Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
Elm Heights Care Center (CCN: 16-5529),	)	Date: April 21, 2008
Petitioner,	)	Docket No. C-05-287
	)	Decision No. CR1774
v.	)	
Centers for Medicare & Medicaid Services.	)	

DECISION

Petitioner, Elm Heights Care Center, violated 42 C.F.R. § 483.25, as alleged by a complaint survey completed at Petitioner's facility on December 29, 2004. Petitioner's violation of 42 C.F.R. § 483.25 provides a basis for imposition of a denial of payment for new admissions (DPNA) for the period March 1 through March 24, 2005. Withdrawal of Petitioner's authority to conduct a Nurse Aide Training and Competency Evaluation Program (NATCEP) for the two-year period from December 29, 2004 through December 28, 2006, was required by law.

I. Background

Petitioner, located in Shenandoah, Iowa, is authorized to participate in the federal Medicare program as a skilled nursing facility (SNF) and the Iowa Medicaid program as a nursing facility (NF). Petitioner was subject to a complaint investigation or survey by the Iowa Department of Inspections and Appeals (state agency) that was completed on December 29, 2004, the results of which are reported in a Statement of Deficiencies (CMS-2567) (SOD) bearing that date. The surveyor cited Petitioner for one deficiency,

an alleged violation of 42 C.F.R. § 483.25[1] (Tag F309),[2] at a scope and severity of "G."[3] Petitioner was subject to a second complaint survey on January 28, 2005, that found that Petitioner was not in substantial compliance and that there was immediate jeopardy.

The Centers for Medicare & Medicaid Services (CMS) advised Petitioner by letter dated February 14, 2005, that it concurred with the state agency findings of deficiency in the January 28, 2005 complaint survey, and that it intended to impose a civil money penalty (CMP) of $3050 for the period January 22, 2005 through January 25, 2005 based upon that survey. CMS also advised Petitioner that based upon the January 26, 2005 survey and the survey that ended December 29, 2004, it was instructing the state agency to deny payment for new admissions effective March 1, 2005, until such time as Petitioner achieved substantial compliance or its provider agreement was terminated. By letter dated April 14, 2005, Petitioner waived hearing as to the CMP and the alleged deficiency from the January 2005 survey upon which it was based. However, Petitioner requested a hearing as to the alleged deficiency from the December 29, 2004 survey and the DPNA imposed from March 1 through March 24, 2005, based on that alleged deficiency. Petitioner's Exhibit (P. Ex.) 2. By letter dated April 22, 2005, CMS advised Petitioner

---

[1] Citations are to the regulations in effect at the time of the survey unless otherwise indicated.

[2] This is a "Tag" designation as used in the State Operations Manual (SOM), Appendix PP – Guidance to Surveyors for Long Term Care Facilities. The "Tag" refers to the specific regulatory provision allegedly violated and CMS's guidance to surveyors. Although the SOM does not have the force and effect of law, the provisions of the Social Security Act and regulations implementing the Act clearly do have such force and effect. *State of Indiana by the Indiana Dep't of Public Welfare v. Sullivan*, 934 F.2d 853 (7th Cir. 1991); *Northwest Tissue Center v. Shalala*, 1 F.3d 522 (7th Cir. 1993). Thus, while the Secretary of Health and Human Services (Secretary) may not seek to enforce the provisions of the SOM, he may seek to enforce the provisions of the Act or regulations as interpreted in the SOM.

[3] According to the scope and severity matrix published in the SOM section 7400E, a scope and severity level of A, B, or C indicates that a deficiency has the potential for no actual harm and has the potential for no more than minimal harm. A scope and severity level of D, E, or F indicates a deficiency that presents no actual harm but has the potential for more than minimal harm that does not amount to immediate jeopardy. A scope and severity level of G, H, or I indicates a deficiency that involves actual harm that does not amount to immediate jeopardy. A scope and severity level of J, K, or L indicates that a deficiency poses immediate jeopardy to resident health or safety. The matrix, which is based on 42 C.F.R. § 488.408, specifies which remedies are required and optional at each level based upon the frequency of the deficiency. *See* SOM section 7400E.

that based upon a second revisit completed March 25, 2005, Petitioner was again in substantial compliance as of that date, thus ending the period subject to the DPNA on March 24, 2005. Transcript page (Tr.) 106.

On May 5, 2005, the case was assigned to me for hearing and decision. I convened a hearing in Des Moines, Iowa on October 18, 2005, the substance of which is recorded in a 225-page transcript. CMS exhibits (CMS Ex.) 1 and 2 were admitted with the exception of CMS Ex. 2, page 48, which was removed by agreement of the parties due to the listing of Social Security Numbers for multiple of Petitioner's residents found on that page that are not relevant to the matter before me.[4] Tr. 13-16. Petitioner's exhibits 1 through 7 were admitted. Tr. 16-17. CMS elicited testimony from Surveyor Aaron Kephart. Petitioner called as witnesses its Administrator Carolee Hamblin, and its Director of Nursing (DON) Lisa Johnson. The parties submitted post-hearing briefs and reply briefs. CMS requested in its post-hearing brief that I reconsider my ruling at hearing excluding CMS Ex. 3. Tr. 208-18; CMS Post-Hearing Brief (CMS Brief) at 17-20. I have reconsidered and CMS Ex. 3 is not admitted on the grounds articulated at hearing. Petitioner submitted P. Ex. 8 with its post-hearing reply brief (P. Reply) and requested that I admit it as evidence or that I take judicial notice. CMS filed no objection. P. Ex. 8 is a five-page extract from the Minimum Data Set (MDS) 2.0 User's Manual, 2003 edition, which CMS would require Petitioner to use in preparing a resident's MDS. The pages offered contain the instructions for testing a resident's balance. P. Ex. 8 is admitted and considered as evidence.

II. Discussion

A. Findings of Fact

The following findings of fact are based upon the testimony of witnesses and exhibits admitted and the parties' joint stipulations of fact (Jt. Stip.). Citations to evidence may be found in the analysis section of this decision if not indicated here.

---

[4] Post hearing, counsel for CMS submitted a copy of the complaint/incident investigation report filed by Petitioner with the state that precipitated the complaint survey. I inquired about the existence of this report at hearing. Tr. 202-03. CMS does not offer the document as an exhibit and Petitioner did not request that it be admitted and considered as evidence. Therefore, the document is not marked, admitted, or considered as substantive evidence going to the merits.

1. The December 29, 2004 survey resulted in the finding of a deficiency for the alleged violation of 42 C.F.R. § 483.25 (F309) at a scope and severity of a "G" level arising out of a series of falls by Resident 2.

2. CMS imposed a DPNA against the facility for a period from March 1 through March 24, 2005.

3. During the relevant period, Resident 2 was an 87-year-old female who was admitted to the facility on June 14, 2004. CMS Ex. 2, at 63.

4. Nurse's notes indicate that on June 21, 2004, staff heard a noise in Resident 2's room and entered the room to find Resident 2 sitting on the floor of her room, and Resident 2 stated, "I was going to the bathroom and just sat down." Jt. Stip.; CMS Ex. 2, at 26, 50.

5. On June 25, 2004,[5] Resident 2 was found sitting on the floor of her room with one shoe on, the other shoe and her walker were in the bathroom, and she told staff that she was going to the bathroom and just sat down. Jt. Stip.; CMS Ex. 2, at 50, 53.

6. In June 2004, the facility began providing restorative services to promote Resident 2's range of motion (ROM) to her hips, knees and ankles, and the exercises continued to and including November 2004. Jt. Stip.; P. Ex. 3, at 1-7; CMS Ex. 2, at 50, 53.

7. The clinical record for Resident 2 shows no other incidents of her being on the floor until September 2, 2004. Jt. Stip.; P. Ex. 3, at 1-7; CMS Ex. 2, at 50, 53.

8. On September 2, 2004, Resident 2 was found on the floor of her room and the resident stated that she rolled out of the chair and facility staff assisted her up to her feet. Jt. Stip.; CMS Ex. 2, at 52.

9. A nurse's note at 11:00 p.m. on September 4, 2004, states that Resident 2 is up "ad lib" and requires supervision with the use of the walker and is at risk for falls due to improper use and not using it at all times. Jt. Stip.; CMS Ex. 2, at 52.

---

[5] The parties stipulated that the nurse's notes at CMS Ex. 2, at 50 are incorrectly dated June 24, 2004 and the fall actually occurred on June 25, 2004. CMS Ex. 2, at 50, 53. I note that the parties' stipulation that the fall occurred on June 25, 2005, is in error and the parties obviously intended the date to be June 25, 2004, as the resident died December 21, 2004. Jt. Stip. at 2, para. 7.

10. On September 27, 2004, Resident 2's new MDS with an assessment reference date of September 21, 2004, was completed and she was coded as a "1" for Cognitive Skills for daily decision making, indicating she had some difficulty in new situations only. Jt. Stip.; CMS Ex. 2, at 58.

11. On September 30, 2004, the physician's assistant noted that Resident 2 was "moderately confused today." Jt. Stip.; CMS Ex. 2, at 29.

12. The record reveals no further instances of Resident 2 being on the floor until October 14, 2004. Jt. Stip.; CMS Ex. 2, at 52, 76.

13. On October 14, 2004, the staff was summoned to Resident 2's room and the resident was found sitting on the floor of her room in front of her easy chair, and the resident stated she had leaned forward to pick up a Kleenex off the floor and slid off the chair. Jt. Stip.; CMS Ex. 2, at 52, 76, 95, 120-21.

14. After the fall on October 14, 2004, the facility promptly applied a non-slip Dysom pad in Resident 2's recliner to prevent further incidents related to her chair and there were no other incidents involving her chair. Jt. Stip.; CMS Ex. 2, at 52, 95, 120-21.

15. A nurse's note dated October 15, 2004, shows that at 10:00 p.m. Resident 2 was found sitting on her buttocks on the floor in her bathroom and she reported that she slipped. Jt. Stip.; CMS Ex. 2, at 76.

16. The nurse's note dated October 15, 2004, shows that Petitioner assessed Resident 2's surroundings and her condition and found: the resident barefoot; floor dry; her walker was in the bathroom in an upright position; the resident reported that she had been holding her walker at the time of the fall; her extremities were freely moveable, she denied discomfort related to the fall, and had no apparent injuries; but the resident was noted to be unsteady when up and was noted not to use her walker appropriately and attempts made to assist with proper use of walker were without success. Jt. Stip.; CMS Ex. 2, at 76.

17. On October 15, 2004, Petitioner noted interventions in the form of reminding Resident 2 to use the call light and she was given non-skid socks and slippers. Jt. Stip.; CMS Ex. 2, at 124.

18. On November 22, 2004, Resident 2 was found lying on her left side with her face facing the floor, with abrasions above her eyebrows and bridge of her nose, a raised area mid-forehead, and ecchymosis[6] at the middle and index fingers of her left hand. Jt. Stip.; CMS Ex. 2, at 78, 86.

19. Following the November 22, 2004 fall, interventions were to leave Resident 2's room door open, observe her frequently especially when in bed, keep her call light within reach, encourage and remind her to use the call light, and the possibility of using side rails was discussed but not implemented. Jt. Stip.; CMS Ex. 2, at 127.

20. On November 23, 2004, the physician's assistant noted that Resident 2 was "quite confused today," she noted abrasions to her forehead and nose, and attributed to the nurses the statement that the resident's fall the day before may have been due to her "simply tripping on her shoes." Jt. Stip., CMS Ex. 2, at 28.

21. The facility did a MDS with an assessment reference date of December 3, 2004.[7] CMS Ex. 2, at 80-84.

22. The MDS with an assessment reference date of December 3, 2004, the last day of the MDS assessment period, shows that her cognitive skills for daily decision-making had declined to moderately impaired, which means her decisions were considered poor and that she required cues and supervision; she was understood only sometimes and could understand and respond to simple direct communication; she was rated as requiring extensive assistance of one person to walk between locations in her room, a decline from the prior MDS; she could no longer walk in the hall; her locomotion on and off the unit remained rated as

---

[6] Petitioner's staff used the term "ecchymosis" or "ecchymotic" several times in Resident 2's records; however, it appears staff really meant that contusions or bruising were observed. This was not clarified on the record and so I do not conclude the observed "ecchymosis" to be evidence of "actual harm."

[7] The parties stipulated that this was a "significant change of condition assessment." Jt. Stip. at 3, para. 30. However, the MDS is clearly coded as a quarterly review assessment (CMS Ex. 2, at 80, Section AA, block 8), and that is consistent with the dates of the other MDS's produced as evidence. CMS Ex. 2, at 58-62. A note among the clinical records admitted indicates that a nurse opined that the MDS should have been a significant change MDS. CMS Ex. 2, at 101.

limited physical assistance of one; her balance standing was unsteady but she could rebalance without physical support; she was incontinent of bladder two or more times per week and bowel one time per week; she was rated as having fallen within the last 30 and last 180 days. CMS Ex. 2, at 81-82.

23. On December 13 and 14, 2004, Petitioner altered care plan interventions for the resident, adding and deleting interventions. Jt. Stip.; CMS Ex. 2, at 109-15.

24. On December 21, 2004, at 1:30 a.m., the nurse's notes reveal that the nurse was summoned to Resident 2's room where she found Resident 2 sitting on the floor beside the bed with a one-centimeter cut to the back of her head. Jt. Stip.; CMS Ex. 2, at 54.

25. The nurse's note dated December 21, 2004, at 1:30 a.m., records that the resident told the nurse that she did not know what happened and that she just fell and the nurse noted blood on the bottom edge of the television stand and the resident's right hand. CMS Ex. 2, at 54, 96.

26. At 5:10 a.m. on December 21, 2004, Resident 2 was reported to have become unresponsive, she was transferred to a hospital, where a CT scan revealed a subdural hematoma, and it is not disputed that she died at the hospital on December 21, 2004. CMS Ex. 1, at 5; CMS Ex. 2, at 30, 32, 54; P. Brief at 4.

27. Petitioner's interventions were not adequate to effectively minimize the foreseeable risk of harm to Resident 2 from falling when she got out of bed and attempted to ambulate unassisted.

B. Conclusions of Law

1. Petitioner's request for hearing was timely filed and I have jurisdiction.

2. Petitioner received sufficient notice of the alleged deficiency to defend in this case.

3. Petitioner violated 42 C.F.R. § 483.25 and its included subsection (h)(2).

4. CMS's selection of a DPNA as the enforcement remedy is not subject to review.

5. The duration of the DPNA is reasonable.

6. Withdrawal of Petitioner's authority to conduct a NATCEP for the period December 29, 2004 through December 28, 2006, was required as a matter of law.

C. Issues

The issues in this case are:

> Whether there is a basis for the imposition of an enforcement remedy and
>
> Whether the enforcement remedy is reasonable.

D. Applicable Law

Petitioner is a long-term care facility participating in the federal Medicare program as a SNF and in the state Medicaid program as a NF. The statutory and regulatory requirements for participation by a long-term care facility are found at sections 1819 and 1919 of the Social Security Act (Act) and at 42 C.F.R. Part 483. Sections 1819 and 1919 of the Act vest the Secretary with authority to impose CMPs against a long-term care facility for failure to comply substantially with federal participation requirements.

Pursuant to the Act, 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. Facilities that participate in Medicare may be surveyed on behalf of CMS by state survey agencies in order to determine whether the facilities are complying with federal participation requirements. 42 C.F.R. §§ 488.10-488.28, 488.300-488.335. CMS is authorized to impose a DPNA as an enforcement remedy pursuant to 42 C.F.R. §§ 488.406, 488.408, and 488.417.

The imposition of a DPNA caused the state agency to withdraw Petitioner's authority to conduct a NATCEP. Pursuant to sections 1819(b)(5) and 1919(b)(5) of the Act, SNFs and NFs may only use nurse aides who have taken a training and competency evaluation program. Sections 1819(e) and 1919(e) of the Act impose upon states the requirement to specify what NATCEPs they will approve that meet the requirements established by the Secretary and a process for reviewing and re-approving those programs using criteria set by the Secretary. Pursuant to sections 1819(f)(2) and 1919(f)(2) of the Act, the Secretary was tasked to develop requirements for approval of NATCEPs and the process for review of those programs. The Secretary promulgated regulations at 42 C.F.R. Part 483, subpart D. Pursuant to 42 C.F.R. § 483.151(b)(2) and (e)(1), a state may not approve and must withdraw any prior approval of a NATCEP offered by a skilled nursing or nursing facility that: (1) has been subject to an extended or partial extended survey under sections 1819(g)(2)(B)(i) or 1919(g)(2)(B)(i) of the Act; (2) has been assessed a CMP of not less than $5000; or (3) that has been subject to termination of its participation agreement, a DPNA, or the appointment of temporary management. Extended and partial extended surveys are triggered by a finding of substandard quality of care during a standard or

abbreviated standard survey and involve evaluating additional participation requirements. "Substandard quality of care" is identified by the situation where surveyors identify one or more deficiencies related to participation requirements established by 42 C.F.R § 483.13 (Resident Behavior and Facility Practices), § 483.15 (Quality of Life), or § 483.25 (Quality of Care) that are found to constitute either immediate jeopardy, a pattern of or widespread actual harm that does not amount to immediate jeopardy, or a widespread potential for more than minimal harm that does not amount to immediate jeopardy and there is no actual harm. 42 C.F.R. § 488.301.

The Act and regulations make a hearing before an administrative law judge (ALJ) available to a long-term care facility against which CMS has determined to impose a remedy. Act, § 1128A(c)(2); 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 Pavilion*, 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 amount of the CMP that could be collected by CMS or impact upon the facility's nurse aide training program. 42 C.F.R. §§ 498.3(b)(14) and (d)(10)(i). CMS's determination as to the level of noncompliance "must be upheld unless it is clearly erroneous." 42 C.F.R. § 498.60(c)(2). This includes CMS's finding of immediate jeopardy. *Woodstock Care Center*, DAB No. 1726, at 9, 39 (2000), *aff'd, Woodstock Care Center v. U.S. Dept. of Health and Human Services*, 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 governed by 42 C.F.R. § 488.438(e).

The Board has addressed the allocation of the burden of persuasion and the burden of production or going forward with the evidence in past cases, in the absence of specific statutory or regulatory provisions. Application of the Board's analysis and approach is not disputed in this case and is appropriate. When a penalty is proposed and appealed, CMS must make a *prima facie* case that the facility has failed to comply substantially with federal participation requirements. "Prima facie" means generally that the evidence is "[s]ufficient to establish a fact or raise a presumption unless disproved or rebutted." *Black's Law Dictionary* 1228 (8th ed. 2004).

In *Evergreene Nursing Care Center*, DAB No. 2069 (2007), the Board explained as follows:

> CMS has the burden of coming forward with evidence related to disputed findings that is sufficient (together with any undisputed findings and relevant legal authority) to establish a prima facie case of noncompliance with a regulatory requirement. If CMS makes this prima facie showing, then the SNF must carry its ultimate burden of persuasion by showing, by a preponderance of the evidence, on the record as a whole, that it was in substantial compliance during the relevant period. *See Hillman Rehabilitation Center*, DAB No. 1611 (1997), *aff'd*, *Hillman Rehabilitation Ctr. v. HHS*, No. 98-3789 (GEB) (D. N.J. May 13, 1999); *Batavia Nursing and Convalescent Inn*, DAB No. 1911 (2004), *aff'd*, *Batavia Nursing and Convalesent Center v. Thompson*, No. 04-3687 (6th Cir. 2005); *Guardian Health Care Center*, DAB No. 1943 (2004); *Fairfax Nursing Home, Inc.*, DAB No. 1794 (2001), *aff'd*, *Fairfax Nursing Home v. Dep't of Health & Human Srvcs.*, 300 F.3d 835 (7th Cir. 2002), *cert. denied*, 2003 WL 98478 (Jan. 13, 2003).
>
> CMS makes a prima facie showing of noncompliance if the evidence CMS relies on is sufficient to support a decision in its favor absent an effective rebuttal. *Hillman Rehabilitation Center*, DAB No. 1663, at 8 (1998), *aff'd*, *Hillman Rehabilitation Ctr. v. HHS*, No. 98-3789 (GEB) (D. N.J. May 13, 1999); *see also Guardian Health Care Center*. A facility can overcome CMS's prima facie case either by rebutting the evidence upon which that case rests, or by proving facts that affirmatively show substantial compliance. *Tri-County Extended Care Center*, DAB No. 1936 (2004). "An effective rebuttal of CMS's prima facie case would mean that at the close of the evidence the provider had shown that the facts on which its case depended (that is, for which it had the burden of proof) were supported by a preponderance of the evidence." *Id.* at 4 (quoting *Western Care Management Corp.*, DAB No. 1921 (2004)).

DAB No. 2069, at 7-8.

E. Analysis

1. Petitioner violated 42 C.F.R. § 483.25 (Tag F309).

The general quality of care regulation requires that each resident receive, and the participating facility must provide, the necessary care and services to attain or maintain a resident's highest practicable physical, mental, and psychosocial well-being, in accordance with the resident's comprehensive assessment and plan of care. 42 C.F.R. § 483.25. Among the various types of care and services that Petitioner is required to provide under the regulation are supervision and assistance devices necessary to prevent accidents, such as Resident 2's repeated falls in this case. 42 C.F.R. § 483.25(h)(2).

The surveyor chose to characterize the alleged violation in this case as a violation of the general quality of care regulation 42 C.F.R. § 483.25 (Tag F309), rather than the more specific quality of care requirement to provide assistance devices and supervision found at 42 C.F.R. § 483.25(h)(2) (Tag F324). Petitioner objects, based upon the case presented by CMS, that the state agency should have charged Petitioner with a violation of 42 C.F.R. § 483.25(h)(2) (Tag F324) and that it was error for CMS not to have done so. P. Brief at 27. Petitioner argues that it did not receive notice of a violation of 42 C.F.R. § 483.25(h)(2). My review of the SOD shows that despite the citation as a violation of Tag F309, the specific allegations clearly put Petitioner on notice that the basis of the alleged violation is Petitioner's failure to implement appropriate interventions to minimize the risk of falls for Resident 2 after she displayed a pattern of falls and cognitive changes. CMS Ex. 1, at 1. This allegation of the SOD states a violation of either Tag F309 or Tag F324. I find it appropriate to judge whether CMS has made a *prima facie* showing of a violation of the more specific quality of care requirement at 42 C.F.R. § 483.25(h)(2). If the CMS case satisfies the elements for a violation of the specific quality of care requirement, it will also satisfy the elements for the more general requirement. Judging the case under the specific requirement will cause no prejudice to Petitioner as, given the facts of this case and the nature of the allegations in the SOD, Petitioner would have to show the same facts to establish a defense to a charge couched in terms of either the specific or general regulatory provision.

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. *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 583, 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 assistance devices to prevent accidents, given what was reasonably foreseeable. *Alden Town Manor Rehabilitation & HCC*, DAB No. 2054, at 5-6, 7-12 (2006). An "accident" is "an unexpected, unintended event that can cause a resident bodily injury," excluding "adverse outcomes associated as a direct consequence of treatment or care (e.g., drug side effects or reactions)." SOM, App. PP, Tag F324; *Woodstock Care Center*, DAB No. 1726, at 4.

Despite Petitioner's arguments to the contrary, I have no difficulty finding that CMS has made a *prima facie* showing of a violation of 42 C.F.R. § 483.25 and subsection (h)(2). Petitioner admits the resident was assessed from her admission on June 14, 2004, as at risk for falls and her care plan shows that Petitioner foresaw the risk of falls. CMS Ex. 2, at 73. It is undisputed that Resident 2 experienced a number of falls between her admission to Petitioner on June 14, 2004, and her death on December 21, 2004. Petitioner did implement interventions. However, the resident continued to fall giving rise to the inference that Petitioner's interventions, whether the interventions were assistance devices, supervision, or others such as reminding her to use the call light or requiring her to ambulate in a wheelchair, were inadequate. The resident continued to fall, until her final fall on December 21, 2004, which indisputably caused a head injury that resulted in a large brain hemorrhage and the resident's death. CMS Ex. 2, at 31-33, 38. Thus, CMS has made a *prima facie* showing of a violation. The burden of persuasion is upon Petitioner to show by the preponderance of the evidence that it was in substantial compliance. Although Petitioner produced evidence that it implemented interventions, Petitioner has not shown substantial compliance because it cannot demonstrate that its interventions were adequate under the circumstances, including whether they were effective or effectively implemented.

Petitioner asserts that the single surveyor involved lacked credibility, arguing that his investigation was not thorough and that he failed to consider evidence favorable to Petitioner. P. Brief at 24-27; P. Reply at 18-19. I find that the surveyor was credible. His allegations are supported by the clinical records for the resident that he obtained from the facility. Other than restorative records and a five-line correction to nurse's notes dated December 23, 2004, Petitioner has offered me no clinical records allegedly not considered by the surveyor. Petitioner faults the surveyor for not interviewing

Petitioner's staff to obtain possibly exculpatory information. I note, however, that other than calling the Petitioner's Administrator and DON to testify and presenting three affidavits of limited content and with no cross-examination of the affiants possible, Petitioner brought no staff to the hearing where the effectiveness of Petitioner's interventions might have been more fully explored. Furthermore, as I have already noted, my review is *de novo*; thus, the surveyor's inferences and conclusions are not binding upon me. Rather, I consider all the evidence to determine whether or not Petitioner violated a regulation in its delivery of care and services to Resident 2.

Examination of Petitioner's clinical records for Resident 2 is necessary. Resident 2's initial care plan, which is undated but was prepared upon her admission (Tr. 127), shows that Resident 2 was assessed as being at high risk for falls. No specific intervention is noted in "Comments" on that line. However, under ambulation, it is noted that she propels herself in her wheelchair or walker and that she needs "standby assistance" with her walker. It is also noted that she is incontinent of bladder and requires assistance with perineal care when incontinent. CMS Ex. 2, at 73. On Resident 2's MDS for June 2004, her cognitive skills for daily decision-making were coded as modified independence, which means she had some difficulty in new situations, and she required a limited physical assist of one person for locomotion; she was unsteady while standing but could rebalance without physical assistance; she used a walker or wheelchair and the wheelchair was the primary mode of locomotion; she was incontinent once per week or less; and she was assessed as having fallen within the last 30 and last 180 days with a hip fracture in the last 180 days. CMS Ex. 2*,* at 64-67. Resident 2's MDS for September 2004, shows no change in the areas mentioned from the June 2004 MDS. CMS Ex. 2, at 60-61. The MDS with an assessment reference date of December 3, 2004, the last day of the MDS assessment period, shows that her cognitive skills for daily decision-making had declined to moderately impaired, which means her decisions were considered poor and that she required cues and supervision; she was understood only sometimes and could understand and respond to simple direct communication; she was rated as requiring extensive assistance of one person to walk between locations in her room, a decline from the prior MDS; she could no longer walk in the hall; her locomotion on and off the unit remained rated as limited physical assistance of one; her balance standing was unsteady but she could rebalance without physical support; she was incontinent of bladder two or more times per week and bowel one time per week; she was rated as having fallen within the last 30 and last 180 days. CMS Ex. 2, at 81-82.

The comprehensive care plan with the goal that the resident be free of injuries from falls dated June 28, 2004, includes the following interventions: (1) allow use of walker and keep in reach at all time; (2) assess muscle strength, balance; (3) assure non-skid, well-fitting footwear; (4) assure that call light is within easy reach in room at all times; (5) clear environment of unnecessary objects that might cause injury; (6) encourage client to ask for assistance daily with ambulation and transfers; (7) if fall occurs, assess for injury,

notify MD and family; (8) maintain calm attitude when assisting or redirecting; (9) maintain clean, uncluttered environment; (10) assess for restlessness, agitation or increased confusion; (11) keep record of any behaviors on behavior sheet; (12) monitor ambulation for steadiness and safety; (13) monitor for constipation, urinary retention and sedation, report to doctor if noted; (14) report any changes in cognition to charge nurse; and (15) assist of one with transfers. Interventions 1, 6, 9, and 12 are marked through with a single line followed by the date "December 14," presumably 2004, indicating that those interventions were removed at that time. CMS Ex. 2, at 104. Standby assistance with Resident 2's use of the walker from the initial care plan is not listed. CMS Ex. 2, at 104. The care plan dated June 28, 2004, related to activities of daily living (ADL), specifies that staff is to walk Resident 2 to the bathroom. CMS Ex. 2, at 105. The care plan dated December 14, 2004, with the goal that the resident is to be free of injuries from falls, includes all the same interventions as the June 28, 2004 care plan, with interventions 1, 6, 9, and 12 stricken through and dated "December 14, 2004." The intervention "assist of one with transfers" is followed by the hand-written entry "with walker" and the date "December 14." The care plan additionally has three handwritten interventions: resident to ambulate, presumably walk, three times per week; wheelchair for mobility at other times; and body alarm. The first two of the handwritten entries are followed by the date "December 14." The entry "body alarm" is stricken through and followed by the word "error" and the date "December 14." The comprehensive care plan with the goal that the resident's skin will remain intact includes the intervention that she is to be toileted per facility routine or as she requests, and is dated December 14, 2004. CMS Ex. 2, at 113. Resident 2's ADL care plan dated December 14, 2004, includes the intervention that staff is to walk her to the bathroom. CMS Ex. 2*,* at 115.

Nurse's notes entries dated June 21, 2004, reflect that a Certified Nurse Assistant (CNA) heard a noise just after midnight, entered Resident 2's room, and found her sitting on the floor. The resident told the CNA that she just sat down. The call light button was on the bed. CMS Ex. 2, at 50. The notes show that staff characterized the incident as a fall and reported it to family as such (CMS Ex. 2, at 50) and they reported the incident to Resident 2's physician as a fall (CMS Ex. 2, at 26).[8] The physician, Dr. Janet Bumgarner, made no change in orders due to the fall. CMS Ex. 2, at 50. I have no documents that show Petitioner conducted an investigation of this fall or made any conclusions regarding the cause of the fall, other than the resident's assertion she just sat down. There is no evidence of new specific interventions to prevent falls, except she was moved to a new room. On June 22, 2004, Resident 2 was moved to a new room across from the nurse station. CMS Ex. 2, at 50; Tr. 68-70, 102, 130, 148.

---

[8] Although Petitioner suggests in its post-hearing reply brief that this incident was not a fall (P. Reply at 10), it was appropriately characterized and treated as such by staff.

On June 24, 2004 at 10:00 a.m., Resident 2 was found sitting on the floor by her bed with one shoe on. Resident 2 reported she was going to the bathroom, lost her balance, and sat down on the floor. Her walker and a shoe were in the bathroom. The fall was reported to Dr. Bumgarner and the family. CMS Ex. 2, at 27, 50-53, 75. The records provided to me do not reflect any specific interventions following this fall until the comprehensive care plan dated June 28, 2004. I have no documents that show Petitioner conducted an investigation of this fall or made any conclusions regarding the cause of the fall, other than the resident's statements.

A September 2, 2004, nurse's notes entry shows that Resident 2 was found on the floor near her chair. She reported she rolled out of the chair. Dr. Bumgarner and family were notified of the fall. No specific interventions are reflected in the documents presented for my consideration. CMS Ex. 2, at 52, 74. Resident 2 fell from her chair again on October 14, 2004, and she reported it was due to bending over to pick up a tissue. CMS Ex. 2, at 52, 74, 76, 95, 122. On October 15, 2004, Petitioner placed a non-skid pad, referred to in notes as a Dysom, in the resident's recliner. CMS Ex. 2, at 120-21. The surveyor testified that use of the non-skid pad was an effective intervention. Tr. 79-80. Counsel for CMS advised me at hearing that Petitioner acted and intervened appropriately regarding Resident 2's falls from her chair. Tr. 143.

An October 15, 2004 entry to the nurse's notes at 11:00 p.m. shows that Resident 2 was found on the floor in her bathroom. The resident reported that she slipped. She was noted to be barefoot, the floor was dry, and her walker was upright in the bathroom. A phone message was left for Dr. Bumgarner, but the family was not notified until the next day due to the late hour. The nurse noted that Resident 2 was unsteady when up and that she did not use the walker appropriately, but attempts to assist with proper use were unsuccessful. CMS Ex. 2, at 76. Petitioner's variance report for the incident does not list a cause for the fall, but lists two specific interventions: Resident 2 was to be reminded to use the call light; and she was to use non-skid socks or slippers. CMS Ex. 2, at 123-24. These interventions are similar to the third and fourth interventions from the June 28 comprehensive care plan: assure non-skid, well-fitting footwear; and assure that call light is within easy reach in room at all times. CMS Ex. 2, at 104.

Nurse's notes entries at 5:20, 6:30, 8:30, and 9:00 a.m. on November 22, 2004, show that the nurse was summoned to Resident 2's room around 5:20 a.m. The nurse records that she saw the resident lying on the floor. The resident was noted to have a raised area mid-forehead; two one-centimeter abrasions above her eyebrows; and an abrasion on the bridge of her nose. The family was also notified. CMS Ex. 2, at 78. Dr. Bumgarner was notified, but orders were not received. CMS Ex. 2, at 78, 86. Dr. Bumgarner's physician's assistant (PA) saw Resident 2 on November 23, 2004. He notes that she seemed quite confused and the nurses confirmed that she was slowly becoming more confused. He noted the abrasions from the fall on November 22 and that the resident

could not recall what caused her to fall. However, he reported that the nurses reported that the fall may have been due to her tripping on her shoes. The PA notes that he discussed the recent fall with Dr. Bumgarner and that no changes were being ordered. CMS Ex. 2, at 28. Petitioner's Fall Assessment Form dated November 22, 2004, does not include any conclusion as to the cause for the fall, but notes the resident did not call for assistance. The form does list as an immediate intervention to encourage the resident to use the call light. CMS Ex. 2, at 56-57. The variance report dated November 22, 2004, describes the incident similarly to the nurse's notes entries. The report does not make any conclusion regarding the cause of the fall. Actions and interventions listed include: staff to leave room door open; staff to observe her frequently especially when in bed; assure her call light is in reach, and encourage her to use it. I note that the first two are in addition to the fact that Resident 2 was in a private room across from the nurse station. The third intervention was similar to an intervention from the June 2004 comprehensive care plan to assure her call light was in reach, with the additional direction to encourage or remind her to use it. The report also shows that the possibility of using side rails was discussed, but the form does not indicate who was involved in the discussion, the conclusion, or the reasons for the conclusion. CMS Ex. 2, at 126-27. DON Johnson testified that the use of side rails was discussed and it was rejected because it was a dignity issue, it would be a restraint, and there was a risk that the resident might climb over the rail and fall. Tr. 146.

Resident 2's final fall occurred on December 21, 2004. Nurse's notes entries on December 21, 2004 at 1:30 a.m., reflect that the nurse was summoned to Resident 2's room where the resident was sitting on the floor with blood on her right hand, a one-centimeter cut on the back of her head, and blood on the bottom edge of the television stand. The resident reported she did not know what happened she just fell. The cut was closed with steri-strips and neurologic checks were done. Dr. Bumgarner was notified by facsimile. At 4:30 a.m., there was still a small amount of bleeding, the resident did not complain of pain, nausea, blurred vision or headache, and neurologic checks were normal. It is noted that the resident's call light was in easy reach. The 5:10 a.m. entry shows the nurse was summoned again because while a CNA was attempting to assist the resident to the bathroom, the resident became unresponsive. She was transported to the hospital at 5:25 a.m. and died later in the day on December 21. CMS Ex. 2, at 54, 87, 96-98. I have received no evidence that shows Petitioner made any conclusions regarding the cause of the fall.

Petitioner knew Resident 2 was at risk for falls when she was admitted on June 14, 2004. The risk for falls was confirmed by her fall on June 21, 2004, after which she was moved to a new room across from the nurse station. On June 24, 2004, she fell again and four days later on June 28, 2004, a comprehensive care plan with the goal to prevent injuries from falls was adopted. On October 15, 2004, Resident 2 fell in her bathroom at night and unattended, despite her June 2004 care plan and the fact that she was in a room across

from the nurse station. Therefore, Petitioner was on notice that the June 24 care plan interventions and the placement in a room across from the nurse station were not adequate to minimize the risk of harm to Resident 2 from falling. I have no evidence that Petitioner's investigation of the October 15 fall led to a conclusion as to the cause. Petitioner did not adopt new interventions, but simply rephrased interventions from the June 28, 2004 care plan, regarding non-skid footwear and use of the call light. Resident 2 fell again on November 22, 2004, at 5:20 a.m., with injuries to her face. This fall demonstrated that all prior interventions were ineffective to prevent this resident from having the type of falls that she had. I have no evidence that Petitioner determined the cause of the fall but the PA note indicates that some of the nurses speculated that Resident 2 tripped on her shoes (possibly her non-slip shoes). The evidence shows that there were additional interventions adopted following this fall: staff again to encourage the resident to use the call light; room door to be open; and staff to observe frequently especially when in bed. Encouraging the resident to use the call light had clearly been shown not to be an effective intervention. Leaving the room door open, particularly as the room was directly across from the nurse station, might seem effective, but only if the station is occupied most of the time and the occupants are not busy with work. Petitioner has not shown that the nurse station was occupied most of the time or that the proximity of the room to the nurse station was at all effective to prevent falls with the door open. Certainly the proximity did not effectively prevent the falls on October 15 and November 22. Petitioner has also not shown that the intervention to observe the resident frequently was effective, absent more specific guidance as to who was to observe and when the observations were to be made. The ineffectiveness of both the new interventions is demonstrated by the fall on December 21, 2004.

Sometime between her comprehensive assessment reflected by the MDS with the assessment reference date September 21, 2004, and the MDS with the assessment reference date December 3, 2004, Resident 2 declined cognitively and physically. In December 2004, her decision-making was considered poor and she required supervision and cues, she had difficulty understanding and being understood, her incontinence of bowel and bladder had increased, and her ability to walk had declined. Resident 2's care plan dated June 28, 2004, was modified on December 14, 2004, by deletion of the following interventions: allow use of walker and keep in reach at all times; encourage client to ask for assistance daily with ambulation and transfers; maintain clean, uncluttered environment; monitor ambulation for steadiness and safety. CMS Ex. 2, at 105. The new care plan dated December 14, 2004, lists all the same printed interventions as the June 28 care plan and lines were drawn through the same interventions on both. The December 14 care plan shows three new interventions: transfers are to be with the walker, the resident was to ambulate three times per week, and she was supposed to use the wheelchair for mobility at other times. CMS Ex. 2, at 109. Although it is listed on the fall care plan, the instruction that Resident 2 is to ambulate three times per week is not an effective intervention against falls; rather, it would have been more appropriately listed

on a restorative care plan. Use of the walker for transfers may be an appropriate intervention for falls, but because the resident never fell while being transferred with assistance, it does not address the problem of the resident falling at other times. Limiting the resident to use of the wheelchair for mobility may also be an appropriate intervention for falls, but again it does not address the problem of the resident falling while unassisted. There is no evidence that explains why the interventions adopted after the fall on November 22, i.e., to keep the resident's room door open and to observe her frequently, are not listed on the December 14, 2004 care plan. The fact that those two interventions are not listed on the December 14, 2004 care plan gives rise to the inference that they were no longer followed after December 14, 2004. Petitioner has presented no specific evidence to the contrary. For purposes of this decision, I assume those two interventions were not discontinued but, as I have already discussed, I find them inadequate.

The December 14, 2004 care plan listed "body alarm," but it was stricken and "error" is entered there. CMS Ex. 2, at 109. The use of side rails was also discussed and rejected following the November 22, 2004 fall. I have no problem accepting Petitioner's rejection of the use of side rails, particularly because the evidence tends to show that Resident 2's falls were not from her bed but after she was already out of bed. The fact that Petitioner did not document a thorough investigation of the cause and circumstances of each fall makes it difficult to determine with absolute certainty that Resident 2 did not fall attempting to get out of bed on November 22. However, she was found in the bathroom on October 15 and the blood on the television stand on December 21 shows that in those incidents she fell after getting out of bed. Petitioner argues that an alarm was not used because the family did not want it, that it might only have worsened Resident 2's anxiety, and that alarms do not prevent falls anyway. P. Brief at 9-11; P. Reply at 14-17. Whether the sounding of an alarm would have increased Resident 2's anxiety is totally speculative in this case. However, even assuming her anxiety might have been increased, there is no documentation that Petitioner actually considered whether the risk of increasing her anxiety outweighed the benefit of staff being alerted to the fact the resident was getting out of bed prior to a fall occurring. There is no evidence that the resident's attending physician was consulted about the risks and benefits of using an alarm relative to the resident's anxiety or her general condition. There is also no documentation or testimony that the resident's decline in her ability to understand and be understood, her decline in judgment, her decline in mobility as reflected in her December MDS, or the increased confusion noted by the PA were considered when the decision to reject an alarm was made.

Petitioner's DON testified that the use of a personal alarm was discussed at the care planning conference related to the December 14, 2004 care plan. She recalled that Resident 2's family was present for that conference, but she could not recall the details of the discussion including whether the pros and cons for using an alarm was explained to the family. She recalled that the "body alarm" was stricken from the care plan because

the family did not want it. She testified that the wishes of the resident and her family were followed and that, in her opinion, alarms do not prevent falls. She also testified that she believed that the family was most concerned about the impact upon Resident 2's dignity. Tr. 154-56, 184-87, 189-93. Petitioner has presented no documentary evidence that the family was counseled by staff or the attending physician regarding the risks and benefits of the use of an alarm as an intervention to alert staff that the resident was out of bed. Petitioner argues that because Resident 2's room was across from the nurse station and that her door was to remain open, there was no need for an alarm. However, the fall on December 21 shows these interventions were not effective. Petitioner incorrectly asserts that the DON testified that staff heard the resident "attempting to get out of bed and found her on the floor." P. Reply at 16. Responding to my questioning, the DON was uncertain as to what caused the CNA to enter the resident's room, but she believed that the CNA heard a noise from the room, entered, and found the resident on the floor by the bed. The DON did not testify that the CNA heard the resident attempting to get out of the bed. Tr. 196-97. The DON did testify about the function of a pressure alarm used under a mattress, and her testimony is consistent with the fact that, had a pressure alarm such as she described been used, it could have alerted staff that the resident was getting out of bed on October 15, November 22, or December 21, 2004, before she fell. Tr. 189-90.

A resident has the right to refuse treatment. 42 C.F.R. § 483.10(b)(4). However, for the resident or family to meaningfully participate in care planning, they need to be fully informed in an understandable way of the risks and benefits associated with care and services accepted or rejected. If care or services are refused, a facility is not relieved of its obligation to protect the resident from harm. Rather, the facility must assess and implement other adequate means to protect the resident. The intervention of frequent observation as implemented in this case was inadequate because it did not specify who was to observe and when. Petitioner might have cured the defect by presenting evidence to show that frequent observation occurred or who was doing the observations, but Petitioner did not do so. Absent documentation that observations were being done, the effectiveness of frequent observation as an intervention could not be assessed by Petitioner. Petitioner has presented no evidence that it considered ordering room checks every 15 or 30 minutes to ensure observation was frequent with documentation so that Petitioner could have assessed that the intervention was actually implemented. Petitioner also failed to present evidence that other interventions such as taking the resident to the toilet every two to four hours was considered. There is evidence that shows the resident got out of bed to go to the bathroom and that is where she was found on October 15. Toileting in advance of need every two to four hours might have been adequate to minimize the known risk that the resident was going to get out of bed to go to the bathroom, attempt to ambulate unassisted, and fall.

Petitioner refers to the statement of Dr. Janet Bumgarner to the surveyor to the effect that Petitioner provided adequate care for the resident and there was nothing more that could have been done. Petitioner argues that Dr. Bumgarner's statement precludes finding that Petitioner's treatment of Resident 2 did not meet professional standards for nursing care. P. Brief at 24. Petitioner did not call Dr. Bumgarner to testify and no actual statement of Dr. Bumgarner appears in the record. Rather, the surveyor's summary of an interview of Dr. Bumgarner appears at CMS Ex. 2, at 19, 21, and 25. Although only a summary, it is clear that Dr. Bumgarner's comments were limited to whether staff acted appropriately in response to the fall the morning of December 21, 2004. The summaries of Dr. Bumgarner's interview do not include any comments about the adequacy of interventions to minimize the foreseeable risk of harm to the resident from falling. Whether Petitioner's staff acted appropriately in response to the fall on December 21, 2004, is debatable, but that conduct is not subject to a charge before me.

Petitioner also argues that the evidence does not show actual harm in this case. P. Brief at 28. My review of the evidence shows that Resident 22 suffered actual harm in the form of abrasions and swelling on her forehead resulting from the fall on November 22, 2004. Resident 2's fall on December 21, 2004, also resulted in actual harm in the form of the one-centimeter cut to the back of her head and the large hematoma that caused her death.

I conclude that Petitioner violated 42 C.F.R. § 483.25 and its subsection (h)(2) and that Resident 2 suffered actual harm as a result.

2. The CMS selection of a DPNA is not subject to review and the period of the DPNA is reasonable.

Petitioner violated 42 C.F.R. § 483.25 and that violation resulted in actual harm to Resident 2. Thus, there is a basis for the imposition of an enforcement remedy. CMS imposed a DPNA for the period March 1, 2005 through March 24, 2005. CMS's choice of a DPNA as a remedy is within CMS's discretion and is not appealable. 42 C.F.R. § 488.408(g)(2). Petitioner has not offered any argument as to why the period of the DPNA should be lessened or otherwise changed. Accordingly, I sustain the imposition of the DPNA for the period March 1, 2005 through March 24, 2005.

Furthermore, as a consequence of the imposition of the DPNA, the state agency was required to withdraw Petitioner's authority to conduct a NATCEP. 42 C.F.R. § 483.151(e) and § 483.151(b)(2)(v).

III. Conclusion

For the foregoing reasons, I conclude that Petitioner violated 42 C.F.R. § 483.25 (Tag F309), and the DPNA imposed is reasonable.

/s/
Keith W. Sickendick
Administrative Law Judge