Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Golden Oaks Medical Care Facility,
(CCN: 23-5260),

Petitioner

v.

Centers for Medicare and Medicaid Services.

Docket No. C-10-272

Decision No. CR2468

Date: December 7, 2011

DECISION

Petitioner, Golden Oaks Medical Care Facility, was not in substantial compliance with program participation requirements from October 8, 2009 through October 21, 2009. There is a basis for the imposition of an enforcement remedy. A civil money penalty (CMP) of $700 per day from October 8, 2009 through October 21, 2009, a total CMP of $9,800, is a reasonable enforcement remedy.

I. Background

Petitioner, located in Pontiac, Michigan, participates in Medicare as a skilled nursing facility (SNF) and the Michigan Medicaid program as a nursing facility (NF). On October 8, 2009, the Michigan Department of Community Health (state agency) conducted a complaint survey and determined that Petitioner was not in substantial compliance due to a violation of 42 C.F.R. § 483.25(h)[1] that caused actual harm to a

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

resident. On November 4, 2009, the state agency conducted a revisit survey and determined that Petitioner returned to substantial compliance on October 22, 2009. The Centers for Medicare and Medicaid Services (CMS) notified Petitioner by letter dated January 6, 2010, that it was imposing a CMP of $700 per day for the period October 8, 2009 through October 21, 2009, totaling $9,800. CMS also advised Petitioner that Petitioner was ineligible to conduct a Nurse Aide Training and Competency Evaluation Program (NATCEP) for two years due to the amount of the CMP. Parties' Joint Stipulation of Undisputed Fact (Jt. Stip.) ¶¶ 1-2, 10-11; CMS Exhibit (CMS Ex.) 1.

On December 14, 2009, Petitioner timely filed a request for hearing before an administrative law judge (ALJ). On January 6, 2010, this case was assigned to me for hearing and decision and an Acknowledgement and Prehearing Order was issued on January 11, 2010. A hearing was scheduled for September 7, 2010, in Detroit, Michigan. However, on August 19, 2010, Petitioner filed a waiver of oral hearing and requested that I establish a schedule for briefing and submission of documentary evidence. On August 30, 2010, I accepted Petitioner's waiver of oral hearing and set a briefing schedule. On November 4, 2010, Petitioner filed its brief (P. Br.) and Petitioner exhibits (P. Exs.) 1 through 14. On November 5, 2010, CMS filed its brief (CMS Br.) and CMS Exs. 1 through 21. On December 6, 2010, the parties filed their reply briefs (CMS Reply and P. Reply). CMS did not object to my consideration of P. Exs. 1 through 14 and they are admitted. Petitioner filed an objection to CMS Ex. 20 on July 23, 2010, on grounds that it was not timely exchanged and that it presented a danger of unfair prejudice and confusion of the issues. Petitioner's objection is overruled. Petitioner does not articulate any specific prejudice that might occur if I consider the document. Furthermore, CMS Ex. 20 is not confusing. Petitioner also had the opportunity to offer contrary evidence, either in the form of documents or testimony. CMS Exs. 1 through 21 are admitted.

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 denial of payments for new admissions (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. Noncompliance refers to any deficiency that causes a facility not to be in substantial compliance. 42 C.F.R. § 488.301. State survey agencies survey facilities that participate in Medicare on behalf of CMS to determine whether the facilities are complying with federal participation requirements. 42 C.F.R. §§ 488.10-.28, 488.300-.335. The regulations specify the enforcement remedies that CMS may impose if a facility is not in substantial compliance with Medicare requirements. 42 C.F.R. § 488.406.

The regulations specify that a CMP that is imposed against a facility on a per day basis will fall into one of two ranges of penalties. 42 C.F.R. §§ 488.408, 488.438. The upper range of a CMP, $3,050 per day to $10,000 per day, is reserved for deficiencies that pose immediate jeopardy to a facility's residents and, in some circumstances, for repeated deficiencies. 42 C.F.R. § 488.438(a)(1)(i), (d)(2). "*Immediate jeopardy* means a

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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 the participation requirements established by sections 1919(b), (c), and (d) of the Act.

situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301 (emphasis in original). The lower range of CMPs, $50 per day to $3,000 per day, is reserved for deficiencies that do not pose immediate jeopardy, but either cause actual harm to residents, or cause no actual harm but have the potential for causing more than minimal harm. 42 C.F.R. § 488.438(a)(1)(ii).

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

The Act and regulations make a hearing before an ALJ available to a long-term care facility against which CMS has determined to impose an enforcement remedy. Act §§ 1128A(c)(2), 1866(h); 42 C.F.R. §§ 488.408(g), 498.3(b)(13). The hearing before an ALJ is a *de novo* proceeding. *The Residence at Salem Woods*, DAB No. 2052 (2006); *Cal Turner Extended Care*, DAB No. 2030 (2006); *Beechwood Sanitarium*, DAB No. 1906 (2004); *Emerald Oaks*, DAB No. 1800, at 11 (2001); *Anesthesiologists Affiliated*, DAB CR65 (1990), *aff'd*, 941 F.2d 678 (8th Cir. 1991). A facility has a right to appeal a "certification of noncompliance leading to an enforcement remedy." 42 C.F.R. § 488.408(g)(1); 42 C.F.R. §§ 488.330(e), 498.3. However, the choice of remedies, or the factors CMS considered when choosing remedies, 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 standard of proof, or quantum of evidence required, is a preponderance of the evidence. CMS has the burden of coming forward with 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. United States*, No. 98-3789 (GEB), 1999 WL 34813783 (D.N.J. May 13, 1999).

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

CMS alleges that Petitioner was not in substantial compliance with program participation requirements from October 8 through 21, 2009, due to a violation of 42 C.F.R. § 483.25(h) (Tag F323), which resulted in an isolated incident of actual harm to a resident but did not pose immediate jeopardy. The Statement of Deficiencies (SOD) for the survey that ended on October 8, 2009, cited two examples as support for the deficiency related to Resident 101 and Resident 102. The parties stipulated and agreed, however, that CMS is not proceeding upon the example of Resident 101. Jt. Stip. ¶ 4; CMS Br. at 2, n.1; P. Br. at 1-2.

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, even though not all may be specifically discussed in this decision. I discuss the credible

evidence given the greatest weight in my decision-making.[3] 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(h).

2. Petitioner's violation of 42 C.F.R. § 483.25(h) caused actual harm.

3. Petitioner was not in substantial compliance due to its violation of 42 C.F.R. § 483.25(h) from October 8 through 21, 2009.

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

a. Facts

The parties stipulated to the following facts. Jt. Stip., ¶¶ 5-9. Resident 102 was an 83 year old male who was readmitted to the facility on June 13, 2009. On June 13, 2009, Resident 102 was assessed to be at high risk for falls. CMS Ex. 13, at 57; P. Ex. 8, at 1. Resident 102's Minimum Data Set (MDS) completed in June 2009, shows that he had fallen in the last 30 days and in the last 31 to 80 days. CMS Ex. 13, at 6, 9. Resident 102 was assessed as totally dependent on staff for all activities of daily living (ADLs), including bed mobility (he required a one person assist) and transfers (he required a two person assist). CMS Ex. 13, at 8. Resident 102 was assessed as being in unstable condition and he suffered from cognitive loss, confusion or dementia, contractures, and pain secondary to the contractures. CMS Ex. 13, at 9, 14-31. On June 16, 2009, at 10:30 a.m., Resident 102 rolled out of his bed and onto a floor mat. CMS Ex. 15, at 1; CMS Ex. 3, at 4. On June 22, 2009 at 8:00 p.m., Resident 102's bed alarm sounded and staff found him on the floor with his head on the floor and his body on the floor mat. Resident 102 suffered a laceration on the back, right side of his head that required multiple stitches. CMS Ex. 8, at 2-4; CMS Ex. 13, at 60; CMS Ex. 15, at 3-6.

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[3] "Credible evidence" is evidence that is worthy of belief. *Black's Law Dictionary* 596 (18th ed. 2004). The "weight of evidence" is the persuasiveness of some evidence compared to other evidence. *Id*. at 1625.

The following facts are gleaned from the clinical records for Resident 102 that are in evidence. On June 15, 2009, two days after the resident's readmission, a Rehabilitation Screen was completed that identified the following devices as required or in use: bilateral floor mats; bed sensor; a hi-low bed; a high-back, reclined wheelchair with anti-tipper device; and a tab alarm. P. Ex. 9, at 1. A physician's order for the interventions, dated and signed on June 17, 2009, substituted a geriatric chair for the high-backed wheelchair. CMS Ex. 13, at 51, 56. Resident 102's care plan dated June 16, 2009, listed as a problem Resident 102's history of falls and that he was "always throwing [his] lower extremities over the mattress of his bed due to poor safety awareness." CMS Ex. 13, at 17; P. Ex. 11, at 1. The care plan cautioned staff to "be mindful that resident will throw lower extremities over the mattress" and listed the following interventions: assist resident with turns and repositioning every two hours; assess for orthostatic hypotension; check for incontinence and change every two hours and as necessary; observe Foley catheter for placement to avoid discomfort; mechanical lift for all transfers; floor mats on both sides of bed; bilateral heel protectors while in bed; geriatric chair while up with a tab alarm; hi-low bed with bed in lowest position except when giving care; and low air mattress. CMS 13, at 17; P. Ex. 11, at 1. The bed sensor listed as recommended by the Rehabilitation Screen on June 15, 2009 (P. Ex. 9, at 1), is not listed in the June 16 care plan. Resident 1 fell from his bed on June 16. CMS Ex. 15, at 1; P. Ex. 10. The evidence shows additional interventions following the fall from bed on June 16, 2009, that were not added to the care plan, including: the facility tied down Resident 102's mattress more securely to the bed;[4] applied a bed sensor alarm to Resident 102's bed, and arranged for a physical therapy evaluation. CMS Ex. 13, at 51, 59; CMS Ex. 15, at 1; P. Ex. 4, at 2; P. Ex. 10, at 1.

The Incident and Accident Report for the June 16, 2009 fall shows that the resident rolled off the bed onto the floor mat. The report does not state that the resident was in a hi-low bed prior to the fall and, if so, whether it was in the low position. The report also does not state what other interventions were in use or in place at the time of the fall. CMS Ex. 15, at 1.

Resident 102 fell from his bed again on June 22, 2009, and suffered a laceration on the back of his head that required stitches. Facility incident and accident reports and progress notes for the June 22, 2009 fall indicate that staff responded to the resident's bed sensor alarm. The reports do not indicate whether the resident's bed was in the high or the low position when the fall occurred. The reports do not indicate the size of the floor

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[4] Resident 102's air mattress was a low air-loss mattress and was an intervention to help prevent pressure sores. CMS Ex. 13, at 24.

mat or provide any description of the resident's positioning on the floor mat other than that his head was on the floor and his body was on the floor mat. P. Ex. 12; CMS Ex. 8, at 2; CMS Ex. 13, at 60; CMS Ex. 15, at 3, 5-6. After the June 22, 2009 fall from bed, the facility gave the resident a different mattress; added bolsters on both sides of the bed; and conducted in-service training of staff regarding fall prevention equipment, interventions, safety, and positioning. CMS Ex. 8, at 4; CMS Ex. 13, at 15, 22, 52; CMS Ex. 15, at 3, 6; P. Ex. 4, at 3; P. Ex. 9, at 1; P. Ex. 12. Physician's orders dated June 23, 2009, required bed bolsters, a low air mattress, and the discontinuation of the vinyl mattress overlay wings that the facility implemented immediately after the June 22, 2009 fall. CMS Ex. 13, at 2, 5, 50, 52, 56, 60; P. Ex. 9, at 1; P. Ex. 12; P. Ex. 14. Undated interventions on the care plan to perform neurologic checks and to check incision are clearly related to the June 22, 2009 fall, as is the intervention to add bolsters on both sides of the resident's bed, which is dated June 23, 2009. CMS Ex. 13, at 17; P. Ex. 11, at 1.

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. 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).

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) (emphasis added).

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 6-7 (2010); *Eastwood Convalescent Ctr.*, DAB No. 2088 (2007); *Century Care of Crystal Coast*, DAB No. 2076 (2007*), aff'd*, 281 F. App'x 180 (4th Cir. 2008); *Liberty Commons Nursing and Rehab. - Alamance*, DAB No. 2070 (2007); *Golden Age Skilled Nursing & Rehab. Ctr.*, DAB No. 2026 (2006); *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). The regulation does not make a facility strictly liable for accidents that occur, but it does require that a facility take all reasonable steps to ensure that a resident receives supervision and assistance devices that meet his or her assessed needs and mitigates foreseeable risks of harm from accidents. *Woodstock Care Ctr. v. Thompson*, 363 F.3d at 589 (noting 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.

CMS offered the declaration of Surveyor Denise Young-Bean, R.N., in which she testifies that she conducted the complaint survey that ended on October 8, 2009, and that she wrote the Statement of Deficiencies (SOD), which reflects her findings and conclusions. CMS Ex. 21. Surveyor Bean alleges in the SOD, based on record review and interviews, that Petitioner violated 42 C.F.R. § 483.25 because Petitioner failed to provide Resident 102 adequate supervision to prevent accidents, one of which resulted in actual harm. CMS Ex. 3, at 1-2; P. Ex. 1, at 1-2. Surveyor Bean alleges in her declaration that Petitioner failed to provide Resident 102 adequate supervision and assistance devices prior to the June 16 fall to prevent Resident 102 from falling from bed. Surveyor Bean alleges that Petitioner's interventions were also inadequate prior to the fall from bed on June 22, 2009. CMS Ex. 21, at 4-6. Surveyor Bean opines that Petitioner could have increased the resident's supervision by implementing 15 or 30 minute checks, moving him to a room closer to the nurse's station or another more readily accessible location, or implementing a sitter program. She also alleges that there is no evidence that Petitioner assessed the cause for Resident 102 throwing his legs over the mattress, which she apparently considered a contributing factor to both falls. Although not specifically stated, Surveyor Bean's allegations clearly suggest that she also considered that Petitioner not only failed to assess the cause of the behavior, but also failed to implement interventions to address the behavior prior to the fall on June 22. Surveyor Bean also commented that the effectiveness of an alarm is dependent upon how quickly staff can respond to prevent an accident. She alleged that Resident 102's behavior of throwing his legs over his mattress was known to Petitioner and it was foreseeable that the resident would throw his legs out of bed and fall before staff could respond to a sounding alarm. CMS Ex. 21, at 6.

There is no dispute that Petitioner assessed Resident 1 as at risk for falls on June 13, 2009, and implemented some interventions to address that risk. There is no dispute that Resident 102 fell from bed on June 16, 2009 and again on June 22, 2009. There is no dispute that Resident 102 suffered actual harm as a result of the June 22 fall when his head hit the floor, in the form of a laceration on his head that required stitches. I conclude that CMS has made a prima facie showing of noncompliance due to a violation of 42 C.F.R. § 483.25(h) that resulted in actual harm to Resident 102. Thus, the burden of proof and persuasion is upon Petitioner to rebut the prima facie case or to establish an affirmative defense. I conclude, after consideration of all the evidence of record and the arguments of the parties, that Petitioner has failed to rebut the prima facie showing or to establish an affirmative defense.

The evidence shows that upon his readmission to the facility on June 13, 2009, Petitioner assessed the resident as being at risk for falls. Thus, it was clearly foreseeable that the

resident could fall from bed or his wheelchair. The resident's care planning team planned multiple interventions to address the fall-risk. The evidence shows that the resident also had the behavior of throwing his legs over the side of his mattress. The evidence shows that the behavior was recognized as contributing to the risk of the resident falling from bed. Petitioner has presented no evidence that there was an attempt to identify the cause for the behavior or to control the behavior to reduce the risk for falls from bed.

On June 16, 2009, Resident 102 fell from his bed. Petitioner's accident report shows that it was determined the resident rolled off his bed. In response to the accident, Petitioner tied down the resident's mattress more securely to the bed, implemented a bed sensor alarm to alert staff if the resident was exiting the bed, and ordered a physical therapy evaluation. Petitioner argues that its interventions following the June 16 fall were adequate. Petitioner's Prehearing Brief (P. Ph. Br.) at 7; P. Br. at 11; P. Reply at 4-5. Petitioner provides no evidence to explain why the mattress was not secured tightly to the bed frame in accordance with manufacturer's instructions prior to the June 16 fall. Petitioner does not explain why no bed sensor alarm was in place prior to the June 16 fall. Petitioner also submitted no evidence that the care planning team assessed the effectiveness of any of the interventions in place at the time of the fall. Petitioner has not shown that the resident was in the hi-low bed or that the bed was in the low position when he fell. Petitioner presented no evidence that the care planning team considered additional or different interventions, including more restrictive interventions such as side rails or bolsters to prevent falls.

On June 22, 2009, Resident 102 fell again. Petitioner has presented no evidence that the care planning team determined the cause of the fall, what interventions were in use at the time of the fall, or whether the interventions were effective to reduce the risk for accidental injury of the resident. The evidence does show the bed sensor alarm was effective to alert staff that the resident was falling or had fallen. But clearly, the alarm did not prevent the fall or the injury. There is no evidence that Petitioner assessed whether the alarm might be more effective if the resident was in a different room where staff could respond more quickly, or whether he required closer supervision to permit a quicker response to prevent a fall from his bed or his wheelchair. There is no evidence that the care planning team assessed whether the resident's bed was in the low position at the time of the fall or whether the floor mats were adequately sized and positioned to prevent his head from striking the floor or furniture when he rolled or fell from bed. There is no evidence that the care planning team assessed the effectiveness of alternative interventions including restrictive interventions, other than the physician ordered bed bolsters, a different mattress, and discontinuation of the use of the mattress wings.

Petitioner advances several arguments for why it should be found in compliance or why its noncompliance should be excused.

Petitioner argues that the previous history of falls may not have all been from Resident 102's bed and that Resident 102's high risk for falls may not have been limited to falls from his bed. P. Br. at 9-10; P. Reply at 3-4. This argument is no defense. Petitioner clearly knew that Resident 102 was at risk to fall from his bed before the June 16 fall, as Petitioner had planned interventions to address the risk for such falls. Petitioner fails, however, to show: that the interventions were actually implemented; that their effectiveness was evaluated, particularly after the fall on June 16; and that the care planning team considered alternatives.

Petitioner argues that Resident 102 was totally dependent on staff for mobility and "was not a resident who would be expected to move about or out of his bed quickly." Therefore, Petitioner asserts that the bed sensor alarm was a reasonable intervention and adequate under the circumstances. Petitioner argues that its staff responded promptly to the alarm. P. Br at 11-12; P. Reply at 5-7. The bed sensor alarm clearly alerted Petitioner's staff that Resident 102 was getting out of bed, and it was effective for that purpose. A bed sensor alarm is not effective to prevent a fall or related injury when a resident falls attempting to get out of bed, unless there is also some increased supervision so that staff can get to the resident prior to the fall. Petitioner, however, did not increase its supervision of Resident 102. Therefore, a bed sensor was not an adequate and reasonable intervention, by itself, particularly given this resident's leg throwing behavior. The hi-low bed and floor mats are reasonable interventions to minimize or totally prevent accidental injury from a fall, but only if properly implemented. Petitioner has not shown that the interventions of a hi-low bed and floor mats were properly implemented at the time of either fall.

Petitioner argues that it did not adopt the intervention of bed bolsters until after the June 22 fall because bed bolsters are a form of restraint like bed side rails, and Petitioner wanted to try a less restrictive intervention first. Petitioner argues that a bed alarm is a reasonable alternative to a restraint and that it balanced the amount of the restraint in light of the potential risk of harm. Petitioner argues, inconsistently, that Resident 102 was totally dependent on staff for bed mobility but also argues that it did not want to restrict Resident 102's freedom of movement by using bed bolsters. P. Ph. Br. at 7-10; P. Br. at 12-16; P. Reply at 7-11. Whether or not the bed bolster is a restraint is not the issue. The issue is whether Petitioner has shown that it took all reasonable steps to protect the resident from injury due to accidental falls from his bed. Even if a bed bolster is considered a restraint, the use of restraints is clearly permissible under statutory and regulatory participation requirements so long as criteria are met. Ensuring the physical safety of the resident is an authorized purpose for the use of restraint. Act §§ 1819(c)(1)(A)(ii), 1919(c)(1)(A)(ii); 42 C.F.R. § 483.13(a). Petitioner has not presented any evidence that bolsters, side rails, or other restraints were considered by the care planning team prior to either fall, despite the fact that Petitioner was clearly on notice that Resident 102 threw his legs over the mattress and recognized that such behavior could result in a fall.

I conclude that Petitioner has failed to show that it took all reasonable steps to ensure that Resident 102 received supervision and assistance devices to meet his assessed need for prevention of falls and to mitigate the foreseeable risks of harm to him secondary to accidental falls from his bed or wheelchair. Accordingly, I conclude that Petitioner has failed to rebut the CMS prima facie case or to establish an affirmative defense.

5. A CMP of $700 per day from October 8, 2009 through October 21, 2009 is reasonable.

I have concluded that Petitioner violated 42 C.F.R. § 483.25(h) and that the violation caused actual harm to Resident 102. Thus, Petitioner was not in substantial compliance with program participation requirements, and there is a basis to impose an enforcement remedy. 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. 42 C.F.R. § 488.430(a). Petitioner has not argued or shown that it returned to substantial compliance prior to October 21, 2009. Authorized CMPs are divided into two ranges. The lower range is from $50 to $3,000 per day and is authorized for noncompliance that does not pose immediate jeopardy but has the potential for more than minimal harm. 42 C.F.R. §§ 488.408, .438(a)(1)(i), (d)(2). The lower range is applicable in this case.

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

widespread. My review of the reasonableness of the CMP is *de novo* and based upon the evidence in the record before me. I am not bound to defer to the CMS determination of the reasonable amount of the CMP to impose but my authority is limited by regulation as already explained. I am to determine whether the amount of any CMP proposed is within reasonable bounds considering the purpose of the Act and regulations. *Emerald Oaks*, DAB No. 1800, at 10; *CarePlex of Silver Spring*, DAB No. 1683, at 14–16 (1999); *Capitol Hill Cmty. Rehab. and Specialty Care Ctr.*, DAB No. 1629 (1997).

Petitioner was cited for noncompliance under Tag F323 in two survey cycles occurring within the ten months prior to the survey at issue. A May 19, 2009 complaint and annual survey cited Petitioner for noncompliance under Tag F323 that caused actual harm. Petitioner was also cited for noncompliance under Tag F323 that resulted in actual harm by a February 19, 2009 complaint survey. CMS Ex. 19, at 1. The noncompliance under Tag F323 in the present survey was serious, as it caused actual harm to Resident 102, which required a trip to the hospital and multiple sutures for his laceration. CMS Ex. 8, at 4; CMS Ex. 13, at 60; CMS Ex. 15, at 3. Petitioner has not alleged an inability to pay the CMP imposed or presented evidence to support such an allegation. The evidence supports a conclusion that Petitioner was culpable because the evidence does not show that the care planning team assessed the need for interventions, whether interventions were implemented, and whether interventions implemented were effective. Petitioner also failed to assess Resident 102's leg throwing behavior and to adopt interventions to limit or prevent the behavior, even though Petitioner was clearly aware of this behavior. I also note that the CMP is at the low end of the range of authorized CMPs. I conclude, based upon my consideration of the required factors, that a CMP of $700 per day from October 8, 2009 through October 21, 2009, is a reasonable enforcement remedy.

III. Conclusion

For the foregoing reasons, Petitioner was not in substantial compliance with program participation requirements from October 8, 2009 through October 21, 2009. A CMP of $700 per day from October 8, 2009 through October 21, 2009, totaling $9,800, is a reasonable enforcement remedy.

/s/
Keith W. Sickendick
Administrative Law Judge