

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Pigeon Forge Care and Rehab Center
(CCN: 44-5382),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-13-294

Decision Number. CR3909

Date: May 28, 2015

DECISION

Pigeon Forge Care & Rehab Center (Petitioner or facility) is a long-term care facility located in Pigeon Forge, Tennessee, which participates in the Medicare program. Based on findings of a survey completed by the East Tennessee Regional Office of Health Care Facilities (state agency) on November 8, 2012, the Centers for Medicare & Medicaid Services (CMS) determined that Petitioner was not in substantial compliance with Medicare participation requirements. Due to this noncompliance, CMS imposed on Petitioner a civil money penalty (CMP) of \$3,550 per day from July 18 through October 30, 2012, and a CMP of \$200 per day from October 31 through December 1, 2012, the date the state agency determined that Petitioner returned to substantial compliance. Based on the record as a whole, I conclude that Petitioner has shown that it was in substantial compliance with Medicare participation requirements on the dates for which CMS imposed the CMP. Therefore, I reverse CMS's determination to impose a CMP.

I. Background and Procedural History

The Social Security Act (Act) sets forth requirements that nursing facilities must meet to participate in the Medicare program and authorizes the Secretary of the United States

Department of Health and Human Services (Secretary) to promulgate regulations implementing those statutory provisions. Act § 1819 (42 U.S.C. § 1395i-3). The Secretary's regulations are found at 42 C.F.R. Parts 483 and 488. To participate in the Medicare program, a facility must maintain substantial compliance with program requirements. To be in substantial compliance, a facility's deficiencies may "pose no greater risk to resident health or safety than the potential for causing minimal harm." 42 C.F.R. § 488.301.

The Secretary contracts with state agencies to conduct periodic surveys to determine whether skilled nursing facilities are in substantial compliance. Act § 1864(a) (42 U.S.C. § 1395aa(a)); 42 C.F.R. § 488.10. Each facility must be surveyed once every 15 months, or more often if necessary, to ensure that it corrects identified deficiencies. Act § 1819(g)(2)(A) (42 U.S.C. § 1395i-3(g)(2)(A)); 42 C.F.R. §§ 488.20(a), 488.308.

The Act also authorizes the Secretary to impose enforcement remedies against a long-term care facility that does not comply with the federal participation requirements. Act § 1819(h)(2) (42 U.S.C. § 1395i-3(h)(2)). 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. Among other enforcement remedies, CMS may impose a per-day CMP for the number of days a facility is not in substantial compliance or a per-instance CMP for each instance of the facility's noncompliance. 42 C.F.R. § 488.430(a). A per day CMP, which CMS imposed in this case, may range from either \$50 to \$3,000 per day for less serious noncompliance, or \$3,050 to \$10,000 per day for more serious noncompliance that poses immediate jeopardy to the health and safety of residents. 42 C.F.R. § 488.438(a)(2). "Immediate jeopardy" exists when "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.

If CMS imposes a CMP based on a noncompliance determination, then the facility may request a hearing before an administrative law judge to challenge the noncompliance finding and enforcement remedy. Act §§ 1128(c)(2) (42 U.S.C. § 1320a-7a(c)(2)), 1819(h)(2)(B)(ii) (42 U.S.C. § 1395i(h)(2)(B)(ii)); 42 C.F.R. §§ 488.408(g), 488.434(a)(2)(viii), 498.3(b)(13).

On November 8, 2012, surveyors from the state agency completed an abbreviated/partial extended survey at the facility. On November 16, 2012, CMS notified Petitioner that CMS found Petitioner out of substantial compliance with the following five participation requirements based on the state agency's survey results as documented on Form CMS-2567 Statement of Deficiencies (CMS Exhibit (Ex.) 1):

42 C.F.R. § 483.10(b)(11) (Tag F157, Physician Notification) at a scope and severity level of D (no actual harm with the potential for more than minimal harm);

42 C.F.R. § 483.20(b)(1) (Tag F272, Comprehensive Assessments) at a scope and severity level of J (immediate jeopardy);

42 C.F.R. § 483.25(h) (Tag F323, Accidents) at a scope and severity level of J;

42 C.F.R. § 483.75 (Tag F490, Administration) at a scope and severity level of J; and

42 C.F.R. § 483.75(o)(1) (Tag F520, Quality Assurance) at a scope and severity level of J.

CMS Exs. 1, 2. CMS also notified Petitioner that it was imposing a CMP of \$3,550 per day from July 18 through October 30, 2012, and \$200 per day effective October 31, 2012 until Petitioner achieved substantial compliance or CMS terminated its Medicare participation. CMS Ex. 2 at 2. On December 4, 2012, the state agency conducted a revisit which found Petitioner in substantial compliance as of December 1, 2012. CMS Ex. 5. The total CMP imposed is \$378,950. CMS Ex. 8 at 1.

On January 14, 2013, Petitioner timely requested a hearing to contest CMS's findings of noncompliance and CMP. The case was assigned to me for hearing and decision. On January 18, 2013, I issued an Acknowledgment and Initial Pre-Hearing Order establishing a briefing schedule.

In accordance with that schedule, on May 2, 2013, CMS submitted a pre-hearing brief (CMS Br.), accompanied by 21 exhibits (CMS Exs. 1 – 21). CMS offered the written direct testimony of one proposed witness, state agency surveyor Cindy Wilson, RN (Surveyor Wilson), which was marked as CMS Ex. 21.

On June 6, 2012, Petitioner submitted a pre-hearing brief (P. Br.), accompanied by 16 exhibits (P. Exs. 1 – 16). Petitioner offered the written direct testimony of seven proposed witnesses: Keith Boyce, NHA (P. Ex. 1), Petitioner's Administrator (NHA Boyce); Zhanna Efflandt, RN (P. Ex. 2), an RN employed by Petitioner (RN Efflandt); Vicki Chambers Freshour, RN (P. Ex. 3), an RN employed by Petitioner as a restorative nurse (RN Freshour); Robin Jones, RN (P. Ex. 4), Petitioner's Director of Nursing (DON Jones); Melinda Little, LPN (P. Ex. 5), an LPN employed by Petitioner (LPN Little); Annette Wenzler, RN (P. Ex. 6), the Chief Nurse Executive for Signature Healthcare, LLC, Petitioner's owner (RN Wenzler); and Michael L. Williams, LPTA (CMS Ex. 7), a

licensed physical therapist assistant performing physical therapy services at Petitioner (LPTA Williams).¹

Following the pre-hearing exchanges, I directed my staff attorney to contact the parties to determine whether they intended to cross-examine the opposing party's witnesses and to ask whether they objected to the other party's exhibits. She did so, and a series of electronic mail communications began on June 12, 2014 and culminated on June 23, 2014. On June 13, 2014, CMS stated that it did not intend to cross-examine Petitioner's witnesses, but that it objected to P. Ex. 12, described as "Photographs of Resident 2 and Side Rail" and to parts of P. Exs. 1 and 6 that referenced the photographs.² Petitioner responded on June 16, 2014, stating that it intended to cross-examine CMS's proposed witness, Surveyor Wilson, who it noted was now employed by a facility owned by Petitioner's parent company. Petitioner also stated that it did not object to CMS's exhibits and it offered a response to CMS's objection to its exhibits, which I discuss below.

Apparently in light of Surveyor Wilson's employment with a facility owned by Petitioner's parent company, on June 23, 2014, CMS informed me that it had decided to withdraw her testimony, stating: "CMS will not reference Ms. Wilson's written testimony as evidence in future pleadings in this case." On June 23, 2014, I directed my staff attorney to advise the parties that, as CMS had withdrawn the only witness who would be subject to cross-examination, I would not hold an oral hearing and would instead decide the case on the written record. I offered the parties the opportunity to file final briefs. CMS and Petitioner both filed final briefs (CMS Final Br. and P. Final Br., respectively).

II. Evidentiary Rulings and Decision on the Record

In the absence of objection, I admit CMS Exs. 1 – 20.³ As noted above, CMS withdrew CMS Ex. 21.

¹ Petitioner filed a motion for partial summary judgment regarding the duration of the CMP in this case. CMS responded to the motion for partial summary judgment. Because this decision is favorable to Petitioner, Petitioner's motion is moot.

² CMS also asked for clarification that the person providing physical therapy services to Resident 2 in July 2012, described in RN Jones' testimony (P. Ex. 4 at 2) as "Joe Williams," was the "Michael L. Williams" whose written direct testimony Petitioner offered as P. Ex. 7. On June 16, 2014, Petitioner's counsel clarified that Joe Williams and Michael L. Williams are the same individual.

³ In its briefing, CMS references Surveyor Wilson's surveyor notes (CMS Ex. 16). I rely on CMS Ex. 16 only to the extent the notes are supported by other evidence of record

CMS objects to P. Ex. 12, a two-page exhibit that Petitioner offers as “[p]hotographs of Resident 2 and side rail.” The photographs depict, at page 1, a woman sitting on the side of a bed with her left forearm coming through the upper middle of a side rail, and another individual who is helping to support her (P. Ex. 12 at 1), and a photograph of her arm only (P. Ex. 12 at 2). CMS asserts that: 1) the photographs were not taken at the time of the July 18, 2012 incident which is the subject of this appeal; 2) the individuals depicted are not identified; and 3) the position of the elderly woman is inconsistent with the descriptions of the incident contained in other evidence (P. Ex. 3 at 3; P. Ex. 5 at 2) that state the resident was “half out of the bed.” CMS argues that it does not believe the photographs are “true and accurate” images of the circumstances as they existed at the time of the incident involving Resident 2 on July 18, 2012. CMS also objects to P. Ex. 1 (the testimony of NHA Boyce) which references P. Ex. 12 as a “true and accurate depiction[.]” CMS states that NHA Boyce was not present at the time of the incident and did not witness it. CMS also objects to RN Wenzler’s testimony referencing P. Ex. 12.

Petitioner responds that NHA Boyce’s testimony clearly identifies the resident on the bed as Resident 2. Petitioner states that the purpose of offering the photograph is to show that Resident 2’s arm could not possibly have been entrapped in her bed rail, as Surveyor Wilson claimed, and that the bed rail is appropriate for the purpose for which it was used. Petitioner argues that any differences between the photographs and the survey report should go to the photographs’ evidentiary weight, not their admissibility. Petitioner also asserts that CMS misstates NHA Boyce’s testimony, which is that Resident 2’s arm looks in the two photographs the way it did in July 2012, and that the bed rail in the second photograph is like the one Resident 2 used in July 2012. NHA Boyce’s testimony in this regard is found at P. Ex. 1 at 1 ¶ 8 and is that:

The photographs that are included as exhibits to Pigeon Forge’s Prehearing Brief in this case are true and accurate depictions of (1) Resident 2’s left arm as it was in July of 2012, (2) her left arm inside the quarter rail that was in place in July of 2012, and (3) the halo ring that was used to replace the quarter rail in August 2012.

I note that the picture of the halo ring he references is found at P. Ex. 14. CMS did not object to admission of the photograph of the halo ring.

because CMS withdrew Surveyor Wilson as a witness and Petitioner was precluded from cross-examining her. I note also that there is now no witness testimony authenticating the findings of the November 8, 2012 survey set forth in the November 8, 2012 Statement of Deficiencies (CMS Ex. 1). I rely on the Statement of Deficiencies, but only to the extent its findings are not rebutted by other evidence of record.

I agree with Petitioner that CMS's objections go to the evidentiary weight of P. Ex. 12 and NHA Boyce's and RN Wenzler's testimony, and not to the admissibility of the exhibit itself. Accordingly, I overrule CMS's objection.

In the absence of any other objection, I admit P. Exs. 1 – 16.

My Order advised the parties that they must submit written direct testimony for each proposed witness and that I would only schedule an in-person hearing if a party requested an opportunity to cross-examine a proposed witness. As noted above, CMS did not ask to cross-examine any of Petitioner's witness. CMS withdrew the written direct testimony of its only proposed witness. Thus, there are no witnesses subject to cross-examination and nothing for me to hear. Accordingly, I issue this decision on the written record. The written record in this case includes the parties' briefs and the admitted exhibits, which include the written direct testimony of Petitioner's seven witnesses (P. Exs. 1-7).⁴ See Order ¶ 10.

III. Issue

The issue in this case is whether Petitioner was in substantial compliance with participation requirements from July 18, 2012 to December 1, 2012. Because, as explained below, I conclude that Petitioner was in substantial compliance on the relevant dates, I do not need to consider whether CMS's immediate jeopardy findings are clearly erroneous or the CMPs that CMS imposed are reasonable.

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

This case involves the care Petitioner provided to two residents, Residents 1 and 2. CMS alleges Petitioner continued to use assistive devices with Residents 1 and 2 after the residents had accidents, without assessing their safety, leading to the regulatory citations noted above and justifying the imposition of the CMPs at issue. As discussed below, I find that at all relevant times Petitioner was in substantial compliance with participation requirements. I first discuss the facts relating to the two residents and then discuss why the facts do not support a conclusion that Petitioner was out of substantial compliance with the participation requirements at issue. My findings of fact and conclusions of law in this case are set forth in italics and bold font.⁵

⁴ Below I rely on the testimony of Petitioner's seven witnesses regarding the facts of the case and, in the absence of other evidence, for their opinions consistent with their education and training. As indicated below, I find that their testimony is consistent with the documentary evidence.

⁵ Petitioner noted in its final brief (P. Final Br. at 22-23) that CMS's citation to the record in its final brief was often either incorrect (i.e., citing to the medical record or

1. ***On July 18, 2012, facility staff found Resident 2 on the edge of her bed with her flaccid left hand through an open area in the bed's partial bed rail, following which facility staff: assisted Resident 2 back into her bed, determined Resident 2 was unharmed; assessed and concluded that it was still appropriate and necessary for Resident 2 to have partial bed rails on her bed; and immediately implemented additional interventions for Resident 2, including additional physical therapy related to the use of the bed rails, adding a bed pressure alarm, ensuring safety mats were on the floor by the bed, moving the bed to a lower position, and placing bed controls out of Resident 2's reach.***

Resident 2 was a 68-year-old woman who was admitted to the facility on June 20, 2012 (and readmitted on August 25, 2012 after a hospital stay) with diagnoses that included cerebral vascular accident (CVA), left sided hemiparesis secondary to the CVA, dysphagia, and multiple pressure ulcers. CMS Ex. 4 at 2; CMS Ex. 18 at 7, 8, 10; P. Ex. 3 at 2 ¶ 15; P. Ex. 4 at 2 ¶ 16. RN Freshour, a restorative nurse at Petitioner's facility, testified that due to Petitioner's "flaccid" left arm she could not independently move the arm and had to use her right hand to reposition her left arm. P. Ex. 3 at 3 ¶ 25. DON Jones testified that Resident 2's left arm was "completely non-functional" and like a "noodle." P. Ex. 4 at 2 ¶ 26. While Petitioner assessed Resident 2 as having physical problems as a result of her CVA, Resident 2 was not assessed as having problems with cognitive or mental status. CMS Ex. 1 at 6; CMS Ex. 18 at 28-29, 54, 68-69, 94, 124, 125; P. Ex. 6 at 4 ¶ 38.

On the day of her admission, June 20, 2012, the facility completed a side rail evaluation for Resident 2. The evaluation showed that the resident was not noted to have an alteration in safety awareness due to a cognitive decline. It noted that the resident had a history of falls; demonstrated poor bed mobility; had difficulty moving to a sitting position on the side of the bed; had difficulty with balance or poor trunk control; and was currently using side rails for position or support. The side rail evaluation recommended that: side rails were indicated to serve as an enabler to promote independence; the resident expressed a desire to have side rails raised while in bed; and that half rails were necessary to assist with repositioning. The side rail evaluation also called for Resident 2 to be assessed by physical therapy regarding her current functional ability. CMS Ex. 18 at 5; P. Ex. 3 at 2 ¶ 16-17; P. Ex. 4 at 2 ¶ 18-20. On June 20, 2012, Resident 2, who was

other exhibit for Resident 1 when referring to Resident 2) or overbroad (i.e., citing to the entire medical record of a resident (a 129 page exhibit for Resident 2 (CMS Ex. 18) and a 274 page exhibit for Resident 1 (CMS Ex. 17)) when making a specific point. *See, e.g.*, CMS Final Br. at 1-2. Moreover, although CMS withdrew the exhibit, its final brief still references and relies on CMS Ex. 21, Surveyor Wilson's written direct testimony. CMS Final Br. at 2. CMS's citation in this regard has made it difficult to credit CMS's arguments in support of its initial determination.

mentally competent, signed an “Informed Consent for Use of Side Rails.” CMS Ex. 18 at 14. Bilateral quarter rails were fitted to her bed.⁶ P. Ex. 4 at 2 ¶ 21.

The informed consent that Resident 2 signed on June 20, 2012 reflects her acknowledgment that she understood the risks of side rails (which include getting caught in the rails, between the rails and mattress, strangulation, hitting against the rails causing skin tears and/or bruising, and crawling over the top of the rail risking a fall and injury or death). She also acknowledged that she understood that alternative methods of treatment were available to her, including positioning, placing her mattress on the floor, placing a mat on the floor next to her bed, and use of a new specialty bed. Despite these alternatives, Resident 2 decided to use rails for safety and mobility. CMS Ex. 18 at 14.

LPTA Williams testified that he provided physical therapy services to Resident 2 in July 2012. He testified that they “work[ed] on bed mobility skills, including the safe use of half rails that were on both sides of her bed for rolling to help with hygiene and for transferring from a supine to a sitting position for functional independence.” He also “instructed Resident 2 to use her unaffected upper extremity to reach over and grab onto the side rail in order to use her own strength in that arm to pull so that she could roll over onto her side, slide her legs over the edge of the bed, and push herself up into a sitting position on the side of the bed.” P. Ex. 7 at 1; P. Ex. 8.

On July 18, 2012, at around 8:40 a.m., LPN Little testified that she heard someone call for assistance. She entered Resident 2’s room and saw that a certified nursing assistant (CNA), Courtney Clark, was assisting Resident 2. LPN Little testified she saw Resident 2 “partially sitting on the bed with her feet on the floor and her left arm through the opening in her quarter rail. She was very calm and did not appear to be in any distress.” P. Ex. 5 at 1-2 ¶¶ 13-15. LPN Little’s testimony is consistent with a nursing note that she made contemporaneous with the incident, stating that she observed Resident 2 with her “lower half of body, from thighs down off of [the left] side of [the] bed when entering room. Assisted back onto bed per staff.” CMS Ex. 11 at 32. On November 9, 2012, CNA Clark described the incident in a written statement, stating that when she observed Resident 2 she was:

halfway out of her bed . . . left arm was in the bedside rail. Her waist down was off the bed. I asked her what she was doing and she said nothing. I got her legs and put them back in the bed. I then removed her arm from the bedside rail. There were no marks on her arm. I asked her if she was ok and she said yes. There were mats on the floor by her bed. I

⁶ I note that the side rail evaluation references half rails. But it appears bilateral quarter rails were fitted to her bed. There is no indication in the parties’ submissions that there is a material difference between the two types of rails for the purposes of this case.

have witnessed [Resident 2] use her bed side rail to pull herself over while she is being changed.

P. Ex. 9. Another LPN, Rose Holman, stated in a written statement that she entered Resident 2's room and "saw [Resident 2] with her arm through the upper left bed rail and her feet were on the floor mat. [Resident 2] never hit the floor that I witnessed. [Resident 2's] back was still on bed." P. Ex. 11.

DON Jones testified that Resident 2 had no history of trying to get out of bed without assistance, her room was only two doors from the nurse's station, and she was able to ask for help when she needed it. DON Jones testified that she spoke to Resident 2 following the incident. Resident 2 explained to DON Jones that she got up because she thought she heard someone. DON Jones counseled her to ask for help the next time she needed assistance and the resident responded: "Okay." P. Ex. 4 at 3 ¶¶ 35-37.

LPN Little completed an "Incident/Occurrence Report" regarding this incident. She described the incident as "Resident in bed. Observed by staff sliding off side of bed [with] left arm through quarter side rail."⁷ She stated that a complete body assessment was done, and a red area was noted on her left cheek and left upper arm, but there were no "open areas."⁸ At the time of the incident, the resident's bed was in a high position, the foot of the bed was elevated, and the resident could change the position of the bed (up or down) at will. The Incident/Occurrence Report noted that interventions suggested to address the incident were to: have physical therapy continue working with the resident; have a bed alarm placed; have floor mats put beside the bed; keep the bed in a low position; keep the bed control out of the resident's reach; and have a side rail assessment done. Handwritten notes appearing at the bottom of the first page of the report indicate that Petitioner's interdisciplinary team (IDT) reviewed the incident on July 19, 20, 23, and 24, 2012. CMS Ex. 18 at 15-16.

Resident 2 was assessed by Nurse Practitioner Wanda Lancaster (NP Lancaster), at around 9:00 a.m. on July 18, 2012. NP Lancaster made no recommendations for changes

⁷ Inconsistently, LPN Little stated in a Fall/Observed-on-Floor Incident Report Worksheet and Fall/Change in Functional Status Report concerning the incident that Resident 2 was sitting on the floor. CMS Ex. 18 at 17. However, the record otherwise contradicts this statement and I find that the weight of evidence in the record supports that Resident 2 received assistance while still partially on the bed and that Resident 2 did not actually sit on the floor.

⁸ LPN Little testified, however, that the red areas on her cheek and ear were present on admission, and that she did not know what caused a minor abrasion on Resident 2's left arm. P. Ex. 5 at 2 ¶¶ 22-25.

in treatment. P. Ex. 3 at 4 ¶ 31; P. Ex. 4 at 3 ¶ 38. DON Jones testified also that RN Freshour interviewed and assessed Resident 2 and had her demonstrate how she used the quarter rails to turn and reposition in her bed. P. Ex. 4 at 4 ¶¶ 47-49.

RN Freshour testified that she interviewed and assessed Resident 2 as part of her normal follow-up of residents involved in incidents.⁹ She asked Resident 2 to perform a “return demonstration” to show how she used the rails to move, turn, and reposition herself. Resident 2 showed RN Freshour that she could use the rails appropriately and stated she had a “strong desire” to keep them. P. Ex. 3 at 5 ¶¶ 41, 42. Nursing notes prepared by RN Freshour on July 20, 2012 support her testimony, stating “[r]esident interviewed/assessed concerning using side rails. Resident states she uses both side rails for turning [and] repositioning. Resident displayed how side rails were necessary for this.” CMS Ex. 11 at 30.

DON Jones, who conducts clinical meetings with the facility’s IDT each morning during the work week, testified that the IDT discussed Resident 2’s incident “at length” at its morning meeting on July 18, 2012. P. Ex. 4 at 1, 3 ¶¶ 7, 40. They determined that the factors identified in the June 20, 2012 side rail assessment (CMS Ex. 18 at 5) remained the same. Resident 2 still had a history of falls, poor bed mobility, and difficulty with balance and body control, and was still using a side rail for positioning in bed. They saw no reason to change the “still-accurate” side rail assessment in her chart. P. Ex. 4 at 3-4 ¶¶ 40, 41, 43, 46. RN Freshour also testified that the factors identified in Resident 2’s June 20, 2012 side rail assessment were still accurate following the July 18 incident. P. Ex. 3 at 4 ¶ 33.

DON Jones testified that both RN Freshour and LPTA Williams told her that Resident 2 continued to need side rails in her bed for positioning, because she could not turn over without them. P. Ex. 4 at 4 ¶ 49. RN Freshour testified that, without the side rails,

⁹ RN Freshour, the facility restorative nurse, testified that she works with a staff of restorative aides to evaluate and assist residents completing physical therapy in order to help them maintain their level of functioning. She conducts monthly, quarterly and annual assessments of all the facility’s residents and she regularly reviews side rail, fall risk, restraint and other assessments. She reviews and logs incident reports with the facility’s IDT and keeps the incident reports in her office. When changes are made to a care plan in response to an incident she routinely conducts in-service sessions with the nurses responsible for the patient to ensure changes are communicated to the care staff. She also observes the patient for a few days to confirm that the interventions are an appropriate and effective response. The restorative aides she supervises check daily to see all safety alarms are in place and working and that batteries are changed, and they document these activities. RN Freshour served as a nursing home surveyor for the state of Tennessee from 2004 to 2009. P. Ex. 3 at 1-2 ¶¶ 1-14.

Resident 2 would have been at risk for falling, unable to engage in the turning and repositioning necessary to keep pressure off existing and potential areas of skin breakdown, and that the rails were necessary for her mental and psychosocial well-being. P. Ex. 3 at 2-3 ¶¶ 20-22.

Although Resident 2's assessment did not change, the facility immediately implemented the interventions documented in the incident report, which included having physical therapy work with the resident, putting in place a bed pressure alarm, ensuring safety mats were placed on the floor by the bed, moving the bed to a low position, placing the bed controls out of reach, and having a side rail assessment done. P. Ex. 3 at 4 ¶¶ 34, 35; P. Ex. 4 at 4 ¶ 44; P. Ex. 6 at 5 ¶¶ 53, 54. DON Jones testified that the bed alarm was particularly important because it helped notify staff of any attempt by the resident to get out of bed without assistance. P. Ex. 4 at 4 ¶ 45. RN Freshour, LPN Little, and RN Wenzler testified that a daily alarm report was begun on July 19, 2012, to confirm that Resident 2's alarm was in place and Petitioner's staff monitored the alarm daily thereafter. P. Ex. 3 at 4 ¶ 36; P. Ex. 5 at 3 ¶ 30; P. Ex. 6 at 5 ¶ 58; P. Ex. 13. The facility also changed the resident's care plan to note that she could have bilateral side rails in the up position while in bed. CMS Ex. 18 at 115.

Resident 2 was discharged to the hospital on August 14, 2012, and readmitted to Petitioner on August 25, 2012. DON Jones testified that upon readmission her side rails were replaced with halo rings; halo rings can be a safer assistive device because they present less risk of skin tears. The halo rings were on Resident 2's bed during the survey. P. Ex. 4 at 4-5 ¶¶ 50-55.

2. ***On October 18, 2012, after facility staff found Resident 1 sitting on the floor in front of her wheelchair with the wheelchair's releasable seat belt around Resident 1's chest, facility staff: assisted Resident 1 into her bed and determined Resident 1 was unharmed; concluded that Resident 1 slipped from the wheelchair when Resident 1 tried to remove a blanket from underneath her; informed Resident 1's physician of the incident the next morning; assessed and concluded that Resident 1 should not have a seat belt on her wheelchair any longer and that Resident 1 needed a new cushion in the wheelchair; removed the seat belt from the wheelchair and added a new cushion to the wheelchair; and, at Resident 1's request, added a new releasable seat belt to Resident 1's wheelchair after Resident 1 and her family protested the removal of the seat belt.***

Resident 1 was admitted to the facility on August 12, 2009. CMS Ex. 17 at 6. Resident 1 still resides at the facility. P. Ex. 4 at 5 ¶ 56. Resident 1 had diagnoses including CVA, left-sided hemiplegia, muscle weakness, a history of drug abuse, and bipolar disorder. CMS Ex. 17 at 1; P. Ex. 3 at 5 ¶ 49; P. Ex. 4 at 5 ¶ 56; P. Ex. 6 at 6 ¶ 71. She was admitted from another nursing home with a physician's order in place for a self-releasing seat belt. P. Ex. 3 at 5 ¶ 49; P. Ex. 16 at 1. Resident 1's care plan for fall related injury

notes that the seat belt should be checked every 30 minutes and released for 10 minutes every two hours. It also notes that the resident can self-release and prefers and requests a seat belt and that the seat belt was to be marked for the area to be fastened for comfort. CMS Ex. 17 at 158. Because Resident 1 could release her seat belt on command, it was not viewed as a restraint and no restraint assessment was done. P. Ex. 3 at 5-6 ¶¶ 49, 50; P. Ex. 4 at 5 ¶¶ 56, 57; P. Ex. 16. DON Jones testified that based on her observations of Resident 1, the seat belt was used less as an assistive device to keep her from falling out of her chair and more to address her psychological and emotional needs. P. Ex. 4 at 5 ¶ 58.

RN Freshour testified that Resident 1's use of the seat belt was monitored and assessed as an assistive device on a regular and ongoing basis and her use of the seat belt was frequently discussed by Petitioner's staff. RN Freshour testified that Resident 1 engaged routinely in attention-getting behaviors: going down the hall in her wheelchair crying and screaming to get attention; and accusing staff and other residents of calling her names, stealing her belongings, and going into her room in her absence. She also complained that the self-releasing seat belt was too tight, and she loosened it and slid forward in her wheelchair. RN Freshour testified further that to prevent these behaviors she brought in white fingernail polish and drew a line on Resident 1's self-releasing seat belt to mark the safest and most comfortable setting. However, Resident 1 still continued to loosen her seat belt as an attention getting behavior. Resident 1's behavior of loosening her seat belt was a regular topic of conversation at morning meetings and her chart was discussed almost daily. Resident 1 was sent to a psychiatric hospital numerous times for counseling and review of her medication regimen and was regularly seen by a psychologist. P. Ex. 3 at 6 ¶¶ 51-56.

Despite her conduct, however, Resident 1's mental status was assessed as alert and oriented to year and month. *See, e.g.*, CMS Ex. 17 at 28, 196. As RN Wenzler testified, the resident is "mentally cognizant." P. Ex. 6 at 6 ¶ 73; *see also* CMS Ex. 1 at 9.

DON Jones also testified that Resident 1 had a history of attention-getting behaviors, one of her most common being to complain that her seat belt was too tight, and she would then loosen the belt and slide forward in her wheelchair to the edge of the seat. DON Jones noted that to combat this behavior a white line was marked on the seat belt, at a safe and comfortable setting, in an effort to keep the belt at that setting. However, Resident 1 still complained about the belt being too tight and loosened it. Petitioner's IDT reviewed this behavior regularly at morning meetings. P. Ex. 4 at 5 ¶¶ 59-61.

RN Efflandt, a charge nurse on the wing where Resident 1 resided at the time relevant to this case, testified that Resident 1 spent most of her time in a wheelchair and had a self-releasing seat belt in the wheelchair. RN Efflandt testified she observed Resident 1 loosen her seat belt and slide to the front of her chair to get attention, create drama, and get staff to pay attention to her, especially after an incident where she had physically or

verbally abused a staff member or other resident “so that she would look like the victim and get sympathy.” Resident 1 used her right hand to loosen her seat belt because she had left-sided hemiplegia, which left her unable to use her left arm. Resident 1 had contractures on her left hand that made her unable to use it. Resident 1 could not lift her left arm away from her body enough to get the seat belt over it, so RN Efflandt did not view the seat belt as a choking risk. P. Ex. 2 at 1 ¶¶ 6-17.

On October 18, 2012, RN Efflandt was working the 6:00 p.m. to 6:00 a.m. shift. *See* P. Ex. 2 at 2 ¶ 29. RN Efflandt wrote in Resident 1’s nurse’s notes that at 7:00 p.m.:

CNA walked to the resident’ room and found resident sitting on the floor in front of her chair. Resident states “I slid from the chair because I was sitting on the blanket.” Prior to incident, CNA Charles tightened resident’s waist belt after she used the bathroom. Resident has no injury or bruises.

CMS Ex. 11 at 26.

RN Efflandt testified that on the evening of October 18, 2012, CNA Charles Saylor (CNA Saylor) called her to Resident 1’s room. CNA Saylor told RN Efflandt that he had taken Resident 1 to the bathroom and left her, for a few minutes, with her seat belt tight in her wheelchair. He came “back a short time later to find her out of the seat of her wheelchair with her seat belt still around her.” RN Efflandt does not recall whether CNA Saylor told her whether Resident 1 was on the floor or on the footrests of her wheelchair. When RN Efflandt saw Resident 1, the resident was seated on the floor and her seat belt had been unfastened. RN Efflandt testified that Resident 1 did not appear to be agitated, scared, or upset. Resident 1 told RN Efflandt that she slipped from her chair because she was sitting on a blanket. RN Efflandt and CNA Saylor put Resident 1 back in bed, checked her vital signs, and performed an assessment. Based on her observation and assessment, RN Efflandt testified that Resident 1 did not suffer any injury as a result of sliding from her wheelchair. P. Ex. 2 at 1-2 ¶¶ 18-24, 26; *see* CMS Ex. 17 at 18.

During the course of her shift that night, RN Efflandt completed a change of condition form, an incident report, and a nursing note regarding the incident. P. Ex. 2 at 2 ¶ 28; CMS Ex. 11 at 26; CMS Ex. 17 at 16. RN Efflandt noted in an “incident/occurrence” report that:

CNA walked in the resident’s room and found the resident sitting on a floor in front of her chair. Resident states: “I slid from the chair because I was sitting on the blanket.” CNA Charles tightened resident’s wheelchair waist belt after she used the bathroom prior to incident. When the resident was observed on a floor the waist belt was loose.

CMS Ex. 17 at 16. RN Efflandt noted that the contributing factor/root cause of the incident was that the resident had a blanket on her wheelchair which caused her to slide to the floor. As interventions, she noted the facility would: remove the blanket from the wheelchair; order a wheel chair cushion; and remove the resident's seat belt. CMS Ex. 17 at 17.

DON Jones testified that she entered Resident 1's room while RN Efflandt was performing the assessment of the resident. DON Jones testified "I asked Resident 1 what had happened and she said that she had been sitting on a blanket and was trying to get it out from under her." DON Jones instructed that Resident 1 be put to bed. P. Ex. 4 at 6 ¶¶ 64, 65.

RN Efflandt faxed Petitioner's physician at the end of her shift, 6:00 a.m. on October 19, 2012, to notify him of the incident. RN Efflandt testified that she did not believe it was necessary to notify him earlier because Resident 1 was not injured and her behavior did not change from "what it had always been." RN Efflandt testified that she did not see a significant change in condition requiring physician notification outside of normal business hours. Her expectation, based on past experience, was that the physician would not see the FAX until he came in to work at 8:00 or 9:00 a.m. on the morning of October 19, 2012. P. Ex. 2 at 2 ¶¶ 29-32. DON Jones testified that this notification was timely per Petitioner's policy. Because Resident 1 suffered no injury and the incident occurred after normal business hours, physician notification could wait until the end of the reporting nurse's shift. P. Ex. 4 at 6 ¶ 66.

RN Efflandt testified that after the incident, the blanket was removed from Resident 1's chair and a new cushion was placed in the chair. P. Ex. 2 at 2 ¶ 33. Resident 1's care plan reflects the blanket was removed from her chair and a new cushion ordered. CMS Ex. 17 at 267, 272. RN Efflandt testified that at some point Resident 1 got a new adjustable self-releasing seat belt. Resident 1 still loosens the belt and complains that it is too tight. RN Efflandt testified that, based on her observations, Resident 1's functional status for use of a self-releasing seat belt in her wheelchair has not changed since the October 18, 2012 incident. P. Ex. 2 at 2-3 ¶¶ 34-36.

DON Jones testified that the IDT, after reviewing RN Efflandt's October 18, 2012 incident report, recommended removing Resident 1's blanket, which she used as a seat cushion and getting her a new wheelchair cushion, which was done. In addition, Resident 1 was counseled not to adjust her seat belt and was referred for psychiatric consultation. P. Ex. 4 at 6 ¶¶ 67, 68; CMS Ex. 17 at 272.

DON Jones testified that around the time of the October 18, 2012 incident, Resident 1's Lexapro, an anti-depressant medication, was discontinued. DON Jones testified that the IDT initially considered removing Resident 1's self-releasing seat belt, but it was not

immediately done. The IDT believed that removing the seat belt would have been extremely upsetting to Resident 1 and the IDT wanted to see what her reaction to the discontinuation of the Lexapro would be before taking that step. Resident 1 was already very upset due to family issues and the fact she had been placed on a sit-to-stand lift device for transfers on October 15, 2012, something she strongly disliked. DON Jones testified that Resident 1 made it “crystal clear” that she needed her self-releasing belt to protect herself from injury and that she would not willingly give it up. However, on October 30, 2012, the facility removed Resident 1’s self-releasing seat belt and discarded it for hygienic reasons. Resident 1 became hysterical, screamed at DON Jones, and demanded her seat belt be put back at once. Resident 1’s former husband and two sons also asked for reinstatement of the seat belt. DON Jones explained to Resident 1 and her family that she would re-evaluate the situation in consultation with the IDT. Resident 1 was adamant that she have a seat belt. DON Jones testified that Resident 1 asserted: “I am afraid I will fall.” DON Jones testified that in January 2012, Resident 1 suffered a fall after releasing her seat belt and fractured her shoulder, which DON Jones believes in part led to her fear of falling. P. Ex. 4 at 6 ¶¶ 69-76, 82.

DON Jones testified that the state surveyors entered Petitioner on November 1, 2012. DON Jones testified that Surveyor Wilson “questioned me intensively on why Resident 1’s seat belt had been removed. From the tone of her questioning, it was clear to me that she was critical of that decision.” P. Ex. 4 at 7 ¶¶ 77, 78.

DON Jones testified that she met with the IDT over several days and, consistent with her promise to Resident 1 and Resident 1’s family, Petitioner re-evaluated the seat belt situation. Petitioner determined to replace the belt with a self-releasing and adjustable seat belt picked out by Resident 1. Before deciding to do so, DON Jones testified that she attended a meeting with two corporate nurses from Signature Healthcare, LLC, RN Wenzler and RN Jeanne A. Boschert, and also NHA Boyce, to weigh the risks and benefits of the new seat belt. Once they agreed on the new seat belt, they prepared a consent form for it, which Resident 1 signed. DON Jones testified that Resident 1 and her son both stated they were glad the seat belt was back. P. Ex. 4 at 7 ¶¶ 79-81, 83-84; CMS Ex. 17 at 269 (nurse’s notes reflecting November 4, 2012 meeting attended by DON Jones, RN Wenzler, RN Boschert and NHA Boyce).

The consent form Resident 1 signed on November 4, 2012, reads:

I [Resident 1] want to express my desire to continue to be allowed to wear my lap belt. I am fearful that without the belt I will fall and hurt myself like I did in January. When I fell in January I had removed the belt myself and I then fell. Since that time the seat belt has been used. I did have an incident on the 18th in which I was attempting to get my blanket out from under me and I slid forward in my chair and the belt

actually caught me under my arms and possibly prevented another more serious injury or break if I had not had it present.

The staff has discussed with me in detail the possible risks of this belt and I continue to choose to wear it for my emotional comfort as well as my physical safety.

I expressed to [RN Boschert] on 11-3-12 at 5pm that the fall on the 18th to me was “not a big deal” because I could have released the belt if I felt that I was in any danger. I also told her that I had a much greater fear of falling and possibly breaking something than of encountering an injury with the belt.

The staff has given me choices regarding my belt and has asked that I demonstrate my ability to release it. I also understand that if I become unable to release the belt or my condition changes, then I will be reassessed and alternative actions may be recommended.

CMS Ex. 17, at 274.¹⁰ DON Jones testified that since the new seat belt was put in use, staff has documented twice daily that Resident 1 can release it on her own. P. Ex. 4 at 7 ¶ 85.

DON Jones testified that the IDT found no feasible alternatives to the self-releasing seat belt and ultimately concluded that honoring Resident 1’s wish to keep the device in place was their best option. A non-releasing belt would have constituted a physical restraint that could have impaired Resident 1’s mental and physical well-being, and could have resulted in serious injury were she to slide out of it. The IDT decided that removing her seat belt altogether might unnecessarily put her at risk of falling out of her wheelchair while causing her great mental and emotional distress. P. Ex. 4 at 7-8 ¶¶ 87-88, 90.

¹⁰ CMS suggests that, despite Petitioner’s statement that Resident 1 continued to use a seat belt as an exercise of her rights under 42 C.F.R. § 483.10, the consent form Resident 1 signed during the survey to continued use of a seat belt (CMS Ex. 17 at 274) was simply an “attempt to absolve itself of responsibility for its noncompliance.” CMS Br. at 3-4. CMS has not shown, however, that Resident 1 was not competent to give such consent, and the evidence of record shows that she (and her family) strongly desired that a seat belt be used in her wheelchair.

DON Jones testified that she does not believe Resident 1 was at risk of a choking injury from the seat belt, since her hemiplegia prevented her from sliding in such a way as to get her immobile left arm out from under the seat belt. P. Ex. 4 at 8 ¶ 89.

DON Jones testified that the state surveyors had the opportunity to observe Resident 1 with the new self-releasing seat belt during the survey and had no complaint about its use. P. Ex. 4 at 7 ¶ 86.

RN Wenzler testified that the IDT found that none of the alternatives to a self-releasing seat belt were feasible, and that the best option was to honor Resident 1 and her family's wish to keep the seat belt in place. Also, to put the resident in a non-self-releasing seat belt would have constituted a restraint and required a physician's order, and her physician never suggested such a restraint was appropriate. Restraining her against her will could violate her rights and harm her mental and psychosocial well-being. A non-self-releasing belt could have put the resident at an increased risk of harm. Resident 1 was not at great risk for choking if she slid from the front of her wheelchair because she could not get the seat belt out from underneath her armpits, given her left-sided hemiplegia. Taking away Resident 1's seat belt on a permanent basis could place her at risk of physical harm because, instead of sliding forward in her wheelchair she could have toppled forward to the ground and sustained a fracture or potential fatal head injury. Because she was terrified of being without the self-releasing seat belt, and desperately wanted it to be in place, taking it away permanently could have been harmful to her mental and psychosocial well-being. P. Ex. 6 at 8-9 ¶¶ 103-111.

3. Petitioner did not fail to provide adequate monitoring, supervision and assistive devices to prevent accidents and thus was not out of substantial compliance with the regulatory requirement at 42 C.F.R. § 483.25(h).

CMS asserts that Petitioner failed to be in substantial compliance with the requirement for participation at 42 C.F.R. § 483.25(h) with regard to both Resident 1 and Resident 2. This regulation requires that:

§ 483.25 Quality of care.

Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.

...

(h) *Accidents.* The facility must ensure that –

- (1) The resident environment remains as free of accident hazards as possible; and
- (2) Each resident receives adequate supervision and assistance devices to prevent accidents.

The Statement of Deficiencies alleges that Petitioner contravened this requirement when it failed to immediately assess for appropriate and safe use Resident 2's bed rails and Resident 1's seat belt after falls with entrapment from the devices. CMS Ex. 1 at 11-12.

The Departmental Appeals Board (DAB) has explained that this section of the regulations:

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. 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 regulatory requirement[s]. 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).

With regard to Resident 2, CMS alleges specifically that the resident could not use her flaccid left arm to grasp the quarter bed rail in order to break her fall from the bed. Yet, after entangling her left arm in the rail, Petitioner "took no steps" to free her environment from this known hazard. Petitioner's failure to remove the accident hazard placed Resident 2 at risk for another accident, likely with injury given her frail physical condition, history of falls, poor bed mobility, and difficulty with balance and body control. CMS Final Br. at 4.

While a side rail not used in accordance with a manufacturer's directions or one that is defective or poorly maintained may be considered ipso facto an accident hazard, CMS does not allege that was the case here. Nor does CMS allege that Resident 2's initial assessment or the initial placement of the side rail constituted a hazard. Instead, CMS alleges that Petitioner's response to finding Resident 2 with her arm through the side rail

contravened this regulatory requirement because, after the incident, Petitioner took no steps to reassess the resident and remove the side rails CMS alleges were newly shown to be hazardous.

I make no conclusion whether or not the incident actually constituted a fall, although I note that the preponderance of the evidence shows that Resident 2 was not found on the floor, but instead partially on the bed with her feet on the floor. Further, I note that LPTA Williams was teaching Resident 2 to transfer from a supine to a sitting position on the side of the bed. P. Ex. 7 at 1. I conclude that whether or not the incident constitutes a fall, Petitioner had properly assessed and determined that Resident 2 needed the bed rails that were in place on July 18, 2012. Further, after the incident, Petitioner took the necessary steps to assess the resident, evaluate the risks of continuing to use side rails, and institute interventions to keep her safe while at the same time maintaining her mobility. CMS Ex. 18 at 15-16; P. Ex. 3 at 2-3 ¶¶ 20, 21; P. Ex. 4 at 4 ¶ 49. Although Petitioner did not complete a new side rail evaluation form, I accept DON Jones' testimony that Petitioner assessed Resident 2 following the incident and determined that the side rail evaluation form itself did not have to be re-written because Resident 2's functional status was the same and the form was still "complete and accurate." P. Ex. 4 at 4 ¶¶ 42, 43.

Petitioner has shown that it completed an assessment that bed rails were needed for Resident 2 and provided physical therapy to Resident 2 related to the use of the bed rails. P. Ex. 3 at 2-3 ¶¶ 16-22; P. Ex. 4 at 2 ¶¶ 18-23; P. Ex. 6 at 3-4 ¶¶ 34-39; P. Ex. 7; P. Ex. 8; CMS Ex. 18 at 5. Therefore, I conclude that the bed rails placed on Resident 2's bed did not create an environment that failed to be as free from accident hazards as possible under 42 C.F.R. § 483.25(h)(1).

Further, the preponderance of the evidence in the record shows that following the July 18 incident, Petitioner quickly and carefully assessed the resident, evaluated use of the side rails, and implemented new interventions to protect the resident. Resident 2 was assessed by NP Lancaster immediately after the incident and NP Lancaster did not suggest any changes in the resident's treatment, including removal of the side rails. P. Ex. 3 at 4 ¶ 31; P. Ex. 4 at 3 ¶ 38. RN Freshour later assessed the resident and asked her to show how she used the rails to move, turn, and reposition herself, and Resident 2 showed RN Freshour that she could use the rails appropriately and stated she wanted to keep them. P. Ex. 3 at 5 ¶¶ 41, 42; CMS Ex. 11 at 30. The incident was reviewed by Petitioner's IDT at the morning meeting on the day of the incident, July 18, 2012, and for several days thereafter. P. Ex. 4 at 3 ¶¶ 40, 41; CMS Ex. 18 at 15. Petitioner's staff prepared an incident report containing several interventions designed to protect the resident while still maintaining the benefit of the side rails, including re-evaluating the use of the rails, having physical therapy continue to work with the resident, placing a bed pressure alarm, placing safety mats on the floor, moving the bed to a low position, and placing the bed controls out of reach. CMS Ex. 18 at 16; P. Ex. 3 at 4 ¶¶ 32, 34; P. Ex. 4 at 4 ¶ 44; P. Ex.

6 at 5 ¶ 53. DON Jones testified that the bed alarm was particularly important as it would notify staff if the resident attempted to get out of bed. P. Ex. 4 at 4 ¶ 45. These interventions were implemented immediately. P. Ex. 3 at 4 ¶ 35; P. Ex. 6 at 5 ¶ 54. CMS does not explain why these interventions were an ineffective response to the incident, especially given that Resident 2 was mentally cognizant and told DON Jones that she would ask for help getting up in future. P. Ex. 4 at 3 ¶ 36.

Petitioner also concluded that removing the rails would be detrimental to Resident 2. Specifically, Petitioner's care staff concluded that the resident's side rails should not be removed or replaced after the incident because without them there was no way she could turn herself over. DON Jones testified that both RN Freshour and LPTA Williams found after assessing Resident 2 that she needed the side rails in her bed for positioning because she could not turn herself over without them. P. Ex. 4 at 4 ¶ 49. RN Freshour testified that without the rails on her bed Resident 2 would be at risk of falling with resultant injury and would be unable to engage in the turning and repositioning necessary to keep pressure off of existing and potential areas of skin breakdown. Moreover, RN Freshour testified that not keeping the rails in place might be harmful to Resident 2's mental and psychosocial well-being, because it could contribute "to a feeling of being helpless and trapped in her bed." P. Ex. 3 at 2-4 ¶¶ 20-22, 33, 34, 37-42.

Following the incident and the interventions implemented by Petitioner, Resident 2 had no more problems with the side rails. Resident 2's bed was later fitted with halo rings instead of side rails, and the halo rings were on her bed during the state survey. DON Jones testified that halo rings can be a safer assistive device than quarter rails because the halo rings present less risk of skin tears. P. Ex. 4 at 4-5 ¶¶ 51-55; P. Ex. 14. Placement of the halo rings shows me not that Petitioner was noncompliant due to continued use of the side rails, but instead illustrates Petitioner's ongoing effort to address and evaluate Resident 2's safety while attempting to maintain her mobility in bed.

With regard to Resident 1, CMS references the decision in *Briarwood Nursing Ctr.*, DAB No. 2115, at 11 (2007), in asserting that "whether the facility took 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." The DAB has held that although a facility is not to be held strictly liable for accidents that occur in the facility, the facility is required to take reasonable steps to ensure that a resident receives supervision and assistance devices designed to meet their needs and to mitigate foreseeable risks of harm. While the facility may choose its own methods to prevent accidents, the methods must be adequate under the circumstances. The adequacy of the supervision and assistance devices depends on a resident's ability to protect him or herself from harm. *Guardian Health Care Ctr.*, DAB No. 1943, at 17-18 (2004).

CMS alleges that Petitioner knew that Resident 1 frequently loosened her seat belt and slid to the front of her wheelchair. CMS notes that Resident 1 fell out of her wheelchair

and injured her shoulder before the October 18 incident. Thus, the possibility of another accident, which could result in serious injury, was apparent. Yet, Petitioner's staff did not discuss the risks associated with loosening the seat belt or consider interventions to reduce the risk of injury. CMS argues that Petitioner's failure to take reasonable steps to supervise Resident 1 or to provide her with safe assistance devices placed her at risk for a range of serious injuries, including death, fractures, cuts and abrasions. CMS Final Br. at 4-5. The record shows, however, that Petitioner's staff did consider interventions to reduce Resident 1's risk of injury and did discuss with her the risk of loosening the seatbelt during her time at the facility, including after the October 18 incident. However, this mentally cognizant resident and her family insisted that she continue to use a self-releasing seat belt.

Resident 1 began residing at the facility in 2009. From that time through to the incident in question she used a self-releasing seat belt in her wheelchair. Her falls care plan specifically noted the use of the seat belt and included instructions for staff to check and release the seat belt and to mark the seat belt to show Resident 1 where she should fasten it for her comfort. CMS Ex. 17 at 158. During this time also, Resident 1 would loosen the seat belt and slide forward in her wheelchair as an attention seeking device. Petitioner's witnesses testified that Petitioner addressed those behaviors almost daily at IDT meetings and had Resident 1 counseled about her attention seeking behaviors at a psychiatric hospital and by a psychologist. Her medication regimen was also reviewed. A white line was marked on her seat belt to show her where a safe and comfortable setting was. P. Ex. 3 at 6 ¶¶ 51-56; P. Ex. 4 at 5 ¶¶ 59-61; P. Ex. 6 at 7 ¶¶ 78-80.

Resident 1 stated, and Petitioner determined, that she slid out of her wheelchair on October 18, 2012 due to her attempt to remove a blanket that she was sitting on. To address the fall itself, Petitioner determined to remove the blanket and order a new wheelchair cushion. Petitioner also instructed Resident 1 not to adjust her seat belt and referred her for psychiatric evaluation. CMS Ex. 17 at 267, 272; P. Ex. 4 at 6 ¶¶ 67, 68. DON Jones testified that the IDT considered removing Resident 1's self-releasing belt entirely, but determined to hold off doing so because removal of the belt would have been upsetting to the resident. However, on October 30, 2012, they did remove her seat belt. But they replaced it on November 4, 2012, given the strong desire of Resident 1 and her family that she have a seat belt. In a consent form signed on November 4, 2012, Resident 1 indicated that staff discussed with her in detail the possible risks of the belt, but Resident 1 indicated that she chose to wear it. This new seat belt could be loosened by Resident 1 and was self-releasing as was her former seat belt. P. Ex. 6 at 8 ¶ 98. As RN Wenzler testified, "[t]he state surveyors had the opportunity to observe Resident 1 with the new self-releasing seat belt in place and had no complaint about it, as indicated by the fact that they found no immediate jeopardy to be present after the removal of the original self-releasing seat belt on October 30, 2012." P. Ex. 6 at 9 ¶ 102. The evidence shows that the new self-releasing seat belt was functionally identical to the original seat belt. Thus, it appears that the state surveyors found the facility in compliance with regard to

this resident exactly as she was on the day of the incident; using a wheelchair, although now with a chair cushion, and with the same type of self-releasing seatbelt and no additional interventions.

Therefore, I do not sustain a violation of 42 C.F.R. § 483.25(h) in this case.

4. Petitioner did not fail to assess the safety of devices that its residents required for mobility and positioning and thus was not out of substantial compliance with the requirement for participation at 42 C.F.R. § 483.20(b)(1) .

CMS asserts that Petitioner was out of substantial compliance with the regulation at 42 C.F.R. § 483.20(b)(1) with regard to both Resident 1 and Resident 2. This regulation requires the following:

§ 483.20 Resident Assessment

The facility must conduct initially and periodically a comprehensive, accurate, standardized, reproducible assessment of each resident's functional capacity. . . .

(b) Comprehensive assessments – (1) Resident assessment instrument. A facility must make a comprehensive assessment of a resident's needs, using the resident assessment instrument (RAI) specified by the State. The assessment must include at least the following:

- (i) Identification and demographic information.
- (ii) Customary routine.
- (iii) Cognitive patterns.
- (iv) Communication.
- (v) Vision.
- (vi) Mood and behavior patterns.
- (vii) Psychosocial well-being.
- (viii) Physical functioning and structural problems.
- (ix) Continence.
- (x) Disease diagnoses and health conditions.
- (xi) Dental and nutritional status.
- (xii) Skin condition.
- (xiii) Activity pursuit.
- (xiv) Medications.
- (xv) Special treatments and procedures.
- (xvi) Discharge potential.

(xvii) Documentation of summary information regarding the additional assessment performed on the care areas triggered by the completion of the Minimum Data Set (MDS).

(xviii) Documentation of participation in assessment.

The assessment process must include direct observation and communication with the resident, as well as communication with licensed and nonlicensed direct care staff members on all shifts.

CMS asserts that under this regulation, Petitioner is required to assess the safety of any intervention or assistive device put in place for resident use. The DAB has indicated that a facility's use of an assistive device without a risk safety assessment is the basis for finding a facility noncompliant with the regulation. *Maine Veterans Home – Scarborough*, DAB No. 1975, at 10-14 (a safety assessment includes an analysis of the risks and benefits of a particular assistive device initiated by a facility); *Laurelwood Care Ctr.*, DAB No. 2229, at 9 (2009).

CMS argues that although the regulation does not dictate when a facility must perform a safety assessment, the comprehensive assessment requirement is broad because the need to perform a safety assessment varies by resident and facility. Thus, it may be necessary for a facility to assess a resident's needs at a time not explicitly set forth in the regulation. Here, CMS argues, "a consistent and systematic approach to the timing of safety assessments was needed." CMS Final Br. at 7.

Specifically, CMS alleges that Petitioner did not perform a safety assessment of Resident 2's use of quarter rails and Resident 1's use of an adjustable seat belt after their accidents. CMS acknowledges that Petitioner evaluated Resident 2's use of the rails on June 20, 2012, but asserts that it should have reassessed the Resident's ability to continue to use the rails after the July 18, 2012 incident to ensure that the evaluation was accurate. The June 20 evaluation did not include a description of her physical condition on July 18 and detail the reasons she slid from the bed. CMS indicates that without this information the June 20 evaluation was incomplete and Petitioner did not have all the information necessary to assess the safety of Resident 1's continued use of side rails. CMS alleges with regard to Resident 1 that Respondent did not perform a safety assessment prior to her fall from her wheelchair and it did not assess her ability to continue to safely use the seat belt after her accident. CMS Final Br. at 6.

However, CMS has not shown that Petitioner was required to use a specific form to document that it assessed a resident for side rail safety after an incident with a side rail. A facility is required to assess a resident after an incident and implement interventions to protect that resident. Here, I conclude that Petitioner has shown through testimony and documents that it assessed Resident 2 (a mentally cognizant resident), determined the cause of the incident, assessed the resident's use of side rails, and implemented

interventions to further protect the resident. CMS Ex. 18 at 15-16; P. Ex. 3 at 4-5 ¶¶ 31-42; P. Ex. 4 at 3-4 ¶¶ 35-49; P. Ex. 5 at 2-3 ¶¶ 22-30; P. Ex. 6 at 5 ¶¶ 51-62.

With regard to Resident 1, Resident 1 was admitted to the facility with a physician's order for a self-releasing seat belt and the facility had a care plan for its use. Because it was not to be used as a restraint, no restraint assessment was done. Following the incident, the facility assessed the root cause of the incident, determined that it was due to the resident having a blanket under her, and the blanket was removed and a seat cushion placed. The facility then assessed whether or not Resident 1 should continue to have a self-releasing seat belt in her wheelchair and ultimately concluded that she should. Resident 1's consent form notes that Petitioner discussed with her the risks of a seat belt and documents her intention to continue to use a seat belt. There is no evidence that shows that the replacement self-releasing seat belt was any different in function from the prior seat belt or that Petitioner performed any safety assessments or evaluations other than what is in the record before me. CMS apparently concluded that this was sufficient and found Petitioner in substantial compliance.

Therefore, I do not sustain a violation of 42 C.F.R. § 483.20(b)(1) in this case.

5. Petitioner did not have an ineffective quality assessment and quality assurance committee and thus was not out of substantial compliance with the requirement for participation at 42 C.F.R. § 483.75(o).

CMS asserts that Petitioner was out of substantial compliance with the regulation at 42 C.F.R. § 483.75(o) with regard to both Resident 1 and Resident 2. This regulation requires that:

§ 483.75(o)

(o) *Quality assessment and assurance.*

(1) A facility must maintain a quality assessment and assurance committee consisting of –

- (i) The director of nursing services;
- (ii) A physician designated by the facility; and
- (iii) At least 3 other members of the facility's staff.

(2) The quality assessment and assurance committee-

- (i) Meets at least quarterly to identify issues with respect to which quality assessment and assurance activities are necessary; and
- (ii) Develops and implements appropriate plans of action to correct identified quality deficiencies.

(3) A state or the Secretary may not require disclosure of the records of such committee except in so far as such disclosure

is related to the compliance of such committee with the requirements of this section.

(4) Good faith attempts by the committee to identify and correct quality deficiencies will not be used as a basis for sanctions.

CMS does not assert that the IDT was not functioning as Petitioner's quality assessment and assurance committee, only that, if it was, it was not addressing problems identified by these two incidents. CMS argues that the appropriate role for the IDT, assuming it was intended to function as the quality assurance committee, was to identify systemic causes of resident falls, recommend changes in policy or practice to prevent them, and ensure that the recommendations it made were implemented. CMS alleges that the IDT did not carry out this role here. Specifically, the IDT was not alerted by the developing pattern of accidents and falls with assistive devices to a problem that needed attention. *Jewish Home of Eastern Pennsylvania*, DAB No. 2380, at 9, 13 (2011) (petitioner failed to implement a corrective action plan to prevent the recurrence of falls). CMS asserts that the IDT was familiar with Resident 1's use of a seat belt and tendency to loosen the belt, but did not implement a plan to monitor her behavior, even after she fell out of her wheelchair. Given that Petitioner was aware of the dangers associated with seat belts and quarter bed rails (strangulation, entrapment, serious injury or death), the IDT was obliged to review facility records and information and identify potential and actual quality deficiencies that were systemic in nature and then develop a corrective action plan for those deficiencies. Thus it is reasonable to conclude, CMS avers, that Petitioner did not have a functioning quality assessment and assurance committee or that the IDT simply failed to do what it was required to do under this section. *Jewish Home of Eastern Pennsylvania*, DAB No. 2380, at 14. CMS Final Br. at 9-10.

These two isolated incidents, however, do not show the continuous pattern of falls found in *Jewish Home*. There is un rebutted testimony that Petitioner's IDT discussed the incident regarding Resident 2 at length and addressed it several other times. CMS Ex. 18 at 15; P. Ex. 4 at 3-4 ¶¶ 40-41, 43, 46; P. Ex. 6 at 5 ¶¶ 55, 57. Interventions were identified and implemented. P. Ex. 3 at 4-5 ¶¶ 33-40; P. Ex. 4 at 3-4 ¶¶ 40-48; P. Ex. 5 at 3 ¶¶ 28-30; P. Ex. 6 at 5 ¶¶ 52-60; P. Ex. 13. With regard to Resident 1, there is un rebutted testimony that the IDT was regularly reviewing Resident 1's behavior and weighing the risks and benefits of using a seat belt for the very specific behaviors of this resident. Therefore, I do not sustain a violation of 42 C.F.R. § 483.75(o) in this case.

6. *Petitioner did not fail to administer the facility effectively and thus was not out of substantial compliance with the requirement for participation at 42 C.F.R. § 483.75.*

CMS asserts that Petitioner was out of substantial compliance with the regulation at 42 C.F.R. § 483.75 with regard to both Resident 1 and Resident 2. This regulation requires that:

§ 483.75 Administration

A facility must be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.

CMS notes first that a deficiency citation alleging noncompliance with this requirement may be derived from findings of noncompliance with other participation requirements. *Stone County Nursing & Rehab. Ctr.*, DAB No. 2276, at 15-16 (2009); *Odd Fellow and Rebekah Health Care Facility*, DAB No. 1839, at 16-17 (2002); *Asbury Ctr. at Johnson City*, DAB No. 1815, at 11 (2002). CMS asserts that the facts underlying the accident prevention deficiency and the quality assurance systems deficiency provide “ample basis” to find noncompliance under this regulation. CMS argues that the deficiencies show that Petitioner’s resources were not being used effectively to protect its residents from accidents or to ensure that they attained their “highest practicable well-being.” *Stone County Nursing & Rehab. Ctr.*, DAB No. 2276, at 16; *see also Magnolia Estates Skilled Care*, DAB No. 2228, at 22-23 (2009); CMS Final Br. at 7-8.

CMS alleges specifically that Petitioner failed to perform individualized safety assessments to fully investigate and address the root causes of the two residents’ accidents. *Sunbridge Care and Rehab. for Pembroke*, DAB No. 2170, at 31 (2008) (management failed to ascertain whether staff was properly using equipment or analyze why certain accidents occurred). Petitioner had a duty to determine if the side rails and wheelchair seat belt were effective and safe assistive devices, particularly because the side rail was on Resident 2’s left side, where she had no strength and Resident 1 had a tendency to loosen her seat belt on an ongoing basis. *Sunbridge Care and Rehab. for Pembroke*, DAB No. 2170, at 30 (facility failed to acknowledge that residents were using assistive devices in an unsafe manner). CMS Final Br. at 7-8.

As noted above, however, the record shows that Petitioner did investigate the root causes of the incidents, assess resident safety, and implement measures to address the incidents while, as Petitioner asserts, it “labored continuously to find interventions for Residents 1 and 2 that struck a proper balance between the safety needs and the psychological needs

of those residents.” P. Final Br. at 18. Therefore, I do not sustain a violation of 42 C.F.R. § 483.75 in this case.

7. Petitioner did not fail to timely notify Resident’ 1’s physician of a change in the resident’s condition and thus was not out of substantial compliance with the regulatory requirement at 42 C.F.R. § 483.10(b)(11).

CMS asserts that Petitioner was out of substantial compliance with the regulation at 42 C.F.R. § 483.10(b)(11) with regard to Resident 1. This regulation requires that:

§ 483.10

The resident has a right to a dignified existence, self-determination, and communication with and access to persons and services inside and outside the facility. A facility must protect and promote the rights of each resident, including each of the following rights: . . .

(b)(11) *Notification of changes.* (i) A facility must immediately inform the resident; consult with the resident’s physician; and if known, notify the resident’s legal representative or an interested family member when there is –

(A) An accident involving the resident which results in injury and has the potential for requiring physician intervention;

(B) A significant change in the resident’s physical, mental, or psychosocial status (i.e., a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications);

(C) A need to alter treatment significantly (i.e., a need to discontinue an existing form of treatment due to adverse consequences, or to commence a new form of treatment); or

(D) A decision to transfer or discharge the resident from the facility as specified in § 483.12(a).

CMS states that Petitioner’s staff noted in the Incident/Occurrence Report that Resident 1’s physician was notified of the resident’s accident on October 18, 2012. CMS Ex. 17 at 16. However, Petitioner did not actually notify the resident’s physician until the next day, October 19. CMS notes that the incident was reported at the end of the reporting nurse’s shift because she believed the physician could only receive notice during regular business hours. P. Ex. 2 at 2 ¶¶ 29, 30. However, CMS alleges that the reporting requirement does not contain a limitation to reporting a resident’s change in status only during regular business hours. CMS notes Petitioner’s argument that it was unlikely another fall would occur that night because the resident was put to bed. P. Br. at 22.

CMS alleges that Petitioner is unclear about its requirement to immediately report a fall. Reporting a fall the day after it occurs is inconsistent with “immediately” reporting the fall. CMS Final Br. at 10-11.

The question here is whether it is sufficient that Resident 1’s physician was notified of the incident at the conclusion of RN Efflandt’s shift to comport with the immediacy requirement in the regulation.

RN Efflandt faxed Petitioner’s physician at the end of her shift, 6:00 a.m. on October 19, 2012, to notify him of the incident. RN Efflandt testified that she did not believe it was necessary to notify him earlier because Resident 1 was not injured and her behavior did not change from “what it had always been.” RN Efflandt testified that she did not see a significant change in condition requiring physician notification outside of normal business hours. Her expectation, based on past experience, was that the physician would not see the FAX until he came in to work at 8:00 or 9:00 a.m. on the morning of October 19, 2012. P. Ex. 2 at 2 ¶¶ 28-32. DON Jones testified that this notification was timely per Petitioner’s policy. Because Resident 1 suffered no injury and the incident occurred after normal business hours, physician notification could wait until the end of the reporting nurse’s shift. P. Ex. 4 at 6 ¶ 66. CMS has not explained why this does not comport with the applicable regulation.

While certainly there are situations where a resident’s physician must be notified more quickly than at the end of a nursing shift, here, the resident was assessed, was uninjured, and the facility understood how it was she slid from the wheelchair. The resident was also placed in bed after the incident and not back in the wheelchair, giving Petitioner time to implement its interventions. The record does not support that there was a significant change in Resident 1’s condition warranting immediate consultation with a physician, nor was there an accident that meets the requirement in the regulations. Therefore, I do not sustain a violation of 42 C.F.R. § 483.10 in this case.

V. Conclusion

I reverse CMS’s imposition of a CMP on Petitioner because Petitioner has shown that it was in substantial compliance with Medicare participation requirements in relation to Resident 1 and Resident 2.

/s/
Scott Anderson
Administrative Law Judge