hear and view the witnesses and parties except as I specifically stated during the course of the proceedings and in those instances the witness or party was asked to repeat the testimony or statements affected by poor audio quality. The parties have not specifically objected to either the video teleconference audio or video or the quality of the transcript. I heard all the testimony during the hearing and I find no prejudice to the parties due to poor audio or video quality or the omissions from the transcript.

Director; Megon Fulmer, R.N., Petitioner's Director of Nursing (D.O.N.); Amy Jenkins-Clark, R.N.; Jessica Hill, L.P.N.; and Terri Bodkins, Petitioner's Executive Director (Administrator).

Petitioner filed its post-hearing brief on August 3, 2015 (P. Br.) and its post-hearing reply brief on September 2, 2015 (P. Reply). CMS filed its post-hearing brief on August 14, 2015 (CMS Br.) and its post-hearing reply brief on September 14, 2015 (CMS Reply).

II. Discussion

A. Issues

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

Whether the remedy imposed is reasonable.

B. Applicable Law

The statutory and regulatory requirements for participation of a SNF in Medicare are at section 1819 of the Social Security Act (Act) and 42 C.F.R. pt. 483. Section 1819(h)(2) of the Act authorizes the Secretary to impose enforcement remedies against a SNF for failure to comply substantially with the federal participation requirements established by sections 1819(b), (c), and (d) of the Act.[7] 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 180 days of noncompliance. The Act also grants the Secretary authority to

[7] Participation of a nursing facility (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.

impose other enforcement remedies, including a discretionary DPNA, CMPs, appointment of temporary management, and 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* [complying substantially] 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 (italics in original). A deficiency is a violation of a participation requirement established by sections 1819(b), (c), and (d) of the Act or the Secretary's regulations at 42 C.F.R. pt. 483, subpt. B. Therefore, a facility may violate a statutory or regulatory requirement, but it is not subject to enforcement remedies if the violation does not pose a risk for more than minimal harm. The term "noncompliance" refers to any deficiency (statutory or regulatory violation) that causes a facility not to be in substantial compliance; that is, a deficiency that poses a risk for more than minimal harm. 42 C.F.R. § 488.301. State survey agencies survey facilities that participate in Medicare on behalf of CMS to determine whether the facilities are complying with federal participation requirements. 42 C.F.R. §§ 488.10-.28, 488.300-.335. The regulations specify the enforcement remedies that CMS may impose if a facility is not in substantial compliance with Medicare requirements. 42 C.F.R. § 488.406.

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

The hearing before an ALJ is a de novo proceeding, i.e., "a fresh look by a neutral decision-maker at the legal and factual basis for the deficiency findings underlying the

remedies." *Life Care Ctr. of Bardstown*, DAB No. 2479 at 32 (2012) (citation omitted); *The Residence at Salem Woods*, DAB No. 2052 (2006); *Cal Turner Extended Care Pavilion*, DAB No. 2030 (2006); *Beechwood Sanitarium*, DAB No. 1906 (2004); *Emerald Oaks*, DAB No. 1800 at 11 (2001); *Anesthesiologists Affiliated*, DAB No. CR65 (1990), *aff'd*, 941 F.2d 678 (8th Cir. 1991). The regulations that establish the procedures for adjudication of this case at 42 C.F.R. pt. 498 do not specify the standard of proof or quantum of evidence or the allocation of the burden of persuasion. The Board has determined in prior decisions that the standard of proof is a preponderance of the evidence. The Board has also determined that CMS has the burden of coming forward with the evidence and making a prima facie showing of a basis for the imposition of an enforcement remedy. If CMS makes a prima facie showing, then 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*, 129 F. App'x 181 (6th Cir. 2005); *Emerald Oaks*, DAB No. 1800; *Cross Creek Health Care Ctr.*, DAB No. 1665 (1998); *Hillman Rehab. Ctr.*, DAB No. 1611 (1997) (*remand*), DAB No. 1663 (1998) (*aft. remand*), *aff'd*, *Hillman Rehab. Ctr. v. United States*, No. 98-3789 (GEB), 1999 WL 34813783 (D.N.J. May 13, 1999). Petitioner disputes that the Board has correctly determined the allocation of the burden of persuasion. RFH at 13. Petitioner's argument is discussed under Conclusion of Law 12.

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

My conclusions of law are set forth in bold text followed by my findings of fact and analysis. I have carefully considered all the evidence and the arguments of both parties, although not all may be specifically discussed in this decision. I discuss the credible evidence given the greatest weight in my decision-making.[8] I also discuss any evidence that I find is not credible or worthy of weight. The fact that evidence is not specifically discussed should not be considered sufficient to rebut the presumption that I considered all the evidence and assigned such weight or probative value to the credible evidence that I determined appropriate within my discretion as an ALJ. There is no requirement for me to discuss the weight given every piece of evidence considered in this case, nor would it be consistent with notions of judicial economy to do so. Charles H. Koch, Jr., *Admin. L. & Prac.* § 5:64 (3d ed. 2013).

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[8] "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.

The deficiency citations at issue before me are those alleged in the SOD for the April 11, 2014 survey: 42 C.F.R. §§ 483.20(d)(3) and 483.10(k)(2) (Tag F280); 483.25(h) (Tag F323); 483.30(a) (Tag F353); 483.75 (Tag F490); 483.75(i) (Tag F501); and 483.75(o)(1) (Tag F520). CMS Ex. 1. The surveyors alleged that all six deficiencies posed immediate jeopardy for Petitioner's residents. The survey was a recertification and extended survey that began on March 31, 2014 and ended on April 11, 2014. CMS Ex. 1 at 1. The surveyors allege that Residents 28, 45, 94, 111, and 112, all residents of Petitioner's Alzheimer's care unit (ACU), suffered multiple falls. The residents' falls are the factual basis common to each of the deficiency citations at issue before me. The surveyors allege that immediate jeopardy began on January 13, 2014. CMS Ex. 1 at 1-2. The surveyors did not directly observe any falls and their allegations are based upon their observations of the ACU recorded in the SOD, review of the clinical records for each resident, staff interviews, and review of various documents provided to them by the facility. CMS Ex. 1.

There are no disputed facts related to the falls experienced by Residents 28, 111, 45, 94, and 112 as those facts are documented in Petitioners clinic records for those residents. The facts in dispute relate to whether or not Petitioner met the regulatory requirement and/or standards of care with respect to each resident.

1. Petitioner violated 42 C.F.R. §§ 483. 10(k)(2) and 483.20(d)(3) (Tag F280).

2. Petitioner violated 42 C.F.R. § 483.25(h) (Tag F323).

3. Petitioner violated 42 C.F.R. § 483.30(a) (Tag F353).

4. Petitioner violated 42 C.F.R. § 483.75 (Tag F490).

5. Petitioner violated 42 C.F.R. § 483.75(i) (Tag F501).

6. Petitioner violated 42 C.F.R. § 483.75(o)(1) (Tag F520).

7. Petitioner's violations of 42 C.F.R. §§ 483.20(d)(3) and 483.10(k)(2) (Tag F280); 483.25(h) (Tag F323); 483.30(a) (Tag F353); 483.75 (Tag F490); 483.75(i) (Tag F501); and 483.75(o)(1) (Tag F520) posed a risk for more than minimal harm during the period January 13, 2014 through June 10, 2014.

8. Petitioner has not shown that the declaration of immediate jeopardy for the period January 13, 2014 through April 28, 2014, was clearly erroneous.

9. There is a basis for the imposition of an enforcement remedy from January 13, 2014 through June 10, 2014.

a. Facts

Many of the facts recited here are not in dispute. It is necessary to include detailed findings of fact in order for the reader to understand the bases for the conclusions that Petitioner violated multiple regulations and why Petitioner's defense that the residents' falls were unavoidable is without merit.

(i.) The Facility

Petitioner's facility has wings A, B, C, D, and E. The deficiency citations before me are all related to wings D and E, which comprise the locked ACU. P. Ex. 33; CMS Ex. 1 at 8, 93, 102, 108; CMS Ex. 10; CMS Ex. 28; Petitioner's Proposed Findings of Fact and Conclusion of Law (PFFCL) 13, 16-17, 20. On February 24, 2014, there were 23 residents listed on wing E and 12 residents listed as residing on wing D. CMS Ex. 16 at 3, 6. Petitioner states that at the time of the survey, there were 9 or 10 residents on the D Unit and approximately 20 residents on the E Unit. PFFCL 24.

Petitioner's criteria for admitting a resident to the ACU included:

- A primary diagnosis of Alzheimer's disease or other related cognitive disorder, but not Lewy Body Dementia, Pick's disease (frontotemporal dementia), drug- or alcohol-related dementia, traumatic brain injury, mental illness, or mental retardation.

- May have behaviors associated with dementia such as short and long-term memory problems; poor judgment; disorientation to time, place, and person; decreased attention span; mood fluctuations; wandering behavior; exit-seeking behavior; anxiety related to a specific fantasy; or catastrophic reactions.

- The resident cannot be harmful to self or others.

- The resident must be able to pivot during transfer and be ambulatory, but may use walker, wheelchair, or other assistive devices but not a Geri-chair.

- The resident must be continent of bowel and bladder but may participate in bowel or bladder program.

- The resident must not require skilled nursing care.

- The resident must be able to feed him or herself within 45 minutes with no more than minimal assistance.

CMS Ex. 28 at 1-7; PFFCL 18.

CMS evidence shows that Petitioner had a staff dedicated to the operation of its ACU. CMS Ex. 31. The ACU was a locked unit. Residents were all supposed to be ambulatory. Residents who wandered or were at risk of elopement were permitted to move around freely in the ACU but were not permitted to leave without an escort. No restraints or side rails were used to limit the freedom of movement of the ACU residents. Nursing staff provided the residents hands-on care, activities, assistance with dining, and assistance with activities of daily living. Meals and activities were "conducted family style," which I construe to mean as a group. Activities included Bible study, music, physical activities, painting, crafts, gardening, and church-group visits. PFFCL 18-23. Petitioner consistently assigned the same nurses and CNAs to the ACU to permit the residents to be familiar with their care givers. PFFCL 27. The ACU had a psychologist as its full-time director and a supply clerk who was a Certified Nursing Assistant (CNA). PFFCL 28-29.

Both parties have presented evidence which shows that falls pose a significant risk for injury or death to the elderly and even younger individuals who are institutionalized or at home.[9] Intrinsic risk factors for falls include age; medication use; cognitive impairment; sensory deficits; high or low blood pressure or blood sugar; balance and gait changes or impairment; vision impairment; deconditioning or strength impairment; loss of bone mass; loss of musculoskeletal flexibility; poor judgment; poor understanding; lack of safety awareness; and chronic diseases. Extrinsic risk factors include poor lighting; cluttered spaces; uneven floors; wet floors; unstable furniture; unstable or defective beds; defective wheel chairs, walkers, or other assistance devices; improper footwear; difficult clothing; and inaccessible personal items. CMS Exs. 37-38; P. Exs. 2-3, 5-12.

Petitioner does not dispute that Residents 28, 45, 94, 111, and 112 each had multiple falls on the ACU. P. Reply at 5. Petitioner stipulated at hearing that all five of the residents at issue were assessed by Petitioner as being at high risk for falls associated with all their activities of daily living. Tr. Vol. 1 at 168-71. The surveyors list in the SOD many

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[9] Some of the evidence cited includes data and other assertions of purported facts. Absent expert testimony, no attempt is made to judge the credibility of the data presented or other assertions not summarized here. However, the information summarized here is uncontroverted in any of the articles or by other evidence of record and it is accepted as credible.

interventions developed and implemented by Petitioner's staff and the interdisciplinary teams (IDT) for the various residents. The adequacy of the interventions and the fidelity of their implementation are not conceded by CMS. A brief review of the situation of each resident will be helpful to understand the acuity of these residents, the intensity of the care and services that they required, and the interventions that their IDTs implemented to attempt to address their care-planned needs.

(ii.) Resident 28

The situation of Resident 28 is cited as an example under Tags F280 (CMS Ex. 1 at 10-20), F323 (CMS Ex. 1 at 43-60), F353 (CMS Ex. 1 at 93-95), F490 (CMS Ex. 1 at 102-03), F501 (CMS Ex. 1 at 105-06), and F520 (CMS Ex. 1 at 110). The surveyors cited falls by Resident 28 on December 22, 2013; January 10, 2014; January 13, 2014; January 17, 2014; January 30, 2014; January 31, 2014; February 10, 2014; February 22, 2014; February 24, 2014; February 28, 2014; March 12, 2014; March 19, 2014; March 21, 2014; April 1, 2014; and April 5, 2014. CMS Ex. 1 at 44-59.

Resident 28 was admitted to Petitioner on December 14, 2013. CMS Ex. 5 at 112, 227-28. She was 85 years old at admission. CMS Ex. 5 at 227-28. She suffered from Alzheimer's disease, dementia, coronary artery disease with heart failure, hypertension, anxiety, psychosis, hearing loss, a history of falls, chronic urinary tract infections, a history of a hip fracture, constipation, insomnia, weight loss, osteoarthritis, hypertension, chronic obstructive pulmonary disease, and diabetes, among others. CMS Ex. 5 at 170, 192-93, 235-36. Resident 28 received physical therapy to improve her strength, balance, and gait from August 13, 2013 to September 11, 2013, and from September 16, 2013 to September 27, 2013. Following the initial round of therapy, she was able to walk without an assistive device but she needed supervision due to balance issues. However, at the end of September 2013, she required an assistive device and supervision. P. Ex. 22. Occupational therapy notes also show a functional decline between August 12, 2013 and September 27, 2013.[10] P. Ex. 23. Resident 28 was evaluated on April 16, 2014; she required assistance with all activities of daily living, she was under hospice care, and she had contracture of her left lower extremity with evidence of pain on passive motion. The recommendation was for use of a Broda® chair. P. Ex. 24.

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[10] Petitioner's Exs. 22, 23, and 25 are records of physical, occupational, and speech therapy delivered in August and September 2013, prior to Resident 28's admission to Petitioner on December 14, 2013. They show that Resident 28 was a resident of Petitioner prior to December 14, 2013, the date of admission reflected on her initial MDS (CMS Ex. 5 at 27-28). The reason for this discrepancy is not clear but it is not necessary for this decision to investigate further.

Resident 28 was assessed on admission as at risk for falls due to her history, medication, cognitive and communication deficits, incontinence, and need for transfers from her bed. Resident 28's care plan lists interventions implemented at the time of admission, including: activity programming, assessment for pain, placing her bed in the lowest position, keeping the call bell/light and personal items in easy reach, and assistance of one staff member for bed mobility and dressing. CMS Ex. 5 at 114, 123, 142. The admission assessment, the Minimum Data Set (MDS), with an assessment reference date of December 21, 2013, shows that she had moderate difficulty hearing; her speech was unclear; she could be understood sometimes and sometimes understood others; she had long- and short-term memory problems; she was severely impaired in her ability to make decisions; she had attention problems and disorganized thinking; she could not be interviewed about her mood; she was not noted to have signs of psychosis; she was assessed as wandering and at risk for that reason; she was assessed as incapable of being interviewed about her preferences related to activities of daily living; she required the assistance of one person for bed mobility, transfers, toilet use, locomotion on and off the unit but she could walk in her room and the corridor with setup help; she was unsteady but could stabilize herself when standing from sitting, walking, turning around, moving on and off the toilet, and transferring from one surface to another; her life expectancy was noted to be less than six months and she received hospice care. CMS Ex. 5 at 229-48. A significant change MDS with an assessment reference date of January 31, 2014, shows that her behaviors had worsened; her ability to walk had declined and she required extensive assistance with most activities of daily living; she was no longer able to stabilize herself when standing from sitting, walking, turning around, moving on and off the toilet, or transferring from one surface to another; and she was using a wheelchair for mobility. CMS Ex. 5 at 264-66.

On December 22, 2013, at about 1:00 a.m., Resident 28 rolled out of her bed, which was reported to be in the lowest position, onto the floor. She had a reddened area on her low back but no other injury was noted. Interventions noted: bed to be in lowest position and call light in reach. CMS Ex. 5 at 1-5, 110.

On January 10, 2014, at about 7:15 p.m., Resident 28 was found on the floor in front of her bed. She complained that her elbow hurt but otherwise no injuries were noted. She was placed in her wheelchair and moved to the common area for supervision. An undated entry states that fall mats were placed on the floor near her bed. CMS Ex. 5 at 6-10, 107.

On January 13, 2014, at about 4:30 p.m., Resident 28 stood up from her wheelchair and then fell in the dining room before staff could intervene. No injuries were identified at the time. However, an undated note indicates that she subsequently complained of pain and an x-ray showed a left hip fracture. She was sent to the emergency room for evaluation. No interventions are noted. CMS Ex. 5 at 11-15, 105-06.

Resident 28's care plan was updated with interventions on January 10, 13, and 14, 2014. Her care plan was updated to include the following interventions: she was placed in a low chair; a mat was placed beside her bed; and her physician conducted a medication review. CMS Ex. 5 at 114, 143.

On January 17, 2014, at about 11:44 a.m., the resident was found sitting upright on the floor at the foot of her bed. She had a cut on her head. She was transported to the emergency room and staples were used to close the wound. Interventions noted include her bed was placed against the wall to open up the room, a self-releasing belt was placed in her wheelchair, and a bed alarm was implemented for when she was in bed. CMS Ex. 5 at 16-22, 104, 143. Resident 28's physician ordered: that her bed could be against the wall on January 17, 2014; occupational and physical therapy on January 15, 2014; bed bolsters on February 2, 2014; scheduled toileting on February 11, 2014; and fall precautions and fall mats by her bed on March 30, 2014. CMS Ex. 5 at 172.

On January 30, 2014, at about 9:00 p.m., Resident 28 attempted to walk without assistance in the dining room and fell before staff could respond. It is noted that she was noncompliant with waiting for assistance. No injuries were noted. Resident 28 was placed at the nurses' station for one-on-one supervision. Increased supervision was ordered when the resident was up in her wheelchair. A urinalysis culture and specimen were ordered to determine whether she had a urinary tract infection. CMS Ex. 5 at 23-26, 99-100.

On January 31, 2014, at about 10:30 p.m., Resident 28's alarm sounded. When staff arrived in her room she was observed walking without assistance and starting to fall. The staff member caught the resident and lowered her to the floor. No injury was noted. Resident 28's medications were changed due to her increased restlessness and agitation. CMS Ex. 5 at 27-31, 99-100.

Resident 28's care plan was updated on January 31, 2014, to include a urine analysis, culture, and specimen, and supervision for the resident when she was in the dining room. CMS Ex. 5 at 115. On February 6, 2014, her care plan was updated with the intervention for staff to redirect her to her room when she was wandering in the hallway. CMS Ex. 5 at 124, 153.

On February 10, 2014, at about 6:50 p.m., Resident 28 was found on the floor next to her bed crying and complaining of hip pain. Her hip and bottom were noted to be red. The resident was sent to the emergency room for evaluation and no injuries were noted. Interventions included bed alarm, bed bolsters, floor mats at bedside, and putting her bed in the low position. She was placed on a toileting schedule. CMS Ex. 5 at 32-36, 95.

On February 11, 2014, Resident 28's care plan was updated to require that she be on a toileting schedule. CMS Ex. 5 at 115, 143. On February 14, 2014, her care plan was

updated to require evaluation of whether she should be on scheduled pain medication rather than administration of such medication on an as needed basis. The plan was also modified on March 17, 2014, to require staff to monitor for medication side effects. CMS Ex. 5 at 126, 131, 155.

On February 22, 2014, at about 7:14 p.m., Resident 28 was in her wheelchair outside the nurses' station. When she attempted to self-transfer, the right arm of the wheelchair gave way and she fell to the floor. She suffered a skin tear on her right thumb. She was placed in a wheelchair with both arms in working condition. The skin tear was cleaned and a band-aid was applied. CMS Ex. 5 at 37-43, 90. Her care plan was updated to reflect the change in wheelchair. CMS Ex. 5 at 114.

On February 24, 2014, at about 11:20 a.m., Resident 28 was found on the floor beside her bed. The bed alarm was sounding. Although the fall was apparently unwitnessed, the investigation determined she was attempting to walk without assistance. No injuries were noted. She was offered toileting; returned to bed which was in the low position; the bed alarm was in place; and the call light in reach. CMS Ex. 5 at 44-48, 89.

On February 28, 2014, at about ten minutes after midnight, Resident 28's bed alarm sounded and she was found on the fall mat next to her bed with the bed bolster. She had a small skin tear on a finger and a small abrasion above her left eye. She was returned to bed, the bolster was properly attached to the bed, the bed pressure alarm was checked for proper functioning, first aid was administered to the skin tear and abrasion, and she was encouraged to drink every two hours. The resident was later moved to a room closer to the nurses' station. CMS Ex. 5 at 49-52, 88. Resident 28's care plan was updated on February 28, 2014, with interventions that required encouraging fluids every two hours with scheduled toileting; ensuring alarms and bolsters are in place and functioning when placing the resident in bed or wheelchair; and the resident was moved to a room closer to the nurse's station. I note that according to the care plan, bolsters were added as an intervention on March 17, 2014, but the evidence shows they were in use as of February 28, 2014. CMS Ex. 5 at 114, 142-43.

On March 12, 2014, at 10:15 a.m., Resident 28 was found in the dining room on the floor in front of her Broda® chair (a specialty wheelchair), which was flipped forward. A video recording showed that she sat up at the foot of the chair causing it to flip forward and her to fall to the floor. She was noted to have redness to the right side of her head. The intervention listed was to offer her rest periods after meals. CMS Ex. 5 at 53-58, 83. The care plan was updated on March 12, 2014, with the intervention to have the resident lie down after meals for rest. CMS Ex. 5 at 114, 142. According to Resident 28's care plan, the Broda® chair was not added as an intervention until March 17, 2014. March 17 is also when the resident was required to have staff feed her all meals, to have one staff member assist her with locomotion, and two staff members were to assist her with transfers. CMS Ex. 5 at 123, 151.

On March 19, 2014, at about 7:00 a.m., Resident 28's bed alarm sounded and she was found on her bedside mat. It is noted that her bed was in the lowest position and the bed bolsters were in place. She had an abrasion above her left eye and a skin tear on her left arm near her elbow. First aid was administered and she was returned to bed with the pressure alarm in place. The intervention noted is to get her up in the morning and assist her to the dining room for breakfast. CMS Ex. 5 at 59-63, 81. The care plan was updated on March 19, 2014, to require staff to get the resident up into her Broda® chair in the morning. CMS Ex. 5 at 114, 142.

On March 21, 2014, at about 8:30 p.m., staff heard Resident 28's bed alarm and found the resident on the floor mat beside the bed. No new injuries were noted. CMS Ex. 5 at 80.

On April 1, 2014, at about 9:45 a.m., Resident 28's bed alarm sounded and staff found the resident on the floor by her bed. There was blood on the bedside table and the resident had a laceration above her right eye with a moderate amount of bleeding that was stopped with a cold compress. Resident 28 was sent to the emergency room for evaluation. The incident report listed the following interventions: furniture near the resident's bed was removed; staff was to ensure the resident's bed was in the low position; and staff was to ensure that fall mats and bolsters were in place. CMS Ex. 5 at 64-68, 76-77, 142.

On April 5, 2014, at about 6:50 p.m., a staff member finished feeding Resident 28 and left her sitting near the dining room while the staff member went to help cleanup. The staff member heard a noise and noted that Resident 28 was on the floor in front of her geriatric chair (a special type of wheelchair possibly the Broda® chair). The fall was unwitnessed. Resident 28 had a skin tear on her right hand and a bruise on her forehead. She was sent to the emergency room for evaluation. Hospice made a medication change and a geriatric psychiatric evaluation was ordered, which was noted in the care plan. CMS Ex. 5 at 69-75, 142.

Nursing notes show that Resident 28 was receiving hospice care; she had poor safety awareness; she required total care and all of her activities of daily living were performed for her; she had frequent anxiety, agitation, confusion, and wandering; she required frequent reminders that she could not stand or walk; she frequently attempted to walk with a very unsteady gait; she would release the safety belt in her wheelchair and attempt to walk triggering her wheelchair alarm; and she frequently triggered her bed alarm attempting to get out of bed unassisted with staff stopping her before a fall occurred. She suffered from pressure ulcers and decreased appetite and fluid intake. CMS Ex. 5 at 74-112.

(iii.) Resident 45

Resident 45 is cited as an example under Tags F280 (CMS Ex. 1 at 24-31), F323 (CMS Ex. 1 at 71-80), F353 (CMS Ex. 1 at 93, 95-96), F490 (CMS Ex. 1 at 102-03), F501 (CMS Ex. 1 at 105-06), and F520 (CMS Ex. 1 at 110). The surveyors cited falls by Resident 45 on December 6, 2013; December 8, 2013; December 15, 2013; January 4, 2014; January 10, 2014; January 22, 2014; February 12, 2014; and February 17, 2014. CMS Ex. 1 at 26-31. The surveyors noted that Resident 45 died on March 7, 2014, due to her disease process and not a fall. CMS Ex. 1 at 31; CMS Ex. 7 at 94, 273.

Resident 45 was admitted to Petitioner on June 4, 2013. She was 89 years old when admitted. Her diagnoses included Alzheimer's disease, hypertension, hypothyroidism, anemia, hyperlipidemia, tremor, atrial fibrillation, and a urinary tract infection. Her physician was Donald Vollmer, M.D. CMS Ex. 7 at 1. She received physical and occupational therapy in October 2013 and December 2013 and speech and physical therapy in January 2014. CMS Ex. 7 at 52, 56, 75-76, 78. Her Alzheimer's care plan included an intervention dated December 9, 2013, for her to stroll throughout the Alzheimer's care unit at will in her wheelchair. CMS Ex. 7 at 126. Her fall prevention care plan included the following interventions added on the date indicated: assess for pain; call light and personal items in reach (or provide a reacher) added June 4, 2013; footwear or non-skid socks were required beginning January 8, 2014, to prevent slipping and her environment was to be clutter free and well-lighted; a bed alarm was authorized during hours of sleep beginning on January 11, 2014; bolsters were added to her bed on January 23, 2014; effective February 12, 2014, the resident was to lie down for short periods throughout the day and a medication review was initiated; and on February 18, 2014, her Ativan was decreased to every 12 hours and there was a stool culture for clostridium difficile (c-diff.). CMS Ex. 7 at 96, 121, 153; P. Ex. 26 at 6. Resident 45 was to have staff assistance of one to two staff as necessary for toileting; transfer assistance of one staff member; therapeutic exercises; assistance of staff for locomotion; dressing and hygiene assistance; stand-by assist of staff with assistive devices (type of device was not specified); assistance with bed mobility; and her call light was to be within reach. CMS Ex. 7 at 111-12, 137; P. Ex. 26 at 16. Her care plan also provided for assistance with activities of daily living and mobility and for rendering care as needed, which were initiated on July 1, 2013. CMS Ex. 7 at 115, 140. She was on a toileting plan effective October 5, 2013. CMS Ex. 7 at 118, 146, 149, P. Ex. 26 at 23.

On December 6, 2013, at about 8:30 a.m., Resident 45 fell in the dining hall when she attempted to stand from her wheelchair and hit her foot on another resident's wheelchair. The fall was witnessed. She suffered a skin tear on her left elbow for which first aid was administered. The resident was taken to her room and placed in her recliner. Causal factors listed were her immobility due to multiple deep vein thrombi in her left leg, her unsteady gait when walking, and her weakness. X-rays were ordered and showed no

bony injury. Occupational therapy was ordered. Staff was directed to ensure her bed and chair alarms were in place as a reminder to the resident to request help. CMS Ex. 7 at 9-13, 50, 68.

On December 8, 2013, at about 7:30 a.m., Resident 45 fell in the dining room when she stood up from her wheelchair and then fell when attempting to sit back down because the wheelchair rolled away. No injuries were noted. The intervention implemented was placing anti-breaks/rollbacks on the wheelchair. CMS Ex. 7 at 14-18, 69.

Occupational therapy was ordered for Resident 45 on December 10, 2013, for 30 days for self-feeding and use of her wheelchair. P. Ex. 27 at 11-14.

On December 15, 2013, at about 2:00 a.m., a CNA found Resident 45 sitting on the floor between the door and her roommate's bed. An old skin tear had opened and was bleeding and the resident complained of pain in her left hip. The resident was noted to be unsteady on her feet with a history of falls. The intervention listed was to place her on a bowel and bladder tracker to evaluate her need for a toileting program. CMS Ex. 7 at 19-23, 73.

Resident 45 was provided physical therapy from December 18, 2013 through January 20, 2014, to improve her bed mobility, strength, ability to transfer from bed to chair and back, and to sit and stand. At the conclusion of the physical therapy she was assessed to require moderate assistance with sitting and standing, moderate to maximum assistance with transfers between bed and wheelchair, and moderate assistance with bed mobility. P. Ex. 27 at 2-3.

On January 4, 2014, at about 1:38 a.m., Resident 45 was found sitting on the floor by her bathroom door. She had been incontinent of bowel. She had a hematoma on her left shin with some bleeding. First aid was administered. Resident 45 was assisted to bed, her brief was changed, and peri-care provided. Dementia, impaired safety judgment, incontinence, bare feet, and unsteady gait are listed as causal or contributing factors. Interventions listed include staff visiting the resident's room more frequently, non-skid socks, keeping the resident's room door open, and a night-light. CMS Ex. 7 at 24-28, 77.

On January 10, 2014, at about 7:16 a.m., Resident 45 was walking in the hall without assistance and fell in front of her room door. She was found lying on her back, and I infer the fall was unwitnessed. No injuries were noted. Non-skid socks were applied and it was verified that her night-light was on. Dementia, incontinence, unsteady gait, and muscle weakness were identified as causal or contributing factors. A bed alarm was added with the specification that it be used only at night when the resident was in bed. Non-skid socks, frequent checks, and a night-light are other interventions listed. CMS Ex. 7 at 29-32.

On January 22, 2014, at about 8:30 p.m., Resident 45 was found lying on the floor on her right side at that foot of her bed with her head against the dresser. She had a large hematoma above her right eye and hematomas at her right elbow and knee. Interventions listed are maintaining her bed in the lowest position, providing adequate lighting in her room, non-skid socks, and a bed alarm. It is noted that the resident's roommate was in Resident 45's bed. Fall mats at bed side were also added as an intervention. CMS Ex. 7 at 2-8, 33-39, 79-80, 282-89.

On January 23, 2014, bolsters were added to the resident's bed and the bed pressure alarm was in place. Early the next morning, Resident 45 removed the left bolster and got out of bed without assistance and her alarm sounded. CMS Ex. 7 at 80.

On February 8, 2014, a progress note at 11:01 p.m. shows that the resident had increased behaviors and confusion. She was constantly trying to walk unassisted. Redirection was not effective. The resident was up in her recliner with the pressure alarm in place. CMS Ex. 7 at 84. On February 9, 2014, she continued to attempt to walk unassisted and was not easily redirected. A note on that date also shows that her antipsychotic medications were ceased to reduce sedation and to attempt to get her to eat. She was noted to be anxious and nervous. A progress note on February 10, 2013, at 11:13 a.m. shows that Resident 45 was in the dining room with visitors when she attempted to push up from her chair; her hand slipped and hit the table, and she suffered a skin tear on her left hand on her knuckles. CMS Ex. 7 at 85-86.

On February 12, 2014, at about 8:30 a.m., the resident stood-up from a rocking Broda® chair, and when she attempted to sit down, she missed the chair and fell to the floor. No injuries were noted. The resident was returned to her bed per her request and the pressure alarm was noted to be in place. Poor safety awareness and poor short-term memory are listed as contributing factors. Interventions listed were to have the resident lie down during the day for short rests, a medication review, and a urinalysis to determine whether she had a urinary tract infection. CMS Ex. 7 at 40-44, 86.

On February 17, 2014, in the early evening, Resident 45 fell while attempting to transfer herself and walk unassisted in the dining hall.[11] She suffered a skin tear and a hematoma or ecchymotic area on the left side of her head. She was assisted back to her Broda® chair. Contributing factors were impaired safety judgment, decreased cognition, and

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[11] The record is unclear regarding what time this fall occurred; the verification of investigation of the fall says it occurred at 6:15 p.m. while progress notes say it occurred at 5:15 p.m. CMS Ex. 7 at 45, 51, 89. It is not necessary to pinpoint the time of the fall, however; the crucial point is that a fall occurred.

inability to request assistance. Interventions included one-on-one supervision in the common area, a decreased Ativan dose, and testing her stool for c-diff. Resident 45's responsible party requested that the resident be sedated or restrained to prevent falls but staff explained that was not possible under facility and state policies on restraint. CMS Ex. 7 at 45-49, 51, 88-89.

Resident 45 was reported to be positive for c-diff., placed on isolation, and antibiotics were started on February 18, 2014. CMS Ex. 7 at 89-90.

(iv.) Resident 94

Resident 94 is cited as an example under Tags F280 (CMS Ex. 1 at 31-36), F323 (CMS Ex. 1 at 80-86), F353 (CMS Ex. 1 at 93, 96),[12] F490 (CMS Ex. 1 at 102-03), F501 (CMS Ex. 1 at 105-06), and F520 (CMS Ex. 1 at 110). The surveyors cited falls on January 4, 2014; January 5, 2014; January 9, 2014; January 23, 2014 (three falls); January 24, 2014.

Resident 94 was admitted to Petitioner on January 3, 2014. Resident 94 was 94 years old when she was admitted. Her diagnoses included: dementia with behavioral disturbance, hypertension, history of urinary tract infections, glaucoma, senility, generalized pain, insomnia, osteoarthrosis, pacemaker, atrial fibrillation, atherosclerosis, and hearing loss. CMS Ex. 8 at 55. There is also evidence that she suffered from depression and anxiety. CMS Ex. 8 at 119. Resident 94 received physical and occupational therapy during her brief stay with Petitioner. P. Exs. 28-29.

Resident 94's fall care plan initiated on January 3, 2014, required an activity program including exercise and television; pain assessment; keeping her bed in the low position; and keeping the call light and personal items in easy reach. On January 4, 2014, encouraging the resident to wear footwear was added as an intervention. On January 5, 2014, a pressure pad alarm was added as an intervention but whether the pad was in her wheelchair or bed or both is not specified. On January 9, 2014, her wheelchair was to be assessed for appropriate size, footrests, and locking and unlocking wheels, and anti-tipper devices were to be added. The fall care plan lists keeping the environment well-lighted and free of clutter; a bedside mat; and moving the resident closer to the nurses' station as interventions initiated on January 23, 2014. The care plan lists a Velcro® seatbelt alarm and transfer to the geriatric psychiatric facility as interventions implemented on January 24, 2014. CMS Ex. 8 at 37, 46, 71.

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[12] The citation refers to Resident 95, but that appears to be a scrivener's error based on the description of the two falls that match the facts for the falls suffered by Resident 94.

On January 4, 2014, at about 3:40 p.m., Resident 94 was found on the floor at the foot of her bed. She was wearing Ted hose with no shoes. The resident admitted she was up walking and fell. No injury was noted. The intervention listed was for the resident to wear non-skid shoes or socks over her Ted hose to prevent slipping. CMS Ex. 8 at 1-6, 67.

On January 5, 2014, at about 8:30 a.m., Resident 94 attempted to self-transfer from her wheelchair to a regular chair and fell. The fall was witnessed. No injury was noted. Interventions listed were adding a pressure pad to her wheelchair and a physical therapy evaluation. Contributing factors included the resident often attempting to stand without assistance, weakness, unsteady gait, and while she stated she understood she should not stand without assistance she continued to attempt to do so. Notes reflect that family asked for restraints and Petitioner staff advised that was not possible. CMS Ex. 8 at 7-11, 67.

On January 9, 2014, at about 5:30 a.m., Resident 94's alarm sounded and staff saw the resident standing holding the handrail in the hall; when she attempted to sit down, her wheelchair rolled away and she fell to the floor. Resident 94 suffered a hematoma on her left hand. It is noted that the wheelchair alarm worked, the resident had on her non-skid socks, and the hallway was well-lighted. It is also noted that the resident's cognitive status had declined. Interventions listed included a trial of a seatbelt alarm rather than the pressure pad alarm and testing for a urinary tract infection. CMS Ex. 8 at 12-15, 65.

Progress notes show that Resident 94 was able to undo her safety belt at will and she frequently attempted to stand unassisted. Staff could not appease the resident, who had little ability to understand staff. Progress notes show that on January 15, 2014, staff was providing one-to-one care. From January 16 to 22, 2014, Resident 94 was resisting care, hitting staff, yelling, and undoing her safety belt at will and, one time, she stood unassisted but without falling. CMS Ex. 8 at 57-63.

On January 23, 2014, Resident 94 had three falls, the first at 2:45 a.m., the second at about 10:00 a.m., and the last at about 2:00 p.m. CMS Ex. 8 at 16-32. At about 2:45 a.m. on January 23, staff heard the resident's alarm and found her on the floor in her room. Resident 94 suffered a laceration at her left eye. She was placed in a chair with an alarm near the nurses' station and was then taken to the hospital. Cognitive decline is listed as a contributing factor. Her bed was noted to be in the low position. Interventions listed are floor mats at bed side and moving the resident closer to the nurses' station. CMS Ex. 8 at 16-20, 56-57. At 10:00 a.m., Resident 94 was with a staff member in the bathroom. The resident was sitting near the edge of her chair and staff requested that she scoot back. Staff was holding Resident 94 when she scooted forward rather than backward and staff had to lower her to the floor. No injuries were noted. Dementia and confusion are listed as contributing factors. Interventions listed include changing medication, pain management, and orders for laboratory testing (what tests are not listed).

CMS Ex. 8 at 21-25, 56-57. At about 2:00 p.m., Resident 94 attempted to walk without assistance in a common sitting room and fell. No injury was noted. Her chair alarm was noted to be on and functioning. Her family had just left the facility. Interventions listed are medication change, laboratory testing (what tests are not listed), and a geriatric psychiatric evaluation if there was no improvement. CMS Ex. 8 at 26-31, 56-57.

On January 24, 2014, at about 2:00 p.m., Resident 94 rolled out of her bed on to the floor mats at her bedside. Staff had just placed the resident in her bed and the pressure pad was in place. When staff left the room the alarm sounded and when staff re-entered the room the resident was seen rolling out of bed and onto the mat. No injuries were noted. It is noted as a contributing factor that Resident 94 had increased behaviors and was pending transfer to a geriatric psychiatric facility. The only intervention listed is her transfer to the geriatric psychiatric facility. CMS Ex. 8 at 32-36, 55, 119.

(v.) Resident 111

The case of Resident 111 is cited as an example under Tags F280 (CMS Ex. 1 at 20-24), F323 (CMS Ex. 1 at 60-71), F353 (CMS Ex. 1 at 93, 95, 97), F490 (CMS Ex. 1 at 102-03), F501 (CMS Ex. 1 at 105-06), and F520 (CMS Ex. 1 at 110). The surveyors cited falls on August 16, 2013; August 26, 2013; November 25, 2013; December 25, 2013; January 10, 2014; February 8, 2014; and March 27, 2014.

Resident 111 was admitted to Petitioner on July 10, 2012. He was 77 years old when admitted. He suffered from senile dementia with psychosis, Parkinson's disease and Parkinsonism, depression, a malignant neoplasm of the prostrate, asthma, urinary incontinence, diarrhea, abnormal gait, atherosclerosis, and congestive heart failure, among others. His physician was Donald Vollmer, M.D. CMS Ex. 6 at 1-2, 112, 125, 235, 550-51, 593. Resident 111 was under hospice care beginning about May 23, 2013, through the balance of his stay with Petitioner. CMS Ex. 6 at 47-97, 126. Progress notes placed in evidence, show that Resident 111 was often confused, often had an unsteady gait, wandered aimlessly, was often seeking to exit the facility, he was found naked several times in other resident rooms, he assaulted another resident and staff, and he attempted to pull and/or coax one or more female residents to leave with him after confusing them with his deceased wife. He had repeated urinary tract infections that required treatment with antibiotics. CMS Ex. 6 at 47-112. On or about May 7, 2013, physical therapy was ordered as a way to improve the resident's balance and gait problems due to lower extremity weakness so that he could safely walk without assistive devices and to improve his balance. CMS Ex. 6 at 128, 582-83.

A care plan to address Petitioner risk for falls was initiated on July 19, 2012. He was assessed as at risk for falls due to medication, history of falls, Parkinson's, unsteady gait, cognitive and communication deficits, and his need for assistance with transfers. Interventions listed include activities, assessment for pain, keep his call light and personal

items in reach, a fall mat at bedside, the use of footwear to prevent slipping, keeping his environment well-lighted and free of clutter, the use of a wheelchair, observing for the side effects of medication, medication review, therapy referral, and a toileting schedule. CMS Ex. 6 at 166. Another care plan document reflects additional interventions ordered including, placing non-skid strips at the sides of his bed, use of a Broda® chair, bed and chair alarms, and use of a colored toilet seat. CMS Ex. 6 at 202-03. Physician orders include placing a fall mat at the bedside; a toileting schedule, hospice care on June 7, 2013; use of a wheelchair and a Broda® chair; bed and chair alarms. CMS Ex. 6 at 235, 237, 254-57, 260, 266, 270.

On August 16, 2013, at about 11:05 p.m., Resident 111 was found sitting on his buttocks in the doorway to his room. The fall was unwitnessed. No injuries were noted. The resident was placed in his bed. The noted intervention required that staff monitor his footwear and encourage the resident to have on footwear when walking. CMS Ex. 6 at 3-7. A progress note records this fall as occurring on August 17, 2013, at about 3:16 p.m. CMS Ex. 6 at 104.

On August 26, 2013, at about 9:00 p.m., the resident was found sitting on his buttocks in the doorway of another room. He was not wearing shoes when found. He complained of pain in his right great toe. It is recorded that 30 minutes prior to the fall he was observed with only one shoe on and staff assisted with putting on the second shoe. No injuries were noted other than the complaint of toe pain. The fall was unwitnessed. The intervention listed required staff to remind the resident to wear shoes or nonskid socks. It was noted that Resident 111's dose of Klonopin was increased on August 18, 2013, and that he had two falls thereafter. The note indicates the physician then reviewed and reduced the dosage of Klonopin. CMS Ex. 6 at 8-12. Progress notes show that the resident was also moved to a new room and his medication was adjusted. CMS Ex. 6 at 101-102.

Although not cited by the surveyors, Resident 111 also fell on November 17, 2013, at about 7:30 a.m. Resident 111 was walking unassisted to the dining hall for breakfast. He suffered a skin tear on his left elbow and an abrasion on his left knee. It was noted that the resident's slacks were too big and had fallen below his knees. He fell when he reached down to pull up his pants. It was noted that he had a very unsteady gait, he was receiving hospice services, and he had declined with increased weakness and tremors. Interventions listed included using a wheelchair to aide his mobility and a bed and chair alarm for safety cuing. CMS Ex. 6 at 13-17. A progress note speculates that the resident may have suffered strokes on November 16 and 17, 2013, based on observed right side weakness, dragging of the right leg, and right face and eye droop. CMS Ex. 6 at 84.

On November 25, 2013, at about 3:15 p.m., Resident 111 was sitting at the dining room table eating a snack and he spilled his milk. Before the nurse who was using the phone could react, the resident stood, lost his balance, and fell to the floor. He reopened an old

skin tear on his left arm and he had a bruise on his head. He was lifted up and first aid was performed. It was noted that the resident had become more unsteady and, due to cognitive loss, he continued to attempt to stand and walk independently. The intervention listed was to use a Broda® chair. CMS Ex. 6 at 18-21. Progress notes show that there was a pressure alarm in the resident's chair and bed. The notes reflect that at the time of the fall the resident was alert but confused as usual, and that he had not slept the previous night or during the day; he was anxious, he continued to attempt walking unassisted, he had an unsteady gait, and he needed close supervision. CMS Ex. 6 at 79-81.

On December 25, 2013, at about 10:58 a.m., Resident 111 reported to the certified nursing assistant (CNA) that he fell in his bathroom. No injury was noted. Possible causes for the fall noted were the resident walks with a slightly unsteady gait, he had impaired safety judgment, he wandered aimlessly, and he had Parkinson's. The intervention noted was the installation of a colored toilet seat to help orient the resident to the toilet, which was a problem due to his visual changes and dementia. CMS Ex. 6 at 22-27. Progress notes show that he continued to wander the halls and into other resident rooms, his gait was unsteady, he was exit seeking, he was not easily redirected, his call light was kept in reach when he was in bed, he was confused, and he was unable to follow simple instructions. CMS Ex. 6 at 73-74.

On January 10, 2014, at about 4:15 p.m., Resident 111 reported that he fell in his bathroom and hit his head on the tub. It was noted he had a bruise on the left side of his forehead. Afternoon activity to be offered was listed as an intervention. The resident continued to aimlessly wander in the halls with an unsteady gait and confusion. CMS Ex. 6 at 28-31, 66-67, 71-72.

On February 8, 2014, at about 10:28 a.m., Resident 111 walked on the carpet that was damp from cleaning and he apparently slipped and fell when he stepped on to the tile floor. He suffered a small abrasion on his left knee with some swelling. The interventions noted were using fans to dry the carpet and having the nurses supervise residents in the common area when fans were in use. A verbal order was also received to apply heat to the knee. CMS Ex. 6 at 32-37, 65, 69-70.

On March 25, 2014, Resident 111 was given a new prescription for Depakote after he had increased anxiety or agitation; was wandering in the halls; entered another resident's room and tried to pull a female resident out of her bed; and was pushing and pulling on the windows and exit doors. His wandering and exit seeking behaviors decreased and he was more easily redirected. His walking was noted to be unsteady at times. CMS Ex. 6 at 51-64.

On March 27, 2014, at about 2:15 p.m. a visitor reported to a CNA that a resident had fallen. The CNA found Resident 111 sitting naked on his bed with a puddle of urine on

the floor, and the resident stated that he fell twice. Resident 111 had an abrasion on his right knee and lower back and a skin tear on his upper right arm. The resident was placed on a toileting schedule. Subsequently, the resident was walking about the unit without difficulty, and when he was observed running in the hall staff stopped him and asked him to walk for safety. CMS Ex. 6 at 38-42, 50.

Although not listed in the survey, Resident 111 also fell on March 29, 2014, at about 1:30 a.m. It was noted that he had two raised areas on the right side of his forehead. He was sent to the emergency room for evaluation. His altered mental status was listed as a contributing factor. A fall mat was ordered to be placed at his bedside. CMS Ex. 6 at 43-46. A progress note dated March 30, 2014, at 2:44 p.m. shows that the residents face was purple and his forehead split open. He continued to try to walk and cursed and tried to hit staff. CMS Ex. 6 at 48-49.

Resident 111 died on April 1, 2014, while a resident of Petitioner. CMS Ex. 6 at 2, 553.

(vi.) Resident 112

The case of Resident 112 is cited by the surveyors as examples under Tags F280 (CMS Ex. 1 at 36-39), F323 (CMS Ex. 1 at 86-90), F353 (CMS Ex. 1 at 93, 97), F490 (CMS Ex. 1 at 102-03), F501 (CMS Ex. 1 at 105-06), and F520 (CMS Ex. 1 at 110-11). The surveyors cited falls by Resident 112 on December 29, 2013; January 8, 2014; January 31, 2014; March 10, 2014; March 14, 2014; and March 27, 2014. CMS Ex. 1 at 36-38.

Resident 112 was admitted to Petitioner on December 13, 2013. She was 64 years old when admitted. Her diagnoses included dementia with behavioral disturbance, adjustment disorder with depressed mood, anxiety, history of falls, generalized pain, diabetes, and hypertension. She was noted to have confusion and memory problems, she was incontinent, she did not seem to understand when she was spoken to and she could not be understood except for yes and no answers, she had a steady gait, she wandered the halls, and she entered other resident's rooms. CMS Ex. 9 at 48-49, 59. Resident 112 was assessed as having little or no safety awareness or boundaries related to the personal space of others. The plan of care was for her to be allowed to wander but redirected as necessary for safety and to minimize disturbance of others. CMS Ex. 9 at 60, 68, 87. She was also assessed as at risk for falls due to her history of falls, her wandering, and the fact that she was in a new environment. Interventions initiated on January 8, 2014, were to keep her bed in the low position; maintain her call light and personal items in easy reach; wear footwear or non-skid socks to prevent slipping; keep the environment free of clutter and well-lighted; and orient her to her new room and roommate. On February 3, 2014, staff was to be educated on the use of non-skid socks and shoes to prevent falls. On March 10, 2014, a mat was placed beside the resident's bed. CMS Ex. 9 at 62. On March 14, 2014, a scoop mattress was added as an intervention. On March 27, 2014, the resident was given a toileting schedule. On March 30, 2014, Resident 112 was to be

encouraged to have periods of rest in bed throughout the day. An undated, hand-written note indicates that her night stand was to be removed. CMS Ex. 9 at 70, 89. Resident 112's care plan required the assistance of one or two staff for bed mobility, dressing, toileting, and hygiene. She required the assistance of one staff member for locomotion and for eating. CMS Ex. 9 at 63, 78, 97. Her care plan required assistance as needed for activities of daily living and mobility. She was to be monitored during mealtime if needed. CMS Ex. 9 at 64, 80, 99. Her care plan provided that she was to be allowed to walk through the unit at will. CMS Ex. 9 at 66, 82, 101. She was to be monitored for lightheadedness. CMS Ex. 9 at 76, 95. Physical and occupational therapy was considered and determined not to be necessary. CMS Ex. 9 at 171-74; P. Exs. 31, 32.

A progress note dated December 29, 2013, at 1:09 a.m. shows the resident was up wandering much of the night; she was difficult to redirect even when staff provided one-to-one supervision; she was unwilling to stay in bed; there was increased confusion; and her speech was disorganized. CMS Ex. 9 at 49. Resident 112 wandered the halls at all hours, entered the rooms of other residents, and was difficult to redirect throughout her stay with Petitioner. CMS Ex. 9 at 48-59.

On December 29, 2013, at about 3:56 p.m., Resident 112 was walking in the hallway with other residents and tripped when another resident in a wheelchair crossed her path. No injuries were noted. Interventions noted were to keep pathways clear and try to minimize resident congestion in areas to avoid them running into each other. CMS Ex. 9 at 1-5, 41-43, 49-50.

Progress notes dated January 2 and 4, 2014, show that Resident 112 walks looking straight ahead and does not notice anything below neck-level. Also noted is that the resident continued to grab at people and staff walking in the hall. CMS Ex. 9 at 50-51.

On January 8, 2014, at about 3:00 a.m., Resident 112 was found in her room in front of her bed lying on her left side with her shoulder against her bedside table. The resident had an old abrasion to her right knee with a scab in place and no fresh bleeding. No other injury was noted. Resident responded yes when asked if she was attempting to go to the bathroom. The resident was taken to the bathroom and then placed in the dining room with staff. Non-skid socks were placed on the resident. The fact the resident had nothing on her feet was listed a contributing factor. Notes indicate the resident had been taken to the toilet 40 to 45 minutes before the fall. CMS Ex. 9 at 6-11, 44-46, 51.

On January 31, 2014, at about 10:00 p.m., Resident 112 was found on the floor near the exit door close to the nurses' station. No injuries were noted. She was placed in the common area for better supervision. A contributing factor listed is that the floors are being redone and the resident fell where the new floor ended. The listed interventions included non-skid socks and ensuring staff knew that residents are to wear non-skid socks or shoes. CMS Ex. 9 at 12-16, 54; P. Ex. 30 at 1-3.

On March 10, 2014, at about 4:40 a.m., Resident 112 was yelling and when staff entered her room the resident was on the floor beside her bed. The resident suffered a one-inch laceration to her right eyebrow. The intervention noted is the addition of fall mats at bedside. CMS Ex. 8 at 17-21, 55-56.

On March 14, 2014, at about 4:30 a.m., staff heard noise from Resident 112's room. Staff found the resident on the floor at bedside with her non-slip socks on and her blanket wrapped around her feet. The resident reopened the laceration above her right eye and a hematoma developed in that same area. The intervention listed is to use a scoop mattress or a perimeter mattress on the resident's bed. CMS Ex. 9 at 22-26, 56-57.

On March 27, 2014, at 2:40 a.m., Resident 112 was found lying on the floor in the hall. It is noted that the resident wanders the hallway, on her own, throughout the night. She suffered a laceration on her left cheek. It is noted that the resident did not want to lie down in bed. Interventions listed are non-skid socks, observing the resident for unsteady gait when she gets out of bed, incontinence care every two hours and as necessary, and encouraging fluids and snack every shift. Contributing factors listed include Alzheimer's disease, disorientation, insomnia, history of falls, and narcotic and anti-psychotic use. CMS Ex. 9 at 27-35, 58.

On March 30, 2014, at about noon, Resident 112 was found on the floor near her roommate's bed. Resident 112 was covered with a blanket and she appeared to be sleeping. No new injuries were noted. It is not clear whether the resident fell or simply lay on the floor to sleep. It is noted that the resident had been up without much sleep during the two previous shifts. The intervention listed is to encourage rest periods in bed. CMS Ex. 9 at 37-40, 59; P. Ex. 30 at 4-6.

(vii.) Facility Fall History and Quality Assurance (QA)

Petitioner offered QA records that reflect the following history of falls in all units of Petitioner's facility. P. Exs. 16, 17, 18. It is not possible from the records provided to determine how many falls occurred in the ACU in May, June, and July 2013, as that data is not included.

Month Year	Total Facility Falls	ACU Falls
April 2013	25	13
May 2013	30	
June 2013	20	

Month Year	Total Facility Falls	ACU Falls
July 2013	18	
August 2013	21	10
September 2013	18[13]	11
October 2013	13	10
November 2013	20	8
December 2013	**27**	**19**
January 2014	**50**	**33**
February 2014	**26**	**22**
March 2014	**24**	**15**
April 2014	18	9

QA notes from QA meetings that Petitioner placed in evidence show that Petitioner's QA team was counting and analyzing falls at least as early as May 2013. P. Ex. 17 at 1-2. Petitioner adjusted work and activity schedules in the summer of 2013. In June 2013, a new work schedule was implemented to ensure that management was in the facility later in the day, nighttime activities for residents were increased, and the activity program in the ACU was being assessed and monitored for implementation. P. Ex. 17 at 3-4. In July 2013, staff was reported to have been increased on the ACU, scheduled nighttime activities were being increased, and the ACU program continued to be assessed and monitored. P. Ex. 17 at 5-6. In August 2013, it was determined that the staff structure on the ACU met resident needs, scheduled nighttime activities met needs, and the activity program on the ACU continued to be assessed and monitored. P. Ex. 17 at 7-8. In September 2013, it was commented that staffing and programming on the ACU continued to be successful. P. Ex. 17 at 9-10. In October 2013, it is noted that staffing on the ACU had to be adjusted daily due to the need for increased supervision for some residents. P. Ex. 17 at 11-12.

In December 2013, falls were noted to be up, but staffing is not mentioned and there were no new interventions listed. P. Ex. 17 at 15-16. In January 2014, falls were noted to have been up in December 2013, but no staffing change or other new interventions are listed to address the increase. P. Ex. 17 at 17-18. Notes from February 2014 reflect that falls were up in January 2014. The February notes also reflect the first interventions to address the increase in falls in December 2013 and January 2014; specifically, a facility-wide education effort for fall prevention was begun and an audit to ensure interventions

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[13] One report provided by Petitioner states the total number of falls in September 2013 was 19 (P. Ex. 17 at 12) but another report shows the total number of falls in September 2013 was 18 (P. Ex. 18 at 6).

(which were not specified) were in place was initiated. P. Ex. 17 at 19-20. Notes of the QA team from March 2014, recognize that falls were down in February 2014, facility-wide education on falls was completed, an audit to ensure implementation of interventions was on-going, and there was to be a focus on activities programming in the ACU due to the number of falls in that unit. P Ex. 17 at 21-22.

Following the surveyor's intervention, notes from April 2014, show that falls were again noted to be down in March 2014, a new report was implemented during shift changes for nurses and certified nursing assistants (CNAs), a new R.N. night supervisor position was opened and filled that was intended to relieve staff on the ACU for lunches and breaks and to provide additional assistance, residents with repeated falls were being reviewed for effectiveness of their interventions, a fall prevention performance improvement project was initiated with a weekly fall review, and there was an increased focus on activities in the ACU to ensure residents were engaged and out of their rooms where a majority of falls occur. P. Ex. 17 at 23-24. Notes from the May 2014 meeting show that implementation of the interventions from April 2014 was proceeding. P. Ex. 17 at 25-26.

(viii.) State Standards for ACUs

There is no dispute that Petitioner's ACU was subject to regulation by the State of Tennessee. Tenn. Comp. R. & Regs. 1200-08-06 (2000). The Tennessee regulation applicable to an Alzheimer's unit requires:

> 1200-08-06-.07 SPECIAL SERVICES: ALZHEIMER'S UNITS. Structurally distinct parts of a nursing home may be designated as special care units for ambulatory residents with dementia or Alzheimer's Disease and related disorders. Such units shall be designed to encourage self-sufficiency, independence and decision-making skills, and may admit residents only after the unit is found to be in compliance with licensure standards and upon final approval by the department. Units which hold themselves out to the public as providing specialized Alzheimer's services shall comply with the provisions of T.C.A. § 68-11-1404 and shall be in compliance with the following minimum standards:
>
> (1) In order to be admitted to the special care unit:
>
> (a) A diagnosis of dementia must be made by a physician. The specific etiology causing the dementia shall be identified to the best level of certainty prior to admission to the special care unit; and,

(b) The need for admission must be determined by an interdisciplinary team consisting at least of a physician experienced in the management of residents with Alzheimer's Disease and related disorders, a social worker, a registered nurse and a relative of the resident or a resident care advocate.

(2) Special care units shall be separated from the remaining portion of the nursing home by a locked door and must have extraordinary and acceptable fire safety features and policies which ensure the well being and protection of the residents.

(3) The residents must have direct access to a secured, therapeutic outdoor area. This outdoor area shall be designed and maintained to facilitate emergency evacuation.

(4) There must be limited access to the designated unit so that visitors and staff do not pass through the unit to get to other areas of the nursing home.

(5) Each unit must contain a designated dining/activity area which shall accommodate 100% seating for residents.

(6) Corridors or open spaces shall be designed to facilitate ambulation and activity, and shall have an unobstructed view from the central working or nurses' station.

(7) Drinking facilities shall be provided in the central working area or nurses' station and in the primary activities areas. Glass front refrigerators may be used.

(8) The unit shall be designed, equipped and maintained to promote positive resident response through the use of:

(a) Reduced-glare lighting, wall and floor coverings, and materials and decorations conducive to appropriate sensory and visual stimulation; and,

(b) Meaningful wandering space shall be provided that encourages physical exercise and ensures that residents will not become frustrated upon reaching dead-ends.

(9) The designated units shall provide a minimum of 3.5 hours of direct care to each resident every day including .75 hours of licensed nursing personnel time. Direct care shall not be limited to nursing personnel time and may include direct care provided by dietary employees, social workers, administrator, therapists and other care givers, including volunteers.

(10) In addition to the classroom instruction required in the nurse aide training program, each nurse aide assigned to the unit shall have forty (40) hours of classroom instruction which shall include but not be limited to the following subject areas:

(a) Basic facts about the causes, progression and management of Alzheimer's Disease and related disorders;

(b) Dealing with dysfunctional behavior and catastrophic reactions in the resident;

(c) Identifying and alleviating safety risks to the resident;

(d) Providing assistance in the activities of daily living for the resident; and,

(e) Communicating with families and other persons interested in the resident.

(11) Each resident shall have a treatment plan developed, periodically reviewed and implemented by an interdisciplinary treatment team consisting at least of a physician experienced in the management of residents with Alzheimer's Disease and related disorders, a registered nurse, a social worker, an activity coordinator and a relative of the resident or a resident care advocate.

(12) A protocol for identifying and alleviating job related stress among staff on the special care unit must be developed and carried out.

> (13) The staff of the unit shall organize a support group for families of residents which meets at least quarterly for the purpose of:
>
> (a) Providing ongoing education for families;
>
> (b) Permitting families to give advice about the operation of the unit;
>
> (c) Alleviating stress in family members; and
>
> (d) Resolving special problems relating to the residents in the unit.

Tenn. Comp. R. & Regs. 1200-08-06-.07 (2000) (emphasis added).

The Tennessee regulation requires that designated Alzheimer's units provide a minimum of 3.5 hours per day of direct care to each resident including 0.75 hours of nursing personnel care time. Direct care may be provided by dietary employees, social workers, the administrator, therapists, and other caregivers, including volunteers. Tenn. Comp. R. & Regs. 1200-8-6-.07(9); P. Ex. 19 at 3; Tr. Vol. 3 at 186-87.

Surveyor Varner testified that at the beginning of the survey, the surveyors gave Petitioner's Administrator a blank copy of the document in evidence as CMS Ex. 33. The Administrator completed the form and returned it to the surveyors. CMS Ex. 33 reflects Petitioner's information for the ACU staffing hours for March 18, 2014 through March 31, 2014. CMS Ex. 33; Tr. Vol. 1 at 121-26, Tr. Vol. 3 at 167-69. Administrator Bodkins testified that she completed CMS Ex. 33 based on Petitioner's payroll records. Tr. Vol. 5 at 166, 176-91. The following table is compiled based on the information in CMS Ex. 33.

DATE	**ACU DAILY CENSUS**	**TOTAL HOURS REQUIRED INCLUDING LICENSED NURSE (35 Residents x 3.5 Hours Direct Care)**	**HOURS DELIVERED INCLUDING LICENSED NURSE**	**+ / - HOURS REQUIRED BY STATE**
3/18	35	122.5	120.2	**-2.3**
3/19	35	122.5	115.87	**-6.63**
3/20	35	122.5	122.4	**-0.1**

DATE	ACU DAILY CENSUS	TOTAL HOURS REQUIRED INCLUDING LICENSED NURSE (35 Residents x 3.5 Hours Direct Care)	HOURS DELIVERED INCLUDING LICENSED NURSE	+ / - HOURS REQUIRED BY STATE
3/21	35	122.5	134.55	+12.05
3/22	35	122.5	111.75	**-10.75**
3/23	35	122.5	112.55	**-9.95**
3/24	35	122.5	126.8	+4.3
3/25	35	122.5	131.92	+9.42
3/26	35	122.5	125.47	+2.97
3/27	35	122.5	142.79	+20.29
3/28	35	122.5	131.18	+8.68
3/29	35	122.5	110.85	**-11.65**
3/30	35	122.5	110.97	**-11.53**
3/31	34	119	125.**	+6
** Decimal places cut-off on copy in evidence.				

The SOD does not specifically allege that Petitioner violated the Tennessee regulation by falling below the minimum 3.5 hours of direct care required by the regulation. Of course, it is not the responsibility of CMS to enforce the state regulation through the federal survey process. However, the data supports findings of fact that Petitioner fell below the minimum 3.5 hours of direct care required by the Tennessee regulation for its ACU on March 18, 19, 20, 22, 23, 29, and 30, 2014. While the Tennessee regulation may not be subject to federal enforcement, the regulation certainly establishes a minimum standard of care for an ACU operated subject to the Tennessee regulations. Petitioner concedes this fact in post-hearing briefing. P. Reply at 13.

(ix.) Surveyors

Surveyors Varner and Skidmore testified in depositions that the facts alleged in the SOD are based on Petitioner's investigation of the various falls. P. Exs. 35 at 34; 36 at 7. Surveyor Skidmore testified that the number of unwitnessed falls caused her particular concern. P. Ex. 35 at 24. Surveyor Varner opined that if a resident fell, the fall had to be assessed and a new intervention added to ensure that the resident does not fall again. P. Ex. 36 at 26-27. Surveyor Varner and Surveyor Skidmore concluded that Petitioner did not have sufficient staff working on the Alzheimer's unit based on their observations during the survey. Tr. Vol. 1 at 131-35.

Surveyor Varner testified that the facility was not cited for failure to provide one-on-one supervision, but rather, because the facility did not provide supervision residents needed to prevent falls. Tr. Vol. 1 at 140-41. Surveyor Varner testified on cross-examination that she did not know how many falls one might expect in an Alzheimer's unit or whether the number of falls on Petitioner's unit exceeded what one might typically expect. She testified that she and Surveyor Skidmore believed the number of falls on Petitioner's unit was excessive. But she opined that the number of injuries experienced by residents was less than what she would expect given the number of falls. Tr. Vol. 3 at 117-18. Surveyor Varner agreed on cross-examination that residents on an Alzheimer's unit have a right to privacy and there is no requirement that they be under observation at all times. She opined that closer supervision but not one-on-one supervision is required on an Alzheimer's unit. She testified her opinion was based on the fact that Tennessee requires more staffing hours on an Alzheimer's unit than a regular unit. However, she admitted she had no knowledge of the reason for the Tennessee requirement. Tr. Vol. 3 at 123-32. Surveyor Varner testified that she does not believe that the federal regulation requires that a facility change interventions every time there is a fall but the interventions should be reevaluated and an intervention added. She agreed that in this case she found Petitioner deficient because residents fell and no new intervention was added to their care plan. Tr. Vol. 3 at 136-38.

Surveyor Skidmore testified that Petitioner was cited for a deficiency under Tag F323 due to repeated, unwitnessed falls and her conclusion that interventions were insufficient. She felt the resident upon which she focused, Resident 111, required closer supervision, which she described as more constant and consistent observation to give staff better ability to prevent a fall. Tr. Vol. 4 at 52-57. She testified that she agreed with the citation of a staffing deficiency because of the number of unwitnessed falls and because staff from the ACU told her they were short of staff. She explained that the limited staff was so busy taking care of the residents that they simply could not watch all the residents adequately. Tr. Vol. 4 at 70. Surveyor Skidmore agreed during cross-examination that Petitioner had addressed the increase in falls before the survey. Tr. Vol. 4 at 100-06. Surveyor Skidmore testified in response to my questions that not all falls constitute a deficiency and not all falls pose immediate jeopardy. Tr. Vol. 4 at 223-24. She testified that she does not believe that the regulations require that a new intervention be implemented every time there is a fall, which is different from the opinion expressed by Surveyor Varner. Tr. Vol. 4 at 115.

The surveyors are credible. However, I recognize that their opinions were based on limited direct observations, which lessens to a degree the weight of their testimony.

(x.) Petitioner's Management Team and Staff Leaders

Donald Vollmer, M.D., testified that he is the medical director for six long-term care facilities including Petitioner. He is the attending physician for most of the residents in Petitioner's facility. Tr. Vol. 3 at 6-8. He opined that close supervision or one-on-one supervision is not effective to prevent falls in every case and it may increase agitation and behaviors. Tr. Vol. 3 at 14. He opined that alarms do not prevent falls and, in fact, create more agitation for the resident with the alarm and other residents who hear the alarm. He opined that no intervention is 100 percent effective and that changing an intervention simply because a resident fell is not appropriate. He testified that whenever there is a fall in the facility, he and the D.O.N. review medications to determine whether the medication may have contributed to the fall. If the resident is under hospice care they use the hospice nurse to assess level of pain or comfort. He testified there is delicate balance between allowing a resident to be too agitated and over-sedated. He also testified that some interventions, such as physical therapy, are generally not appropriate for those in hospice. Tr. Vol. 3 at 14-20. Dr. Vollmer testified that he is part of Petitioner's QA team. He testified that at the end of 2013 and early 2014, there was a significant increase in falls among residents in Petitioner's ACU. The QA team investigated. Most of the falls were sustained by several residents in the ACU. The residents were demented but ambulatory and subject to more falls than other residents. The investigation found that the residents who were falling in the ACU had severe psychosis, severe agitation, gait disturbance, and were not easily redirected. Some of the residents were near end of life. One of the residents was ultimately determined to be inappropriate for the facility and was transferred to a geriatric psychiatric hospital. Tr. Vol. 3 at 22-25. Dr. Vollmer opined that staffing of the ACU was appropriate both in number and skill set. He testified that his opinion was based on the facts that he was not hearing a lot of alarms going off, he was not receiving complaints from residents and family members, and residents looked clean and cared for. He opined that the amount of supervision provided for residents in the ACU was appropriate. Tr. Vol. 3 at 25-27. In response to my questioning, Dr. Vollmer attributed the increase in falls in the Alzheimer's unit at the end of 2013 to new residents and residents who had declined. Tr. Vol. 3 at 30-31. Dr. Vollmer's testimony was credible and I give significant weight to his testimony. However, I give little weight to his opinion that staffing was adequate on the ACU in December, January, February, and March. Although, Dr. Vollmer may not have been hearing alarms and complaints and the residents looked clean and cared for, he did not testify that he considered whether or not the significant increase in falls may have indicated a need for additional staffing. Accordingly, his opinion was based on fewer than all the facts, and it is not weighty.

D.O.N. Fulmer described the daily meetings conducted at the facility and the process for revising care plans based on daily resident observations. Tr. Vol. 4 at 260-67, 307-09. She also described the QA process at Petitioner. Tr. Vol. 4 at 309-11. She testified that on the ACU, wings D and E, a licensed nurse was assigned to each wing 24 hours each

day. The licensed nurses worked 12-hour shifts. She testified that a CNA, housekeepers, unit director, therapists, dietary staff, social services staff, managers, and others also spent time in the ACU. She testified that she planned for 0.75 hours per resident for licensed nursing staff. She testified that she planned a total of 3.16 for total direct care which, I note, is fewer than the 3.5 hours required by Tenn. Comp. R. & Regs. 1200-08-06-.07(9). Tr. Vol. 4 at 273-77, 322-23. She testified on cross-examination that the level of staffing does need to be responsive to the needs of residents. Tr. Vol. 4 at 323-24. She opined that the level of staffing was adequate in the ACU from January to March 2014 based on her conclusion that the increase in falls was not due to staffing. Tr. Vol. 4 at 325. D.O.N Fulmer did not explain the basis for her opinion that the increase in falls was not due to staffing and, for that reason, I can give her opinion on that point little weight. She explained that Petitioner does not have a policy for providing one-on-one supervision for residents. However, there are brief periods when staff members provide one-on-one care for residents but one-on-one care would not be listed in the care plan. She opined it would not be appropriate to keep a resident on the ACU for a lengthy period if that resident required close supervision, a term she did not define. Tr. Vol. 4 at 303-05. D.O.N. Fulmer testified that in December 2013 and/or January 2014, the QA committee identified a spike in falls on the ACU. The first intervention was staff education on fall prevention, interventions, and dealing with demented residents. She testified that a root cause analysis was done and they identified that only certain residents were having an increase in falls. She testified that after starting interventions, education, and training the number of falls began to decline. She did not explain why education was deemed an appropriate first intervention or more appropriate than another intervention. She agreed with Petitioner's counsel that when one resident was discharged at the end of January, another was discharged at the end of March, and three died in the intervening period, the rate of falls returned to the historic levels from prior to December 2013. Tr. Vol. 4 at 311-13. D.O.N. Fulmer's testimony was credible and worthy of weight except to the extent that she failed to explain why a temporary increase in staffing was not considered or deemed an appropriate intervention to address the need to reduce the risk for falls and related injuries to the five residents identified as the source of the increase in falls.

R.N. Jenkins-Clark, Petitioner's MDS coordinator, testified as to her role in assessing and care planning for residents. Tr. Vol. 4 at 344-51. R.N. Jenkins-Clark testified to her role in the QA process. She agreed that at the end of 2013 and beginning of 2014 there was evidence of a spike in falls in the Alzheimer's care unit that was discussed by the QA team. The team looked at the falls for the individual residents. Tr. Vol. 4 at 353-57. R.N. Jenkins-Clark was credible.

L.P.N. Jessica Hill testified that she worked in the ACU at the time of the survey and she had worked in that unit for approximately seven and a half years. She described how unit staff members are aware of resident care plan requirements. Tr. Vol. 5 at 9-18. L.P.N. Hill worked on the D hall and testified that staffing was a licensed nurse at all times and

two CNAs at some times and one CNA at others for 11 residents, as well as other staff. The ACU director, a psychologist, was present full-time during the day. Dietary staff dropped off meals which nursing staff served family style. One full-time housekeeper cleaned the unit. The hospice nurse came one day per week to assess residents and visit with families, and hospice CNAs visited twice a week to shower the residents on hospice. A nurse practitioner visited Sunday and Tuesday and the Medical Director visited on Thursday. A restorative CNA visited the unit daily. Therapy staff also visited residents receiving therapy. The MDS nurse was on the unit daily, and the D.O.N. did rounds two or three times per day. Petitioner's Administrator also visited the unit. The facility activity director visited the unit but the nurses and CNAs that worked on the unit supervised most activities. Admissions staff also gave tours during the day. All staff answered call lights. She opined that staffing of the Alzheimer's unit was adequate for the residents on the D unit, but she did not explain the basis for that opinion and it is entitled to little weight. She testified that nurses on the D and E unit would cover for each other. She testified that the residents in the Alzheimer's unit were different than other facility residents because they were ambulatory and their mood could change dramatically and rapidly. Tr. Vol. 5 at 22-35, 63. On cross-examination she testified that the number of falls on the Alzheimer's unit increased in late 2013 and early 2014. She attributed the increase in falls to the worsening condition of the residents. Tr. Vol. 5 at 54-55.

Terri Bodkins, Petitioner's Executive Director or Administrator, testified generally as to the function of the IDT, care planning, and addressing falls. Tr. Vol. 5 at 78-94, 100. She testified that every fall was evaluated by the IDT and a decision was made as to the interventions to implement based on what was known about the fall and resident. Tr. Vol. 5 at 94-97. Administrator Bodkins testified as to staffing of the ACU (the D and E units) that a nurse was scheduled 24 hours, usually an L.P.N. but sometimes an R.N. Shifts were 12 hours. Typically three CNAs were assigned to the 24-bed E unit during the day and night. She testified that for the 18-bed D unit usually 1 or 2 CNAs were assigned. Staffing was reviewed daily considering the census, what was reported on the 24-hour report, anticipated admissions and discharges, and general needs of the facility. She testified that all facility staff had 12 hours of dementia training. She testified that she did not believe that staffing had any correlation to falls and so falls were not considered in assessing staffing. But she did not testify as to the basis for her belief that staffing had no correlation to falls and that opinion is entitled to little weight absent some explanation. She testified that the acuity of patients was considered in deciding the staffing level, but she did not specifically relate resident falls to acuity. Tr. Vol. 5 at 107-10. Again this opinion was not explained. Common sense suggests that the more demented and physically unstable a resident becomes the more staff assistance the resident will require. She testified that others are present in the ACU in addition to the licensed nurse and CNAs, including a restorative CNA and supervisor, the MDS coordinator, the director of clinical education, the D.O.N., hospice nurse and CNAs, the CNA who was the supply clerk, dietary supervisor and dietary staff, the activities director, the marketing and

admissions director, the ACU director, and others. She testified that all staff members provided assistance to residents. Tr. Vol. 5 at 110-19. She testified that she prepared P. Ex. 20 from payroll records to help the surveyors understand staffing on the Alzheimer's unit on various dates from August 16, 2013 through April 5, 2014. Tr. Vol. 5 at 129-32. However, because that document does not reflect the census for the D and E units of the ACU on those days the document does not help determine whether or not Petitioner's staffing of the ACU met the minimum requirements of 3.5 hours of direct care required by the Tennessee regulation (Tenn. Comp. R. & Regs. 1200-08-06-.07(9)). She testified that the QA committee addressed the spike in falls in the Alzheimer's unit prior to the survey. Interventions implemented included staff education covering fall prevention, use of restraints, and alarms, beginning in January 2014. She testified that she observed that falls declined after education began. She opined that the QA program worked as intended. Tr. Vol. 5 at 136-42. She did not explain why education was thought necessary or deemed to be the most appropriate intervention to implement first.

b. Analysis

Petitioner stresses in briefing that Petitioner's ACU is a specialized unit with specialized features, operations, program, and a dedicated staff intended to accommodate the special needs of ambulatory residents suffering from Alzheimer's, dementia, and related symptoms. Petitioner points out that Petitioner' ACU is subject to Tennessee regulations that apply to the handful of ACUs in the state. Petitioner agrees that every resident in the ACU was at risk for falls due to cognitive impairment, wandering, declining health, specific diagnoses such as Parkinson's disease, and such accident hazards as tripping, poor balance, and rolling out of bed. Petitioner argues that the surveyors lacked understanding of Petitioner's ACU and failed to consider how the federal regulations should apply to the unique facility. Petitioner also complains that the surveyors did little more than collect Petitioner's records and allege noncompliance based on those records. Petitioner argues that the surveyors wasted most of the time during the survey reviewing and attempting to decipher Petitioner's payroll and electronic care plan records rather than actually spending time on the ACU with residents and their families. Petitioner asserts that the survey was flawed. P. Br. at 2-4; P. Reply at 1-5. Petitioner is well aware, as the regulation is clear, that inadequate survey performance does not relieve a long-term care facility of its obligation to meet all program participation requirements. Inadequate survey performance also does not invalidate adequately documented deficiencies. 42 C.F.R. § 488.318(b). It is not my task to review the surveyors' performance, which is only relevant to the extent it impacts upon the credibility and weight of their findings and conclusions. My task is to conduct a de novo review and determine whether the competent evidence shows that there was a violation of statutory or regulatory participation requirements that posed a risk for more than minimal harm and thereby constituted a basis for the imposition of an enforcement remedy. *Bardstown*, DAB No. 2479 at 32; *Salem Woods*, DAB No. 2052; *Cal Turner*, DAB No. 2030; *Beechwood*, DAB No. 1906; *Emerald Oaks*, DAB No. 1800 at 11.

The deficiencies alleged by the surveyors and on review before me are cited under 42 C.F.R. §§ 483.20(d)(3) and 483.10(k)(2) (Tag F280) (assessment and care planning); 483.25(h) (Tag F323) (quality of care, specifically accident prevention); 483.30(a) (Tag F353) (sufficient staffing); 483.75 (Tag F490) (administration); 483.75(i) (Tag F501) (medical director); and 483.75(o)(1) (Tag F520) (quality assessment and assurance). All deficiencies at issue are related to the resident falls described in my findings of fact.

The analysis of the deficiencies must begin with a review and understanding of the regulatory scheme. The regulation that requires resident assessment and care planning is 42 C.F.R. § 483.20. A facility "must conduct initially and periodically a comprehensive, accurate, standardized, and reproducible assessments of each resident's functional capacity." 42 C.F.R. § 483.20. The regulation requires that assessments be conducted or coordinated by an R.N. with the appropriate participation of other health professionals. 42 C.F.R. § 483.20(h). Pursuant to 42 C.F.R. § 483.20(d), the facility must "use the results of the assessments to develop, review, and revise the resident's comprehensive plan of care." Pursuant to 42 C.F.R. § 483.20(k)(1), the "facility must develop a comprehensive care plan for each resident that includes measurable objectives and timetables to meet a resident's medical, nursing, and mental and psychosocial needs as identified in the comprehensive assessment." The comprehensive care plan must be prepared by an IDT that includes the attending physician, the R.N. responsible for the resident, and other appropriate staff in disciplines necessary to meet the resident's needs. 42 C.F.R. § 483.20(k)(2)(ii). The services provided or arranged by the facility must meet professional standards of quality and must be provided by qualified persons in accordance with the written plan of care. 42 C.F.R. § 483.20(k)(3). The regulation specifically requires that assessments be done and reported to CMS, including at admission, annually, and when there is a significant change, and there is a requirement for a quarterly review. 42 C.F.R. § 483.20(f)(1)-(3). However, the regulation should not be read to suggest that these are the only assessments. A facility is obligated to ensure that the assessment accurately reflects the resident's status. 42 C.F.R. § 483.20(g). Therefore, assessing a resident should be a continuous process to ensure that the assessment accurately reflects a resident's status. The comprehensive care plan for a resident must be reviewed and revised by the IDT after each assessment. 42 C.F.R. § 483.20(k)(2)(iii). Again this requirement should not be viewed as limited to those assessments required to be reported to CMS. Rather, the comprehensive care plan needs to reflect services necessary to meet the resident's needs based on the comprehensive assessment as it is revised to reflect the resident's correct current status. Revision of the assessment and care plan is necessary as often as it is necessary to ensure that the resident's status and need for care and services are accurately identified and met. The comprehensive care plan must describe the services that are to be furnished to assist the resident to attain or maintain his or her highest practicable physical, mental, and psychosocial well-being as required by 42 C.F.R. § 483.25. Appellate panels of the Board have addressed the care planning requirements in several cases.

> The Board has explained that a comprehensive care plan "functions as a roadmap for all of the resident's caregivers, including those unfamiliar with a resident or without professional training, to provide consistent care and services tailored to 'attain or maintain the [resident's] highest practicable physical, mental and psychosocial well-being.'" *Sheridan Health Care Ctr.*, DAB No. 2178, at 37 (2008), quoting 42 C.F.R. § 483.20(k). "Accordingly, the care plan must include sufficient guidance to ensure that the services provided promote the plan's specified objectives." *Id.*

Deltona Health Care, DAB No. 2511 at 18 (2013) (concluding that a care plan did not provide staff adequate guidance to ensure a resident received required care where it required monitoring but did not specify who was to monitor, how often monitoring was to occur, or how the monitoring was to be done); *Britthaven of Havelock*, DAB No. 2078 at 12-14 (2007) (physician order found insufficient as a care plan).

The quality of care regulation, 42 C.F.R. § 483.25, requires that Petitioner provide and ensure its residents receive the care and services necessary for the residents to attain their "highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care." Among many other quality of care requirements, Petitioner is required to ensure that: (1) "[t]he resident environment remains as free of accident hazards as possible;" and (2) "[e]ach resident receives adequate supervision and assistance devices to prevent accidents." 42 C.F.R. § 483.25(h). An "accident," as that term is used in Tag F323, 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.

Regarding 42 C.F.R. § 483.25(h), CMS instructs its surveyors that the intent of the regulation 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, F323. The CMS interpretation is consistent with a long line of Board decisions. The Board has provided interpretative guidance for adjudicating alleged violations of 42 C.F.R. § 483.25(h)(1):

> The standard in section 483.25(h)(1) itself - that a facility "ensure that the environment is as free of accident hazards as possible" in order to meet the quality of care goal in section

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

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

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 at 4 (2007); *Century Care of Crystal Coast*, DAB No. 2076 at 6-7 (2007), *aff'd*, *Century Care of Crystal Coast v. Leavitt*, 281 F. App'x 180 (4th Cir. 2008); *Liberty Commons Nursing & Rehab - Alamance*, DAB No. 2070 at 2-3 (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). The Board has often stated that the regulation does not make a facility strictly liable[14] for accidents that occur or a failure to deliver adequate supervision and assistance devices. Rather, it is necessary to look at what the facility did or did not do in any given situation to determine whether the actions of the facility were reasonable and adequate. In *Woodstock* the Board stated that "while the regulations do not make facilities unconditional guarantors of favorable outcomes, the quality of care provisions do impose

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[14] Strict liability is generally considered to be "[l]iability that does not depend upon actual negligence or intent to harm, but that is based on the breach of an absolute duty to make something safe." *Black's Law Dictionary* 934 (8th ed. 2004). *Black's* explains that strict liability is most often an issue in cases involving ultra-hazardous activities or product liability. Strict liability and absolute liability are synonymous. The term liability simply means that one is legally obligated, accountable, or responsible to another or society. *Id.* at 932.

an affirmative duty to provide services (in this case, supervision and devices to prevent accidents) designed to achieve those outcomes to the highest practicable degree." *Woodstock*, DAB No. 1726 at 25. A facility, actually the IDT, which is charged with caring for a resident (42 C.F.R. § 483.20(k)), is permitted the flexibility to choose the methods of supervision it uses to prevent accidents, but the chosen methods must be adequate under the circumstances. Whether supervision is "adequate" depends in part upon the ability of the resident to protect him or herself from harm. *Id*. at 29-30.

> The regulation speaks in terms of ensuring that what is "practicable" and "possible" to do is done. What is thus required of facilities is not prescience but reason and professional judgment in assessing what can be done to make residents (given their special needs) safe, through removing accident hazards, providing appropriate devices, and ensuring adequate supervision.

Glenoaks Nursing Ctr., DAB No. 2522 at 8 (2013) (citing *Josephine Sunset Home*, DAB No. 1908 at 14-15 (2004); *Briarwood Nursing Ctr.*, DAB No. 2115 at 11-12 (2007)).

The surveyors allege the deficiency under Tag F280 on grounds that, based on the surveyors' review of Petitioner's records, Petitioner failed to review and revise the care plans of the five residents after every fall to ensure interventions were appropriate to prevent further falls. The surveyors further allege that the "failure to review and revise residents' care plans, develop, and implement appropriate interventions to prevent falls" placed the five residents involved in immediate jeopardy. CMS Ex. 1 at 8. Surveyor Varner opined that when a resident falls, the fall has to be assessed and a new intervention added to ensure that the resident does not fall again. P. Ex. 36 at 26-27. Surveyor Skidmore testified that she does not believe that the regulations require that a new intervention must be implemented every time there is a fall. Tr. Vol. 4 at 115. Whether or not the regulation literally requires the addition of a new intervention each time there is a fall is not an issue I need to resolve. There is no question that the regulations require assessment of the resident because Petitioner is obliged to prevent accidents and make the resident environment as free of accident hazards as possible. To meet this requirement it is obvious that the resident must be assessed for injury and to determine the possible causes of the fall. The regulations also clearly require that available interventions to eliminate the accident hazard or mitigate accidental injury from hazards must be evaluated and implemented. It is also specifically required that Petitioner provide its residents the supervision and assistive devices necessary to prevent accidents. Under Tag F323, the surveyors specifically allege that Petitioner "failed to provide supervision and effective interventions to prevent falls" for the five residents. CMS Ex. 1 at 40.

Under Tag F353, the surveyors more specifically allege that Petitioner failed to ensure that there was sufficient direct care staff working on the ACU to provide the supervision necessary to prevent accidents, specifically falls. CMS Ex. 1 at 93. The staffing regulation requires Petitioner to provide sufficient numbers of licensed nurses and other nursing personnel to provide nursing care "to all residents in accordance with resident care plans." 42 C.F.R. § 483.30(a). Generally, a facility must have a registered nurse on duty eight consecutive hours each day, seven days per week. 42 C.F.R. § 483.30(b), (c), (d). Otherwise the regulation does not specify a minimum number of hours by specific types of staff. The regulation imposes upon Petitioner the obligation to ensure nursing care is provided to all residents as required by those residents' care plans. Petitioner is obliged under the regulation to determine how much staff is necessary at any given time to provide the supervision and other care and services necessary to meet residents' care plan requirements.

The surveyors allege under Tag F490 that Petitioner's Administrator failed to ensure that residents were appropriately assessed and interventions were devised and implemented. More specifically the surveyors alleged that the Administrator failed to ensure that there was enough staff to supervise the ACU residents at risk for falls. CMS Ex. 1 at 101-02. The regulation requires that Petitioner administer its facility "in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident." 42 C.F.R. § 483.75. The Board has held that a determination that a SNF failed to comply substantially with 42 C.F.R. § 483.75 may be derived from findings that the SNF was not in substantial compliance with other participation requirements. *Stone Cnty. Nursing & Rehab. Ctr.*, DAB No. 2276 at 15 (2009); *Life Care Ctr. of Bardstown*, DAB No. 2233 at 28 (2009); *Britthaven, Inc. d/b/a Britthaven of Smithfield*, DAB No. 2018 at 22 (2006).

The surveyors allege under Tag F501 that Petitioner's Medical Director failed to ensure that Petitioner's fall policy and procedures were implemented. The regulation requires that Petitioner have a physician serve as a medical director who is responsible for implementing resident care policies and coordinating medical care in the facility. 42 C.F.R. § 483.75(i). The surveyors point to the falls of the five residents they cited as evidence that Petitioner's Medical Director failed to implement Petitioner's fall prevention policy. CMS Ex. 1 at 105.

Finally, the surveyors blame Petitioner's QA committee for not doing its job under Tag F520. Every long-term care facility is required to establish a functioning quality assessment and assurance (QA) committee. The regulation requires the following:

> (1) A facility must maintain a quality assessment and assurance committee consisting of—
>
> (i) The director of nursing services;

> (ii) A physician designated by the facility; and
> (iii) At least 3 other members of the facility's staff.
>
> (2) The quality assessment and assurance committee—
>
> (i) Meets at least quarterly to identify issues with respect to which quality assessment and assurance activities are necessary; and
> (ii) Develops and implements appropriate plans of action to correct identified quality deficiencies.

42 C.F.R. § 483.75(o)(1)-(2). Petitioner had the required committee and the committee met more frequently than required and for the required purpose. However, the gist of the surveyors' allegations is that the QA committee failed to satisfy 42 C.F.R. § 483.75(o)(2)(ii) by failing to implement an effective plan of action to address the spike in falls in the ACU. CMS Ex. 1 at 108-12.

I have no difficulty concluding that CMS has made a prima facie showing of noncompliance under Tags F280, F323, F353, F490, F501 and F520. CMS has presented far more than mere allegations.

"Prima facie" means generally that the evidence is "[s]ufficient to establish a fact or raise a presumption unless disproved or rebutted." *Black's Law Dictionary* 1228 (8th ed. 2004). In *Hillman Rehab. Ctr.*, the Board described the elements of the CMS prima facie case in general terms as follows:

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

DAB No. 1611 at 8. In the final *Hillman* decision after remand, the Board explained:

> The ALJ should be able to determine the existence of a prima facie case at the close of HCFA's presentation. Hence, as we pointed out in our first decision, HCFA would lose even if the provider offered no evidence at all, if HCFA did not come forward with evidence sufficient to support a conclusion in its

> favor in presenting its prima facie case. Thus, we held that HCFA must make its case "at the outset."
>
> Once HCFA has established a prima facie case, the provider may then offer evidence in rebuttal, both by attacking the factual underpinnings on which HCFA relied and by offering evidence in support of its own affirmative arguments. An effective rebuttal of HCFA's prima facie case would mean that at the close of the evidence the provider had shown that the facts on which its case depended (that is, for which it had the burden of proof) were supported by a preponderance of the evidence.
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> * * * *
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> The major purpose of requiring HCFA to establish a prima facie case is to assure that the action taken by HCFA has a legally sufficient foundation, if the facts are determined to be as alleged by HCFA (since it would be unfair and inefficient to require a provider to defend against a case that, even if proven, would not suffice to support the action taken). In addition, we concluded that fairness requires HCFA to set out evidence of the factual basis for its action in order that the provider not have to offer a shot-gun defense without adequate notice to respond to the case against it. These purposes are accomplished once HCFA has presented a case sufficient, if not effectively rebutted, to sustain its action. At that point, HCFA has established a prima facie case and, to prevail, the provider must proceed to prove its case by the preponderance of the evidence on the record as a whole.

Hillman, DAB No. 1663 (internal citations omitted). Thus, CMS has the initial burden of coming forward with sufficient evidence to show that its decision to impose an enforcement remedy is legally sufficient under the statute and regulations. CMS makes a prima facie showing of noncompliance if the credible evidence CMS relies on is sufficient to support a decision in its favor absent an effective rebuttal. To make a prima facie case that its decision was legally sufficient, CMS must: (1) identify the statute, regulation, or other legal criteria to which it seeks to hold the Petitioner; (2) come forward with evidence upon which it relies for its factual conclusions that are disputed by the Petitioner; and (3) show how the deficiencies it found amounted to noncompliance that warrants an enforcement remedy, that is, that there was a risk for more than minimal harm due to the regulatory violation. *Evergreene Nursing Care Ctr.*, DAB No. 2069 at 7 (2007).

CMS alleges that there was noncompliance under the six Tags beginning January 13, 2014, and that the deficiencies posed immediate jeopardy through April 28, 2014. The CMS evidence, clinical records of Petitioner, shows that five residents had the multiple falls described under the foregoing statement of facts. Petitioner does not dispute that the falls occurred. It is uncontested by Petitioner that in December 2013 and January 2014 through March 2014, residents in the ACU suffered more falls than in months before and after that period. CMS Ex. 33, which was completed by Petitioner's Administrator at the request of the surveyors, shows that on March 18, 19, 20, 22, 23, 29 and 30, 2014, Petitioner's staffing for direct nursing care on the ACU fell below the level required for an ACU by the Tennessee regulation, and that regulation establishes the presumptive standard of practice for an ACU in that state.[15] Furthermore, though they limited their ability to observe the delivery of care in the ACU, the surveyors' perception was that the staffing level was such that staff on duty were having difficulty delivering the level of care and services residents required during the period of the survey. I conclude that this evidence alone adequately establishes a prima facie showing of noncompliance under all six Tags.

Thus, under the prior Board decisions already cited, the analysis of which I find persuasive, the burden is upon Petitioner to show it was in substantial compliance with participation requirements.[16]

Petitioner summarizes its position in its Reply Brief as follows:

> Petitioner wishes to be clear – it is *not* arguing that it should be excused from liability because confused residents nearing the end of life tend fall [sic] a lot, or there is nothing its staff could have done to prevent any or all of the subject falls. Those conclusions may well generally be true, but Petitioner's defense to CMS' charges in this case is much more direct, that is, that the evidence shows that the subject residents' fall were "unavoidable" – as CMS describes that conclusion in its Interpretive Guidelines – because Petitioner's staff, especially its IDT and nurses, actually assessed each resident's specific risk for, among other things,

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[15] The fact that Petitioner was not cited on a state survey for this violation does not negate the fact that it occurred.

[16] Petitioner's legal challenge to the allocation of the burden of persuasion is discussed under a separate conclusion of law, which rejects Petitioner's reasoning in this case.

> falls; considered, planned and implemented interventions to reduce falls, or to reduce the risk of injury should a resident fall, that were consistent with each resident's other needs, his or her preferences, and what had or had not worked before; and then, if the resident nevertheless did fall, the IDT immediately reassessed, reconsidered and revised interventions as appropriate. It is easy for a surveyor, or even counsel, to speculate after the fact that maybe one or another intervention might have been "better" for a specific resident in specific circumstances. But as discussed in Petitioner's Brief and below, that is not the regulatory standard. Nor, Petitioner suggests, is it a particularly useful practice for deficiencies to be based solely upon surveyors' subjective second-guessing of the IDT's judgments, with no evidence that the IDT violated any governing standard of care.

P. Reply at 5 (emphasis in original). Petitioner's approach is that the surveyors have no standard against which to judge Petitioner's delivery of care and services; Petitioner delivered all reasonable care and services and the resident falls were, therefore, unavoidable; and Petitioner was in substantial compliance at all times. P. Br. There is no dispute that residents fell as alleged in the SOD and as shown by Petitioner's clinical records. P. Br. at 2. There is no dispute that IDTs assessed the five residents involved as at risk for falls, devised and implemented interventions, examined facts related to falls, and then either decided to continue with the same interventions or adopted and implemented new interventions. P. Br. at 15-18. CMS wants to debate the effectiveness and timeliness of the interventions decided upon by the IDT. However the principles for determining compliance are specified by the Secretary's regulations:

> (b) The decision as to whether there is compliance with a particular requirement, condition of participation, or condition for coverage depends upon the manner and degree to which the provider or supplier satisfies the various standards within each condition. Evaluation of a provider's or supplier's performance against these standards enables the State survey agency to document the nature and extent of deficiencies, if any, with respect to a particular function, and to assess the need for improvement in relation to the prescribed conditions.
>
> (c) The State survey agency must adhere to the following principles in determining compliance with participation requirements:

> (1) The survey process is the means to assess compliance with Federal health, safety and quality standards;
>
> (2) **The survey process uses resident and patient outcomes as the primary means to establish the compliance process of facilities and agencies.** Specifically, surveyors will directly observe the actual provision of care and services to residents and/or patients, and the effects of that care, to assess whether the care provided meets the needs of individual residents and/or patients.
>
> (3) Surveyors are professionals who use their judgment, in concert with Federal forms and procedures, to determine compliance;
>
> (4) Federal procedures are used by all surveyors to ensure uniform and consistent application and interpretation of Federal requirements;
>
> (5) Federal forms are used by all surveyors to ensure proper recording of findings and to document the basis for the findings.

42 C.F.R. § 488.26(b)-(c) (emphasis added). The Secretary has not authorized surveyors to determine noncompliance simply because the surveyor may have assessed a resident differently or thought one intervention might be more or less effective than another. The Secretary does not authorize or encourage surveyors to attempt to substitute their judgment for that of a resident's IDT. Rather, the survey process uses resident outcomes to determine whether or not a long-term care facility meets program participation requirements. Therefore, much surveyor testimony and CMS argument in this case about whether one intervention may be better than another is of minimal relevance and, in some cases, no more credible than the surveyor's expertise, training, and education support. Testimony of the treating physician and members of the IDT about why certain interventions were adopted or rejected is highly relevant as the treating physician and IDT were responsible for the care planning decisions reflected in the clinical records and they are, presumably, most knowledgeable of the resident's needs. Of course, credibility is affected by the experience, training, and education of medical personnel employed by Petitioner the same as with the surveyors. Surveyor Varner testified that in her opinion failure to identify and implement a new intervention following a fall, is a basis for citing a deficiency. Indeed, she agreed that in this case she thought Petitioner deficient because residents fell and no new intervention was added to their care plan. Tr. Vol. 3 at 136-38. Surveyor Skidmore disagreed, testifying that in her opinion there is no regulatory or other

requirement to implement a new intervention or to change interventions every time there is a fall. Tr. Vol. 4 at 115. The regulation at 42 C.F.R. § 483.20(k) does not impose a requirement and the parties have identified no standard of practice that requires that a new intervention be implemented or that interventions be changed due to the occurrence of an accident. I conclude that failure to implement a new intervention following a fall, standing alone, is not a sufficient basis to find noncompliance. Surveyor Varner's erroneous understanding of program participation requirements demonstrates the importance of de novo review. I give no weight to Surveyor Varner's erroneous opinion that a new intervention must be implemented for every fall. I review the evidence anew applying the regulations and standards of practice supported by the record to determine whether there is noncompliance.

Petitioner asserts that its interventions for the residents were timely and as effective as could be expected considering the state of the residents on the ACU and the operations of the ACU, and that a fall despite the interventions must be found to be unavoidable. P. Br. at 5, 18-25; P. Reply at 7-12; PFFCL 106-376. Neither Petitioner nor CMS point me to a prescriptive legal or medical authority that either requires or prescribes specific interventions to address a particular set of facts or against which I can judge the interventions adopted and implemented by the IDTs for the ACU residents. The medically trained personnel who testified in this proceeding certainly failed to identify a standard of practice, except to the extent that the Tennessee regulation establishes the minimum number of direct care hours required in an ACU, which is strong evidence of the standard of practice for an ACU in Tennessee. Indeed, the briefs of counsel reflect the absence of any prescriptive legal or medical authority that I can cite as determinative of what interventions should be implemented by an IDT based on a given set of facts. The evidence summarized above shows that the residents' IDTs were actively involved in assessing, implementing interventions, and evaluating the effectiveness of those interventions. Whether the choice of interventions was always the best is not for me to decide, and I have no standard to apply to attempt to make that judgment.

The focus in this case must be upon the adequacy of ACU staffing in light of the increase in falls beginning in December 2013 and continuing through March 2014. The question is whether Petitioner's staffing of the ACU was adequate to attain or maintain the highest practicable physical, mental, and psychosocial well-being of all residents on the ACU as determined by their assessments and plans of care. 42 C.F.R. § 483.30. There is no question that ACU residents had to be ambulatory and many care plans called for the ACU residents to be permitted to ambulate at will. There is no question that ambulating demented residents, many with co-morbidities that affected their stability or safety awareness, were at risk for falling and at even greater risk for falling than non-ambulatory or residents with good safety awareness and physical stability. Given the facts, assessing the adequacy of staff on the ACU to supervise the residents would certainly be necessary to determine whether inadequacy in number or skills of staff may have affected the rise in falls on the ACU. Once Petitioner identified that the rise in the

number of falls could be attributed to five specific residents, the need to assess the adequacy of staffing, both in number and skills, was a necessary line of inquiry or assessment for the resident IDTs, management, and the QA committee.

Petitioner asserts that CMS has presented no evidence as to the minimum level of staffing for Petitioner's ACU required by 42 C.F.R. § 483.30(a) (Tag F353). P. Reply at 13. The regulation requires that a facility have sufficient staff on a "24-hour basis to provide nursing care to all residents in accordance with resident care plans." The regulation requires that a registered nurse be on duty eight consecutive hours, seven days a week, which is subject to waiver under certain circumstances. 42 C.F.R. § 483.30(b). The regulation requires designation of a charge nurse on each tour of duty and the designation of a full-time D.O.N. 42 C.F.R. § 483.30(a)(2), (b)(2). The regulation does not otherwise specify a minimum staffing level. Petitioner states that it "does not disagree with the proposition that there is *some* relationship between staffing and *every* aspect of resident care, including protection against falls and other hazards." P. Reply at 13 (emphasis in original). Petitioner admits that too few staff may be unable to meet resident needs. P. Reply at 13. In terms of 42 C.F.R. § 483.30(a), resident needs include those identified by the IDT, whether or not specifically listed in a written care plan. Petitioner points to the Tennessee regulation that establishes minimum staffing requirements for an ACU as being instructive for me because the regulation reflects a determination as to the minimum staffing required in Tennessee for operating an ACU. P. Reply at 13. I agree with Petitioner. Although it could be argued under general notions of comity that the Tennessee regulation establishes the minimum level of staffing applicable in this federal proceeding, it is not necessary to pursue that analysis. Rather, it is sufficient to recognize that the Tennessee regulation establishes a standard of practice in that state for specific minimum level of staffing for an ACU. Therefore, falling below the minimum staffing specified in Tennessee, as Petitioner's evidence shows it did in March 2014, is good evidence of a deviation from the standard of practice in that state.

Dr. Vollmer testified that he attributed the increase in falls in the Alzheimer's unit at the end of 2013, to new residents and residents who had declined. Tr. Vol. 3 at 30-31. Dr. Vollmer, while acknowledging the increase in falls, did not recognize that the new residents and those who declined might require increased staffing so those residents could receive more direct care. Petitioner's clinical records show that the IDTs and QA committee were very proactive in addressing falls of the five individual residents to whom the increase in falls was attributed. But when the number of falls continued to increase, particularly after December 2013 when first identified by the QA committee and management, it was a clear signal that the root cause of the increase in falls had not been fully identified and addressed.

Petitioner's evidence shows that management was adjusting work and activity schedules in the summer of 2013. In June 2013, a new work schedule was implemented to ensure that management was in the facility later in the day, nighttime activities for residents

were being increased, and the activity program in the ACU was being assessed and monitored for implementation. P. Ex. 17 at 3-4. In July 2013, staff was reported to have been increased on the ACU, scheduled nighttime activities were being increased, and the ACU activity program continued to be assessed and monitored. P. Ex. 17 at 5-6. In August 2013, it was determined that the staff structure on the ACU met resident needs, scheduled nighttime activities met needs, the activity program on the ACU continued to be assessed and monitored. P. Ex. 17 at 7-8. In September 2013, it was commented that staffing and programming on the ACU continued to be successful. P. Ex. 17 at 9-10. In October 2013, it is noted that staffing on the ACU had to be adjusted daily due to the need for increased supervision for some residents. P. Ex. 17 at 11-12. In December 2013, falls were noted to be up, but no new interventions related to staffing are listed in QA records. P. Ex. 17 at 15-16. In January 2014, falls were noted to have been up in December 2013, but no new interventions related to staffing are listed to address the increase. P. Ex. 17 at 17-18. There is also no evidence of any effort to adjust staffing on the ACU to address falls in January, February, or March 2014. Notes from February 2014 reflect that falls were up in January 2014 and that a facility-wide education effort for fall prevention was begun as was an audit to ensure interventions (which were not specified) were in place. P. Ex. 17 at 19-20. Notes of the QA committee from March 2014 recognize that falls were down in February 2014; facility-wide education on fall education was completed; an audit to ensure implementation of interventions was on-going; and there was to be a focus on activities programming in the ACU due to the number of falls in that unit. P Ex. 17 at 21-22. But there is no indication that adjusting staffing levels on the ACU was even considered and rejected by the QA committee as an appropriate intervention to address the increase in falls on that unit. Petitioner's management team did not think that staffing might be an appropriate and necessary intervention; thus, it was not considered and rejected or implemented.

D.O.N. Fulmer described the daily meetings conducted at the facility and the process for revising care plans based on daily resident observations. Tr. Vol. 4 at 260-67, 307-09. She also described the QA process at Petitioner. Tr. Vol. 4 at 309-11. She testified that on the ACU a licensed nurse was assigned to each wing 24 hours each day. The licensed nurses worked 12-hour shifts. She testified that a CNA, housekeepers, unit director, therapists, dietary staff, social services staff, managers, and others also spend time in the Alzheimer's unit. She testified that she planned for 0.75 hours per resident for licensed nursing staff. She testified that she planned a total of 3.16 for total direct care which is actually fewer hours than the 3.5 hours required by the Tennessee regulation. Tenn. Comp. R. & Regs. 1200-08-06-.07(9); Tr. Vol. 4 at 273-77, 322-23. She admitted on cross-examination that the level of staffing does need to be responsive to the needs of residents. Tr. Vol. 4 at 323-24. She opined that the level of staffing was adequate in the Alzheimer's unit from January to March 2014 based on her conclusion that the increase in falls was not due to staffing, but her basis for that conclusion is not explained. Tr. Vol. 4 at 325.

Administrator Bodkins testified that she did not believe that staff had any correlation to falls and so falls were not considered in assessing staffing. She testified that the acuity of patients was considered, but she gave no indication that she recognized that resident falls may be an indication of acuity. Tr. Vol. 5 at 107-10.

There is no dispute that from December 2013 through March 2014, the five residents experienced an increase in falls despite repeated efforts by their IDTs to adjust their care plans to mitigate or eliminate the risk for falls and related injuries. It is also conceded that Petitioner's management and QA committee failed to identify adjusting staffing as a necessary and appropriate intervention. Indeed, Medical Director Vollmer, Administrator Bodkins, and D.O.N. Fulmer, the management team, all failed to recognize or consider that increasing staffing to address the increase in falls on the ACU may have been both necessary and appropriate. Their failure is particularly stark in light of the fact that earlier in 2013 staffing levels were being adjusted specifically to meet the care planned needs of residents on the ACU.

Data in CMS Ex. 33 provided by Administrator Bodkin to the surveyors supports findings of fact that Petitioner fell below the minimum 3.5 hours of direct care per resident required by the Tennessee regulation for its ACU on March 18, 19, 20, 22, 23, 29, and 30, 2014. While the Tennessee regulation may not be subject to federal enforcement, the regulation certainly establishes a minimum standard of care for an ACU operated subject to the Tennessee regulations. Petitioner concedes this fact in post-hearing briefing. P. Reply at 13. Although similar data for December 2013, January 2014, February 2014, and March 2014, is not in the record, D.O.N. Fullmer's admission that she only planned a total of 3.16 for total direct care, rather than 3.5 hours as required by the Tennessee regulation (Tr. Vol. 4 at 277, 322-23), supports an inference that Petitioner regularly operated the ACU with less direct care than dictated by the standard of practice established by the Tennessee regulation. Tenn. Comp. R. & Regs. 1200-08-06-.07(9).

Petitioner argues that its QA committee, Administrator, and Medical Director did all that they needed to be in substantial compliance with program participation requirements. P. Br. at 4, 25-27; P. Reply at 22-25. The evidence shows that the QA committee, Administrator, and Medical Director quickly identified the documented increase in falls in December 2013, considered possible root causes, and took actions. In fact, with the elimination of residents by death or discharge, the team managed by April 2014 to reduce the number of falls in the ACU to a number similar to the number of falls experienced on a monthly basis prior to December 2013. Tr. Vol. 4 at 311-13. The point Petitioner misses is that it took four months and 89 falls before Petitioner effectively addressed the increased period of falls in the ACU. Petitioner concedes that Petitioner did not consider increasing staff on the ACU to address the number of falls on the ACU between December 2013 and March 2014 except in April 2014, and then only in the context of forming its plan of correction and allegation of compliance. P. Reply at 14 n.1. Only by

eliminating the five most frequent fallers, by death or discharge, did the number of falls decrease to the level that appears from the evidence to have been normal prior to December 2013. Petitioner does not seem to recognize that by reducing by five the number of higher fall risk residents, it effectively increased the ratio of staff to residents, demonstrating the impact of increasing the staff-to-resident ratio. Increasing staff is an obvious potential intervention to address increased resident needs, something the QA committee and management failed to consider. P. Br. at 26. When the number of falls increased from 8 in November 2013 to 19 in December 2013 and then to 33 in January 2014, it should have been obvious to the QA committee and management that the staffing ratio on the ACU may have required adjustment to provide additional supervision and assistance to the five residents experiencing an increase in falls. At least that intervention should have been considered and there should have been documentation of the consideration and any decision to reject that possible intervention. But Administrator Bodkins admits that she never saw a possible connection. Thus, the QA and management teams clearly failed in their regulatory duties to consider whether or not increased staff to provide direct care might reduce the number of falls in the ACU.

Petitioner's argument that the falls were unavoidable must be rejected. Petitioner cannot establish its defense by a preponderance of the evidence when it cannot show that increased staffing or an adjustment of staffing on the ACU was not an appropriate and effective intervention. Petitioner's defense is even less tenable considering that in the summer of 2013 the QA committee and management actively managed staffing to ensure residents' care planned needs were being met, and successfully, according to Petitioner's records.

I conclude that Petitioner violated 42 C.F.R. §§ 483.20(d)(3) and 483.10(k)(2); 483.25(h); 483.30(a); 483.75; 483.75(i); and 483.75(o)(1). Petitioner has not disputed that a fall by a nursing home resident poses a risk for more than minimal harm. Accordingly, I conclude that Petitioner was not in substantial compliance with program participation requirements and there is a basis for the imposition of enforcement remedies. Although the evidence would support a finding of noncompliance as early as December 2013, I accept the surveyors findings that noncompliance began January 13, 2014, after Petitioner had a reasonable time to attempt to address the increase in falls on the ACU. Petitioner did not seek review as to the duration of the noncompliance, which CMS concluded continued through June 10, 2014.

10. The declaration of immediate jeopardy related to the noncompliance with 42 C.F.R. §§ 483.20(d)(3) and 483.10(k)(2); 483.25(h); 483.30(a); 483.75; 483.75(i); and 483.75(o)(1) was not clearly erroneous.

The surveyors concluded that the violations of 42 C.F.R. §§ 483.20(d)(3) and 483.10(k)(2); 483.25(h); 483.30(a); 483.75; 483.75(i); and 483.75(o)(1) posed immediate

jeopardy that began January 13, 2014, and was abated on April 29, 2014. CMS Ex. 1 at 1-2, 9, 40, 93, 102, 106, 109; CMS Ex. 3; Jt. Stip. ¶ 8. CMS proposes to impose a CMP in the lower half of the upper range of CMPs that may be imposed for immediate jeopardy from January 13 through April 28, 2014, and that is the period of immediate jeopardy at issue before me.

The CMS determination of immediate jeopardy must be upheld unless Petitioner shows the declaration of immediate jeopardy to be clearly erroneous. 42 C.F.R. § 498.60(c)(2). CMS's determination of immediate jeopardy is presumed to be correct, and Petitioner has a heavy burden to demonstrate clear error in that determination. *Yakima Valley Sch.*, DAB No. 2422 at 8-9 (2011); *Cal Turner Extended Care Pavilion*, DAB No. 2384 at 14 (2011); *Brian Ctr. Health & Rehab./Goldsboro*, DAB No. 2336 at 9 (2010) (citing *Barbourville Nursing Home*, DAB No. 1962 at 11 (2005), *aff'd*, *Barbourville Nursing Home v. U.S. Dep't of Health & Human Srvs.*,174 F. App'x 932 (6th Cir. 2006)); *Maysville Nursing & Rehab. Facility*, DAB No. 2317 at 11 (2010); *Liberty Commons Nursing & Rehab Ctr. – Johnston*, DAB No. 2031 at 18-19 (2006), *aff'd*, *Liberty Commons Nursing & Rehab Ctr.–Johnston v. Leavitt*, 241 F. App'x 76 (4th Cir. 2007). "Once CMS presents evidence supporting a finding of noncompliance, CMS does not need to offer evidence to support its determination that the noncompliance constitutes immediate jeopardy; rather, the burden is on the facility to show that that determination is clearly erroneous." *Cal Turner*, DAB No. 2384 at 14-15; *Liberty Commons*, 241 F. App'x at 81.

"*Immediate jeopardy*" under the regulations refers to "a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." 42 C.F.R. §§ 488.301, 489.3 (emphasis in original). In the context of survey, certification, and enforcement related to SNFs and NFs under the regulations, a conclusion by the state agency and CMS that noncompliance with program participation requirements poses immediate jeopardy to the facility residents triggers specific regulatory provisions that require enhanced enforcement remedies, including authority for CMS to impose a larger CMP than may be imposed when there is no declaration of immediate jeopardy. 42 C.F.R. §§ 488.408(e), 488.438(a)(1)(i), (c), (d). The regulations also require termination of the facility's provider agreement on an expedited basis or the removal of the immediate jeopardy through appointment of temporary management. 42 C.F.R. §§ 488.410, 488.440(g), 488.456, 489.53(d)(2)(ii).

Many appellate panels of the Board have addressed "immediate jeopardy."[17] In *Mississippi Care Ctr. of Greenville*, DAB No. 2450 at 15 (2012), the Board commented:

> CMS's determination that a deficiency constitutes immediate jeopardy must be upheld unless the facility is able to prove that the determination is clearly erroneous. 42 C.F.R. § 498.60(c)(2); *Woodstock Care Center*. The "clearly erroneous" standard means that CMS's immediate jeopardy determination is presumed to be correct, and the burden of proving the determination clearly erroneous is a heavy one. *See, e.g.*, *Maysville Nursing & Rehabilitation Facility*, DAB No. 2317, at 11 (2010); *Liberty Commons Nursing and Rehab Center – Johnston*, DAB No. 2031, at 18 (2006), *aff'd*, *Liberty Commons Nursing and Rehab Ctr. – Johnston v. Leavitt*, 241 F. App'x 76 (4th Cir. 2007). When CMS issued the nursing facility survey, certification, and enforcement regulations, it acknowledged that "distinctions between different levels of noncompliance . . . do not represent mathematical judgments for which there are clear or objectively measured boundaries." 59 Fed. Reg. 56,116, 56,179 (Nov. 10, 1994). "This inherent imprecision is precisely why CMS's immediate jeopardy determination, a matter of professional judgment and expertise, is entitled to deference." *Daughters of Miriam Center*, DAB No. 2067, at 15 (2007).

The Board's statement that the CMS immediate jeopardy determination is entitled to deference is subject to being misunderstood to limit ALJ and Board review of immediate jeopardy beyond what was intended by the drafters of the regulations. In the notice of final rulemaking on November 10, 1994, the drafters of 42 C.F.R. § 498.60(c)(2), discussing the merits of the reviewability of deficiency citations, selection of remedy, and scope and severity, commented:

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[17] Decisions often cited include: *Lakeport Skilled Nursing Ctr.*, DAB No. 2435 at 7 (2012); *Liberty Health & Rehab of Indianola, LLC*, DAB No. 2434 at 13, 18-19 (2011); *Yakima Valley Sch.*, DAB No. 2422 at 8; *Lutheran Home at Trinity Oaks*, DAB No. 2111 (2007); *Britthaven of Havelock*, DAB No. 2078 (2007); *Daughters of Miriam Ctr.*, DAB No. 2067; *Koester Pavilion*, DAB No. 1750; *Woodstock Care Ctr.*, DAB No. 1726 at 39.

> We believe that a provider's burden of upsetting survey findings relating to the level of noncompliance should be high, however. As we indicated in the proposed rule, distinctions between different levels of noncompliance, whether measured in terms of their frequency or seriousness, do not represent mathematical judgments for which there are clear or objectively measured boundaries. Identifying failures in a facility's obligation to provide the kind of high quality care required by the Act and the implementing regulations most often reflect judgments that will reflect a range of noncompliant behavior. Thus, in civil money penalty cases, whether deficiencies pose immediate jeopardy, or are widespread and cause actual harm that is not immediate jeopardy, or are widespread and have a potential for more than minimal harm that is not immediate jeopardy does not reflect that a precise point of noncompliance has occurred, but rather that a range of noncompliance has occurred which may vary from facility to facility. While we understand the desire of those who seek the greatest possible consistency in survey findings, an objective that we share, the answer does not lie in designing yardsticks of compliance that can be reduced to rigid and objectively calculated numbers. Survey team members and their supervisors ought to have some degree of flexibility, and deference, in applying their expertise in working with these less than perfectly precise concepts. **For these reasons, we have revised the regulations to require an administrative law judge or appellate administrative review authority to uphold State or HCFA findings on the seriousness of facility deficiencies in civil money penalty cases unless they are clearly erroneous.**

59 Fed. Reg. at 56,179 (emphasis added). It is clear from this regulatory history that the drafters of 42 C.F.R. § 498.60(c)(2) ensured that the state agency or CMS determination that there was immediate jeopardy would receive deferential consideration, by adopting the clearly erroneous standard of review. Thus, caution must be exercised to ensure that the Board's decisions in *Mississippi Care Ctr. of Greenville*, *Daughters of Miriam Ctr.*, and other decisions that have mentioned deference relative to immediate jeopardy not be read to require deference for the determination that there was immediate jeopardy beyond that imposed by adoption of the clearly erroneous standard. Giving deference to the immediate jeopardy determination or requiring that it be given deference in addition to applying the "clearly erroneous" standard would be contrary to the intent of the drafters of the regulation; would significantly limit the review of the determination by an ALJ and

the Board; and would impermissibly deny an affected party the due process right to review intended by the drafters of the regulation.

In the foregoing quotation from *Mississippi Care Ctr. of Greenville*, that panel of the Board states that the clearly erroneous standard means that "the immediate jeopardy determination is presumed to be correct, and the burden of proving the determination clearly erroneous is a heavy one." DAB No. 2450 at 15. Similar formulations have been used in other Board decisions when referring to the "clearly erroneous standard." However, the Board's characterization of the "clearly erroneous standard" in *Mississippi Care Ctr.* and other cases does not define the standard. The "clearly-erroneous standard" is described in Black's Law Dictionary as a standard of appellate review applied in judging the trial court's treatment of factual issues, under which a factual determination is upheld unless the appellate court has the firm conviction that an error was committed. *Black's Law Dictionary* 269 (18th ed. 2004). The Supreme Court has addressed the "clearly erroneous standard" in the context of the Administrative Procedures Act (APA). The Court described the preponderance of the evidence standard, the most common standard, as requiring that the trier-of-fact believe that the existence of a fact is more probable than not before finding in favor of the party that had the burden to persuade the judge of the fact's existence. *In re Winship*, 397 U.S. 358, 371-72 (1970) (Harlan, J., concurring); *Concrete Pipe & Products of California, Inc. v. Construction Laborers*, 508 U.S. 602, 622 (1993). The "substantial evidence" standard considers whether a reasonable mind might accept a particular evidentiary record as adequate to support a conclusion. *Consolidated Edison Co. of New York v. Nat'l Labor Relations Bd.*, 305 U.S. 197, 229 (1938); *Dickinson v. Zurko*, 527 U.S. 150, 162 (1999). Under the "clearly erroneous" standard a finding is clearly erroneous even though there may be some evidence to support it if, based on all the evidence, the reviewing judge or authority has a definite and firm conviction that an error has been committed. *United States v. United States Gypsum Co.*, 333 U.S. 364, 395 (1948); *Dickinson*, 527 U.S. at 162; *Concrete Pipe*, 508 U.S. at 622. The clearly erroneous standard has been characterized by the Court as being stricter than the substantial evidence test and significantly deferential. In discussing the clearly erroneous standard, the Court stressed the importance of not simply rubber-stamping agency fact-finding. The Court also commented that the APA requires meaningful review.[18] *Dickinson*, 527 U.S. at 162; *Concrete Pipe*, 508 U.S. at 622-23.

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[18] The Board's characterization of the clearly erroneous standard as being highly deferential to the fact-finding by the state agency surveyor and CMS, and even triggering a rebuttal presumption, is entirely consistent with the Supreme Court's characterization of the standard. However, the Court's cautions about ensuring meaningful review rather than rubber-stamping agency decisions shows it is important for the ALJ and the Board not to be tempted to simply defer to the surveyor, the state agency, or CMS on the immediate jeopardy issue.

(*Footnote continued next page.*)

Various panels of the Board have recognized other principles applicable to the review of the immediate jeopardy issue. A finding of immediate jeopardy does not require a finding of actual harm, only a likelihood of serious harm. *Dumas Nursing & Rehab., L.P.*, DAB No. 2347 at 19 (citing *Life Care Ctr. of Tullahoma*, DAB No. 2304 at 58 (2010), *aff'd, Life Care Ctr. of Tullahoma v. Secretary of U.S. Dep't of Health & Human Servs.*, 453 F. App'x 610). The definition of immediate jeopardy at 42 C.F.R. § 488.301 does not define "likelihood" or establish any temporal parameters for potential harm. *Agape Rehab. of Rock Hill*, DAB No. 2411 at 18-19 (2011). The duration of the period of immediate jeopardy is also subject to the clearly erroneous standard. *Brian Ctr. Health & Rehab./Goldsboro*, DAB No. 2336 at 7-8. There is a difference between "likelihood" as required by the definition of immediate jeopardy and a mere potential. The synonym for likely is probable, which suggests a greater degree of probability that an event will occur than suggested by such terms as possible or potential. *Daughters of Miriam Ctr.*, DAB No. 2067 at 10. Jeopardy generally means danger, hazard, or peril. The focus of the immediate jeopardy determination is how imminent the danger appears and how serious the potential consequences. *Woodstock Care Ctr.*, DAB No. 1726.

What is the meaning of serious injury, harm, or impairment as used in the definition of immediate jeopardy found in 42 C.F.R. § 488.301? How does serious injury, harm, or impairment compare with "actual harm"? On the first question the Board recognized in *Yakima Valley Sch.*, DAB No. 2422 at 8, that the regulations do not define or explain the meaning of the term "serious" as used in the definition of immediate jeopardy.[19] The Board suggested that the definitions may be unimportant because the Board has held that, under the clearly erroneous standard, once the state agency or CMS declares immediate jeopardy there is a presumption that the actual or threatened harm was serious and the facility can only rebut the presumption of immediate jeopardy by showing that the harm

(*Footnote continued.*)

[19] Appendix Q of the SOM also fails to provide surveyors a working definition of the term "serious" that they can use to determine whether harm, injury, or impairment is serious when deciding whether or not to declare immediate jeopardy. The Act does not define the phrase "immediately jeopardize" and does not introduce the concept of serious harm, injury, or impairment as the basis for finding immediate jeopardy. Thus, one is not in error concluding that absent a definition of the term "serious" in the Act, the regulations, the SOM, or decisions of the Board, it is essentially up to individual surveyors, and whatever unpublished guidance they receive from their superiors or CMS officials, to exercise their individual discretion and judgment to decide that there was immediate jeopardy, which subjects a facility to the maximum imposable CMPs.

or threatened harm meets no reasonable definition of the term "serious." *Id.* (citing *Daughters of Miriam Ctr.*, DAB No. 2067 at 9). In *Daughters of Miriam Ctr.*, the Board discussed that the ALJ attempted to define "serious," finding meanings such as dangerous, grave, grievous, or life threatening. The Board noted that the ALJ stated that serious harm is outside the ordinary, requiring extraordinary care, or having lasting consequences. The Board further noted that the ALJ stated that a serious injury may require hospitalization, result in long-term impairment, or cause severe pain, as opposed to harm, injury, or impairment that is temporary, easily reversible with ordinary care, does not cause a period of incapacitation, heals without special medical intervention, or does not cause severe pain. The Board did not endorse or adopt the ALJ's definitional exercise but concluded that it was simply unnecessary in the context of that case. The Board reasoned, as already noted, that the facility bore the burden to rebut the presumption by showing that the actual or threatened harm met no reasonable definition of serious. *Daughters of Miriam Ctr.*, DAB No. 2067 at 9-10.

Applying the clearly erroneous standard to the record before me related to the noncompliance I have found, I have no definite and firm conviction that an error has been committed. I conclude that Petitioner has failed to show that the declaration of immediate jeopardy for the deficiencies under 42 C.F.R. §§ 483.20(d)(3) and 483.10(k)(2); 483.25(h); 483.30(a); 483.75; 483.75(i); and 483.75(o)(1) was clearly erroneous.

11. A CMP of $5,800 per day from January 13, 2014 through April 28, 2014, and $150 per day from April 29, 2014 through June 10, 2014, a total CMP of $621,250, and a DPNA from April 25, 2014 through June 10, 2014, are reasonable enforcement remedies.

I have concluded that Petitioner violated 42 C.F.R. §§ 483.20(d)(3) and 483.10(k)(2); 483.25(h); 483.30(a); 483.75; 483.75(i); and 483.75(o)(1) from January 13, 2014 through June 10, 2014. I have also concluded that the declaration of immediate jeopardy related to those violations from January 13 through April 28, 2014, was not clearly erroneous. Petitioner did not seek review and does not dispute that it violated 42 C.F.R. §§ 483.10(e) and 483.75(l)(4); 483.15(3)(1); 483.20(d) and 483.20(k)(1) or that those violations posed a risk for more than minimal harm.[20] Petitioner also does not dispute that the

[20] Because Petitioner did not request ALJ review as to these deficiency citations they are administratively final and not subject to my review. These administratively final deficiency citations are only considered here in the context of determining the reasonableness of the enforcement remedies that are based upon both the deficiencies that posed immediate jeopardy and those that did not.

unchallenged deficiency citations would support a CMP in the lower range and a DPNA. CMS Ex. 1 at 1-7; Jt. Stip. ¶11; RFH at 1 n.1.

If a facility is not in substantial compliance with program requirements, CMS has the authority to impose one or more of the enforcement remedies listed in 42 C.F.R. § 488.406, including a CMP. CMS may impose a per-day CMP for the number of days that the facility is not in compliance or a per-instance CMP for each instance that a facility is not in substantial compliance, whether or not the deficiencies pose immediate jeopardy. 42 C.F.R. § 488.430(a). The regulations specify that a CMP that is imposed against a facility on a per day basis will fall into one of two ranges of penalties. 42 C.F.R. §§ 488.408, 488.438. The upper range of a CMP, $3,050 per day to $10,000 per day, is reserved for deficiencies that pose immediate jeopardy to a facility's residents and, in some circumstances, for repeated deficiencies. 42 C.F.R. § 488.438(a)(1)(i), (d)(2). The lower range of CMPs, $50 per day to $3,000 per day, is reserved for deficiencies that do not pose immediate jeopardy but either cause actual harm to residents or cause no actual harm but have the potential for causing more than minimal harm. 42 C.F.R. § 488.438(a)(1)(ii).

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

DAB No. 1800 at 10 (2001); *CarePlex of Silver Spring*, DAB No. 1683 at 14-16 (1999); *Capitol Hill Cmty. Rehab. & Specialty Care Ctr.*, DAB No. 1629 (1997).

I conclude that the CMP of $5,800 per day proposed by CMS for the days of immediate jeopardy for January 13, 2014 through April 18, 2014, is reasonable. I further conclude that the CMP of $150 for the period after immediate jeopardy was abated on April 29, 2014 through June 10, 2014, the day before Petitioner was found to have returned to substantial compliance (Jt. Stip. ¶ 10) is reasonable. The total CMP of $621,250 (Jt. Stip. ¶ 10) is reasonable. The DPNA from April 25 through June 10, 2014, is also a reasonable enforcement remedy. The $5,800 per day CMP is in roughly the middle of the upper range of CMPs authorized when there is immediate jeopardy. The $150 per day CMP is at the low end of the lower range of CMPs authorized. Petitioner has not argued or submitted evidence that its financial condition requires consideration of a lesser total CMP. Some of the residents on the ACU suffered actual harm due to their falls. There was a pattern of immediate jeopardy deficiencies. CMS has not presented evidence of a history of noncompliance prior to the survey-cycle at issue before me.

> *Culpability* . . . 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.

42 C.F.R. § 488.438(f)(4) (emphasis added). Petitioner is culpable for its deficiencies that posed immediate jeopardy because Petitioner's management and QA committees failed to consider the potential impact of staffing levels on the ACU upon the ACU staff's ability to meet the care planned needs of residents when there was clear evidence that those needs were changing.

12. Other issues raised by Petitioner are without merit or are not within my authority to decide.

Petitioner argues 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 Procedure Act, 5 U.S.C. § 551 *et. seq.*—specifically 5 U.S.C. § 556(d)—and deprives Petitioner of due process of law. RFH at 13. 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 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 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) or with the requirements of due process of law, as CMS is required to come forward with the evidence that establishes its prima facie case. Furthermore, because the evidence is not in equipoise, the burden of persuasion did not affect my decision, and Petitioner suffered no prejudice due to the allocation.

Petitioner also argues that the Medicare Act is violated and Petitioner is deprived of due process if CMS is not required to submit evidence to prove it considered the regulatory criteria established by 42 C.F.R. §§ 488.404 and 488.438(f) in determining enforcement remedies. RFH at 13. I reviewed the evidence related to the regulatory factors de novo and perceive no prejudice to Petitioner because I did not require CMS to submit evidence related to its consideration of the regulatory factors.

III. Conclusion

For the foregoing reasons, I conclude that Petitioner was not in substantial compliance with program participation requirements from January 13, 2014 through June 10, 2014. I also conclude that a CMP of $5,800 per day from January 13, 2014 through April 28, 2014, and $150 per day from April 29, 2014 through June 10, 2014, a total CMP of $621,250, and a DPNA from April 25, 2014 through June 10, 2014, are reasonable enforcement remedies.

_____/s/_____
Keith W. Sickendick
Administrative Law Judge