Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Golden Living Center – Rib Lake
(CCN: 52-5329),

Petitioner,

v.

Centers for Medicare and Medicaid Services.

Docket No. C-11-215

Decision No. CR2698

Date: January 25, 2013

DECISION

Petitioner, Golden Living Center – Rib Lake, was not in substantial compliance with program participation requirements on November 9, 2010, due to a violation of 42 C.F.R. § 483.25.[1] There is a basis for the imposition of enforcement remedies. A per instance civil money penalty (PICMP) of $5,500 is a reasonable enforcement remedy.

I. Background

Petitioner is located in Rib Lake, Wisconsin, and participates in Medicare as a skilled nursing facility (SNF) and the state Medicaid program as a nursing facility (NF). On November 9, 2010, Petitioner was surveyed by the Wisconsin Department of Health Services (the state agency) and found not in substantial compliance with program participation requirements. The Centers for Medicare and Medicaid Services (CMS) notified Petitioner by letter dated November 16, 2010, that it was imposing the following

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

enforcement remedies: a PICMP of $5,500; a discretionary denial of payment for new admissions (DPNA) effective December 15, 2010, and termination effective May 9, 2011. CMS also notified Petitioner that its approval to conduct a Nurse Aide Training and Competency Evaluation Program (NATCEP) would be withdrawn. A revisit survey determined that Petitioner returned to substantial compliance with program participation requirements on November 18, 2010, and the DPNA and termination were not effectuated. Joint Stipulations of Undisputed Facts and Joint Statement of Issues Presented for Hearing (Jt. Stip.), filed July 19, 2011.

Petitioner requested a hearing before an administrative law judge (ALJ) on January 12, 2011. The case was assigned to me for hearing and decision on January 20, 2011, and an Acknowledgement and Prehearing Order was issued at my direction. On September 7 and 8, 2011, a hearing was convened in Madison, Wisconsin and a transcript (Tr.) of the proceedings was prepared. CMS offered CMS exhibits (CMS Exs.) 1 through 13, which were admitted as evidence. Tr. 23. Petitioner offered Petitioner exhibits (P. Exs.) 1 through 25, 25a, and 26 through 61, which were admitted as evidence. Tr. 25. CMS called the following witnesses: Surveyor Jacquelyn M. Dalzell, RN and Surveyor Yvonne M. Breeden, RN. Petitioner called the following witnesses: Joseph Boero, MD, Petitioner's Medical Director; Christie Grubbs, RN, Petitioner's Director of Nursing (DON) during the survey; Sandra Larson, Petitioner's Executive Director or Administrator; Diane Hengst, RN; Grace Brehm, RN; and Bradley Robb, Occupational Therapist. The parties filed post-hearing briefs and post-hearing reply briefs.

II. Discussion

A. Issues

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

Whether the remedy imposed is reasonable.

B. Applicable Law

The statutory and regulatory requirements for participation of a SNF in Medicare are found at section 1819 of the Social Security Act (Act) and at 42 C.F.R. Part 483. Section 1819(h)(2) of the Act authorizes the Secretary of Health and Human Services (Secretary) to impose enforcement remedies against a SNF for failure to comply substantially with the federal participation requirements established by sections 1819(b), (c), and (d) of the

Act.[2] 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 impose other enforcement remedies, including a discretionary DPNA, CMPs, appointment of temporary management, and other remedies such as a directed plan of correction. Act § 1819(h)(2)(B).

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

A CMP that is imposed against a facility on a per day basis will fall into one of two ranges of penalties. 42 C.F.R. §§ 488.408, 488.438. The upper range of a CMP, $3,050 per day to $10,000 per day, is reserved for deficiencies that pose immediate jeopardy to a facility's residents and, in some circumstances, for repeated deficiencies. 42 C.F.R. §§ 488.438(a)(1)(i), (d)(2). "*Immediate jeopardy* means a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." 42 C.F.R.

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

§ 488.301 (emphasis in original). The lower range of a CMP, $50 per day to $3,000 per day, is reserved for deficiencies that do not constitute immediate jeopardy but either cause actual harm to residents, or cause no actual harm but have the potential for causing more than minimal harm. 42 C.F.R. § 488.438(a)(1)(ii). CMS is authorized to impose a PICMP from $1,000 to $10,000, whether or not immediate jeopardy is identified. 42 C.F.R. § 488.438(a)(2).

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

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); 42 C.F.R. §§ 488.330(e), 498.3. However, the choice of remedies or the factors CMS considered when choosing remedies are not subject to review. 42 C.F.R. § 488.408(g)(2). A facility may only challenge the scope and severity level of noncompliance determined by CMS if a successful challenge would affect the range of the CMP that may be imposed or impact the facility's authority to conduct a NATCEP. 42 C.F.R. §§ 498.3(b)(14), (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. *Residence at Salem Woods*, DAB No. 2052 (2006); *Cal Turner Extended Care*, DAB No. 2030 (2006); *Beechwood Sanitarium*, DAB No. 1906 (2004); *Emerald Oaks*, DAB No. 1800, at 11 (2001); *Anesthesiologists Affiliated*, DAB CR65 (1990), *aff'd*, 941 F.2d 678 (8th Cir. 1991). The standard of proof or quantum of evidence required is a preponderance of the evidence. CMS has the burden of coming forward with the evidence and making a prima facie showing of a basis for imposition of an enforcement remedy. Petitioner bears the burden of persuasion to show by a preponderance of the evidence that it was in substantial compliance with participation requirements or any affirmative defense. *Batavia Nursing & Convalescent Inn*, DAB No. 1911 (2004); *Batavia Nursing & Convalescent Ctr.*, DAB No. 1904 (2004), *aff'd, Batavia Nursing & Convalescent Ctr. v. Thompson*, 129 F. App'x 181 (6th Cir. 2005); *Emerald Oaks*, DAB No. 1800; *Cross Creek Health Care Ctr.*, DAB No. 1665 (1998); *Hillman Rehab. Ctr.*, DAB No. 1611 (1997), *aff'd, Hillman Rehab. Ctr. v. U.S.*, No. 98-3789 (GEB), 1999 WL 34813783 (D.N.J. May 13, 1999).

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

CMS alleges, based upon the survey that ended November 9, 2010, that Petitioner was not in substantial compliance with program participation requirements due to a violation of 42 C.F.R. § 483.25 (Tag F323) that posed immediate jeopardy to its residents. The only enforcement remedy in issue subject to my review is the $5,500 PICMP that CMS proposes to impose.[3]

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

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[3] The ineligibility to conduct a NATCEP is by operation of law, triggered in this case by the PICMP. It is not an enforcement remedy that CMS or the state has delegated authority to impose and it is not subject to my review for reasonableness.

evidence given the greatest weight in my decision-making.[4] 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.

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

2. Petitioner's violation of 42 C.F.R. § 483.25 (Tag F323) posed a risk for more than minimal harm.

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

The surveyors allege in the Statement of Deficiencies (SOD) for the survey that ended on November 9, 2010, that Petitioner violated 42 C.F.R. § 483.25(h) and that the violation posed immediate jeopardy. CMS Ex. 3. Whether or not the declaration of immediate jeopardy was clearly erroneous is not an issue in this case as neither the PICMP nor the loss of NATCEP authority would be affected by a decision that the declaration of immediate jeopardy was clearly erroneous. The surveyors originally cited examples related to four of Petitioner's residents. However, due to informal dispute resolution, the SOD was revised and CMS proceeds only upon the examples cited in the SOD related to Residents 2, 3, and 7. Jt. Stip. ¶ 6; CMS Ex. 3, 12; P. Ex. 1-2.

The surveyors allege in the revised SOD that Petitioner did not ensure that its environment was as free of accident hazards as possible based on examples related to Residents 2, 3, and 7. The surveyors' charge specifically regarding Resident 2 that he fell on December 16, 2009[5] with injuries and had to be hospitalized; after his return to Petitioner he had ten more falls; and after each fall Petitioner failed to critically analyze the falls to identify and evaluate potential hazards and risks to determine if new interventions to minimize the risk for falls were necessary. Regarding Resident 3, the surveyors charge that the resident suffered eight falls after being admitted on August 18,

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[4] "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.

[5] The surveyors' allegation is in error as the evidence shows that the fall actually occurred around 6:45 p.m. on December 15, 2009. P. Ex. 19 at 1.

2010; and Petitioner failed to implement new interventions to meet the resident's needs. The surveyors' charge regarding Resident 7 that she had several falls and Petitioner did not critically analyze the falls to identify and evaluate the potential hazards or risks to determine whether additional interventions were necessary to minimize the risk for falls for the resident. CMS Ex. 3 at 2. The example of Resident 2 adequately establishes the deficiency and it is, therefore, not necessary to discuss the examples of Resident 3 and Resident 7.

a. Facts Related to Resident 2 – Example 1 in the SOD

It is not disputed that Resident 2 had falls on December 15, 2009, March 13, 2010, May 9, 2010, May 20, 2010, May 24, 2010, July 2, 2010, August 18, 2010, September 1, 2010, October 18, 2010, and October 21, 2010. The surveyors allege generally that Petitioner failed to analyze each fall to identify and evaluate potential hazards and risks to determine if new interventions were necessary to minimize the risk for falls. CMS Ex. 3 at 3-12.

Petitioner's contemporaneous clinical records for Resident 2 are considered the most reliable source of information regarding Resident 2's falls, care plan, and treatment, except as specifically noted. The importance of complete, thorough, readable, and understandable clinical documentation cannot be overstated. In this case the survey occurred within weeks of the resident's last fall, but the hearing did not occur until eleven months after the last fall. It is well understood and accepted that the memories of witnesses fade with the passage of time, therefore, contemporaneous clinical records will typically be the most reliable evidence. Errors and omissions in clinical records may be explained by witnesses, but the witness's direct knowledge and recall will always be subject to challenge. Witness testimony that is inconsistent with contemporaneous clinical records will nearly always be viewed with suspicion. Omissions from clinical records will invariably present the issue of whether the omission was a simple clerical error or documentation error; or whether the omission is conclusive evidence that a care or service was not delivered. This case is made more difficult for Petitioner as it is clear that Petitioner did not keep up-to-date care plans that listed all interventions. Thus, it is necessary for me, as it was for Petitioner's staff, to review the entire clinical record to identify the various interventions in effect at any given time.

Resident 2 was 91 when originally admitted to Petitioner in October 2008. P. Exs. 12, 13. His clinical records list diagnoses including Alzheimer's disease with dementia and agitated features, hypertension, depression, gout, aortic valve disorder, occlusion of the carotid artery without cerebral infarction, arthritis, and renal failure. P. Exs. 12, 13 at 1. Petitioner stipulated that the resident was at high risk for falls. Tr. 92.

Resident 2's care plan with the "Original Date" of November 24, 2008,[6] shows that he had a fall resulting in a concussion without loss of consciousness, a nasal fracture, and an odontid (protuberance of the second cervical vertebra (Tr. 222-23)) fracture. The care plan placed in evidence by Petitioner is cause for confusion.[7] The care plan is prepared in a way that could cause one to infer that it was originally developed on November 24, 2008, based on the original date listed. However, the care plan lists diagnoses and interventions that show that the resident had a nasal fracture, concussion, and a cervical fracture requiring a cervical collar. P. Ex. 13 at 4-5. The clinical records do not show that Resident 2 actually had the injuries or required the use of a cervical collar at admission in October 2008 or in November 2008 when the care plan appears to have been prepared. P. Ex. 16 at 1-2. Nurses' notes from November 30, 2009 through December 15, 2009, show that Resident 2 was often agitated, confused, oppositional, and abusive of staff. But, the nursing notes do not refer to any neck injury, nose injury, or any requirement for a cervical collar. P. Ex. 17 at 17. Medical records show that Resident 2 suffered the cervical fracture requiring use of a cervical collar, the nasal fracture, and the concussion as a result of a fall in Petitioner's facility on December 15, 2009.[8] P. Exs. 16 at 3; 17 at 19-20; 18; 19 at 1. I infer that the fall care plan placed in evidence by Petitioner and the printed interventions listed on the plan were adopted after the December 15, 2009 fall in Petitioner's facility. The care plan shows that Resident 2 was assessed as at risk for injury due to falls, a fact not disputed by Petitioner. P. Ex. 13, at 4-5. I infer that the fall risk interventions in effect after the fall on December 15, 2009, are those mechanically printed on the residents care plan and include the following:

- Resident 2 was to wear a cervical collar at all times;
- Transfers were to be with assist of one as needed;
- Staff was to use a gait belt for all assisted transfers;

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[6] Each page of the Plan of Care form also reflects a date of "July 2008" in a block near the top center of the form. The relevance of the July 2008 date is unknown but I conclude it is not important to my decision because each page near the bottom center also reflects an "Admit Date" of October 10, 2008. P. Ex. 13.

[7] Even the resident's physician, Dr. Joseph Boero, was confused by the dates on the care plan. Tr. 188-89.

[8] Petitioner objected to my consideration of the fall on December 15, 2009 as a basis for the deficiency citation. Tr. 28, 89-90. CMS agreed that the December 15, 2009 fall was not the basis for the deficiency citation. Tr. 89-90. I do not consider the December 15, 2009 fall as a basis for the deficiency citation.

- Resident 2's call-light was to be within reach at all times and answered promptly;
- A bed alarm was to be in place at night;
- Staff was to respond to the call-light promptly as able;
- Staff was to document any falls/injuries and inform the treating physician and family promptly per facility protocol;
- Falls risk assessment were to be done quarterly and/or as needed;
- The resident was to be assessed for a nursing rehabilitation program if indicated;
- Therapies were to be as ordered by the physician;
- Staff was to ensure the resident's room was free from clutter to increase safety with (independent) toileting;
- The resident's medications were to be assessed for possible adverse reactions or side effects related to falls and the physician was to be updated if needed; and
- Grab bars on the bed were to be up when the resident was in bed to assist his mobility and positioning.

CMS Ex. 5 at 85; P. Ex. 13 at 4-5.

Resident 2's care plan placed in evidence by Petitioner also specified that:

- He ambulated with limited assistance of one. P. Ex. 13 at 1.
- He was to be monitored for side effects of medication, including unsteady balance. P. Ex. 13 at 9, 21.

According to a nurse's note dated December 16, 2009 at 12:16 a.m., Resident 2 fell at 6:45 p.m. on December 15, 2009. Resident 2 fell in the middle of the hall about 10 feet from his room. The note states that he was not using his walker at the time. The note also states that Resident 2 had been to see his spouse's room so that he could find her in the morning. The resident's physician ordered that he be transferred to the emergency room if the family agreed. He was sent to the emergency room at 9:25 p.m. P. Ex. 17 at 19; P. Ex. 19 at 1-4. A nursing note dated December 17, 2009 shows that the resident returned to Petitioner at 3:45 p.m. on that date. P. Ex. 17 at 20. A January 7, 2010 physician's note incorrectly states that the fall occurred on December 16, 2009. The note indicates that Resident 2 fell forward while walking with the help of his walker, which is also inconsistent with the nurse's note that shows he was walking without his walker. P. Ex. 18 at 1. Petitioner's accident investigation shows that Resident 2 fell at 6:45 p.m. on December 15, 2009, and records that the resident reported he tripped over his own feet. The accident investigation recommended as interventions that: the resident be evaluated by physical and occupational therapy (PT/OT) and receive treatment for activities of daily living (ADLs), gait, and exercise to maintain independent ambulation with a

walker; and the resident was to have a bed alarm on and monitored at bed time and during the night. The investigation stated that the resident used a wheeled walker but he forgot it in his wife's room, but no intervention was recommended in that regard. P. Ex. 19 at 1-4. The bed alarm is listed on Resident 2's fall care plan but not the PT/OT evaluation and training to maintain the resident's walking independently with a walker. CMS Ex. 5 at 85; P. Ex. 13 at 4-5. However, there is a record of physician orders dated January 9 and January 11, 2010 for occupational therapy and gait training. P. Ex. 14 at 1. There is also evidence of a nursing order dated June 25, 2009, that Resident 2 was to have a bed alarm during hours of sleep with the alarm box at the head of the bed with checks twice each day. This order was in effect through October 2010. P. Ex. 12 at 2, 5, 8, 11, 14; P. Ex. 15 at 1-7, 12, 14, 16, 18.

From December 17, 2009 to March 13, 2010, Resident 2's behavior was better due to a medication change. He would refuse to wear his cervical collar at times. After a brief period of wheelchair use, he returned to walking independently with his wheeled walker but there is no evidence of the rescission of the intervention that he was to have the limited assistance of one for ambulation. P. Exs. 16 at 3-4; 17 at 20-50. Nurse notes show that on December 19, 2009, his bed alarm sounded three times on one shift. P. Ex. 17 at 21. Resident 2's wife passed on December 22, 2009 and he attended the funeral but the nurse notes to March 13, 2010 show that he frequently could not recall her passing or the funeral. Resident 2's Minimum Data Set (MDS) with an assessment reference date of December 24, 2009 after the December 15, 2009 fall, shows that he was severely impaired cognitively and he had short and long term memory problems. His mental functioning varied over the course of the day. He was easily distracted and sidetracked. He was verbally abusive and resisted care. He was assessed as requiring limited assistance of one person for bed mobility, transfers, walking in his room, walking along the corridor, locomotion on and off the unit and for toilet use. The MDS does not show that he had a toileting plan. The MDS shows that his balance while standing was unsteady and he had an unsteady gait. CMS Ex. 5 at 113-18; P. Ex. 5 at 2-7. A nurse's note on December 25, 2009, shows that Resident 2 continued to walk out of his room without his wheelchair or walker. P. Ex. 17 at 26. A January 13, 2010 Resident Assessment Protocol (RAP) for falls based on the December 24, 2009 MDS, assessed the resident at risk for falls based on his diagnoses; because he had a fall in the past 30 to 180 days; he received antidepressant and anti-anxiety medication regularly; and he had declines in his ADLs and cognition. The RAP noted that Resident 2 was currently in therapy. Social Services evaluated the resident on January 20, 2010 and assessed him as being moderately cognitively impaired and not oriented but lucid. P. Ex. 17 at 39. A Plan of Care form with an "Original Date" of January 15, 2010 for a problem with incontinence imposed a toileting schedule under which the resident was to be offered toileting upon arising, before and after meals, at bedtimes, and during nightly rounds. P. Ex. 13 at 2. Dr. Joseph Boero, Resident 2's physician and Petitioner's Medical Director, testified about the importance of a toileting schedule as an intervention to prevent falls. Dr. Boero also testified that it was necessary to discontinue the resident's physical

therapy around February 5, 2010, due to his impaired cognition. Tr. 199-203. Nurse notes from February 24, 2010 show that he was having trouble getting along with his new roommate, telling him to get out and threatening to kill him. P. Ex. 17 at 47.

A nurse's note on March 14, 2010 at 1:27 a.m., records that Resident 2 suffered a witnessed fall at 11:40 p.m. on March 13, 2010. The note indicates that a nurse heard his alarm sounding and she arrived at the room in time to see him fall with his back to the door of his room landing on his elbows and right hip, resulting in small skin tears at the elbows and bruising. P. Ex. 17 at 51. Petitioner's staff completed a "Change In Condition Report – Post Fall/Trauma" on March 14, 2010, which is consistent with the nurse's note. P. Ex. 19 at 6. Interventions in place at the time of the fall are listed on the report as: change in footwear; night light; bed/chair alarm; bed in low position; safety cues, reinforcement, reminder, and call light within easy reach. P. Ex. 19 at 6. Petitioner placed in evidence a document titled "Change in Condition Report—Post Fall Investigation Summary Guidelines for Completion." The guidelines specify that nurses are to record interventions that were in place at the time of the fall. P. Ex. 56. Petitioner's former DON, Christie Grubbs, testified that the policy set forth in P. Ex. 56 was to be followed in the case of every fall. She also testified that the "Change In Condition Report – Post Fall/Trauma" (P. Ex. 58) is a computer generated form to be completed for every fall and the form is intended to capture the required information regarding a fall input by a nurse. Tr. 454-58. Based upon DON Grubbs testimony and the guidelines for reporting falls, I presume that when checking the list of interventions in place prior to the fall on the "Change In Condition Report – Post Fall/Trauma" Petitioner's nurses complied with Petitioner's policy and checked all the interventions in use at the time of a fall when completing the report form. The post fall interventions recommended by the report for the March 13 fall were to have the resident use different footwear, to use a night light, use of a bed/chair alarm, place the resident's bed in the low position, use safety cues/reinforcement/reminders, and keep the call light in easy reach. A PT screen was also recommended. The report also noted that the resident was known to be noncompliant with the plan of care at times and that he suffered from agitation, severe dementia, and delusions. P. Ex. 19 at 7. The March 13, 2010 fall is not listed as a problem on Resident 2's care plan. However, a hand-written entry near the date March 13, 2010, lists the intervention of encouraging the resident to wear shoes or gripper socks at night. Another hand-written entry with no date near it provides that the bed alarm was to be on when the resident was in bed to alert staff when he got up. Another entry near the date March 13, 2010 states that the resident's pain was to be monitored every shift, but only for 72 hours. P. Ex. 13 at 4-5. The interventions to use safety cues/reinforcement/reminders, use of a night light, placing the resident's bed in the low position, and use of a chair alarm as recommended by the fall investigation are not recorded in the care plan. A physician's note dated March 18, 2010, states that the resident had both a bed and chair alarm. P. Ex. 16 at 5.

During the period between his falls on March 13, 2010 and May 9, 2010, it was noted by staff that the resident occasionally was hostile to staff and confused about the death of his wife. P. Ex. 17 at 51-59. A weekly nursing summary on April 4, 2010, noted that the resident was ambulated to destinations of choice but there was some weakness with ambulation. P. Ex. 17 at 55. Resident 2's MDS with a reference date of April 4, 2010, shows that he continued to be assessed as severely cognitively impaired with a short-term memory deficit. He continued to be easily distracted with his mental functioning varying over the course of the day. He was assessed as being independent with bed mobility requiring setup help only. However, transfers, walking in his room, walking in the corridor and locomotion on the unit required supervision and set up help. Locomotion off the unit required supervision of one person. He continued to be unsteady while standing and to have an unsteady gait. P. Ex. 6.

On May 9, 2010, Resident 2 fell at about 6:00 p.m. CMS Ex. 5 at 38-39, 73; P. Ex. 17 at 59. A Certified Nursing Assistant (CNA) assisted Resident 2 to his room and to bed after the evening meal. A nurse at the nurse's station, heard a loud noise, went to investigate, and found the resident in his room on his knees, and right elbow with the right-side of his head against his bathroom door. His bedside table was overturned. A nickel-sized bruise was on the resident's right elbow. P. Ex. 15 at 59; CMS Ex. 5 at 73. The record does not show that Resident 2's alarm sounded when he got out of bed. Petitioner's "Change In Condition Report – Post Fall/Trauma" dated May 9, 2010, indicates that prior to the fall the interventions established for Resident 2 included half bedrails, change in footwear, night light, toileting schedule, assistive device within reach, bed/chair alarm, safety cues/reinforcement/reminder, and call light within reach. P. Ex. 19 at 8. The nurse that completed the report recommended the addition of one intervention listed as wheelchair positioning. P. Ex. 19 at 9. Notes of the review of the accident by the interdisciplinary team (IDT), which is responsible for care planning for the resident, state that the resident is known to have significant cognitive impairment; he is known to be noncompliant at times with the plan of care; his vital signs did not appear to contribute to his fall, but he has agitation, impaired decision making ability, and he lacked safety awareness. The IDT recommended a therapy screen. Resident 2's fall care plan placed in evidence by Petitioner, does not include the interventions to use half bedrails, to use a night light, to keep his assistive device, presumably his roller walker, within reach, use of a chair alarm, or use of safety cues/reinforcement/reminder. The care plan also does not address wheelchair positioning. P. Ex. 13 at 4-5. Indeed, no new interventions were added to Resident 2's care plan due to his fall on May 9, 2010 or the IDT's review of the fall. Physician's orders in Resident 2's clinical record include an order dated May 17, 2010, for a PT evaluation and treatment to improve strength with ambulation but that order has a different resident's name and is marked "wrong chart." P. Ex. 14 at 2. The nurse's note from May 9, 2010 at 10:39 p.m. shows that the nurse placed the resident's roller walker next to his bed and she checked to ensure that his bed alarm was in place. P. Ex. 17 at 59.

On May 20, 2010, Resident 2 fell twice. The first fall is reflected in a nurse's note dated May 20, 2010 at 1:43 p.m. The note states that Resident 2 had been confused much of the shift stating that he left his wife with his brother-in-law who was going to die that afternoon. He used his wheelchair to go to lunch and after lunch he was placed in the chair in his room with the alarm set. He was subsequently found walking in the hall with his walker. The nurse's note does not mention whether or not the chair alarm was sounding. Resident 2 lost his balance while walking near the nurses' station and fell on his buttocks. The records do not state whether or not staff was assisting Resident 2 while he was walking with the walker. The nurse's note states that the floor was dry and the resident was wearing appropriate footwear. P. Ex. 17 at 62; CMS Ex. 5 at 76. Unlike the other falls discussed here, Petitioner has produced no report of an investigation or IDT review of this fall.

The second fall on May 20, 2010 is described by a nurse's note dated May 20, 2010 at 10:38 p.m. At around 5:50 pm, the nurse and CNA heard a call for help and an alarm sounding. They found Resident 2 sitting on the floor at the end of his bed with his back leaning against the bed. His walker was tipped over and his shoes were on. He stated that he was going to put the tissue box that was lying on the floor in the waste basket. He was returned to bed with a sling lift. His bed was noted to be in the low position with the bed alarm active. P. Ex. 17 at 63; CMS Ex. 5 at 77. The "Change In Condition Report – Post Fall/Trauma" form dated May 20, 2010 lists the following interventions in use prior to the fall: the night light; assistive device within reach; bed/chair alarm; pain assessment; bed in low position; physical therapy; safety cues/reinforcement/reminder; and call light within reach. The report does not show that half bed rails, appropriate footwear, or a toileting schedule were in use as they were reported to be by the report related to the May 9, 2010 fall. P. Ex. 19 at 8. The investigator recommended no new interventions following the second fall on May 20. The IDT again noted the resident's significant cognitive impairment, his noncompliance with the care plan, the fact he took psychotropic medications, the fact his vital signs did not reflect a cause for the fall; his agitation; his impaired decision-making and safety awareness, among other things. The IDT recommended only a therapy evaluation. P. Ex. 19 at 11. A note was added to Resident 2's care plan indicating that he fell, he had no injury, he was confused, and he lacked sleep. No intervention appears to have been added to the care plan. No interventions were added to the care plan requiring that resident's bed be in the low position or physical therapy. P. Ex. 13, at 4. According to Petitioner, Resident 2 was sent for PT and OT screening, doctors completed a medication review, OT and PT began between May 20 and June 6, 2010. PT and OT were discontinued on June 16, 2010 due to the resident's refusal to participate. CMS Ex. 5 at 134-35; Tr. 203.

On May 24, 2010, at 4:30 a.m., Resident 2 fell again. The nurse's note states that the nurse was called to the resident's room but who called the nurse is not stated. The resident was observed to be sitting on the floor with his legs crossed at the ankles and leaning back against the recliner chair. He said he fell and hit his head on the floor, but

no bruising or raised areas were noted. P. Ex. 17 at 65; CMS Ex. 5 at 79. There was no mention in the documentation as to whether an alarm sounded. The "Change In Condition Report – Post Fall/Trauma" lists the following interventions as used prior to the fall: half bedrails, recliner chair, bed/chair alarm, call light within easy reach. Post fall recommendations list: half bedrails, toileting schedule, bed/chair alarm, wheelchair positioning, safety cues/reinforcement/reminder, and call light within reach. The IDT review and recommendations are similar to that of prior fall reports with mention of psychotropic medications, his diagnoses, impaired cognitive ability, poor decision-making ability, noncompliance, lack of safety awareness, and the conclusion that his vital signs do not appear to have been a factor. The IDT's only recommendation is related to therapy. The post-fall report states that the care plan was updated but the care plan does not reflect any updates or changes dated May 24, 2010. P. Ex. 19 at 12-13; P. Ex. 13 at 4. The following interventions listed on the fall investigation report are not listed on the fall care plan: use of half bedrails, use of a reclining chair, use of a chair alarm, and therapy. P. Ex. 13 at 4.

A nurse's note dated May 26, 2010, states that staff were reminded that Resident 2's alarms should be answered, but the note does not specify which alarms were in use. The note also states that he was not supposed to be alone. It is not clear from the note whether or not the resident was to have constant one-on-one supervision and that intervention is not documented on the care plan. P. Ex. 17 at 66. A second note dated May 26, 2010, indicates that the resident was screened at staff request due to frequent falls. It is noted that it was discussed with the resident's daughters that the resident was more weak and unsteady on his feet and, while he had not previously cooperated with physical therapy, Petitioner was willing to try therapy again. The daughters apparently requested that physical therapy be delayed one week. P. Ex. 17 at 67. Petitioner concedes that on May 26, 2010, it was noted that Resident 2 could turn his bed alarm off independently. CMS Ex. 5 at 159.

A nurse's note dated May 28, 2010 at 3:46 a.m. states that Resident 2 turned off his alarm and appeared at the nurse's desk requesting his car keys. P. Ex. 17 at 67; CMS Ex. 5 at 81, 134. This incident clearly shows that Resident 2 had the ability to turn off his alarms, but there is no evidence that this was reported to the IDT, the care planning team, and there is no evidence offered by Petitioner of new interventions to address this problem. P. Ex. 13 at 1-5; CMS Ex. 5 at 85, 134. Dr. Boero, Petitioner's Medical Director and Resident 2's physician, testified regarding alarms that when a resident learns how to defeat the alarm it is necessary to adapt by using a different alarm or attaching the alarm in a way that prevents the resident from disabling the alarm. Tr. 194-96.

There is evidence that the physician issued an order on June 1, 2010 for physical therapy and occupational therapy evaluation and treatment due to Resident 2's decreased strength and increased falls. P. Exs. 14 at 2, 20-24. On June 2, 2010, the physician ordered physical therapy five times a week for three weeks and then two times a week for one

week for therapeutic exercises, balance and gait retraining to decrease Resident 2's fall risk. On June 3, 2010, the physician ordered occupational therapy treatment five times a week for four weeks for therapeutic exercise and ADLs for Resident 2's generalized weakness. P. Ex. 14 at 2. Resident 2's MDS with an assessment reference date of June 11, 2010, reflects a decline in his functioning. He continued to be assessed as severely cognitively impaired, with a short-term memory deficit, he was easily distracted, and his mental functioning varied over the course of the day. For bed mobility, Resident 2 required supervision and a one person assist. For transfers and walking in his room, Resident 2 required limited assistance of one person. Somewhat inconsistently, Resident 2 was assessed as independent with walking in the hall but with the assistance of one person. For locomotion on and off his unit, the resident was assessed as requiring the extensive assistance of one person. Toilet use remained the same; limited assistance with a one person physical assist. He was assessed as requiring partial physical support to maintain his balance while standing and he continued to have an unsteady gait. P. Ex. 7; CMS Ex. 5 at 120-23. A nurse's note dated June 14, 2010, states that the resident had to call for help as he could not get to a standing position from his low bed. P. Ex. 17 at 71. A nurse's weekly review note dated June 27, 2012 states that the resident was discharged from therapies due to lack of participation (P. Ex. 17 at 74), which is consistent with orders (P. Ex. 12 at 3). Dr. Boero testified that the physical therapy was discontinued due the resident's cognitive impairment and noncompliance. Tr. 202-03. A June 30, 2010 nurse's note states that the resident set off an alarm when he got up to use the bathroom and staff responded and assisted. P. Ex. 17 at 75.

A nurse's note dated July 2, 2010 at 11:26 p.m. states that Resident 2 fell in his room and suffered a laceration on the back of his head. The noted mentions the resident's habit of walking without assistance. There is no mention in the note if any alarm was sounding. The resident was sent to the emergency room where he had eight staples to close the laceration. P. Ex. 17 at 76; CMS Ex. 5 at 41-42, 52. A nurse's note dated July 3, 2010 at 4:05 p.m., mentions that the resident had safety awareness problems and would forget to use his walker. The note also states that after his return from the hospital he set off the alarm getting up to go to the bathroom and he had an unsteady gait when staff assisted him to the bathroom. The note states he set off the alarm a second and a third time on July 3. A note at 9:58 p.m. on July 3, 2010, states that the resident's bed alarm was on and his bed was in the low position. However, the note also states that the resident was up numerous times asking about his car and staff were giving him one-on-one supervision. P. Ex. 17 at 76. The "Change In Condition Report – Post Fall/Trauma" dated July 2, 2010, states that the resident fell in his room in front of the bathroom door. The report also states that the resident was walking without assistance which was normal for him and he told staff he was going to the bathroom. The report lists the following interventions as in effect at the time of the fall: half bed rails, assistive device within reach, bed/chair alarm, bed in low position, safety cues/reinforcement/reminder, and call light within reach. The one additional intervention recommended by the investigator was for a toileting schedule. The IDT review and recommendations section lists as

additional interventions a PT screen, gripper socks while in bed, and a repeat x-ray. The IDT notes that the resident has a history of poor safety awareness; he has a bed alarm to alert staff to attempts to self-transfer; his bed is in the lowest position; and his call light is within reach. P. Ex. 19 at 14-15. According to Resident 2's incontinence risk care plan with the original date of January 15, 2010, the resident was supposed to be on a toileting schedule that required that the resident be offered toileting upon arising, before and after meals, at bedtimes, and when staff made nightly rounds. P. Ex. 13 at 2. I also note that encouraging the resident to wear gripper socks at night was an intervention added after the March 13, 2010 fall. P. Ex. 13 at 4-5. The fall care plan does not reflect the addition of any new interventions based on the fall on July 2, 2010. There is evidence that the physician issued an order on July 9, 2010 for the resident to ambulate with the standby assistance of staff to and from the bathroom using the wheeled walker. This order was in effect through October 2010. P. Ex. 12 at 6, 9, 12, 14; P. Ex. 15 at 8; CMS Ex. 5 at 35; Tr. 204. The physician order is odd in that it only addresses ambulation to and from the bathroom and not ambulation in the room or the hall. Dr. Joseph Boero, Resident 2's physician and Petitioner's Medical Director, could not explain the anomaly in testimony. Tr. 204-11. The physician's note dated July 15, 2010 adds little insight. The physician notes incorrectly that Resident 2 fell on July 4, rather than July 2. The physician correctly stated that the resident suffered a head laceration. The physician states that the resident can no longer walk the distance to the dining room under his own power as he has become more and more frail. The physician states the resident ambulates and transfers on his own and that he had bed and chair alarms. The physician noted the resident seemed tippy on standing. He discontinued one dose of the resident's Lorazepam due to the resident risk for falling and he noted that there was a major risk for falling. P. Ex. 16 at 9-10. Dr. Boero testified that there is very little that can be done about a resident like Resident 2 who has trouble walking and is supposed to use a walker but forgets to do so. He testified that the resident needed to be reminded to use his walker and that one-on-one supervision is very effective, but not practical. He also opined that it was not standard of care to provide one-on-one supervision except periodically. Tr. 185-86.

Nurse's notes show that the resident set off his alarm going to the bathroom on July 4, 2010. P. Ex. 17 at 77. A note dated July 10 states that the resident is overall unsteady on his feet and needs a walker to get around and sometimes he used a wheelchair. P. Ex. 17 at 81. A nurse's note dated July 15, 2010 indicates that the resident ambulates independently with a walker and occasionally he uses a wheelchair for long distances. There is no mention of the physician's July 9, 2010 order for standby assistance, even if it applied only to going to the bathroom. The note also states that the resident has a bed alarm in bed and a chair alarm in the chair. P. Ex. 17 at 82-83.

On August 18, 2010, at 4:00 a.m., Resident 2 fell. The bed alarm was turned on, but did not sound. The pull alarm sounded and staff responded to this as Resident 2 yelled for help. A CNA found Resident 2 lying on his left side in front of his closet. He had on the

proper footwear and he stated that he was going to the bathroom. Later that day the CNA reported small scrapes on Resident 2's knees, bruising on his left forearm with tiny scrapes, and bruising on his left outer wrist. The resident was noted to be confused. P. Ex. 17 at 91; CMS Ex. 5 at 43-45, 57. Petitioner's "Change In Condition Report – Post Fall/Trauma" dated August 18, 2010, lists interventions in use prior to the fall: change in footwear, night light, OT, bed/chair alarm, pain assessment, safety cues/reinforcement/reminder, call light within reach, and other. Recommended interventions are the same with the exception that "other" is not checked on the form. P. Ex. 19 at 16-17. A hand-written entry was made in the Problems/Strengths column of the falls care plan that indicates the resident fell while ambulating in his rooms with no injury. No new interventions dated around August 18, 2010 appear on the care plan. P. Ex. 13 at 4-5.

On September 1, 2010, at 7:00 p.m., Resident 2 fell again. Resident 2 was ambulating without assistance with his wheeled walker near the nurses' station and a nurse observed him fall and strike the back of his head. He suffered a small abrasion to his head and a small blood blister on his left elbow. P. Ex. 17 at 96. He stated that he tripped over his own feet. P. Ex. 17 at 96; CMS Ex. 5 at 46-47, 60, 136. Petitioner's "Change In Condition Report – Post Fall/Trauma" dated September 1, 2010 lists the following interventions as being used prior to the fall: night light, bed/chair alarm, bed in low position, safety cues/reinforcement/reminder, and call light within reach. Recommended interventions are no different. There is no entry in the area for "IDT Review and Recommendations." P. Ex. 19 at 18-19.

Resident 2's final MDS with an assessment reference date of September 5, 2010, reflects a continued decline. He continued to be assessed as severely cognitively impaired, with a short-term memory deficit, he was easily distracted, and his mental functioning varied over the course of the day. He was also assessed as having altered perception or awareness of his surroundings. His vision was assessed as being highly impaired. Resident 2 was assessed as requiring a one person physical assist for all activities with extensive assistance for locomotion on and off the unit. He was not observed to walk in the corridor during the observation period for the assessment. He required partial physical support to maintain balance while standing and he was assessed to have an unsteady gait. P. Ex. 8; CMS Ex. 5 at 126-30. A physician's note dated September 16, 2010, indicates that the consulting pharmacist suggested that Resident 2's agitation and falling could be due to medication and he recommended that the physician taper some medication. The physician agreed and ordered a reduction in some medications noting specifically that the resident sometimes had low blood pressure and risk for falling. P. Ex. 16 at 11-12. Dr. Boero testified that Resident 2's psychotropic medication contributed to his risk for falls but was necessary to control his behaviors. He testified that it was a matter of weighing risks verses benefits. He testified that he, the consulting psychiatrist, or the consulting pharmacist initiated medication reviews monthly. Tr. 216-

20. The care plan does not reflect any entries related to the September 1, 2010 fall. P. Ex. 13 at 4-5.

A nurse's note on October 1, 2010 states that Resident 2 was in a restorative program that consisted of ambulation to and from the bathroom. P. Ex. 17 at 103. A nurse's note dated October 13, 2010, states that the resident caused his bed alarm to sound two or three times when he tried to get up. P. Ex. 17 at 105.

Resident 2 fell again on October 18, 2010, at 2:50 a.m. in his room. A nurse's note dated October 18, 2010 at 7:09 a.m. states that the nurse heard Resident 2 calling out "help me" The nurse found Resident 2 on the floor, apparently in his room, lying under his wheelchair on his back with his head raised under the wheelchair seat. He denied any pain. The note does not state that there was any alarm sounding. P. Ex. 17 at 108; CMS Ex. 5 at 48-49, 63, 137. Petitioner's "Change In Condition Report – Post Fall/Trauma" dated October 18, 2010, states that the fall was related to a transfer, but does not state the basis for that conclusion. The report lists the following interventions as in use prior to the fall: change in footwear, night light, OT, bed/chair alarm, pain assessment, wheelchair positioning, PT, call light within reach. The one recommended intervention after the fall was safety cues/reinforcement/reminder. The IDT recommendations were to keep the room free of clutter and well lighted; therapy screen; continue bed and chair alarm; appropriate footwear; educate the resident to request assistance with transfers; and medication review. P. Ex. 19 at 21. The care plan did not provide for an alarm in the wheelchair. There care plan reflects no changes dated about the time of the October 18, fall. P. Ex. 13 at 1-5.

On October 21, 2010, at around 9:15 p.m., Resident 2 was found sitting on the floor midway between the bed and the bathroom. There was a skin tear to his right elbow, a bruise on his left shoulder and he complained of pain with movement of his left shoulder. He said he got up from his bed and was going to the bathroom but could not recall how he fell or tripped. There is no documentation that an alarm sounded. P. Ex. 17 at 111; CMS Ex. 5 at 50-51, 66.; Tr. 114. Petitioner's "Change In Condition Report – Post Fall/Trauma" dated October 21, 2010, lists the following interventions as in use prior to the fall: night light, assistive device within reach; bed/chair alarm; bed in low position; safety cures/reinforcement/reminder; and call light within reach. The report recommended that the additional intervention of using a recliner chair because the resident had been sleeping in the chair in his room and the writer recommended using the recliner to elevate his feet, apparently in part to prevent him from standing. The "IDT Review and Recommendations" section of the report lists therapy; bed/chair alarm in place; psychotropic medication review; and appropriate footwear in place. P. Ex. 19 at 22-23. The IDT review did not address whether the resident was in bed or in his chair prior to the fall, whether the bed was in the low position; or whether the alarms worked. The care plan reflects that on October 21, 2010 a notation was added under interventions that states "alarms at all times – responding quickly." P. Ex. 13 at 4-5. The evidence

includes a physician's note dated October 21, 2010, in which the physician states that the resident has not fallen or injured himself recently. P. Ex. 16 at 13. The physician's note does not indicate what time the physician saw Resident 2 on October 21. Apparently, the physician forgot about the fall on October 18, 2010. A nurse's note dated October 22, 2010 that references the fall on October 21 states that the resident was responding to "urination urgency." P. Ex. 17 at 111-12. A nurse's note dated October 23, 2010, states that the resident is most comfortable sitting up in his recliner. A nurse's note dated October 24, 2010, states that chair and bed alarms were in place because the resident attempted to get up on his own, and that the resident had set off alarms once or twice during the day shift. P. Ex. 17 at 113.

Resident 2 died on November 4, 2010 due to congestive heart failure. P. Ex. 17 at 127; P. Ex. 21.

b. Analysis

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

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

42 C.F.R. § 483.25(h). CMS instructs its surveyors that the intent of 42 C.F.R. § 483.25(h)(1) and (2) is "to ensure the facility provides an environment that is free from accident hazards over which the facility has control and provides supervision and assistive devices to each resident to prevent avoidable accidents." The facility is expected to: identify, evaluate, and analyze hazards and risks; implement interventions to reduce hazards and risks; and monitor the effectiveness of interventions and modify them

when necessary. State Operations Manual (SOM), CMS Pub. 100-07, app. PP, Guidance to Surveyors Long Term Care Facilities, F323 (rev. 27; eff. Aug. 17, 2007).[9]

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 (2007); *Century Care of Crystal Coast*, DAB No. 2076 (2007), *aff'd, Century Care of the Crystal Coast*, 281 F. App'x 180 (4th Cir. 2008); *Liberty Commons Nursing and Rehab - Alamance*, DAB No. 2070 (2007); *Golden Age*

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[9] Although the SOM does not have the force and effect of law, the provisions of the Act and regulations interpreted clearly do have such force and effect. *State of Indiana by the Indiana Department of Public Welfare v. Sullivan*, 934 F.2d 853 (7th Cir. 1991); *Northwest Tissue Center v. Shalala*, 1 F.3d 522 (7th Cir. 1993). Thus, while the Secretary may not seek to enforce the provisions of the SOM, she may seek to enforce the provisions of the Act or regulations as interpreted by the SOM.

Skilled Nursing & Rehab. Ctr., DAB No. 2026 (2006); *Estes Nursing Facility Civic Ctr.*, DAB No. 2000 (2005); *Northeastern Ohio Alzheimer's Research Ctr.*, DAB No. 1935 (2004); *Woodstock Care Ctr.*, DAB No. 1726 (2000), *aff'd*, *Woodstock Care Ctr. v. Thompson*, 363 F.3d 583 (6th Cir. 2003). A facility is not strictly liable for accidents that occur, but 42 C.F.R. § 483.25(h) requires that a facility take all reasonable steps to ensure that a resident receives supervision and assistance devices that meet his or her assessed needs and mitigates foreseeable risks of harm from accidents. *Woodstock Care Ctr. v. Thompson*, 363 F.3d at 589 (holding a SNF must take "all reasonable precautions against residents' accidents"). A facility is permitted the flexibility to choose the methods of supervision it uses to prevent accidents, but the chosen methods must be adequate under the circumstances. Whether supervision is "adequate" depends in part upon the resident's ability to protect himself or herself from harm. *Id*. Based on the regulation and the cases in this area, CMS meets its burden to show a prima facie case if the evidence demonstrates that the facility failed to provide adequate supervision and assistance devices to prevent accidents, given what was reasonably foreseeable. *Alden Town Manor Rehab. & HCC*, DAB No. 2054, at 5-6, 7-12 (2006). An "accident" is an unexpected, unintended event that can cause a resident bodily injury, excluding adverse outcomes associated as a direct consequence of treatment or care (e.g., drug side effects or reactions). SOM, App. PP, Tag F323; *Woodstock Care Ctr.*, DAB No. 1726, at 4.

The surveyors charge a violation of 42 C.F.R. § 483.25(h) based on the example of Resident 2 because he fell on December 15, 2009 with injuries and had to be hospitalized; after his return to Petitioner he had ten more falls; and after each fall Petitioner failed to critically analyze the falls to identify and evaluate potential hazards and risks to determine if new interventions to minimize the risk for falls were necessary. CMS Ex. 3 at 2. Based on the surveyors' allegations and the evidence before me, I do not conclude there was a violation of 42 C.F.R. § 483.25(h) based on the December 15, 2009 fall or the care planning prior to that fall. Rather, for purposes of this decision, I treat the December 15 fall as establishing that Petitioner recognized that Resident 2 was at risk for falls, that falls were foreseeable absent interventions to minimize his risk for falls, and that the IDT had engaged in care planning and adopted certain interventions to minimize the resident's risk for accidental injury due to falls. To determine whether or not there was a deficiency as alleged by the surveyors and CMS, I consider in detail the facts of each of the other ten falls that occurred on March 13, 2010, May 9, 2010, two on May 20, 2010, May 24, 2010, July 2, 2010, August 18, 2010, September 1, 2010, October 18, 2010, and October 21, 2010. I consider the evidence of the interventions in use and not in use at the time of each fall; the evidence of the IDT's evaluation of the effectiveness or adequacy of the interventions in use or not at the time of each fall; and the evidence showing that the IDT determined to implement new or modified interventions and whether the interventions were actually implemented.

I infer that the mechanically printed entries on the form titled "Plan of Care," which was admitted as evidence by Petitioner, are the interventions adopted by the IDT that were in

effect after the December 15, 2009 fall. The December 15 fall occurred in the hall when Resident 2 was walking without his walker and he tripped on his own feet. I infer that some of the interventions were adopted by the IDT specifically to address the risk for falling when the resident attempted to walk or walked with or without his walker. P. Ex. 17 at 9; P. Ex. 19 at 1-4. The interventions listed on the plan of care addressing the risk for falls were:

- Resident 2 was to wear a cervical collar at all times;
- Transfers were to be with assist of one as needed;
- Staff was to use a gait belt for all assisted transfers;
- Resident 2's call-light was to be within reach at all times and answered promptly;
- A bed alarm was to be in place at night;
- Staff was to respond to the call-light promptly as able;
- Staff was to document any falls/injuries and inform the treating physician and family promptly per facility protocol;
- Falls risk assessment were to be done quarterly and/or as needed;
- The resident was to be assessed for a nursing rehabilitation program if indicated;
- Therapies were to be as ordered by the physician;
- Staff was to ensure the resident's room was free from clutter to increase safety with (independent) toileting;
- The resident's medications were to be assessed for possible adverse reactions or side effects related to falls and the physician was to be updated if needed; and
- Grab bars on the bed were to be up when the resident was in bed to assist his mobility and positioning.

CMS Ex. 5 at 85; P. Ex. 13 at 4-5. Other pages of Resident 2's care plan addressing other problems also listed interventions that, arguably, would help minimize his risk for injury due to falls, for example:

- He was to ambulate with limited assistance of one. P. Ex. 13 at 1.
- He was to be monitored for side effects of medication, including unsteady balance. P. Ex. 13 at 9, 21.

There are physician orders dated January 9 and 11, 2010 for occupational therapy and gait training that was terminated on February 5, 2010 due to the resident's cognitive decline. P. Ex. 14 at 1, Tr. 199-203. There is also evidence of a nursing order from June 25, 2009, that Resident 2 was to have a bed alarm during hours of sleep with the alarm box at the head of the bed with checks twice each day. The evidence shows that this order was in effect through October 2010. P. Ex. 12 at 2, 5, 8, 11, 14; P. Ex. 15 at 1-7,

12, 14, 16, 18. Diane Hengst, RN, who cared for Resident 2, testified that she knew the resident was supposed to use a walker; the walker was to be available to him at all times; and he was to be reminded to use the walker. Tr. 575-76. Nurse Hengst did not identify the source of these interventions, where they were documented, or when they were implemented. It is surprising that the interventions reflected in the clinical evidence after the December 15, 2009 fall do not include interventions as described by Nurse Hengst to ensure that resident walked only with his walker. It is also surprising that the IDT did not implement interventions related to use of a walker, even though for a time Resident 2 was limited to a wheelchair. CMS Ex. 19 at 1-4. Resident 2's MDS with a reference date of December 24, 2009, shows that he was assessed as requiring limited assistance of one person for bed mobility, transfers, walking in his room, walking along the corridor, locomotion on and off the unit and for toilet use. The MDS also shows that his balance while standing was unsteady and he had an unsteady gait. CMS Ex. 5 at 113-18; P. Ex. 5 at 2-7. The intervention of a toileting schedule was adopted on January 15, 2010. The toileting schedule intervention required that the resident be offered toileting upon arising, before and after meals, at bedtimes, and during nightly rounds. P. Ex. 13 at 2. Although the intervention was listed on a care plan for incontinence, Dr. Boero testified that it was also an important intervention to prevent falls. Tr. 199-203. DON Grubbs also testified to the importance of a toileting schedule for a resident like Resident 2. Tr. 491-92.

Resident 2 fell on March 13, 2010, at 11:40 p.m. A nurse heard the resident's alarm sounding and she arrived in time to see him fall with resulting injuries. Petitioner's investigation report states that the resident fell responding to bladder or bowel urgency. The report shows that the following interventions were in place at the time of the fall: change in footwear; night light; bed/chair alarm; bed in low position; safety cues, reinforcement, reminder; and call light within easy reach. P. Ex. 19 at 6. The report does not show that the toileting schedule that was adopted on January 15, 2010 had been followed. The report does not indicate whether the floor of the resident's room was clear of clutter and trip hazards as required by his falls care plan, but does mention that the floor was dry. The report does not mention the resident's walker, an assistive device. The report shows that the IDT did not recommend any new interventions except a physical therapy screen. The report shows the IDT recognized that the resident had severely impaired decision-making and was noncompliant with the plan of care at times, but the IDT made no recommendation for interventions to address those problems. The IDT review on the report does not reflect any analysis of the effectiveness of the interventions in place or why the toileting plan may not have been followed. P. Ex. 19 at 6-7. The care plan was updated with three interventions that appear as hand-written entries: to encourage the resident to wear shoes or gripper shocks at night; the bed alarm was to be on when the resident was in bed; and his pain was to be monitored for 72 hours. P. Ex. 13 at 4-5. It appears from Petitioner's report of investigation of the fall that there were already interventions regarding footwear and the bed alarm prior to the fall. In fact, Petitioner's records show the bed alarm was first ordered June of 2009 and some sort of alarm alerted the nurse the resident was falling on March 13.

Resident 2 fell on May 9, 2010 at about 6:00 p.m. The resident had been placed in his bed after the evening meal. A nurse at the nurse's station heard a loud noise and found the resident on the floor. His bedside table was overturned and he was injured. P. Ex. 15 at 59; CMS Ex. 5, at 73. Petitioner's investigation report shows that the resident was responding to bladder or bowel urgency. The report lists the following interventions as being in place: half bedrails,[10] change in footwear, night light, toileting schedule, assistive device within reach, bed/chair alarm, safety cues/reinforcement/reminder, and call light within reach. P. Ex. 19 at 8. The nurse that completed the report recommended the addition of one intervention which is listed on the report form as wheelchair positioning. P. Ex. 19 at 9. Notes of the review of the accident by the IDT, which is responsible for care planning for the resident, state that the resident is known to have significant cognitive impairment; he is known to be noncompliant at times with the plan of care; his vital signs did not appear to contribute to his fall, but he has agitation, impaired decision-making ability, and he lacked safety awareness. The IDT recommended a therapy screen, but the type of screen is not specified. P. Ex. 19 at 9. The IDT notes do not reflect an analysis of the effectiveness of the interventions in place prior to the fall. The IDT notes do not show that the IDT determined whether or not an alarm sounded. The report indicates that a toileting schedule was an intervention in effect but the evidence does not reflect that the IDT determined whether or not Resident 2 had been taken to the toilet prior to being put to bed. The IDT notes show that the team recognized his cognitive deficit, his noncompliance, and his lack of safety awareness; but the notes do not show that the IDT considered any possible interventions to address those problems. The notes also show that the IDT considered that he was taking psychotropic medications but failed to request a pharmacist and physician review to determine whether the medications may be contributing to the resident's falls. There is no evidence that any new interventions were ordered or implemented or that any existing interventions were modified due to the May 9, 2010 fall.

On May 20, 2010, Resident 2 fell twice. The first fall is reflected in a nurse's note dated May 20, 2010 at 1:43 p.m. The note states that Resident 2 had been confused much of the shift stating that he left his wife with his brother-in-law who was going to die that afternoon. He used his wheelchair to go to lunch and after lunch he was placed in the chair in his room with the alarm intact. He was subsequently found walking in the hall with his walker. The nurse's note does not mention whether or not the chair alarm was sounding. Resident 2 lost his balance while walking near the nurses' station and fell on his buttocks. The records do not state whether or not staff was assisting Resident 2 while he was walking with the walker. The nurse's note states that the floor was dry and the

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[10] This entry conflicts with the testimony of RN Grace Brehm, who unequivocally testified that Petitioner does not use side rails. Tr. 574.

resident was wearing appropriate footwear. P. Ex. 17 at 62; CMS Ex. 5 at 76. Unlike the other falls discussed here, Petitioner has produced no report of an investigation or IDT review of this fall. Accordingly, I conclude that the IDT did no analysis of the cause of this fall, the effectiveness of interventions in place at the time of the fall, or whether new interventions needed to be implemented or old interventions needed to be modified to minimize the resident's risk for accidental injuries.

Resident 2 fell a second time on May 20, 2010 at about 5:50 p.m. A nurse and CNA heard a call for help and an alarm sounding and they found the resident on the floor in his room. The resident's walker was tipped over and he had his shoes on. His bed was in the low position and the alarm was active. The resident told staff that he was going to put a tissue box lying on the floor into the waste basket. P. Ex. 17 at 63; CMS Ex. 5 at 77. Petitioner's report of investigation of this fall lists the following interventions in use prior to the fall: night light; assistive device within reach; bed/chair alarm; pain assessment; bed in low position; physical therapy; safety cues/reinforcement/reminder; and call light within reach. The report does not state that appropriate footwear was being used, but I will infer that the shoes he was wearing were appropriate. The report also does not show that the toileting schedule and half bedrails were interventions in use as shown on the report related to the May 9, 2010 fall. The report does not indicate whether there was a tissue box or other clutter on the floor. The report of investigation indicates that Resident 2 was confused more than normal due to being awake the night before with signs and symptoms of an upper respiratory infection. No new interventions are recommended by the person who did the investigation. The report shows that the resident was doing his usual activities at the time of the fall. However, the report does not state what the activities were. When the resident fell on May 9, 2010 at about 6:00 p.m. at about the same time as the 5:50 p.m. fall on May 20, he had been put in bed. The nurse's note indicates that the resident had been toileted about 5:00 p.m. but does not state whether he was put in the bed or his chair after. The note indicates that after the fall he was "returned to bed." The fact he had his shoes on is inconsistent with him having been in bed. Neither the nurse's note nor the report of investigation state whether the alarm that sounded was on the resident's bed or his chair. The IDT could not appropriately assess the effectiveness of the alarm without knowing which alarm sounded. Even though the evidence shows the alarm sounded and therefore worked as intended, if it was the chair alarm the IDT may have considered, for example, whether a reclining chair or a more reclined chair would be a better intervention to give staff more time to respond to the alarm. Similarly, if the alarm was on the bed the IDT may have inquired as to why the resident was wearing shoes in bed, potentially issues of resident's rights, dignity, or quality of care, and the IDT may also have considered whether a "concave" or "winged mattress" may have been an appropriate intervention to delay the resident while staff responded to an alarm. The IDT noted the resident's significant cognitive impairment, his noncompliance with the care plan, the fact he took psychotropic medications, the fact his vital signs did not reflect a cause for the fall; his agitation; his impaired decision-making and safety awareness, among other things. The IDT recommended only a

therapy evaluation. P. Ex. 19 at 11. The report does not show that the IDT considered any interventions to address the resident's behavior, the possible impact of psychotropic medication, or his impaired cognition and safety awareness, other than the intervention already in effect to use safety cues, reinforcement, and reminders – an intervention shown by multiple falls to be mostly ineffective. A note was added to Resident 2's care plan indicating that he fell, he had no injury, he was confused, and he lacked sleep. No intervention appears to have been added to the care plan based on the IDT evaluation of this fall. P. Ex. 13 at 4. According to Petitioner, Resident 2 was sent for PT and OT screening, doctors completed a medication review, and OT and PT began between May 20 and June 6, 2010. A nurse's note dated May 26, 2010, indicates that the resident was screened at staff request due to frequent falls. It is noted that it was discussed with the resident's daughters that the resident was more weak and unsteady on his feet and, while he had not previously cooperated with therapy, Petitioner was willing to try therapy again. The daughters apparently requested that therapy be delayed one week. P. Ex. 17 at 67. The physician issued an order on June 1, 2010 for a PT and OT evaluation and treatment due to Resident 2's decreased strength and increased falls. P. Exs. 14 at 2, 20-24. On June 2, 2010, the physician ordered physical therapy five times a week for three weeks and then two times a week for one week for therapeutic exercises, balance and gait retraining to decrease Resident 2's fall risk. On June 3, 2010, the physician ordered OT treatment five times a week for four weeks for therapeutic exercise and activities of daily living to address Resident 2's generalized weakness. P. Ex. 14 at 2. PT and OT were discontinued on June 16, 2010 due to the resident's refusal to participate. CMS Ex. 5 at 134-35; P. Ex. 12 at 3; P. Ex. 17 at 74; Tr. 203. Dr. Boero testified that the physical therapy was discontinued due the resident's cognitive impairment and noncompliance. Tr. 202-03. The evidence does not show that the IDT reconsidered the facts of the fall or the appropriate interventions in light of the resident's PT and OT failure, which should have been no surprise to the IDT.

Resident 2 fell again on May 24, 2010 at about 4:30 a.m. The nurse's note states that the nurse was called to the resident's room but who called the nurse is not stated. The resident was observed to be sitting on the floor with his legs crossed at the ankles and leaning back against the recliner chair. He said he fell and hit his head on the floor, but no bruising or raised areas were noted. P. Ex. 17 at 65; CMS Ex. 5 at 79. There was no mention in the nurse's note as to whether an alarm sounded or whether the resident fell from bed or the reclining chair. Petitioner's report of the investigation of the fall indicates that the following interventions were in use prior to the fall: half bedrails, recliner chair, bed/chair alarm, call light within easy reach. The investigation report does not state that the resident continued to be on a toileting schedule as implemented on January 15, 2010, or if he was, that he had been toileted according to that schedule. However, the report of investigation clearly shows that Resident was responding to bladder or bowel urgency when he fell. P. Ex. 19 at 12. The investigation report does not state that he was wearing appropriate footwear; that his bed was in the low position; that his walker was in reach; or that the nightlight was on. The report also does not show

that the intervention of safety cues, reinforcement, and reminders was still in effect. Whoever completed the report -- it is unsigned -- recommended additional interventions of a toileting schedule and wheelchair positioning. The IDT review and recommendations are similar to that of prior fall reports with mention of psychotropic medications, his diagnoses, impaired cognitive ability, poor decision-making ability, noncompliance, lack of safety awareness, and the conclusion that his vital signs do not appear to have been a factor, with no evidence that interventions to deal with these problems were considered by the IDT. The IDT's only recommendation is related to therapy. The post-fall investigation report states that the care plan was updated but the care plan does not reflect any updates or changes dated May 24, 2010. P. Ex. 19 at 12-13; P. Ex. 13 at 4. As noted in my discussion related to the second fall on May 20, Resident 2 was sent for PT and OT screening, doctors completed a medication review, OT and PT began but were discontinued on June 16, 2010 due to the resident's refusal to participate. CMS Ex. 5 at 134-35; Tr. 203. The evidence does not show that the IDT reconsidered the facts of the fall or the appropriate interventions in light of the resident's PT and OT failure. The IDT notes on the investigation report form do not show that the IDT considered that the resident fell while going to the bathroom, that the report does not show that a toileting schedule was in effect or being followed, or that the person who completed the report recommended a toileting schedule for the resident.

A nurse's note dated May 26, 2010, states that staff was reminded that Resident 2's alarms should be answered. The note also states that the resident was not supposed to be alone. It is not clear from the note whether or not the resident was to have constant one-on-one supervision and that intervention is not documented on the care plan or any physician order in evidence. P. Ex. 17 at 66. Petitioner concedes that on May 26, 2010, it was noted that Resident 2 could turn his bed alarm off independently. CMS Ex. 5 at 159. A nurse's note dated May 28, 2010 at 3:46 a.m. states that Resident 2 turned off his alarm and appeared at the nurse's desk requesting his car keys. P. Ex. 17 at 67; CMS Ex. 5 at 81, 134. This incident clearly shows that Resident 2 had the ability to turn off his alarms, but there is no evidence that this was reported to the IDT and there is no evidence offered by Petitioner of new interventions to address this problem. P. Ex. 13 at 1-5; CMS Ex. 5 at 85, 134. Dr. Boero, Petitioner's Medical Director and Resident 2's physician, testified that when a resident learns how to defeat the alarm it is necessary to adapt by using a different alarm or attaching the alarm in a way that prevents the resident from disabling the alarm. Tr. 194-96.

Resident 2's MDS with an assessment reference date of June 11, 2010, reflects a decline in his functioning and he required more assistance with activities of daily living. P. Ex. 7; CMS Ex. 5 at 120-23. A nurse's note dated June 14, 2010, states that the resident had to call for help as he could not get to a standing position from his low bed. P. Ex. 17 at 71.

Resident 2 fell in his room on July 2, 2010 at about 8:20 p.m. and suffered a laceration on the back of his head that required a trip to the emergency room and eight staples. A nurse's note records the event mentioning the resident's history of walking without assistance but not recording details such as how staff was alerted or what the resident was doing when he fell. P. Ex. 17 at 76; CMS Ex. 5 at 41-42, 52. The report of investigation states that Resident 2 was again responding to bladder or bowel urgency and he fell in front of his bathroom door. The report lists the following interventions as in effect at the time of the fall: half bed rails, assistive device within reach, bed/chair alarm, bed in low position, safety cues/reinforcement/reminder, and call light within reach. The report does not indicate that a toileting schedule was in effect at the time of the fall and the one additional intervention recommended by the investigator is that the resident have a toileting schedule. The IDT review and recommendations section lists as additional interventions a PT screen, gripper socks while in bed, and a repeat x-ray. The IDT notes that the resident has a history of poor safety awareness; he has a bed alarm to alert staff to attempts to self-transfer; his bed is in the lowest position; and his call light is within reach. P. Ex. 19 at 14-15. The report does not indicate whether or not an alarm sounded or whether staff heard and responded to the alarm. The report does not address why the investigator did not state that there was a toileting plan that was being followed and felt it necessary to implement such a plan even though a toileting plan had been implemented on January 15, 2010. P. Ex. 13 at 2. The IDT adopted the intervention to have the resident wear gripper socks following the March 13, 2010 fall. P. Ex. 13 at 4-5. Thus, the IDT's specification that gripper socks were to be used supports an inference that the resident was not wearing gripper socks or other appropriate footwear when he fell. The report also indicates that a night light was no longer an intervention in use for this resident. Nurse's notes show that after his return from the hospital, on July 3, 2010 he set off his alarms multiple times getting up to go to the bathroom and staff on duty decided to give him one-on-one supervision. P. Ex. 17 at 76. Nurse's notes show he continued to set-off his alarm going to the bathroom on July 4, 2010. P. Ex. 17 at 77. The clinical record does not show that this problem was reviewed by the IDT for additional or modified interventions. There is evidence that the physician issued an order on July 9, 2010 for the resident to ambulate with the standby assistance of staff to and from the bathroom using the wheeled walker. This order was in effect through October 2010. P. Ex. 12 at 6, 9, 12, 14; P. Ex. 15 at 8; CMS Ex. 5 at 35; Tr. 204. The physician order is odd in that it only addresses ambulation to and from the bathroom and not ambulation in the room or the hall. Dr. Joseph Boero, Resident 2's physician and Petitioner's Medical Director, could not explain the anomaly in testimony. Tr. 204-11. On July 15, 2010, Dr. Boero discontinued one dose of the resident's Lorazepam, a psychotropic medication, due to the resident's risk for falls. P. Ex. 16 at 9-10. Dr. Boero testified that there is very little that can be done about a resident like Resident 2 who has trouble walking and is supposed to use a walker but forgets to do so. He testified that the resident needed to be reminded to use his walker and that one-on-one supervision is very effective, but not practical. He also opined that it was not standard of care to provide one-on-one supervision except periodically. Tr. 185-86. Dr. Boero's opinion seems to be at odds

with the interventions he implemented after the resident's sixth fall. Ordering standby assistance for bathroom trips, which is essentially one-on-one supervision, was clearly an appropriate intervention. Reducing the resident's Lorazepam which is well known to increase the risk for falls due to side effects including increased confusion and light-headedness or dizziness, was also clearly appropriate. Staff also found it necessary to implement one-on-one supervision of the resident. Therefore, one-on-one supervision was clearly possible, at least for limited periods, even with a combative and cognitively impaired resident such as Resident 2. But it is not for me to say and the focus of my review is not what interventions were possible and practicable, but whether or not the IDT did its job of reviewing each fall, the interventions in effect to mitigate the risk for injury due to falls, the effectiveness of those interventions, and whether the IDT took action to implement new interventions or modify existing interventions to address the risks the IDT identified by its investigation and review. Clearly, as of the July 2, 2010 fall, the IDT's performance in this regard was wholly inadequate. An excellent example of the IDT's failure is shown by the fact that the IDT was not addressing that Resident 2 fell several times while attempting to go to the bathroom unassisted. The resident's care plan called for a toileting plan as early as January 15, 2010. However, the reports of investigation already discussed show that the fall investigators were not aware that a toileting plan was already in effect or being followed prompting the investigators to recommend implementation of a toileting schedule. The evidence does not show that the IDT considered the investigators recommendation to implement a toileting schedule. The evidence also does not show that the IDT questioned why the intervention of using a toileting schedule adopted January 15, 2010 may not have been followed by staff causing the resident to need to use the bathroom at night. Other good examples of the IDT's failure to analyze falls and the effectiveness of interventions and the need for new or modified interventions, is the failure of the IDT to address whether or not alarms were being heard or responded to by staff and the failure of the IDT to specifically address the resident's ability to defeat or disable the alarms. The evidence shows that the IDT performed no better for the falls in August, September, and October.

Resident 2 fell with injury again about 4:00 a.m. on August 18, 2010, while attempting to go to the bathroom unassisted. The evidence shows that the pressure sensitive alarm in the bed was on but did not sound, but the pull alarm that was also in use did sound and staff responded as the resident was calling for help. A CNA found Resident 2 lying on his left side in front of his closet. He had on the proper footwear and he stated that he was going to the bathroom. Later that day the CNA reported small scrapes on Resident 2's knees, bruising on his left forearm with tiny scrapes, and bruising on his left outer wrist. The resident was noted to be confused. P. Ex. 17 at 91; CMS Ex. 5 at 43-45, 57. The report of investigation for the fall indicates that the resident was responding to bladder or bowel urgency when he fell. The report lists the following interventions in effect at the time of the fall: change in footwear, night light, OT, bed/chair alarm, pain assessment, safety cues/reinforcement/reminder, call light within reach, and "other" with nothing written in the blank provided. A toileting schedule is not listed as an intervention

in effect. No new interventions are recommended by the unknown investigator. The IDT review notes list the interventions in effect prior to the fall and list the same interventions for after the fall, except for "other." The evidence does not show that the IDT considered any of the problems or risks that I have previously identified, the effectiveness of existing interventions, or the need for new or modified intervention. No new interventions dated around August 18, 2010 appear on the care plan. P. Ex. 13 at 4-5.

Resident 2 fell again on September 1, 2010 at about 7:00 p.m. Resident 2 was ambulating without assistance with his wheeled walker near the nurses' station and a nurse observed him fall and strike the back of his head. He suffered a small abrasion to his head and a small blood blister on his left elbow. P. Ex. 17 at 96. He stated that he tripped over his own feet. P. Ex. 17 at 96; CMS Ex. 5 at 46-47, 60, 136. Petitioner's investigation of the fall lists the following interventions as being used prior to the fall: night light, bed/chair alarm, bed in low position, safety cues/reinforcement/reminder, and call light within reach. Recommended interventions are no different. There is no entry in the area for "IDT Review and Recommendations" based on which I infer that the IDT did not conduct a review of the fall or consider the effectiveness of interventions or the need for new or modified interventions. P. Ex. 19 at 18-19. The care plan does not reflect any entries related to the September 1, 2010 fall. P. Ex. 13 at 4-5.

Resident 2's final MDS with an assessment reference date of September 5, 2010, reflects a continued decline. He was assessed as having altered perception or awareness of his surroundings. His vision was assessed as being highly impaired. Resident 2 was assessed as requiring a one person physical assist for all activities, with extensive assistance for locomotion on and off the unit. He was not observed to walk in the corridor during the observation period for the assessment. He required partial physical support to maintain balance while standing and he was assessed to have an unsteady gait. P. Ex. 8; CMS Ex. 5 at 126-30. A physician's note dated September 16, 2010, indicates that the consulting pharmacist suggested that Resident 2's agitation and falling could be due to medication and he recommended that the physician taper some medication. The physician agreed and ordered a reduction in some medications noting specifically that the resident sometimes had low blood pressure that contributed to the risks for falling. P. Ex. 16 at 11-12. Dr. Boero testified that Resident 2's psychotropic medication contributed to his risk for falls but was necessary to control his behaviors. He testified that it was a matter of weighing risks verses benefits. He testified that he, the consulting psychiatrist, or the consulting pharmacist, initiated medication reviews monthly. Tr. 216-20. Medication review seems to be appropriate particularly review of psychotropic medication. In fact, Dr. Boero previously reduced the resident's Lorazepam. The pharmacist triggered the review in this case which demonstrates that Petitioner's consulting pharmacist was doing his job. However, there is no evidence that the IDT considered medication review following the September 1, 2010 fall, which is another example of the failure of the IDT.

A new intervention was implemented about October 1, 2010. A nurse's note on October 1, 2010 states that Resident 2 was in a restorative program that consisted of ambulation to and from the bathroom. P. Ex. 17 at 103. A nurse's note dated October 13, 2010, states that the resident caused his bed alarm to sound two or three times when he tried to get up. P. Ex. 17 at 105. There is no evidence of action by the IDT related to the alarms.

On October 18, 2010, at 2:50 a.m. Resident 2 fell in his room. A nurse's note dated October 18, 2010 at 7:09 a.m. states that the nurse heard Resident 2 calling out "help me" and that she found him on the floor, apparently in his room, lying under his wheelchair on his back with his head raised under the wheelchair sea. The note does not state that there was any alarm sounding. P. Ex. 17 at 108, CMS Ex. 5 at 48-49, 63, 137. Petitioner's report of investigation of the fall indicates the following interventions were in effect: change in footwear, night light, OT, bed/chair alarm, pain assessment, wheelchair positioning, PT, call light within reach. The one recommended intervention after the fall was safety cues/reinforcement/reminder, though there is evidence that that was an intervention that was supposed to be in effect since the December 2009 fall. The IDT recommendations were to keep the room free of clutter and well lighted; therapy screen; continue bed and chair alarm; appropriate footwear; educate the resident to request assistance with transfers; and medication review, although the IDT notes reflect that the medication review had already been done. P. Ex. 19 at 21. I doubt that the IDT intended that the resident's room be "well lighted" at 2:50 a.m. but the investigation shows that a night light was once again an intervention that was in use. The report is not clear as to the facts of this fall. The report states that the resident said his bed broke. The report also states that the fall was due to an unassisted transfer, but whether from bed to wheelchair or wheelchair to bed is not specified. The value or appropriateness of the IDT's new and modified interventions needs to be judged based upon the facts of the fall – facts not recorded in the report of the investigation or the nurse's notes. The report also does not reflect that the IDT investigated why previously ordered interventions such as safety cues, reinforcement, and reminders, were either not being used by staff or were not adequate. The care plan reflects no changes dated about the time of the October 18 fall. P. Ex. 13 at 1-5.

The final fall to be considered occurred on October 21, 2010 at about 9:15 p.m. when the resident again attempted to go to the bathroom unassisted. He suffered injuries due to the fall. There is no documentation that any alarm sounded. P. Ex. 17 at 111; CMS Ex. 5 at 50-51, 66.; Tr. 114. Petitioner's report of investigation of this fall indicates that the following interventions were in effect at the time of the fall: night light, assistive device within reach; bed/chair alarm; bed in low position; safety cures/reinforcement/reminder; and call light within reach. The report recommended that the additional intervention of using a recliner chair because the resident had been sleeping in the chair in his room and the writer recommended using the recliner to elevate his feet, apparently to prevent him from standing. I note that prior investigations indicated that a recliner chair was in use but this inconsistency was not addressed by the IDT. The "IDT Review and

Recommendations" section of the report lists therapy; bed/chair alarm in place; psychotropic medication review; and appropriate footwear in place. P. Ex. 19 at 22-23. The IDT review did not address whether the resident was in bed or in his chair prior to the fall, whether the bed was in the low position; or whether the alarms worked. The IDT did not address why the investigator did not indicate that a toileting plan was in effect or that the plan was being followed. The IDT notes do not show that the IDT considered the recommendation that the resident have a recliner. The care plan reflects that on October 21, 2010, a notation was added under interventions that states "alarms at all times – responding quickly," which was not a new intervention but I will treat it as a modified intervention to the extent that staff was instructed it must respond quickly. P. Ex. 13 at 4-5.

The evidence includes a physician's note dated October 21, 2010, in which Dr. Boero states that the resident has not fallen or injured himself recently. P. Ex. 16 at 13. The physician's note does not indicate what time the physician saw Resident 2 on October 21. Possibly, the physician forgot about the fall on October 18, 2010.

A nurse's note dated October 22, 2010, that references the fall states that the resident was responding to a "urination urgency." P. Ex. 17 at 111-12. A nurse's note dated October 23, 2010, states that the resident is most comfortable sitting up in his recliner. A nurse's note dated October 24, 2010, states that chair and bed alarms were in place because the resident attempted to get up on his own, and that the resident had set off alarms once or twice during the day shift. P. Ex. 17 at 113.

I conclude, based upon the foregoing analysis of the facts, that Petitioner violated 42 C.F.R. § 483.25(h) based on the example of Resident 2, with Resident 2 suffering actual harm from several of the ten falls he suffered between March and October 2010.

I agree with Petitioner that a facility is not strictly liable or subject to a conclusion that it was negligent per se simply because an accident occurred. However, 42 C.F.R. § 483.25(h) requires that a facility take all reasonable steps to ensure that a resident receives supervision and assistance devices that meet his or her assessed needs and to mitigate foreseeable risks of harm from accidents. *Woodstock Care Ctr. v. Thompson*, 363 F.3d at 589. While a facility is permitted the flexibility to choose the methods of supervision it uses to prevent accidents, the chosen methods must be adequate under the circumstances. Whether supervision is "adequate" depends in part upon the resident's ability to protect himself or herself from harm. *Id*. Based on the regulation and the cases in this area, CMS meets its burden to show a prima facie case if the evidence demonstrates that the facility failed to provide adequate supervision and assistance devices to prevent accidents, given what was reasonably foreseeable. *Alden Town Manor Rehab. & HCC*, DAB No. 2054, at 5-6, 7-12 (2006). In this case, the evidence showed that Resident 2 was unable to conform his conduct to the wishes of Petitioner's staff. He was consistently noncompliant with instructions and often abusive of staff. He was not

physically strong throughout the period reviewed. The facts related to his fall in December 2009 and his assessment by staff made it foreseeable that he would have future falls and the risk for future falls became more certain with each fall after the March 2010 fall. There is no dispute that Petitioner attempted many interventions to mitigate the risk for falls but the evidence CMS presented shows that those interventions were not consistently applied, the facts related to falls were not investigated and reported to the IDT, the effectiveness of interventions was not assessed, and new or modified interventions were not implemented to address the resident's risk for falls. Petitioner's evidence does not rebut the CMS prima facie showing, but in fact supports it by providing a more clear picture of the failures of Resident 2's IDT.

I conclude that Petitioner violated 42 C.F.R. § 483.25(h) based on the example of Resident 2 and there was a risk for more than minimal harm. Accordingly, there is a basis for the imposition of an enforcement remedy.

4. A PICMP of $5,500 is a reasonable enforcement remedy.

I have concluded that Petitioner violated 42 C.F.R. § 483.25 and the evidence shows that the violation caused Resident 2 to suffer actual harm. If a facility is not in substantial compliance with program requirements, CMS has the authority to impose one or more of the enforcement remedies listed in 42 C.F.R. § 488.406, including a CMP. CMS may impose a per day CMP for the number of days that the facility is not in compliance or a PICMP for each instance that a facility is not in substantial compliance, whether or not the deficiencies pose immediate jeopardy. 42 C.F.R. § 488.430(a). The minimum amount for a PICMP is $1,000 and the maximum is $10,000. 42 C.F.R. § 488.438(a)(2). I conclude that there is a basis for the imposition of a PICMP in this case. The PICMP proposed by CMS is slightly above the middle of the authorized range.

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 (e) I may only consider the factors specified by 42 C.F.R. § 488.438(f) when determining the reasonableness of the CMP amount. In determining whether the amount of a CMP is reasonable, the following factors specified at 42 C.F.R. § 488.438(f) must be considered: (1) the facility's history of noncompliance, including repeated deficiencies; (2) the facility's financial condition; (3) the seriousness of the deficiencies as set forth at 42 C.F.R. § 488.404(b), the same factors CMS and/or the state were to consider when setting the CMP amount; and (4) the facility's degree of culpability, including but not limited to the facilities neglect, indifference, or disregard for resident care, comfort, and safety and the absence of culpability is not a mitigating factor. The factors that CMS and the state were required to consider when setting the CMP amount and that I am required to consider when assessing

the reasonableness of the amount are set forth in 42 C.F.R. § 488.404(b): (1) whether the deficiencies caused no actual harm but had the potential for minimal harm, no actual harm with the potential for more than minimal harm, but not immediate jeopardy, actual harm that is not immediate jeopardy, or immediate jeopardy to resident health and safety; and (2) whether the deficiencies are isolated, constitute a pattern, or are widespread. My review of the reasonableness of the CMP is de novo and based upon the evidence in the record before me. I am not bound to defer to the CMS determination of the reasonable amount of the CMP to impose but my authority is limited by regulation as already explained. I am to determine whether the amount of any CMP proposed is within reasonable bounds considering the purpose of the Act and regulations. *Emerald Oaks*, DAB No. 1800, at 10 (2001); *CarePlex of Silver Spring*, DAB No. 1683, at 14–16 (1999); *Capitol Hill Community Rehabilitation and Specialty Care Center*, DAB No. 1629 (1997).

I have reviewed the factors and the evidence presented by the parties. I have considered Petitioner's history of noncompliance, including one citation of a deficiency under Tag F323 in 2008 that allegedly posed a risk for more than minimal harm. CMS Ex. 11. Petitioner's history does not weigh heavily against Petitioner. Petitioner has not presented evidence to show that it is unable to pay the PICMP. I conclude that the deficiency was serious based on the repeated actual harm suffered by Resident 2. I also conclude that Petitioner was culpable in its failure to act as required by the regulations to protect Resident 2 from very foreseeable risks of harm due to accidental falls.

I conclude that a PICMP of $5,500 is reasonable to ensure that Petitioner maintains its compliance with program participation requirements. Petitioner was ineligible to be approved to conduct a NATCEP for a period of two years by operation of law.

5. 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 Procedures Act, 5 U.S.C. § 551 *et. seq.*, specifically 5 U.S.C. § 556(d). Request for Hearing. Pursuant to the scheme for the allocation of burdens adopted by the Board in its prior cases, CMS bears the burden to come forward with the evidence and to establish a prima facie showing of the alleged regulatory violations that posed a risk for more than minimal harm 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), 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.

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). Request for Hearing; P. Pre-hearing Brief at 25. 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 on November 9, 2010. I also conclude that the enforcement remedy proposed by CMS is reasonable.

/s/
Keith W. Sickendick
Administrative Law Judge