Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	
Rensselaer Care Center,	)	Date: May 4, 2009
(CCN: 15-5287),	)	
	)	
Petitioner,	)	
	)	
- v. -	)	Docket No. C-07-165
	)	Decision No. CR1944
Centers for Medicare & Medicaid	)	
Services.	)	
	)	

DECISION

Petitioner, Rensselaer Care Center, violated 42 C.F.R. § 483.25(h)(2) and was not in substantial compliance with program participation requirements from October 17, 2006 through December 14, 2006. A $200 per day civil money penalty (CMP) for the period October 17, 2006 through December 14, 2006, is reasonable.

I. Background

Petitioner is a long-term care facility, located in Rensselaer, Indiana. Petitioner is authorized to participate in Medicare as a skilled nursing facility (SNF) and in the Indiana Medicaid program as a nursing facility (NF). On October 17, 2006, the Indiana State Department of Health (the state agency) completed a complaint survey of Petitioner and alleged in a Statement of Deficiencies (SOD) dated October 17, 2006, that Petitioner violated 42 C.F.R. § 483.25(h)(2). The state agency notified Petitioner by letter dated October 25, 2006, that a mandatory denial of payment for new admissions (DPNA) would be imposed effective January 17, 2007, and that it was recommending that the Centers for Medicare and Medicaid Services (CMS) impose a CMP of $400 per day effective October 17, 2006. The state agency completed a revisit survey of Petitioner on

December 15, 2006, and alleged additional deficiencies in a SOD of the same date that are not at issue on this appeal.[1] Joint Stipulation (Jt. Stip.) ¶¶ 1-4, 9-10, 12-13. Petitioner requested a hearing by an administrative law judge (ALJ) by letter dated December 18, 2006. The case was assigned to me for hearing and decision on January 10, 2007, and a Notice of Case Assignment and Prehearing Case Development Order (Prehearing Order) was issued at my direction on that date.

CMS notified Petitioner by letter dated January 18, 2007, that a mandatory DPNA was effective January 17, 2007, and that it was imposing a CMP of $400 per day effective October 17, 2006, and termination effective March 17, 2007, if substantial compliance was not achieved before that date. The state agency determined after a revisit survey that Petitioner returned to substantial compliance with program participation requirements on February 1, 2007. Jt. Stip. ¶¶ 11, 14. The parties agreed at hearing that only the alleged violation of 42 C.F.R. § 483.25(h)(2) from the October 17, 2006 survey and the CMP of $400 per day for the period October 17, 2006 through December 14, 2006, remain at issue and subject to my review. Tr. 54-57; Jt. Stip. ¶¶ 15-18.

A hearing was convened in Indianapolis, Indiana on July 17 and 18, 2007. A transcript (Tr.) of the hearing was prepared. CMS offered and I admitted CMS exhibits (CMS Ex.) 1 through 28 and 46 through 51.[2] Tr. 16-18. Petitioner offered and I admitted Petitioner's exhibits (P. Ex.) 1 through 86. Tr. 19. The parties submitted post-hearing briefs (CMS Brief and P. Brief) and post-hearing reply briefs (CMS Reply and P. Reply). Attached to Petitioner's post-hearing brief were Petitioner's proposed exhibits 87 through 89. CMS did not object to P. Exs. 87 through 89. I admit P. Exs. 87 through 89.

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[1] Petitioner amended its request for hearing to challenge the findings of the December 15, 2006 survey, and the continuation of remedies based thereon. However, prior to hearing the parties resolved all disputes related to the December 15, 2006 survey and the continued remedies after that date.

[2] CMS notified me by letter dated July 11, 2007, that it withdrew proposed CMS Exs. 29 through 45.

II. Discussion

A. Issues

The issues in this case are:

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

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

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

facilities are complying with federal participation requirements. 42 C.F.R. §§ 488.10-488.28, 488.300-488.335. The regulations specify the enforcement remedies that CMS may impose if a facility is not in substantial compliance with Medicare requirements. 42 C.F.R. § 488.406.

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 CMP, $3050 per day to $10,000 per day, is reserved for deficiencies that pose immediate jeopardy to a facility's residents, and in some circumstances, for repeated deficiencies. 42 C.F.R. §§ 488.438(a)(1)(i), (d)(2). Pursuant to 42 C.F.R. § 488.301, "*(i)mmediate jeopardy* means a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." (Emphasis in original.) The lower range of CMP, $50 per day to $3000 per day, is reserved for deficiencies that do not constitute immediate jeopardy but either cause actual harm to residents, or cause no actual harm, but have the potential for causing more than minimal harm. 42 C.F.R. § 488.438(a)(1)(ii).

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. *Anesthesiologists Affiliated, et al*, DAB CR65 (1990), *aff'd*, 941 F.2d 678 (8th Cir. 1991); *Emerald Oaks*, DAB No. 1800, at 11 (2001); *Beechwood Sanitarium*, DAB No. 1906 (2004); *Cal Turner Extended Care*, DAB No. 2030 (2006)*; The Residence at Salem Woods*, DAB No. 2052 (2006). A facility has a right to appeal a "certification of noncompliance leading to an enforcement remedy." 42 C.F.R. § 488.408(g)(1); *see also* 42 C.F.R. §§ 488.330(e) and 498.3. However, the choice of remedies by CMS or the factors CMS considered when choosing remedies are not subject to review. 42 C.F.R. § 488.408(g)(2). A facility may only challenge the scope and severity level of noncompliance found by CMS if a successful challenge would affect the range of the CMP that could be imposed by CMS or impact the facility's authority to conduct a nurse aide training and competency evaluation program. 42 C.F.R. §§ 498.3(b)(14) and (d)(10)(i). The CMS determination as to the level of noncompliance "must be upheld unless it is clearly erroneous" (42 C.F.R. § 498.60(c)(2)), including the finding of immediate jeopardy. *Woodstock Care Center*, DAB No. 1726, at 9, 38 (2000), *aff'd, Woodstock Care Center v. Thompson*, 363 F.3d 583 (6th Cir. 2003). The Departmental Appeals Board (the Board) has long held that the net effect of the regulations is that a provider has no right to challenge the scope and severity level assigned to a noncompliance finding, except in the situation where that finding was the basis for an immediate jeopardy determination. *See e.g., Ridge Terrace*, DAB No. 1834 (2002); *Koester Pavilion*, DAB No. 1750 (2000). Review of a CMP by an ALJ is subject to 42 C.F.R. § 488.438(e).

The standard of proof or quantum of evidence required is a preponderance of the evidence. CMS has the burden of coming forward with the evidence and making a prima facie showing of a basis for imposition of an enforcement remedy. Petitioner bears the burden of persuasion to show by a preponderance of the evidence that it was in substantial compliance with participation requirements or any affirmative defense. *See Hillman Rehabilitation Center*, DAB No. 1611 (1997), *aff'd, Hillman Rehabilitation Ctr. v. United States Dep't of Health and Human Services, Health Care Fin. Admin.*, No. 98-3789 (GEB), slip op. at 25 (D.N.J. May 13, 1999); *Cross Creek Health Care Center*, DAB No. 1665 (1998); *Emerald Oaks*, DAB No. 1800; *Batavia Nursing and Convalescent Center*, DAB No. 1904 (2004), *aff'd, Batavia Nursing & Convalescent Ctr. v. Thompson*, 129 F. App'x. 181 (6th Cir. 2005); *Batavia Nursing and Convalescent Inn*, DAB No. 1911 (2004).

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

My conclusions of law are set forth in bold followed by my findings of fact and analysis.

1. Petitioner was in violation of 42 C.F.R. § 483.25(h)(2) (Tag F324) from October 17, 2006 through December 14, 2006.

A facility must ensure that "[e]ach resident receives adequate supervision and assistance devices to prevent accidents." 42 C.F.R. § 483.25(h)(2). The Board has explained the requirements of 42 C.F.R. § 483.25(h)(2) in numerous decisions. *See e.g.*, *Eastwood Convalescent Center*, DAB No. 2088 (2007); *Liberty Commons Nursing and Rehab - Alamance*, DAB No. 2070 (2007); *Golden Age Skilled Nursing & Rehabilitation Center*, DAB No. 2026 (2006); *Estes Nursing Facility Civic Center*, DAB No. 2000 (2005); *Northeastern Ohio Alzheimer's Research Center*, DAB No. 1935 (2004); *Woodstock Care Center*, DAB No. 1726, at 28 (2000), *aff'd, Woodstock Care Center v. Thompson*, 363 F.3d 583 (6th Cir. 2003). Section 483.25(h)(2) does not make a facility strictly liable for accidents that occur, but it does require that a facility take all reasonable steps to ensure that a resident receives supervision and assistance devices that meet his or her assessed needs and mitigate foreseeable risks of harm from accidents. *Woodstock Care Center v. Thompson*, 363 F.3d at 589 (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. *Id*. 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/or assistance devices to prevent accidents, given what was reasonably foreseeable. *Alden Town Manor Rehabilitation & HCC*, DAB No. 2054 (2006), at 5-6, 7-12. 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)." State Operations Manual (SOM), App. PP, Tag F324; *Woodstock Care Center*, DAB No. 1726, at 4.

The October 17, 2006 SOD alleges that Petitioner violated 42 C.F.R. § 483.25(h)(2) (Tag F324) in the case of four residents identified as Residents A, B, C, and D and that Residents B and C suffered actual harm as a result. CMS Ex. 1; P. Ex. 1.

(a) The examples cited by the surveyors involving Residents A and D do not show violations of 42 C.F.R. § 483.25(h)(2) for failure to use gait belts while transferring or ambulating the residents.

(b) Petitioner's failure to ensure that the alarm in Resident D's wheelchair was properly attached and operating is a violation of 42 C.F.R. § 483.25(h)(2), based upon the facts of this case.

Resident A is discussed in example 2 under Tag F324 in the SOD (CMS Ex. 1, at 9-12; P. Ex. 1, at 9-12) and Resident D is discussed in example 4 (CMS Ex. 1, at 22-25; P. Ex. 1, at 22-25). I discuss the two examples and residents together as I conclude neither example describes a violation of 42 C.F.R. § 483.25(h)(2) related to the use of gait belts. However, I conclude that Petitioner did violate 42 C.F.R. § 483.25(h)(2) by failing to ensure that Resident D's wheelchair alarm was attached and on as required by her care plan.

(1) Resident A, Example 2.

Resident A was a 77-year old female who was admitted to Petitioner's facility in May of 1999. P. Ex. 9; Jt. Stip. ¶ 5. Resident A was dependent on staff for all activities of daily living and was assessed as requiring a two person assist for transfers. Resident A suffered from dementia, she could rarely or never be understood or understand others, she had severely impaired decision-making ability, and she was incontinent of bowel and bladder, and she weighed 148 pounds. CMS Ex. 15, at 13-14, 18; P. Ex. 18, at 1. Her care plan reflects that she was assessed as at risk for falls and required a two person assist for transfers. CMS Ex. 15, at 18. Her Certified Nurse Aide (CNA) instructions or CNA care plan provided that she required assistance of two staff or a Hoyer lift for transfers. CMS Ex. 17, at 112. On September 27, 2006 at about 5 p.m., two CNAs were transferring the resident by each holding her under an arm and holding onto her incontinence brief. The incontinence brief broke, one of the CNAs felt that Resident A

would fall, and so they lowered the resident to the floor. According to nurse's notes and Petitioner's incident form, Resident A was not injured and the CNAs were counseled about the "importance of not using a brief as a transfer aid" and given in-service training. CMS Ex. 15, at 8, 9.

The surveyors cited Petitioner for violation 42 C.F.R. § 483.25(h)(2) based upon the September 27, 2006 incident because the CNAs were not using a gait belt to transfer the resident. CMS Ex. 1, at 11-12. CMS argues before me that 42 C.F.R. § 483.25(h)(2) was violated because the CNAs used an improper transfer technique by not using an assistive device such as a gait belt or a Hoyer lift. CMS Brief at 13-18; CMS Reply at 4-7. CMS argues that when the Director of Nursing (DON) was interviewed, she admitted that the CNAs should have used a gait belt to transfer Resident A. CMS Brief at 14; CMS Ex. 1, at 11-12; CMS Ex. 15, at 2, Tr. 94, 113. CMS also relies upon the testimony of Surveyor DeAnn Mankell to support its argument that the CNAs improperly transferred Resident A and that the use of a gait belt or a Hoyer lift would have reduced the risk of a fall. CMS Brief at 14; Tr. 95, 101. According to CMS, the improper transfer of Resident A created the potential for more than minimal harm secondary to a fall including skin tears, bruises, or broken bones. CMS Brief at 15; Tr. 96.

Petitioner contends that Resident A did not fall to the floor, but was properly lowered by facility staff when they perceived that the resident might fall when the incontinence brief tore. According to Petitioner, the facility's staff members are trained to protect residents who begin to fall by lowering them to the floor. Petitioner argues that there is no regulation, standard of care, or facility policy that requires the use of a gait belt during all resident transfers. Petitioner cites the testimony of Petitioner's Executive Director (Administrator), Paula Powers, and its Rehabilitation Coordinator, Carly Runyon, that CNAs are taught to assess the specific situation and use their best judgment as to how to transfer a particular resident. Petitioner cites the testimony of Administrator Powers that Resident A had fragile skin and wore open-backed clothing and that use of a gait belt could cause skin injury. P. Brief at 5-7; Tr. 282, 306, 334. Petitioner calls my attention to the testimony of Surveyor Mankell who testified that there was more than one safe technique for transferring a resident and that there is no requirement to use a particular assistive device. P. Brief at 7-8; Tr. 97-98, 107, 111-13. Petitioner does not deny that its nurses concluded after investigation that the two CNAs had not used the optimal technique when transferring Resident A and that the CNAs were instructed to use gait belts in the future. P. Brief at 8; P. Ex. 22. Petitioner asserts that CMS does not allege or offer evidence that there was any injury or even a risk for more than minimal harm in this example related to Resident A. P. Brief at 8. Petitioner argues that CMS has not made a prima facie showing of a violation of 42 C.F.R. § 483.25(h)(2) based on the example of Resident A because CMS failed to show that there was any legal standard or standard of care that required the use of a gait belt that the CNAs conduct violated. P. Brief at 19-20.

Petitioner is obliged by the regulation to take reasonable steps to ensure that a resident receives supervision and assistance devices that meet his or her assessed needs and mitigate foreseeable risks of harm from accidents. Two CNAs were assisting Resident A when the incident occurred, thus supervision was being provided. The issue is whether the failure of the CNAs to use an assistive device for transferring Resident A, specifically a gait belt or a Hoyer lift, resulted in a violation of 42 C.F.R. § 483.25(h)(2). The pertinent facts are not disputed. Resident A's care plan authorized staff to transfer her with a two person assist or with a Hoyer lift. CMS Ex. 15, at 18; CMS Ex. 17, at 112. On September 27, 2006, two CNAs were transferring Resident A by lifting her under her arms and by holding onto her incontinence brief.[4] Surveyor Mankell testified that transfers are usually made by lifting a resident under the arms. Tr. 94. The surveyors did not cite Petitioner because its staff held the resident's incontinence brief but, rather, because staff failed to use a gait belt. CMS makes the additional argument before me that a Hoyer lift should have been used as an alternative.

I conclude that the example of Resident A does not show a violation of 42 C.F.R. § 483.25(h)(2) based upon the testimony of Surveyor Mankell. Surveyor Mankell testified in response to my questions that she concluded an improper transfer occurred because the two CNAs were immediately in-serviced and told that they needed to use a gait belt. However, Surveyor Mankell testified that there was no requirement to use a gait belt or a Hoyer lift given the facts related to Resident A. Tr. 96-100, 112. Administrator Powell agreed that there was no regulatory requirement, standard of care, or policy that required staff to use a gait belt to accomplish a transfer by two person assist. Tr. 333-39. Absent a statutory or regulatory requirement to use a gait belt to accomplish a transfer by two person assist, failure to use a gait belt is not a per se violation of a condition of participation including 42 C.F.R. § 483.25(h)(2). Furthermore, the weight of the evidence is that it is neither a standard of care nor a policy requirement of Petitioner that a gait belt be used to accomplish a transfer by two person assist. Rather, the weight of the evidence indicates that the standard of care is to permit staff to accomplish a two person assist by lifting a resident under the arms and to determine whether an assistive device is reasonably required or not. Thus, failure to use a gait belt did not amount to a failure to take reasonable steps to protect against accidentally

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[4] Surveyor Mankell indicated that she believed that the CNAs did not grab the resident's incontinence brief until the resident started to slip from their grasp. Tr. 93-94, 116-17. However, Petitioner's contemporaneous records state that the CNAs were transferring Resident A by holding her under each arm and holding onto her brief and when the brief broke one of the CNAs felt she would fall so they lowered her to the floor. CMS Ex. 15, at 8. The evidence does not show whether the CNAs were actually lifting Resident A with her brief although the fact that the brief broke permits an inference that there was some weight applied to the brief.

dropping or otherwise injuring Resident A. In fact, in this case the evidence shows that use of a gait belt also posed a risk of injury and to permit the CNAs discretion to determine the appropriate assistive devices was reasonable. Similarly, there is no regulatory requirement, standard of care, or policy that required the CNAs to use a Hoyer lift for transferring Resident A. The resident's care plan permitted the CNAs discretion to do a two person transfer or use the Hoyer lift. Permitting the CNAs discretion is not inconsistent with the standard of care according to the evidence before me.

(2) Resident D, Example 4.

Resident D is cited by the surveyors as example 4 in the SOD. CMS Ex. 1, 22-25; P. Ex. 1, 22-25. Resident D was a 55-year old female who was admitted to Petitioner's facility in May of 2003. P. Ex. 71. Resident D suffered from moderate mental retardation, osteoporosis, obesity, a brain injury, and a previous right leg fracture. CMS Ex. 18, at 1; P. Ex. 71. Resident D required extensive assistance of one person for transfers, toileting, and walking. P. Ex. 74, at 2-3. She was assessed as being at high risk for falls. CMS Ex. 18, at 17-18; P. Ex. 75, at 1-2. Her care plan included ten interventions to address her potential for falls, prior to September 27, 2006, including the requirement for an alarm in her wheelchair. The intervention of a two person assist for transfers was added on September 27. CMS Ex. 18, at 30.

According to Petitioner's records, on September 27, 2006, at 4:50 a.m., one CNA was transferring Resident D from the toilet to her wheelchair. Resident D stated that her right leg "gave out" due to right hip pain and the CNA had to lower the resident to the floor. The resident told the nurse that the pain was present before her leg gave out. CMS Ex. 18, at 10, 13-14, 34; P. Ex. 79, at 5; P. Ex. 85; P. Ex. 86. Petitioner's accident/incident committee review shows that the resident suffered no injury from the incident. CMS 18, at 13; P. Ex. 86. According to Petitioner's records, Resident D had a history of an old fracture of her right femur that had been fixed with an intramedullary rod and screw, possibly the source of the resident's pain. CMS Ex. 18, at 12, 13, 29.

The surveyors allege in example 4 of the SOD that Petitioner violated 42 C.F.R. § 483.25(h)(2) because: (1) the surveyor observed the resident in her wheelchair at a table in the dining room without her string alarm attached to her wheelchair and the alarm was not turned on; and (2) staff do not always use the gait belts assigned to them. CMS argues that Petitioner violated 42 C.F.R. § 483.25(h)(2) because the CNA did not use a gait belt to transfer Resident D and Petitioner failed to ensure that the wheelchair alarm intervention was used properly. CMS Brief at 24-26; CMS Reply at 21-23.

Petitioner argues that Resident D did not fall to the floor, but was properly lowered to the floor by the CNA on September 27, 2006. Petitioner points out that a goal of Resident D's care plan was for her to ambulate and that it was not out of the ordinary for her to suddenly sit down on the ground when ambulating. Petitioner argues, as it did related to

the example of Resident A, that there is no regulation or standard of care that a gait belt be used for transferring or walking a resident, and the facility does not require its staff to use a gait belt during all resident transfers. P. Brief at 16-17; P. Reply at 11-12. Petitioner argues based on the testimony of Surveyor Carlson and Administrator Powers that there was no evidence that the resident was lowered to the floor in a way that was not safe, and the CNA prevented injury by lowering Resident D to the floor. P. Brief at 17; Tr. 251, 357-358. Petitioner argues that given Resident D's weight, not using a gait belt may have been safer for the resident. P. Brief at 16. Petitioner argues, regarding the unhooked alarm observed by the surveyor, that it was not mentioned in testimony at hearing, that a sounding alarm would be annoying to other residents during meals, and that one would think that residents are more closely supervised in the dining room so that the alarm would be unnecessary. P. Reply at 12.

There is no dispute that during the survey on October 13, 2006 at about 11:10 a.m., Surveyor Lisa Carlson observed Resident D in the dining area in her wheelchair, an alarm was attached to the back of her wheelchair. The pull tab of the alarm was not attached to the resident and the alarm box was not turned on. The DON who was present commented to Surveyor Carlson that the alarm should have been attached and on. Tr. 194. The reported statement of the DON is consistent with the fact that Resident D's care plan required that she have an alarm in her wheelchair. CMS Ex. 18, at 30. Although the care plan does not state that the alarm had to be on and appropriately attached to Resident D while she was in her wheelchair, I have no difficulty inferring that the care planning team intended that the alarm be properly used when the intervention was added to the care plan on September 5, 2006. The fact that the intervention was added indicates that the care planning team determined that the intervention was reasonable and necessary to address the problem identified in the care plan, which was the potential for injuries due to falls, and the care planning team's assessment and intervention appears to have been made consistent with the requirements of 42 C.F.R. § 483.20(k). Petitioner did not present evidence to show that the care planning team determined that the use of the alarm was unnecessary while Resident D was in the lunch room because supervision of the resident was sufficient at such times to obviate the need for the alarm. Petitioner's speculation that the noise of an alarm in the dining area would disturb other residents and Petitioner's assumption that there would be adequate supervision in the dining area, are no substitute for evidence that Petitioner took reasonable steps to avoid harm to Resident D due to a fall from her wheelchair. Accordingly, I conclude that Petitioner violated 42 C.F.R. § 483.25(h)(2) by failing to ensure that the alarm in Resident D's wheelchair was properly attached and operable when observed by the surveyor.

The facts related to the incident on September 27, 2006 are also not in dispute. One CNA was transferring Resident D from the toilet to her wheelchair. Resident D stated that her right leg "gave out" due to right hip pain and the CNA had to lower the resident to the floor. The resident told the nurse that the pain was present before her leg gave out. CMS Ex. 18, at 10, 13-14, 34; P. Ex. 79, at 5; P. Ex. 85; P. Ex. 86. The resident's care plan did

not require more than a one person assist at the time of the incident. Administrator Powers testified that the investigation of the incident revealed that the CNA was not using a gait belt. Tr. 357.

I conclude that the CNA's failure to use a gait belt for the transfer of Resident D on September 27, 2006, did not result in a violation of 42 C.F.R. § 483.25(h)(2) based upon a rationale similar to that discussed in the example of Resident A. Absent a statutory or regulatory requirement to use a gait belt to accomplish a transfer of a resident, failure to use a gait belt is not a per se violation of a condition of participation including 42 C.F.R. § 483.25(h)(2). Further, it is consistent with the standard of care to permit a CNA to determine whether or not to use a gait belt when the use of a gait belt is not required by the resident's care plan or by facility policy. Failure to use a gait belt did not amount to a failure to take reasonable steps to protect against accidentally dropping or otherwise injuring Resident D in this case.

(c) Petitioner violated 42 C.F.R. § 483.25(h)(2) in the case of Resident B as alleged in Example 1 of the SOD.

The alleged violation regarding Resident B is cited as example 1 in the SOD. CMS Ex. 1, at 2-9; P. Ex. 1, at 2-9. Resident B was admitted to Petitioner's facility in November 2001 and she was 66 at the time of the survey. Her diagnoses included Alzheimer's disease, osteoporosis, dementia, hypertension, depression and a seizure disorder. P. Ex. 23, at 1. Her Minimum Data Set (MDS) with an assessment reference date of September 13, 2006, reflects that her cognitive skills for daily decision-making were severely impaired, she seldom understood or made herself understood, and she was totally dependent on others and required a one or two-person assist for all her activities of daily living. CMS Ex. 16, at 29-30; P. Ex. 24, at 2-3. Resident B was assessed as being at high risk for falls and she had a history of falls. CMS Ex. 16, at 54; P. Ex. 25. She was also assessed as have an excessive forward trunk flexion, i.e. she leaned forward excessively particularly when sitting. CMS Ex. 16, at 34-35; P. Ex. 35, 37. Resident B's care plan recognizes that she was at risk for injury due to falls and includes hand-written notes indicating numerous falls and two instances when seizures were observed. The falls care plan lists factors contributing to her risk for injury due to falls including her lack of safety awareness, severe cognitive impairment, seizure disorder, and the fact that she leans and slides forward, including on the toilet. The care plan indicates that on September 20, 2006, Resident B received a Broda™ chair.[5] Her care plan provided that she was to be in a reclining position at all times except while feeding until Occupational

[5] A Broda chair is an adjustable wheelchair, with side wings on the back to keep the person in the chair upright, a back that reclines, and a seat that can be adjusted. Tr. 79; P. Ex. 46.

Therapy evaluated her;[6] she was to be observed while in a wheelchair for improper body/trunk alignment or positioning and she was to be repositioned as necessary. CMS Ex. 16, at 53-54.[7] Physical therapy records show that on September 19, 2006, Resident B was issued the Broda chair to address her poor sitting posture. The records reflect that Resident B was to be reclined slightly back while sitting in the Broda chair to keep her from slumping and sliding forward, staff received in-service training on proper positioning between September 19 and 25, 2006, and Resident B was discontinued from physical therapy on September 25, 2006. P. Ex. 37; CMS Ex. 16, at 42, 44-46. The physical therapy records do not mention whether or not Resident B was to be upright while feeding. The in-service training record dated September 19-25, 2006 lists as objectives that Resident B was to be in a comfortable sitting position in her Broda chair with the seat[8] tilted slightly backward at 110 degrees to prevent her from slumping or sliding in the chair, and she was to be supervised at all times. CMS Ex. 16, at 36; P. Ex. 47, at 1.

On October 13, 2006, the special unit care manager pointed out to the surveyor that Resident B had fallen and had staples in her forehead. The surveyor recorded in the SOD that she observed that Resident B had a line of staples in the center of forehead approximately three inches long running from her forehead into her hairline. CMS Ex. 1, at 2-3. Based upon a records review, the surveyor alleged in the SOD that on October 4, 2006 at approximately noon, Resident B was in her Broda chair for lunch sitting upright because her husband did not want her reclined as much. Staff concluded that the brakes on the Broda chair were not locked. Staff heard a loud noise and they found Resident B laying face down on the floor in the dining room, with her Broda chair behind her, and a large amount of blood from a three to four inch cut on the top middle of her forehead. CMS Ex. 1, at 5-9.

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[6] The date that this approach was added is difficult to read but it appears to be October 5, 2006, the day after the fall, which is consistent with other evidence from Petitioner's records discussed hereafter.

[7] The care plan admitted by CMS at CMS Ex. 16, at 53-54 is dated January 12, 2006 with updates and changes dated to October 2006 and an updated target date of December 20, 2006. Petitioner submitted a care plan for Resident B dated October 13, 2005 with updates and changes dated to November 2005 and a revised target date of April 18, 2006. P. Ex. 27.

[8] I conclude that the physical therapist meant that the seat-back needed to be reclined back at 110 degrees or 20 degrees off of vertical. The seat bottom was adjustable but adjusting it to 110 degrees is nonsensical.

Petitioner's records reflect the following facts. Petitioner's Incident Report dated October 4, 2006, indicates that at 12 p.m. Resident B was in the dining room sitting in an upright position in her Broda chair at the table for the afternoon meal; facility staff was passing out trays and feeding other residents; and Resident B fell out of her Broda chair. The report indicates that Resident B was upright because her husband insisted. The report also listed as a preventive measure that the brakes on the Broda chair would be locked during meal times. CMS Ex. 16, at 6-7. The statements of staff present in the dining room indicate that no staff observed Resident B leaning forward before the fall, but no staff admitted to actually seeing Resident B fall. CMS Ex. 16, at 8-11, 15; P. Ex. 45, at 1-4. An Incident Follow-up & Recommendation Form signed by Administrator Powers on October 5, 2006 states that on October 4, 2006 at 12 noon, Resident B was found face down on the floor in the dining room, the resident fell forward out of her Broda chair, and had a laceration to her forehead which required 13 staples. The report listed follow-up actions of keeping the resident in a reclining position except for meals until Occupational Therapy screened for possible thigh straps, locking the brakes on the Broda chair at mealtime, and adding a personal alarm to the Broda chair. CMS Ex. 16, at 13, 55; P. Ex. 44, at 2.

Petitioner argues that Resident B had to be in an upright position while eating to permit her to swallow properly as her dementia placed her at increased risk of aspiration citing P. Ex. 36 and 37. P. Ex. 36 is a Rehabilitation Services Progress Notes form with an entry dated October 5, 2006. The note indicates the resident was screened following her fall on October 4, 2006 with the instruction that while she was up in her Broda chair she was to be reclined 100 degrees when not eating. The note also states that nursing staff was instructed on September 19 through 25, 2006, on the correct positioning of the resident. The progress note was created the day after the fall. Further it refers to no prior assessment of Resident B that showed she had difficulty swallowing or that being reclined 10 degrees from vertical or straight-up would negatively impact her ability to swallow. P. Ex. 1. P. Ex. 37 consists of physical therapy documents that include no statement that Resident B needed to be in a vertical position in the Broda chair while eating. Rather, the physical therapy documents are consistent that Resident B needed to be reclined slightly for safety. P. Ex. 37. Furthermore, the in-service training record dated September 19-25, 2006, states that Resident B was to be in a comfortable sitting position in her Broda chair with the seat tilted slightly backward at 110 degrees to prevent her from slumping or sliding in the chair, and she was to be supervised at all times. The training record does not indicate that staff was trained to place Resident B in an upright position when she was eating. CMS Ex. 16, at 36; P. Ex. 47, at 1. The care plan Petitioner produced does not reflect an assessment indicating swallowing difficulty or any intervention to address such a problem. P. Ex. 27. The resident's MDS with an assessment reference date of September 13, 2006, does not indicate Resident B had a swallowing problem. P. Ex. 24, at 3 (Block K1.b.). The MDS does show that she was totally dependent upon staff for eating and required the assistance of one, from which I infer that Resident B was not eating when she fell forward from her chair as she was not

then attended by anyone. P. Ex. 24, at 3 (Block G1.h.). I further note that Petitioner's incident report states that "Resident place in upright position per POA [Power of Attorney – her husband] request against therapies recommendations." CMS Ex. 16, at 6. The incident report also mentions that the husband was insistent that Resident B be in the upright position. CMS Ex. 16, at 7. The incident report does not state nor suggest that Resident B was placed in the upright position to be fed due to swallowing difficulty or a risk of aspiration. Ms. Runyon testified that Resident B had dementia and was at risk for aspirating while she was eating, thus, it was care planned that she would be upright while eating. Tr. 287, 302. Ms. Runyon's testimony in this regard is inconsistent with Resident B's September 13, 2006 MDS and not supported by Petitioner's clinic evidence that was admitted as evidence. Ms. Runyon opined that while Resident B needed supervision while sitting up at 90 degrees to eat, she also opined that her supervisor did not need to be right next to her and there was no way to catch her if she began to fall. Tr. 287-88. Administrator Powers testified that she spoke with the physical therapist, Ms. Bagwan, who provided the in-service training to staff on using the Broda chair with Resident B. Administrator Powers testified that Ms. Bagwan told her that when she indicated the resident needed supervision, she meant that someone needed to be in the vicinity of the resident when she was in an upright position. She also testified that Resident B needed to be upright for eating and also that the resident's husband wanted her upright and he would adjust the chair. Tr. 342-44. Administrator Powers' testimony that Resident B needed to be upright is not supported by the clinical records introduced for Resident B, which include no indication that the resident had swallowing difficulty or had to be upright to eat. Her testimony that Ms. Bagwan told her that by stating that Resident B needed supervision while in her Broda chair meant only that staff needed to be in the vicinity, has no probative value as it is impossible to determine what Ms. Bagwan meant by "in the vicinity."

I conclude after review of all the evidence related to Resident B and consideration of Petitioner's arguments, that Petitioner violated 42 C.F.R. § 483.25(h)(2) in the case of Resident B. I have no doubt that the Broda chair was the appropriate assistance device for Resident B based upon the evidence presented. However, the violation occurred due to the lack of appropriate supervision of Resident B and the failure to follow the physical therapists instructions based upon her assessment, that Resident B needed to be reclined to 110 degrees and that she required supervision. Petitioner's staff violated the specific directions of the physical therapist by not using the Broda chair in a manner determined to be safe by the physical therapist for the resident and also by failing to provide any supervision for the resident at the time of the fall. The evidence before me includes no care plan or instructions for how staff was to use the Broda chair with the resident other than those provided by the physical therapist, instructions upon which staff was specifically trained by the therapist. When Resident B fell, she was sitting upright at a 90 degree angle and unsupervised. Even if Petitioner is correct in its position that Resident B needed to be upright to eat, there is no dispute that she was not eating at the time, a conclusion that is consistent with the fact that she was assessed as being totally dependent

upon the assistance of one staff member to eat and that no staff member was with her. Because she was not eating, there was no reason for her to be upright at the dining table. I also conclude that, contrary to the physical therapist's instructions and training for staff, Resident B was unsupervised when she fell. The evidence shows that no staff saw the fall and therefore I conclude that no staff was supervising or even observing the resident from within her "vicinity." Petitioner has failed to show that the instructions of the physical therapist were not reasonable means to minimize the risk for harm to Resident B due to accidental injury or that Petitioner took other reasonable steps to accomplish the same result.

I am also urged by CMS to consider that the wheels of Resident B's Broda chair were not locked at the time of the fall, a fact that is not disputed by Petitioner. Petitioner introduced some manufacturer's information regarding the Broda chair, but it contained no specific instructions regarding the use of the chair or its features. P. Ex. 46. I can infer from the fact that the Broda chair had brakes that they were a safety feature provided by the manufacturer. Petitioner presented no evidence that the brakes were not to be applied when the chair was not being moved or that applying the brakes was not a reasonable means to make the chair safer for any occupant of the chair. Petitioner's undisputed failure to ensure that a safety device provided by the chair manufacturer was properly used permitting the chair to roll back when Resident B apparently pitched forward in her chair, is an independent basis for finding a violation of 42 C.F.R. § 483.25(h)(2). However, I stress that even if staff locked the brakes and Resident B hit her head on the table rather than the floor, Petitioner never the less violated 42 C.F.R. § 483.25(h)(2) by leaving the resident unsupervised in an upright position in her Broda chair.

Accordingly, I conclude that Petitioner violated 42 C.F.R. § 483.25(h)(2) because it failed to take reasonable steps to mitigate the foreseeable risk of harm due to accidental injury by ensuring that the Broda chair, an appropriate assistance device, was properly used and that Resident B had necessary supervision. Resident B suffered actual harm due to the violation.

(d) Petitioner did not violate 42 C.F.R. § 483.25(h)(2) in the case of Resident C as alleged in Example 3 of the SOD.

The alleged violation regarding Resident C is cited as example 3 in the SOD. CMS Ex. 1, at 12-22; P. Ex. 1, at 12-22. Petitioner is alleged to have violated 42 C.F.R. § 483.25(h)(2) in the case of Resident C on two bases, because Petitioner "failed to prevent [Resident C] from falling and sustaining a fractured left hip and failed to ensure the same resident had continuing care planned interventions in place." CMS Ex. 1, at 2; P. Ex. 1, at 2.

Resident C was nearly 98 when the survey occurred. She was admitted to Petitioner's facility in March 2004. Her diagnoses included senile dementia, diabetes, a cataract in her left eye, degenerative joint disease, osteoporosis, osteoarthritis, hypertension, and chronic dizziness, among others. P. Ex. 48, at 1; P. Ex. 49, at 1; CMS Ex. 17, at 6; Tr. 158. Her MDS with an assessment reference date of October 2, 2006, shows she required extensive assistance of one or two staff for all activities of daily living except eating which she could do with supervision after set-up; she could not balance while standing without physical help; she had limited use of both arms, both hands, and both legs; she was usually continent of bowel and occasionally incontinent of bladder; she had a scheduled toileting plan; and she had fallen in the past 30 days and had a hip fracture within the last 180 days. P. Ex. 53. She suffered from a neurogenic bladder and did not want to be catheterized, causing frequent bathroom visits. P. Ex. 64. Resident C was consistently assessed as being at high risk for falls and she had a history of falls. P. Ex. 55; P. Ex. 56, at 4. Resident C's care plan, offered by Petitioner and dated May 25, 2006 with hand-written entries to January 2007, indicates she had falls on July 1, 2005, July 3, 2005 with a skin tear, August 22, 2005, November 12, 2005, a skin tear on August 29, 2006; September 2, 2006, and a couple more falls after the survey. Her care plan states in the section captioned "Problem" that she had an alarming lap buddy in her wheelchair that she was able to remove, an alarm on her bed, and an alarm on her bedside chair. Interventions listed at the time of the survey included: reminding her to call for assistance with transfers, keeping the call light within easy reach, and answering promptly because Resident C attempts self-transfer; assistance of one or two for transfers; quarterly restraint and fall assessments and as necessary with star on door; educating on transfer techniques; alarming lab buddy in wheelchair, bed alarm, alarm in recliner, half side-rails up on both sides when in bed; toileting plan upon rising, before and after meals, at bedtime, and as needed; observing for incontinence and providing incontinence care as needed; occupational therapy; physical therapy; observing alarm at least every shift and as necessary due to history of disabling or disconnecting; keeping the wheelchair close to the recliner when she was in the recliner; and the use of skin sleeves. P. Ex. 56, at 4-5; CMS Ex. 17, at 30-31, 112. The copy of the care plan offered as evidence by Petitioner includes changes and interventions added after the survey: the lap-buddy in the wheelchair was discontinued in December 2006; in January 2007 she was placed in a low bed with floor mats; on October 27, 2006 a personal alarm was applied to the wheelchair with the alarm box under the seat so Resident C could not reach it and disable the alarm; and in January 2007 she received a concave mattress for her bed and a pommel cushion for her wheelchair. P. Ex. 56, at 4-5. I note that both copies of the care plan in evidence are dated May 25, 2006 and I infer that all the printed entries were on the care plan when it was prepared in May 2006. There are only three hand-written interventions on the copy of the care plan obtained by CMS during the survey and admitted at hearing as CMS Ex. 17, at 30-31, including physical therapy for transfers, standing, and gait among

other things; keeping wheelchair close to the recliner; and use of skin sleeves. No dates are discernable on the copies admitted as evidence for the first two hand-written interventions but the note regarding the skin sleeves is dated September 6, 2006.[9] CMS Ex. 17, at 30-31; P. Ex. 56, at 4-5. I infer that the other hand-written entries were made sometime between May 25, 2006 and the October 2006 survey and that inference is consistent with a Nurse's Notes entry dated September 6, 2006, that indicates that placing the wheelchair near the recliner was discussed during a fall risk assessment review and a September 20, 2006 Nurse's Notes entry and a doctor's order dated September 20, 2006, that indicate the resident's doctor issued a new order for physical therapy five times per week for three weeks for therapeutic exercises related to transfers, standing, and gait, among other things. P. Ex. 61, at 19 and 22; P. Ex. 59, at 11. A new order for physical therapy was issued on October 11, 2006, for an additional four weeks. P. Ex. 59, at 13.

The SOD records that on October 13, 2006 at 1:02 p.m., Surveyor Carlson saw Resident C in her wheelchair in the bathroom. Resident C was not attended and the Velcro strap of her alarming lap buddy was unhooked from one side of her wheelchair but the alarm was not sounding. Resident C was leaning forward in her wheelchair, pulling down on the waistband of her pants and lifting her top. At 1:03 p.m. a CNA entered the bathroom and assisted the resident in the use of the toilet. The CNA told Surveyor Carlson that she did not know why the lap buddy alarm did not sound but the resident was known to unfasten and then fasten the Velcro so staff did not catch her trying to get up. When the CNA tested the alarm by attaching and then unhooking the alarm, it sounded properly. CMS Ex. 1, at 12-13; P. Ex. 1, at 12-13; Tr. 163-66, 236-244, 259-60. Surveyor Carlson testified that she was concerned because she found the resident alone in the bathroom, appearing to ready herself to self-transfer, with the lap buddy detached and not alarming, and that there was a risk the resident might fall. Tr. 165-66. Surveyor Carlson opined that Petitioner's interventions were not working because Resident C continued to attempt self-transfers. Tr. 164. Surveyor Carlson also testified that the interventions on Resident C's care plan were not effective to prevent her self-transfers or a fall on September 2, 2006, that she believed resulted in a fractured hip. Tr. 175. Surveyor Carlson opined that through the date of the October 2006 survey, Petitioner did not provide Resident C adequate supervision or assistive devices to prevent falls and that there was a risk for more than minimal harm. Tr. 190. She also testified that she did not find evidence that Petitioner consistently implemented other interventions on Resident C's care plan. Tr. 244-48. She testified that Petitioner could have attempted to use either a pommel cushion or a pressure pad alarm with Resident C to deter or prevent self-transfers. Tr. 253.

[9] An Accident/Incident Committee Review form dated September 1, 2006, indicates that skin sleeves were initiated on that date to address the problem of the resident causing a skin tear on her wrist when she propelled herself into the bathroom door frame.

Petitioner offered as evidence Nurse's Notes forms dated from May 12, 2006 through November 2, 2006. P. Ex. 61. Review of the notes for the period May 25, 2006, the date of her care plan, through October 17, 2006, the last day of the survey, reveals the following: from May 25 to July 9, 2006, there were 33 entries that indicated the resident was noncompliant with her lap buddy, that one or more attempts were made by the resident to unhook her lap buddy, and/or to self-transfer to the toilet or her recliner, some entries reflect that staff responded to the lap buddy alarm or otherwise caught the resident in the act of transferring, and many entries indicate the resident was instructed to use her call-light; between May 25 and July 9, 2006, the fall risk committee considered the resident's case on May 30, June 6, and on June 14, 2006; from July 10 through September 1, 2006, no incidents are reported. P. Ex. 61, at 5-16.

The parties agree that Resident C fell on September 2, 2006, and it was subsequently discovered on about September 25, 2006 (P. Ex. 63, at 3-4; P. Ex. 64, at 6) that Resident C had a fractured left hip. A Nurse's Notes entry dated September 2, 2006 at 4:30 p.m. indicates that Resident C attempted to transfer herself from her lounge chair to her wheelchair, she grabbed the blankets to hold on to and when they gave way, she fell on her left hip. She complained of slight pain in her left hip. P. Ex. 61, at 17. A post-fall assessment dated September 2, 2006, provides little additional detail except that it indicates a chair alarm was placed in the resident's lounge chair. P. Ex. 69. A September 5, 2006 entry on an Accident/Incident Committee Review form indicates that on September 2, 2006 Resident C was sitting in her recliner, the CNA had just left the room a minute or less before the resident attempted to transfer from her recliner to her wheelchair, when she grabbed the blankets on her bed to help her stand-up they came loose and the resident fell to her buttocks, she used the call light to call for assistance. The intervention ordered was for the CNAs to keep the residents wheelchair close to her recliner when she was sitting in the recliner, and she only needed a limited assist to transfer but could not ambulate. P. Ex. 70, at 2. An Incident Follow-Up & Recommendation Form dated September 5, 2006, indicates that on September 2, 2006, at 4:30 p.m. the resident was found on the floor in front of her recliner and next to the bed, and that she had attempted transferring from the recliner to the bed. The intervention ordered was to keep the wheelchair locked and next to the recliner when the resident was in the recliner. The note also indicates that CNAs were to be in-serviced regarding placing the wheelchair "in front of recliner." CMS Ex. 17, at 75. A Nurse's Notes entry dated September 6, 2006 at 1:20 p.m., shows that the fall risk committee met and reviewed the resident's fall risk and she scored 14; the decision was made to continue the alarming lap buddy; the note states "alarm bed & w/c;" and that the wheelchair was to be placed close to the recliner when the resident was in the recliner. P. Ex. 61, at 19. According to Petitioner's care plan dated May 25, 2006, she was supposed to have a bed alarm prior to September 6 and the note is not clear whether a new bed alarm was added or whether the decision was to continue the bed alarm. Although the note indicates that there was to be an alarm in Resident C's wheelchair, it is not clear whether this was an error and that the note should have stated recliner rather than wheelchair, but there is no

evidence of any alarm used in the resident's wheelchair from May 25, 2006 through the date of the survey, except the alarming lap buddy. The Nurse's Notes from September 2, 2006, after the fall, through October 17, 2006 include eight entries that indicated the resident was noncompliant with her lap buddy, that one or more attempts were made by the resident to unhook her lap buddy, and/or to self-transfer to the toilet or her recliner. These entries include: September 13, Resident C attempted to self-transfer after breakfast but the nurse heard the alarm, assisted the resident, and reminded her to call for help; September 28, the resident removed her lap buddy twice on the evening shift apparently planning on transferring herself to the toilet;[10] September 29, the resident removed the lap buddy during the morning shift to transfer herself to her recliner, staff assisted and reminded her to use her call light; September 29, during the evening shift the resident attempted to self-transfer to the toilet twice, the resident was assisted and reminded to use the call light; September 30, Resident C attempted to self-transfer twice during the morning, unhooking the lap buddy on her own; October 6, the resident attempted to self-transfer to toilet after breakfast, the lap buddy alarm was heard and staff assisted; and October 17, the resident attempted to transfer from her wheelchair to her recliner. P. Ex. 61, at 17-25.

Physician's orders reflect that Resident 8's alarming lap buddy was intended to be an "enabler" and she was to be able to release it upon command. P. Ex. 59, at 5; P. Ex. 60, at 1-2. The physician's order is consistent with a restraint verses enabler evaluations dated January 16, 2006 and June 14, 2006, which indicate that the purpose was to remind the resident to call for assistance with transfers and to alert staff that the resident was attempting a transfer without assistance. P. Ex. 57, at 1-2.

CMS argues before me that Petitioner continued to follow a failed care plan for Resident C that "never worked nor was even consistently implemented." CMS Brief at 18; CMS Reply at 7-8. CMS correctly asserts that Resident C continued to attempt self-transfers after unhooking her alarming lap buddy. CMS incorrectly asserts that Petitioner failed to do quarterly updates of the resident's fall risk assessment. CMS points to interventions implemented by Petitioner after the survey in support of its position that Petitioner failed to implement new more effective interventions prior to the survey. CMS. Br. at 18-24; CMS. Reply at 7-10.

Petitioner objected at hearing and in post-hearing briefing to my consideration of the fact that Resident C fell and suffered a fractured hip on about September 2, 2006 as the basis for imposition of an enforcement remedy. Petitioner argues that Petitioner was found in

[10] The note is not clear as to whether staff heard an alarm or simply caught the resident in the act or whether the resident actually completed a transfer by herself. However, based on the wording of the note, I conclude that the resident did not complete a transfer herself but was assisted by staff which responded to the lap buddy sounding.

substantial compliance as of September 8, 2006, by a survey completed on September 29, 2006, and events prior to that finding should not be the basis for a deficiency citation or an enforcement remedy. Tr. 20, 26-30, 39, 44; P. Brief at 25-30; P. Ex. 87, 88, 89. CMS agreed that Resident C's records were reviewed during a revisit survey to a prior complaint survey that was completed on September 29, 2006 and no deficiencies were cited and Petitioner was certified as being in substantial compliance. However, CMS argued that the surveyors only reviewed the period from September 8 through 29, 2006. Counsel for CMS stated that CMS relies upon evidence from before September 8 and after September 29, 2006, but not the intervening period subject to review during the revisit survey. Tr. 22-25. Counsel for CMS also asserted CMS proceeded upon the theory that Resident C's fractured hip on September 2, 2006, was appropriately considered as actual harm when CMS determined the CMP to impose. Tr. 41-42. Petitioner argued that it construed the statement of deficiency to be that Petitioner failed "to do interventions following the fall and the fracture, but that . . . she wasn't injured again after the fracture." Tr. 42-43. Surveyor Mankell testified that Resident C's records were reviewed during the revisit survey that ended on September 29, 2006. Tr. 140. Surveyor Carlson testified that she participated in the survey that ended on September 29, 2006, and that the records of Resident C were reviewed for the period September 8 through 29, 2006 during that survey but no deficiency was cited based upon her treatment or care. Tr. 195-97, 220. I find it unnecessary to resolve Petitioner's objection because I find no violation of 42 C.F.R. § 483.25(h)(2) based upon the facts related to Resident C in example 3.

Based upon my review of all the evidence and consideration of the arguments of the parties, I find no violation of 42 C.F.R. § 483.25(h)(2) based upon the facts related to Resident C. The CMS argument that Resident C's care plan had "failed" or was ineffective is belied by the facts. In 2005, Resident C had several falls. The care plan in question before me was adopted on May 25, 2006. CMS Ex. 17, at 30-31. Between May 25, 2006 and September 2, 2006, the resident had no falls. Her clinical records show that Resident C was being toileted as required by her care plan, she was being frequently monitored, she received physical therapy regarding safe transfer techniques, she was frequently reminded to call for assistance rather than attempt self-transfers unassisted, and her alarms were being checked. The evidence shows that the purpose of the lap buddy was to remind the resident to call for help and to alert staff if she did not. The clinical evidence shows that the lap buddy worked well both to remind the resident and to alert staff. Administrator Powell testified that Resident C set off her lap buddy alarm numerous times and staff responded, which is the purpose of the alarm. Tr. 352, 369. The alarming lap buddy was not intended to be a restraint to prevent self-transfer and the physician's order specified that Resident C be able to release the lap buddy, albeit under supervision. The fact that Resident C could release the lap buddy was not a violation of the regulation. The fact that Surveyor Carlson found Resident C in her bathroom with her lap buddy disconnected is not disputed. It is also not disputed that a CNA arrived in the bathroom in no more than a minute according to the SOD and before Resident C

could attempt a self-transfer. Whether or not the CNA entered because she saw the surveyor enter the room is pure speculation. The records show consistent toileting after meals and consistently frequent monitoring of the resident, facts that are consistent with an inference that the CNA entered the bathroom to monitor and toilet the resident rather to intervene with the surveyor. CMS is correct that P. Ex. 55 only reflects fall risk assessments on May 8 and October 9, 2006. However, other evidence shows Resident C's fall risk was assessed more often than quarterly as required by her care plan. During the period May 25 through October 17, 2006, she was assessed four times in less than six months and no more than 90 days passed between any two evaluations. P. Ex. 61, at 6, 9, 11, 17. The evidence does not indicate that an assessment was not done when it was needed. Staff consistently recorded that the resident's alarms were functioning and/or in place and that the resident was receiving her toileting programs on rising, before and after meals, at bed time, and as necessary. P. Ex. 65. When Resident C fell on September 2, 2006, she was attempting to transfer from her recliner to her bed or wheelchair (the evidence is conflicting as to her destination) and the lap buddy was not involved. The care plan required an alarm in the recliner but the evidence does not show if the alarm was operating or sounded or whether staff could not respond in time to prevent the fall. The evidence does show that staff did respond promptly when alerted by the resident with the call light and found the resident sitting on the floor. Within days a new intervention was added and staff was in-serviced to keep the wheelchair locked and next to the recliner when the resident was in the recliner. Whether the intent of the intervention was to block the resident from exiting her recliner (arguably a restraint), to remind her to call for assistance, to give her a more stable assist than the bed linen, or to minimize the distance she might attempt to ambulate when attempting a self-transfer, is not clear. What is clear is that after the new intervention was added the record shows no further attempt to transfer from the recliner prior to the survey.

I conclude that Petitioner has presented sufficient evidence to meet its burden to show by a preponderance of the evidence that it provided adequate assistance devices and supervision to mitigate the foreseeable risk of harm to Resident C due to accidental injury from falls. Accordingly, Petitioner did not violate 42 C.F.R. § 483.25(h)(2) based upon the facts related to Resident C.

2. There is a basis for the imposition of a CMP.

3. A CMP of $400 per day for the period October 17, 2006 through December 14, 2006, is not reasonable, but a CMP of $200 per day for the period is reasonable.

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 CMP for the number of days that the facility is not in compliance or for each instance that a facility is not in substantial

compliance. 42 C.F.R. § 488.430(a). There are two ranges for per day CMPs. 42 C.F.R. §§ 488.408, 488.438. The upper range of CMP from $3050 per day to $10,000 per day is for deficiencies that constitute immediate jeopardy to a facility's residents, and, in some circumstances, for repeated deficiencies. 42 C.F.R. §§ 488.438(a)(1)(I), (d)(2). There was no finding of immediate jeopardy and the upper range is not applicable to this case. The lower range of CMP from $50 per day to $3000 per day is 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). The $400 per day CMP proposed by CMS in this case is at the low end of the lower range of authorized CMPs.

In determining whether the amount of the 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; and (4) the facility's degree of culpability.

CMS proposed a $400 per day CMP based on the findings and conclusions that there were four examples establishing Petitioner's violation of 42 C.F.R. § 483.25(h)(2), two of which involved actual harm. I conclude that Petitioner violated the regulation due to its failure to ensure that Resident D's wheelchair alarm was properly used and its failure to ensure that Resident B was properly supervised in her Broda chair and that the chair was properly used. I conclude that only Resident B suffered actual harm due to the regulatory violation. I conclude that the regulatory violation was serious, but it was not as serious as CMS may have considered based on the findings and conclusions of the survey. Thus, adjustment of the CMP is reasonable. Resident B suffered a serious injury. Petitioner stipulated it had the ability to pay. Tr. 16. Petitioner was culpable considering that specific elements of its care plans for the two residents were not implemented. Petitioner has not presented evidence to show it corrected the deficiency or achieved substantial compliance prior to December 14, 2006. Based upon my evaluation of all the required factors, I conclude that a $200 per day CMP for the period October 17 through December 14, 2006 (a total of 59 days), a total CMP of $11,800 is reasonable.

4. The burden of persuasion does not affect the outcome of this case.

5. Review of the reasonableness of the proposed enforcement remedy was de novo and review of how CMS considered the regulator factors when proposing an enforcement remedy is not relevant to my review.

Petitioner attempts to preserve two additional issues for appeal. 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). Petitioner's Prehearing Brief at 19. 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). Petitioner's Prehearing Brief at 20. 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 violated 42 C.F.R. § 483.25(h)(2) and a $200 per day CMP for the period October 17, 2006 through December 14, 2006, totaling $11,800 is reasonable.

/s/
Keith W. Sickendick
Administrative Law Judge