Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
Woodland Village Nursing Center (CCN: 25-5163),	)	Date: October 6, 2007
Petitioner,	)	Docket No. C-03-339
	)	Decision No. CR1668
v.	)	
Centers for Medicare & Medicaid Services.	)	

DECISION

Petitioner, Woodland Village Nursing Center, was not in substantial compliance with Medicare participation requirements based on surveys of Petitioner's facility completed on January 24, 2003 and March 12, 2003. There is a basis for the imposition of a civil money penalty (CMP), and a denial of payment for new admissions (DPNA). A CMP of $350 per day for the 47 days from January 24, 2003 through March 11, 2003, and $50 per day for the 72 days from March 12, 2003 through May 22, 2003 is reasonable. The total CMP is $20,050.

I. Background

Petitioner, located in Diamondhead, Mississippi, is authorized to participate in Medicare as a skilled nursing facility (SNF) and the Mississippi Medicaid program as a nursing facility (NF). On January 24, 2003, the Mississippi Department of Health (the state agency) completed a survey of Petitioner's facility, the results of which are reported in a Statement of Deficiencies (SOD) bearing that date. The state agency determined that Petitioner was not in substantial compliance with Medicare and Medicaid participation requirements and recommended that the Centers for Medicare and Medicaid Services (CMS) impose remedies. CMS notified Petitioner by letter dated February 11, 2003, that it concurred with the state agency findings and recommendations and that it intended to impose the following remedies: a CMP of $350 per day effective January 24, 2003, until Petitioner returned to substantial compliance; a DPNA effective March 10, 2003, until

Petitioner returned to substantial compliance; and termination effective July 24, 2003, if substantial compliance was not achieved before that date. Petitioner requested a hearing by an administrative law judge (ALJ) on March 20, 2003. The case was docketed as number C-03-339 and assigned to me for hearing and decision on April 30, 2003, and a Notice of Case Assignment and Prehearing Case Development Order (Prehearing Order) was issued at my direction on that date.

On March 12, 2003, the state agency completed a revisit survey at Petitioner's facility and determined that the facility had not returned to substantial compliance with participation requirements. An SOD dated March 12, 2003, was prepared and issued by the state agency surveyors setting forth the alleged deficiencies. By letter dated March 31, 2003, CMS notified Petitioner that the remedies imposed by its letter of February 11, 2003, would continue. On April 10, 2003, Petitioner filed a hearing request with respect to CMS's notice letter of March 31, 2003. On June 26, 2003, the hearing request was docketed as number C-03-508, assigned to me for hearing and decision, and another Prehearing Order was issued at my direction.

During a telephonic prehearing conference the parties requested that C-03-339 and C-03-508 be consolidated for hearing and decision. By order dated July 25, 2003, I consolidated the two cases under docket number C-03-339.[1]

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[1] There is information in the record that follow-up surveys were completed on May 23, 2003 and June 12, 2003. Transcript (Tr.) 41-49. I have no evidence that shows when the state agency concluded that Petitioner returned to substantial compliance. Petitioner was not ultimately terminated for remaining out of compliance for six months. Thus, I infer that Petitioner returned to substantial compliance prior to July 24, 2003, the date on which the Act would mandate termination for six months of noncompliance. CMS requests a CMP of $350 per day from January 24 to March 11, 2003 and a CMP of $50 a day from March 12 to May 22, 2003. CMS Prehearing Brief at 12; CMS Reply Brief at 30. I will also apply the May 22, 2003 end-date to the DPNA for purposes of this decision.

I conducted an in-person hearing in Gulfport, Mississippi, on February 5 and 6 and April 8 and 9, 2004. CMS offered exhibits (CMS Exs.) 1 through 39, which were admitted. Tr. 15. Petitioner offered exhibits (P. Exs.) 5 through 10, and 20 through 47, which I admitted as evidence. Petitioner withdrew P. Exs. 1 through 4 and 11 through 19. Tr. 17-25. CMS subsequently offered and I admitted CMS Exs. 40 and 41. Tr. 78, 324.[2] CMS requested that P. Exs. 11 through 19 which were not offered by Petitioner, be remarked and admitted as CMS Exs. 42 through 48. CMS marked Petitioner Exs. 11 through 16 as CMS Exs. 42 through 47, respectively. CMS marked P. Ex. 18 as CMS Ex. 48. P. Ex. 19 was subsequently remarked as CMS Ex. 49. Tr. 264. CMS did not remark P. Ex. 17 and it was not received as evidence.[3] CMS Exs. 42 through 49 were received as evidence. Tr. 28-29, 132, 264. Subsequently, Petitioner offered and I admitted P. Ex. 48. Tr. 723. In summary, CMS Exs. 1 through 49 were admitted and considered as evidence. P. Exs. 5 through 10, and 20 through 48, were admitted and considered as evidence. CMS elicited testimony from Robert Trigg, Life Safety Code Inspector for the January 2003 survey (Tr. 67-68); Joycelyn Pevey, a state agency surveyor who participated in both the January and March 2003 surveys (Tr. 109); Paula Bradford, a surveyor who participated in the January 2003 survey (Tr. 281); Dan Osterweil, M.D., who was qualified as an expert (Tr. 338); Patricia Magee, a surveyor who participated in the January and March 2003 surveys (Tr. 453); and Judy Hughes, a surveyor who participated in the January 2003 survey. Petitioner elicited testimony from Sharon Legg, a registered dietician employed by Petitioner (Tr. 497); Richard Tilley, M.D., Medical Director for Petitioner (Tr. 560) and the treating physician for many of Petitioner's residents (Tr. 561); Julie Cain, administrative supervisor for Petitioner at the time of the January and March 2003 surveys; and Ann Byerly, who was qualified as an expert (Tr. 710). CMS called Paula Bradford and Julie Cain as rebuttal witnesses.

Both parties submitted a post hearing brief (CMS Brief and P. Brief, respectively) and response brief (CMS Reply and P. Reply, respectively) and each party received a copy of the hearing transcript.

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[2] CMS Exs. 40 and 41, copies of the floor plan of the facility, were marked for use as demonstrative evidence. Tr. 14, 65, 70, 77, 132. CMS Ex. 40 was admitted as evidence. Tr. 78. CMS Ex. 41 was also offered and admitted into the record. Tr. 324.

[3] P. Ex. 17 is a Roster/Sample Matrix. A redacted copy of the same document is in evidence as CMS Ex. 5. To the extent that there was any failure to properly remark and admit P. Ex. 17 as a CMS exhibit, it is not prejudicial error as the document is already in evidence, albeit in slightly altered state.

II. Discussion

A. Issues

The issues in this case are:

> Whether there is a basis for the imposition of enforcement remedies; and, if so,
>
> Whether the remedies imposed are reasonable.

B. 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.

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. Pursuant to 42 C.F.R. Part 488, CMS may impose a per instance CMP (PICMP) or per day CMP against a long-term care facility when a state survey agency concludes that the facility is not complying substantially with federal participation requirements. 42 C.F.R. §§ 488.406; 488.408; 488.430. The regulations in 42 C.F.R. Part 488 also give CMS a number of other remedies that can be imposed if a facility is not in compliance with Medicare requirements. *Id.*

The regulations specify that a CMP that is imposed against a facility on a per day basis will fall into one of two broad ranges of penalties. 42 C.F.R. §§ 488.408, 488.438. The upper range of CMP, of from $3050 per day to $10,000 per day, is reserved for deficiencies that constitute immediate jeopardy to a facility's residents, and, in some circumstances, for repeated deficiencies. 42 C.F.R. §§ 488.438(a)(1)(i), (d)(2). The lower range of CMP, from $50 per day to $3000 per day, is reserved for deficiencies that do not constitute immediate jeopardy, but either cause actual harm to residents, or cause no actual harm, but have the potential for causing more than minimal harm. 42 C.F.R. § 488.438(a)(1)(ii). There is only a single range of $1000 to $10,000 for a PICMP that applies whether or not immediate jeopardy is present. 42 C.F.R. §§ 488.408(d)(1)(iv); 488.438(a)(2).

The Act and regulations make a hearing before an ALJ available to a long-term care facility against which CMS has determined to impose a CMP. 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 *Hillman Rehabilitation Center*, DAB No. 1611, at 8 (1997), *aff'd Hillman Rehabilitation Center v. HHS*, No. 98-3789 (GEB) (D.N.J. May 13, 1999), the Board described the elements of the CMS prima facie case in general terms as follows:

> HCFA [now known as CMS] must identify the legal criteria to which it seeks to hold a provider. Moreover, to the extent that a provider challenges HCFA's findings, HCFA must come forward with evidence of the basis for its determination, including the factual findings on which HCFA is relying and, if HCFA has determined that a condition of participation was not met, HCFA's evaluation that the deficiencies found meet the regulatory standard for a condition-level deficiency.

DAB No. 1611, at 8. Thus, CMS has the initial burden of coming forward with sufficient evidence to show that its decision to terminate is legally sufficient under the statute and regulations. To make a prima facie case that its decision was legally sufficient, CMS must: (1) identify the statute, regulation or other legal criteria to which it seeks to hold the provider; (2) come forward with evidence upon which it relies for its factual conclusions that are disputed by the Petitioner; and (3) show how the deficiencies it found amount to noncompliance that warrants an enforcement remedy.

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.

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

Following in bold are my conclusions of law followed by the pertinent findings of fact and analysis.

Based upon the survey that ended on January 24, 2003, state agency surveyors cited Petitioner with violations of 42 C.F.R. §§ 483.15(h)(1) (Tag F 252)[4]; 483.20(k)(2) (Tag F 280); 483.25 (Tag F 309); 483.25(c) (Tag F 314); 483.25(h)(1) (Tag F 323); 483.25(h)(2) (Tag F 324); 483.35(d)(1) & (2) (Tag F 364); 483.35(d)(4) (Tag F 366); and 483.35(h)(2) (Tag F 371). Petitioner was also cited with the following violations of Life Safety Code standards: Tag K 028, Tag K 038, and Tag K 056. Based upon the survey that ended on March 12, 2003, Petitioner was cited for violations of 42 C.F.R. §§ 483.13(c)(1)(i) (Tag F 224); 483.25(c) (Tag F 314); 483.25(j) (Tag F 327); 483.75(j) (Tag F 502). Each violation cited was at a scope and severity level of "D" or higher, and thus may be the

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[4] State surveyors use "Tag" designations that refer to the part of the State Operations Manual (SOM), Appendix P, "Survey Protocol for Long Term Care Facilities," "Guidance to Surveyors" that pertain to the specific regulatory provision allegedly violated.

basis for the imposition of an enforcement remedy.[5] During the hearing, CMS announced that it would not proceed on the Life Safety Code violation identified as Tag K 056. Tr. 85.

Petitioner requested informal dispute resolution (IDR) pursuant to 42 C.F.R. § 488.331 as to both the January and March surveys. I have received no evidence of any IDR related to the January survey. However, there is no dispute that IDR was conducted regarding the March survey that resulted in the recommendations that all the cited deficiencies except the alleged violation of 42 C.F.R. §§ 483.13(c)(1)(i) (Tag F 224), be deleted and that the scope and severity of that deficiency be cited as a "D" rather than a "G". CMS agreed to reduce the scope and severity as recommended by the IDR, but rejected the recommendation to delete the other cited deficiencies.[6] CMS Ex. 25; P. Ex. 27; Tr. 50. Petitioner argues that I should consider the IDR results as reflecting negatively upon the credibility of the alleged deficiencies cited in the March survey. P. Brief at 27. I have already noted my review is de novo and I will consider all the evidence to determine whether or not the deficiencies are supported by the evidence. Nevertheless, I do consider that the state agency recommendation to delete the citations from the March Survey is evidence that tends to reflect negatively upon the deficiencies recommended for deletion.

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[5] The cited deficiencies are set forth in a SOD, prepared by the state agency surveyors. Each deficiency includes a scope and severity (SS) level such as "SS=D." *See, e.g.,* CMS Ex. 1, at 1 (left column). Scope and severity levels are used by CMS and a state agency when selecting remedies. The scope and severity level is designated by an alpha character, A through L, selected by CMS or the state agency from the scope and severity matrix published in the SOM, section 7400E. A scope and severity level of A, B, or C indicates a deficiency that presents no actual harm but has the potential for no more than minimal harm. Facilities with deficiencies of a level no greater than C remain in substantial compliance. 42 C.F.R. § 488.301. 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. Scope and severity levels J, K, and L are deficiencies that constitute immediate jeopardy to resident health or safety. Letters A, D, G, and J indicate an isolated occurrence, letters B, E, H, and K indicate a pattern of occurrences, and letters C, F, I, and L indicate widespread occurrences. 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.

[6] When CMS and the state agency disagree over whether a facility participating in Medicare is in substantial compliance, the opinion of the one that concludes that the facility is noncompliant prevails, in this case CMS. 42 C.F.R. § 488.452(a).

I do not address and make no findings or conclusions regarding three alleged violations of 42 C.F.R. § 483.35 and the alleged violation of 42 C.F.R. § 483.15(h)(1) from the January 2003 survey in the interest of judicial economy. The violations discussed hereafter provide a sufficient basis for the enforcement remedies proposed by CMS that I approve. *See Beechwood Sanitarium*, DAB No. 1824, at 22 (2002). I do not consider the deficiencies not specifically addressed bases for the imposition of an enforcement remedy.

1. Petitioner violated 42 C.F.R. § 483.70(a)(1).

This regulation requires that Petitioner's facility meet the requirements of the 1985 version of the Life Safety Code of the National Fire Protection Association, which were incorporated by reference. Robert Trigg, Life Safety Code Inspector, alleged in the SOD for the January 2003 survey, and testified at hearing, that Petitioner violated the provisions of the Life Safety Code and the regulation in two respects. First, upon inspection on January 23, 2003, he found that one section of a smoke barrier door would not close into its frame, thus defeating the intended purpose of the door to limit the escape of smoke. Second, he also found during his inspection on January 23, 2003, that one exit door could not be opened with a pressure of 15 pounds. CMS Ex. 21; Tr. 68-77; 86-88; 92-96.

Petitioner does not dispute the allegation under Tag K 028 that the smoke barrier door would not close into its frame as alleged by Mr. Trigg. Rather, Petitioner argues that the requirement of the Life Safety Code cited does not mandate that the doors actually work. P. Brief at 18. Petitioner also argues that there are other sets of smoke doors that do work. P. Brief at 18-19. I find Petitioner's arguments to be without merit. Inherent within the requirement to have smoke barrier doors is that they be operational. Furthermore, Mr. Trigg's testimony regarding the potential harm to residents posed by a defective smoke door is both credible and unrebutted. I am not persuaded that the witness' lack of familiarity or confusion regarding the scope and severity matrix from the SOM reflects adversely upon his credibility.

The second example cited under Tag K 038 is that an exit door did not open with 15 pounds of pressure. Again Petitioner does not dispute the facts alleged in the SOD or testified to by Mr. Trigg. The door was damaged and would not open properly. P. Brief at 19. Petitioner's argument that the door was recently damaged does not excuse the violation. Mr. Trigg's testimony regarding the potential for harm associated with a defective exit door is credible and unrebutted.

I conclude that Petitioner was in violation of 42 C.F.R. § 483.70(a)(1) on January 23, 2003. No violation of this regulation was alleged by the survey completed on March 12, 2003, and I presume Petitioner corrected the deficiency by the date of that survey.

2. CMS has not made a prima facie showing of a violation of 42 C.F.R. § 483.20(k)(2) (Tag F 280).

The regulation governing care plans requires that Petitioner develop a comprehensive care plan for each resident. A resident's care plan must include "measurable objectives and timetables to meet a resident's medical, nursing, and mental and psychosocial needs that are identified in the comprehensive assessment." 42 C.F.R. § 483.20(k)(1). The comprehensive care plan must be developed within seven days after completion of the comprehensive assessment of the resident and it must be "[p]eriodically reviewed and revised by a team of qualified persons after each assessment." 42 C.F.R. § 483.20(k)(2). The surveyors allege in the SOD dated January 24, 2003, that Petitioner failed to review and revise care plans for Residents 2, 5, 13, and 10. CMS Ex. 1, at 2-4.

The surveyors allege in the SOD under example 1, related to Resident 10, that the resident's care plan had not been updated to reflect orders for a bedside commode chair, restorative nursing care, or respiratory treatments. The surveyors allege, regarding Resident 2, that no care plan with interventions for care of specific wounds on the residents feet and toes could be located. The surveyors allege regarding Resident 5 that the resident's care plan had not been updated to include references to additional wounds on her buttocks. The surveyors allege that the care plan for Resident 13 had not been updated to include reference to additional wounds on the resident's toes and buttocks.

CMS advances a common sense argument that as new problems develop and new interventions are implemented for the care and treatment of a resident, the comprehensive care plan should be updated to reflect those problems and interventions. CMS Reply at 15-19. CMS does not argue in this case that Petitioner failed to do a comprehensive assessment of any of the four residents or to develop a comprehensive care plan based upon that assessment. Rather, CMS argues that Petitioner needed to update resident care plans whenever additional problems developed or treatment was ordered. CMS fails to present a prima facie case of a violation of the regulation because the requirement it seeks to impose and enforce is not found in the regulation it cites.

Section 483.20 of 42 C.F.R. imposes upon a facility the obligation to conduct "initially and periodically a comprehensive, accurate, standardized, reproducible assessment of each resident's functional capacity." Upon admission the facility must have physician orders for the resident's immediate care. 42 C.F.R. § 483.20(a). Within 14 calendar days after admission, excluding certain readmissions after a temporary absence, within 14 days after the facility determines or should have determined that there has been a "significant

change in the resident's physical or mental condition," and not less than every 12 months, a facility must do a comprehensive assessment using an instrument specified by the state to assess at a minimum the areas specified in the regulation. 42 C.F.R. § 483.20(b). Additionally, a facility must do a quarterly assessment of the resident using a "quarterly review instrument specified by the state and approved by CMS not less frequently than once every 3 months." 42 C.F.R. § 483.20(c). The results of a resident's assessments for the previous 15 months must be maintained and used to "develop, review, and revise the resident's comprehensive plan of care." 42 C.F.R. § 483.20(d). The regulation requires that assessments must accurately reflect the resident's status, presumably at the time of assessment. 42 C.F.R. § 483.20(g). A resident's assessment must be coordinated and certified by a registered nurse (RN) and there is a penalty for falsification. 42 C.F.R. § 483.20(h), (i), and (j). A facility must develop a comprehensive care plan for each resident that includes "measurable objectives and timetables to meet a resident's medical, nursing, and mental and psychosocial needs that are identified in the comprehensive assessment." 42 C.F.R. § 483.20(k)(1). The comprehensive care plan must be developed within seven days after completion of the comprehensive assessment of the resident by a team that includes the attending physician, an RN with responsibility for the resident, and other appropriate staff determined based on the assessed needs of the resident, and the resident, the resident's family, or the resident's legal representative; and it must be "[p]eriodically reviewed and revised by a team of qualified persons after each assessment." 42 C.F.R. § 483.20(k)(2). Contrary to the argument of CMS, 42 C.F.R. § 483.20 does not require that every new problem identified, or that every new intervention attempted, be recorded on the resident's comprehensive plan of care.[7] *See Evergreene Nursing Care Center*, DAB CR1337 (2005), *aff'd in part, rev'd in part*, DAB No. 2069 (2007) (regarding alleged violation of 42 C.F.R. § 483.20(k)(2), the Board affirmed that CMS failed to show more than minimal harm). Rather, the comprehensive plan of care is intended to be based upon the comprehensive assessments required by the regulation. CMS does not allege that Petitioner failed to conduct a required comprehensive assessment (initial, annual, or significant change) or a quarterly review of any of the four resident's cited. CMS does not allege that Petitioner failed to review and revise any of the four residents' comprehensive care plans in accordance with the scheme established by the regulation.

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[7] I do not intend to suggest that resident problems and related interventions need not be reflected somewhere in the clinical record, ideally in a form readily accessible to staff who deliver care. In this case, the surveyors and CMS do not allege that there was no documentation, only that the documentation was not on the comprehensive care plan.

Accordingly, I conclude that CMS has failed to establish a prima facie case of a violation of 42 C.F.R. § 483.20 or, more specifically, § 483.20(k)(2).

3. Petitioner violated 42 C.F.R. § 483.25 (Tag F 309).

This regulation requires that a facility provide the necessary care and services so that each resident attains or maintains "the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care. 42 C.F.R. § 483.25. The surveyors allege, based on the January 2003 survey, that Petitioner violated the regulation by its care of Resident 5.

Resident 5 was nearly 82 years old when admitted to Petitioner's facility on October 22, 2002. A Minimum Data Set (MDS) with an assessment reference date of October 29, 2002 shows that she had a history of congestive heart failure, hypertension, peripheral vascular disease, other cardiovascular disease not specified, a history of cerebrovascular accident (CVA or stroke), muscular disuse (atrophy), dysphagia, decubitus ulcers (she was noted to have two Stage II and one Stage III pressure ulcers), and a urinary tract infection (UTI) within the last 30 days.[8] She was taking the antibiotic Keflex every eight hours during the assessment period. She was assessed as having memory problems; moderately impaired decision-making; was sometimes understood with unclear speech; she was noted to be verbally abusive; she required extensive assistance with most activities of daily living (all requiring physical assistance of one or two staff); she could not balance sitting or standing without assistance, she had limited range of motion (ROM) on one side in her arm, hand, leg, and foot; she used a wheelchair pushed by someone for locomotion; she used bed rails for bed mobility and had to be lifted for transfers; and she had an indwelling catheter. P. Ex. 8, at 431-41. An MDS with an assessment reference date of November 4, 2002, reflects little or no change in Resident 5's status, and she was again shown to have had a UTI within the last 30 days and was again noted to be on Keflex every eight hours. P. Ex. 8, at 423-30. The last MDS in the record prior to the January 2003 survey had an assessment reference date of January 9, 2003, and is noted to be a quarterly review. This MDS shows a decline, in that she had become totally dependent on staff for locomotion, dressing, toileting, personal hygiene and bathing. She continued to have an indwelling catheter, and was reported to have had a UTI within the last 30 days. She was reported to have two Stage II ulcers only, with one ulcer resolved or cured in the last 90 days. She was not reported to be on any antibiotic during the assessment period (seven days prior to January 9, 2003). P. Ex. 8, at 414-22. However, a nurses note from January 8, 2003, shows that the resident was being given an antibiotic for a UTI, albeit physician orders may not have been received until January 8, 2003. P.

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[8] See P. Ex. 8, at 448-50 for a more comprehensive listing.

Ex. 8, at 116, 320. She was started on the antibiotic Ampicillian on January 8, 2003, which was continued to January 18, 2003. P. Ex. 8, at 455.

The surveyors allege in the SOD that on January 9, 2003, Resident 5's physician ordered that she receive Ampicillin four times a day for 10 days for a UTI and that a repeat urine culture and sensitivity (C & S) report be obtained on January 20, 2003. The surveyors allege that Petitioner failed to obtain a C & S report for Resident 5 until during the survey on January 23, 2003. CMS Ex. 1, at 5; CMS Ex. 14, at 11, 26; P. Ex. 8, at 277, 320, 322, 340. Petitioner does not deny that it failed to obtain the C & S as ordered, however, it argues that the delay was minor and CMS did not show the delay could cause any harm to the resident. P. Brief at 10-11.

CMS argues that Resident 5's physician ordered the C & S and Petitioner's staff failed to obtain the test as ordered. CMS notes that when the test was finally done, it confirmed that Resident 5's UTI was resistant to treatment with Ampicillin. CMS concludes that there was a risk for more than minimal harm to the resident given her complicated medical condition including significant pressure sores. CMS Reply at 19-20.
CMS clearly has established a prima facie violation of 42 C.F.R. § 483.25 (Tag F 309). Resident 5's physician ordered that laboratory testing of the resident's urine be done on January 20, 2003, to determine the efficacy of his prescribed antibiotic treatment. Petitioner failed to comply with the order for three days. I have no difficulty concluding that Resident 5 suffered actual harm as a result of Petitioner's failure. The resident has a history at this facility of having a chronic UTI, in fact, she was admitted with a UTI. Petitioner actually developed a care plan on January 15, 2003, recognizing that because the resident had an indwelling urinary catheter, she was at increased risk for UTIs. Thus, Petitioner was clearly on notice that this resident required special attention and increased care regarding her catheter and the possibility for UTI. Further, the resident's records show that since her admission she had frequently required antibiotic therapy. This further supports the notion that Petitioner clearly was aware of the need for particular attention to the resident and her treatment for UTIs. Resident 5's physician ordered treatment with Ampicillin for a UTI on January 9, 2003. Petitioner submitted the resident's complete clinical record, but given the minimal nurse's notes, the resident's multiple conditions, and her limited ability to communicate, it is not possible for me to discern whether the resident's condition began to improve or not. It does appear that her urine did not appear normal. P. Ex. 8, at 116, 118. When the C & S was finally done three days late, it confirmed that the Ampicillin was not effective at fighting the infection. This evidence is sufficient to permit me to infer that the resident continued to suffer the effects of the UTI at least three days longer than her physician intended, and that amounts to actual harm. Further, CMS's expert witness, Dr. Osterweil, testified that he observed that the resident's urine and her coccyx pressure ulcer grew the same organism, indicating that her UTI may have been contributing to the infection of her ulcer. Tr. 390-91.

I conclude that Petitioner violated 42 C.F.R. § 483.25. No violation of this regulation was alleged by the survey completed on March 12, 2003, and I presume Petitioner corrected the deficiency by the date of that survey.

4. Petitioner violated 42 C.F.R. § 483.25(c) (Tag F 314).

CMS charges that Petitioner was in violation of 42 C.F.R. § 483.25(c) with respect to Resident 3 during the January 2003 survey and Resident 6[9] during the March 2003 survey. The two alleged violations are discussed together for convenience.

The general quality of care regulation requires that a facility provide the necessary care and services so that each resident attains or maintains "the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care. 42 C.F.R. § 483.25. There is a subsection of the regulation that imposes specific requirements regarding the prevention and treatment of pressure sores:

> (c) Pressure sores. Based on the comprehensive assessment of a resident, the facility must ensure that - (1) A resident who enters the facility without pressure sores does not develop pressure sores unless the individual's clinical condition demonstrates that they were unavoidable; and (2) A resident having pressure sores receives necessary treatment and services to promote healing, prevent infection and prevent new sores from developing.

42 C.F.R. § 483.25(c).

The application of this regulation is well-established by decisions of various appellate panels of the Board. *Koester Pavilion*, DAB No. 1750 (2000), and *Cross Creek Health Care Center*, DAB No. 1665 (1998), are leading decisions in this area. The Board has noted that the pressure sore regulation contains two prongs: (1) a facility must ensure a resident who enters the facility without sores does not develop sores unless the resident's clinical condition demonstrates that pressure sores are unavoidable; and (2) a resident with pressure sores must receive necessary treatment and services to promote healing, prevent infection and prevent new sores. With respect to prevention and treatment of pressure sores, the Board has concluded that a facility bears a duty to "go beyond merely what seems reasonable to, instead, always furnish what is necessary to prevent new sores

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[9] There is no dispute that the resident designated "Resident 5" during the January survey was the same resident as the resident designated "Resident 6" during the March survey. Tr. 122-23.

unless clinically unavoidable, and to treat existing ones as needed." *Koester Pavilion*, DAB No. 1750, at 32; *see also*, *Meadow Wood Nursing Home*, DAB No. 1841 (2002) (loose dressing contaminated with fecal matter constitutes violation); *Ridge Terrace*, DAB No. 1834, at 15-16 (a single observation by a surveyor of a nurse aide cleaning an open sore area with a stool-stained washcloth was sufficient to sustain a deficiency finding under this Tag).

In order to establish a prima facie case, CMS must show either: (1) that a resident who entered Petitioner's facility without pressure sores developed such sores at Petitioner's facility; or (2) a resident at Petitioner's facility had one or more pressure sores that became worse, or became infected, or the resident developed additional sores, indicating the facility did not provide treatment and services to promote healing, prevent infection, and prevent new sores from developing. If CMS makes a prima facie showing, Petitioner then bears the burden of showing that the development of pressure sores or their worsening was "clinically unavoidable."

An appellate panel of the Board, in *Clermont Nursing and Convalescent Center*, DAB No. 1923 (2004), provided the following analysis:

> The standard of necessity is expressly articulated in the regulation. The primary regulatory requirement is that residents must receive, and facilities must provide, "the necessary care and services" for attainment or maintenance of the highest practicable resident well-being. 42 C.F.R. § 483.25 (emphasis supplied). The regulation then goes on to provide that a resident with pressure sores must receive "necessary treatment and services" for healing, prevention of infection, and prevention of yet more pressure sores. 42 C.F.R. § 483.25(c)(2)(emphasis supplied). We therefore reject Clermont's contention that the standard is "nowhere in the regulation." That argument is belied by the plain language of the regulation.
>
> Moreover, as we explained in *Koester Pavilion*, in the preamble to the final regulation, CMS expressly declined to use "less demanding" language with respect to a facility's obligation to "ensure" outcome of treatment for pressure sores. *Koester Pavilion* at 30, quoting 56 Fed. Reg. 48,826, at 48,850 (Sept. 26, 1991). CMS recognized that factors beyond required treatment and services, such as disease process and resident compliance, affect care outcome. *Id.* However, CMS also recognized that the regulation allows a facility to

> put forward "available clinical evidence" to show that "a negative resident care outcome was unavoidable." *Id.* The preamble further provides that facilities "should always furnish the necessary treatment and services" for pressure sore prevention or healing. *Id.* at 30-31 (emphasis supplied). Thus, a facility may provide necessary treatment and services to ensure the prevention or healing of pressure sores, yet still be confronted with a negative outcome. In that instance, the facility may put forward clinical evidence to show that the outcome was unavoidable.

CMS makes a prima facie case that a facility is out of compliance with 42 C.F.R. § 483.25(c)(2) when residents manifest new ulcers or old ulcers become worse.

Resident 3[10] was admitted to Petitioner's facility on September 30, 2002, and she was nearly 89 at the time of the January survey. P. Ex. 6, at 4, 334-35. Resident 3 had a history of urosepsis, a decubitus ulcer on her left heel that had been infected with MRSA[11], chronic obstructive pulmonary disease (COPD) with pneumonia, chronic UTIs with a urinary catheter, Alzheimer's dementia, chronic anemia, chronic constipation, congestive heart failure, dysphasia, anxiety, and a CVA, among other conditions. P. Ex. 6, at 4, 64-65. Resident 3 was admitted on September 30, 2002, with a decubitus ulcer on her left heel and an order to use bilateral heel protectors. P. Ex. 6, at 149.

According to Petitioner's exhibit list submitted with its post hearing brief, part I of Resident 3's clinical record was provided. Two different care plans were located in P. Ex. 6. Neither clearly indicates when the care plan was developed however both indicate that Petitioner recognized Resident 3 was at risk for skin breakdown around December 19, 2002. One plan has a target date of June 10, 2003, for resolution, and the other a date of August 26, 2003. Interventions listed on both are similar and include turning the resident every two hours and use of heel protectors at all times.[12] P. Ex. 6, at 82-83, 89. Nurses notes for the period January 10 through January 24, 2003 show that heel protectors were

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[10] In its response brief, CMS refers to this Resident as Resident 2. CMS Reply at 21-22. The SOD and the surveyor's notes refer to her as Resident 3, however.

[11] Methicillin Resistant Staphylococcus Aureus. A penicillin resistant staph infection. Sometimes referred to as a "super bug."

[12] The plan with a target date of August 26, 2003, actually provides that the resident be turned every "2 hours in bed and in gerichair" without explanation for how turning in a geri-chair (a wheeled chair) might be accomplished.

applied to both feet on January 10 at 11:55 a.m. There is no other reference to heel protectors during the period. However, notes from January 16 and 17, indicate that "heels floated." From January 10 through 16, 2003, nurse's notes indicate that Resident 3's left heel was cleaned and dressed. Notes from January 17 through 24, 2003, show that Petitioner's staff was cleaning and dressing both heels. P. Ex. 6 at 141-42. A treatment record for January 2003 shows the intervention of "heel protectors" typed, but then a hand-written entry "float heels" with initials indicating compliance for every day except the weekends.[13] P. Ex. 6 at 354. The January 2003 treatment record also shows that the resident was being treated for Stage I ulcers on both heels as of January 13, 2003. P. Ex. 6, at 355.

A physician's order from September 30, 2002, required that the resident be turned every two hours and that she have heel protectors. P. Ex. 6, at 35, 44, 54, 58. A physician's order dated January 13, 2003, shows that the resident had a Stage I ulcer on both the right and left heel. P. Ex. 6, at 57.

Petitioner agrees that Resident 3 was admitted on September 30, 2002, with ulcers on "her heel, toe, and sacral area." Petitioner does not dispute that as of January 13, 2003, its records reflect that the resident had ulcers on both heels. Thus, CMS has clearly made a prima facie showing.

Petitioner does not dispute that the surveyor observed this resident on January 23, 2003, at 8:35 a.m., 10:45 a.m., 11:55 a.m., 12:45 a.m., and 4:20 p.m., and on January 24, 2003 at 8:20 a.m., 12:40 a.m., and 3:50 p.m. The surveyor recorded that she concluded that the resident was not being turned and that she was not wearing heel protectors as required by the resident's care plan. CMS Ex. 1, at 5-6; CMS Ex. 12, at 4-5. Petitioner argues that Resident 3 was being properly turned based on the testimony of the resident's treating physician. Petitioner further argues that the surveyor's findings "make no mention of a lack of heel protectors." P. Brief at 11. Petitioner's argument is without merit, as both the Petitioner's failure to turn Resident 3 and to ensure she had heel protectors is clearly alleged in the SOD. CMS Ex. 1, at 5. Petitioner's reliance upon the testimony of the resident's treating physician and its medical director is also misplaced, as Dr. Tilley clearly limited his testimony. Dr. Tilley testified he always felt the resident was turned properly, but he specifically noted that he is not there all the time. Tr. 570. He testified that his conclusion that she was being turned properly was based upon the fact that an ulcer in the lower back area had healed. Tr. 570. Dr. Tilley's surmise is not sufficiently weighty to overcome the direct observation of the surveyor.

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[13] My official government calendar for 2003 reflects that January 4, 5, 11, 12, 18, 19, 25, and 26, were either a Saturday or Sunday.

Petitioner argues (P. Brief at 12) that the resident's pressure sores were healing citing a weekly skin report for January 28 through 31, 2003, admitted as P. Ex. 6, at 356-57. Petitioner did not call the RN who completed the form to testify as to the meaning of her entries, which might have been helpful to clarify whether what she characterized as a "skin rash" on the resident's left buttock on January 28 and 29, was actually a Stage I pressure sore, as her entries for January 30 and 31, 2003, show it was. P. Ex. 6, at 356. If my reading of the record is correct, and I believe it is, the weekly skin report shows the resident developed a new Stage I pressure sore on her left buttock around January 28, 2003. Further, the report related to the sores on the left and right heels indicates progress was characterized by the nurse as "good," but there is no objective evidence on the face of the report that the Stage I ulcers had changed at all, they were Stage I on January 28 and Stage I on January 31 (P. Ex. 6, at 357), just as they were Stage I on January 13, 2003 (P. Ex. 6, at 57), and just as the ulcer on the left heel was Stage I at the time of admission on September 30, 2002. P. Ex. 6, at 149. In fact, Petitioner's evidence shows the Stage I on the left heel continued as of April 24, 2003, when Dr. Tilley issued another order related to its treatment. P. Ex. 6, at 37. Thus, I find little credibility in Petitioner's argument that the ulcers were healing prior to the survey, or that healing is sufficient evidence upon which to infer that Petitioner was complying with physician orders and the care plan.

Thus, I conclude that Petitioner has not rebutted CMS's prima facie case. The evidence shows that Petitioner was not complying with the orders of Resident 3's physician or its own care plan for pressure ulcers. Petitioner has not shown it did all that was necessary to treat existing sores and prevent future sores. Given that there is evidence that a pressure sore on the lower back resolved sometime after her admission, and that the ulcer on the right heel resolved sometime after the hearing, Petitioner has also failed to show that the development of new ulcers or the failure to resolve existing ulcers was unavoidable. Although the surveyors and/or CMS assigned this violation a scope and severity level of D, I have no difficulty concluding that this deficiency caused continuing actual harm to the resident. Although Dr. Tilley testified that this resident was vegetative (Tr. 570), the record does not show that she was not subject to the pain associated with continuing pressure sores that were continuing or not promptly resolved.

The example from the March 2003 survey, Resident 6 (Resident 5 at the January survey), is more egregious. I discussed her history in connection with finding Petitioner violated 42 C.F.R. § 483.25 by failing to timely obtain a laboratory test to identify that the antibiotic she was being given was totally ineffective to resolve her UTI. A brief summary of her history is helpful. Resident 5/6 was nearly 82 years old when admitted to Petitioner's facility on October 22, 2002. An MDS with an assessment reference date of October 29, 2002 shows that she had two Stage II and one Stage III pressure ulcers at admission to Petitioner's facility. She required extensive assistance with most activities of daily living; had limited ROM on one side in her arm, hand, leg, and foot; she used a wheelchair pushed by someone for locomotion; she used bed rails for bed mobility and

had to be lifted for transfers; and she had an indwelling catheter. P. Ex. 8, at 431-41. Her November 4, 2002 MDS showed little or no change in Resident 5/6's status. P. Ex. 8, at 423-30. The last MDS in the record prior to the January 2003 survey was a quarterly review with an assessment reference date of January 9, 2003. This MDS showed a decline in functional status, in that she had become totally dependent on staff for locomotion, dressing, toileting, personal hygiene and bathing. However, there was also improvement to the extent that she was reported to have only two Stage II ulcers, with one ulcer resolved or cured in the last 90 days. She was also not reported to be on any antibiotic during the assessment period (seven days prior to January 9, 2003). P. Ex. 8, at 414-22.

The surveyors allege that Petitioner violated 42 C.F.R. § 483.25(c) because Petitioner failed to ensure that Resident 5/6 received care and treatment to prevent decline of a pressure sore from Stage II to Stage IV, as reflected by a physician's progress note dated February 11, 2003. The surveyors point to additional evidence to support their conclusion including that laboratory results showed values not favorable for healing and that there was a lack of documentation that the resident was being provided adequate fluids and nutrition. The surveyors also note that the resident had to be transferred to the hospital for wound treatment on March 11, 2003. CMS Ex. 23, at 4.

Petitioner argues, based upon Dr. Tilley's testimony, that Resident 5/6's ulcers "remained stable until January or February" but concedes that "the decubiti worsened" adding that "wound care became more aggressive." P. Brief at 23-24. Petitioner's concession is sufficient for a prima facie showing to the extent that the concession is an existing ulcer worsened while the resident was under Petitioner's care. Petitioner's defense is that Petitioner did all it could and that the worsening was unavoidable. P. Brief at 24-26.

Resident 5/6's admission MDS, with an assessment reference date of October 29, 2002 shows that she had two Stage II and one Stage III pressure ulcers at admission to Petitioner's facility. P. Ex. 8, at 437. Her admission nursing assessment dated October 22, 2002, shows that she had a Stage II ulcer on the left buttock measuring 1 by 1 centimeters (cm), a Stage II ulcer on her coccyx measuring ½ by ½ cm, and a Stage III ulcer measuring 2 by 1 cm on her left ankle with black eschar (dead tissue) in the center. P. Ex. 8, at 308. A pressure ulcer/wound survey dated October 22, 2002 shows the two Stage II ulcers on the left buttock and coccyx but characterizes the ulcer on the left ankle as Stage II rather than Stage III. P. Ex. 8, at 129. A wound assessment dated December 30, 2002, shows that the coccyx wound was Stage II, the left ankle wound was Stage I, and the left buttock wound was not shown. P. Ex. 8, at 126. I infer from this document that the left buttock wound resolved.

Wound assessments dated January 23, 2003 show that the coccyx wound was rated as worsening to a Stage III ulcer; an excoriation is noted on the right buttock; and the assessments note that new treatment orders were received for both problems. P. Ex. 8, at 127-28. Weekly skin reports from January 28, 2003 through February 5, 2003 show the coccyx ulcer as a Stage III with no change in its size of 2.5 by 2 cm and .5 cm deep, with slight odor, and small amounts of purulent drainage. P. Ex. 8, at 130-31. A weekly skin report dated February 14, 2003, shows the coccyx wound has worsened and measured 2.5 by 2 cm and 1.5 cm deep with red colored slough, slight odor, and a small amount of purulent drainage. A report dated March 3, 2003 shows further worsening to a Stage IV ulcer measuring 5 by 4.5 cm and 3 cm deep with slough, foul odor, and copious amounts of purulent drainage. CMS Ex. 29, at 35; P. Ex. 8, at 8. A report dated March 10, 2003, shows the Stage IV coccyx wound had increased in size to 6 by 5 cm, 3 cm deep. CMS Ex. 29, at 36; P. Ex. 8, at 9.

Weekly skin reports from January 28, 2003 through March 10, 2003 show a Stage II ulcer on the residents left ankle. From January 28, 2003 through February 7, 2003 the ulcer was measured as 2.5 by 2.5 cm, with a small amount of purulent drainage, and was reported to have a slight odor on February 4 and 5, 2003. On February 12, 2003, the ulcer was reported to have decreased to 2 by 1 cm with no drainage. A report dated March 10, 2003 shows that the wound had further improved in size to 1.5 by .5 cm with no drainage. P. Ex. 8, at 132-33, 138-39.

Weekly skin reports from January 28, 2003 through March 3, 2003, show that the resident developed a Stage I ulcer on each buttock that were reported to have resolved on March 3, 2003. P. Ex. 8, 134-36. A weekly skin report dated February 14, 2003, shows a new Stage I sore on the resident's left lower leg below the knee and above the ankle. Reports dated February 26, March 3, and March 10, 2003, show the ulcer had worsened to a Stage II ulcer with a small amount of purulent drainage noted on February 26 and March 3. P. Ex. 8, at 140.

Petitioner submitted a plan of care reflecting the resident was at risk for skin breakdown, and noted that she had a decubitus ulcer on her right ankle. The care plan indicates an ulcer origin date of January 15, 2003. I see no reference to either the coccyx ulcer or the left ankle ulcer that Petitioner's records reflect were clearly present at the time. In the 593 pages of clinical records for this resident that Petitioner submitted for me to consider and the 269 pages CMS submitted related to this resident and deficiency, I have found no reference to a right ankle ulcer on or about January 15, 2003.
Various interventions were listed on the care plan. The resident was to be turned every two hours, skin tears were to be treated per protocol (which is not specified), the treating physician was to be notified of new decubitus ulcers, ulcers were to be treated per order or protocol (unspecified), and the resident was to be checked for incontinence every 2 hours with perineal care done as necessary and every shift. P. Ex. 8, at 3.

A care plan dated January 23, 2003, mentions only a Stage III coccyx decubitus ulcer with interventions of a wet to dry dressing, and preprinted interventions of evaluation of effectiveness, revise as needed, consult with physical therapy, encourage proper nutrition to help healing, and consult with the registered dietician. P. Ex. 8, at 6. A February 13, 2003 care plan shows that the coccyx ulcer had worsened to a Stage IV and specified cleaning, application of wet to dry dressing, and covering with poly skin daily, but the preprinted interventions are not changed from the January 23, 2003 care plan. P. Ex. 8, at 7. A care plan dated March 10, 2003, refers to the Stage IV coccyx ulcer, lists as a goal that "aggressive wound care" be performed. The intervention added to those preprinted on the form specifies how the wound is to be cleaned, packed, and covered. P. Ex. 8, at 10. An undated care plan refers to a Stage II decubitus ulcer on the resident's left lower extremity and includes an intervention regarding cleaning and covering the wound in addition to those preprinted on the form. P. Ex. 8, at 11. The care plan dated January 23, 2003, refers to an excoriation on the resident's right buttock. The interventions added to the form listed Silvadene (but that was stricken), "TAO + cover," and reevaluate in five days. P. Ex. 8, at 12.

The 593 pages of clinical records Petitioner submitted for this resident show that Dr. Tilley issued many orders for the treatment of this resident and her multiple ulcers, some of which were present upon her admission, some of which developed while she was in the care of Petitioner, some of which resolved, and some of which worsened during her stay with Petitioner. There is no dispute that Resident 5/6 was finally transferred to the hospital on March 11, 2003 due to the worsening of her coccyx wound and its infection. Tr. 575; P. Brief at 25.[14] Petitioner argues that it did all it could with this difficult patient, and that it was impeded by her overall condition and the family's refusal to permit a feeding tube to be re-established. P. Brief at 23-26. Resident 5/6's treating physician and the medical director for Petitioner, Dr. Tilley, testified that he believed he and Petitioner did all that could be done. Tr. 571-79.

The CMS expert, Dr. Osterweil, testified that in his opinion, Petitioner did not do all that was necessary. Dr. Osterweil testified as to several interventions Petitioner might have used or recommended to Dr. Tilley. He opined that Petitioner's records do not reflect either adequate hydration or nutrition to prevent worsening of the coccyx pressure ulcer. He also identified that there was a high potential for cross-contamination between the sore and the resident's chronic UTI. Tr. 384-405.

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[14] Petitioner's statement that its documents show improvement in the Resident's ulcer from late January 2003 until March 10, 2003, is clearly inconsistent with its records and the testimony of Dr. Tilley. Tr. 574-75.

CMS has made a prima facie showing of a violation of 42 C.F.R. § 483.25(c). Petitioner has failed to show by a preponderance of the evidence that it did all that was necessary to prevent the development of new sores and promote the healing or prevent the worsening of existing sores. The fact that some ulcers resolved or improved during the period late January to March 10, 2003, is inconsistent with Petitioner's position that worsening was unavoidable. Of course, it is consistent to some extent with Petitioner's position that the resident was receiving adequate nutrition and hydration to promote healing. During the period the coccyx wound worsened, the left ankle wound improved, ulcers on both buttocks developed and then resolved, and an ulcer on the left lower leg developed and worsened. My review of the resident's clinical record provided by Petitioner reveals that its record keeping of application of interventions is spotty at best and not detailed when present, and records related to hydration and nutrition are not completely annotated. Whether Dr. Tilley's orders were appropriate is not the issue before me, rather my focus is upon Petitioner and whether the preponderance of the evidence is that Petitioner did all that was necessary within the parameters of Dr. Tilley's orders to prevent or resolve the resident's ulcers. I do not find that Petitioner has met its burden.

Accordingly, I conclude that Petitioner was in violation of 42 C.F.R. § 483.25(c) at the time of both the January and March 2003 surveys. I conclude that the violation amounted to actual harm due to the failure to prevent new pressure ulcers, the failure to resolve existing ulcers, and the worsening of existing ulcers.

5. Petitioner violated 42 C.F.R. § 483.25(h)(1) (Tag F 323).

The quality of care regulation includes a specific requirement regarding accident hazards. The regulation requires that a facility "ensure that the resident environment remains as free of accident hazards as is possible." 42 C.F.R. § 483.25(h)(1).

The SOD for the January survey records that on January 22, 2003, the surveyor was conducting an environmental tour of the facility and in a shower room she observed a pair of scissors, a gallon container of uric acid eliminator, and a pool of water on the floor near the shower stall. CMS Ex. 1, at 7. CMS alleges the items, which were not under the control of staff, and the pool of water constituted accident hazards. Petitioner has not denied the presence of the items or the pool of water. Petitioner points out that the allegation is in error to the extent it asserts the items and the water were observed in a common shower on the 100 hall, as there is no common shower on that hall. Petitioner does not deny that the items and water were observed by the surveyor in some other common shower, perhaps on the 400 hall. P. Brief at 11-12. In addition to noting the questionable accuracy of the location, Petitioner argues that the regulation does not require it to guarantee that no accidents ever occur, that the uric acid eliminator was the property of a resident, staff are only provided blunt-ended scissors, and the pool of water on the floor was likely there because a resident recently showered.

An appellate panel of the DAB has recently held that CMS makes a prima facie case of noncompliance with the regulation where it "show[s] that a product which potentially was and is believed to be hazardous was left unattended within reach of extremely vulnerable residents." *Alden Town Manor Rehabilitation & HCC*, DAB No. 2054, at 7 (2006). Citing its prior decision in *Maine Veterans' Home - Scarborough*, DAB No. 1975 (2005) the Board stated:

> A prima facie case of noncompliance with this requirement would correspondingly be made out if CMS presented evidence to show that a potentially dangerous condition existed in the facility which was identified or foreseeable but was not removed and that the facility did not take appropriate steps to protect residents from that danger. If CMS set out such evidence, the burden shifts to the facility to rebut the evidence or present other evidence showing substantial compliance.

Alden Town Manor Rehabilitation & HCC, DAB No. 2054, at 7-8 (2006). By these decisions the Board has made clear that when CMS alleges a violation of either subsection of 42 C.F.R. § 483.25(h), CMS need show only the existence of a "potentially dangerous condition" of which the Petitioner was aware or should have been aware in order to put Petitioner to its proof to rebut the CMS evidence or to show substantial compliance.

Regarding the scissors, the evidence does not clearly establish whether they were blunt-end scissors or had pointed or sharp blades or were otherwise capable of causing harm to a vulnerable resident. However, the mere presence of the scissors is sufficient to satisfy the CMS burden to make a prima facie showing. Regarding the uric acid eliminator, Petitioner did not object to the admission of CMS Ex. 8, which includes literature regarding a specific type of uric acid eliminator. The material safety data sheet shows the substance is harmful if swallowed and it is an eye and skin irritant. CMS Ex. 8, at 3. Under the standard adopted by the Board, CMS need only show that the container was present, not its contents or whether it constituted an actual hazard in order to satisfy its burden to make a prima facie showing. Petitioner has the burden to show no hazard was posed, that it took reasonable steps to avoid the hazard, or that it was not reasonable for it to know of the hazard. The pool of water was present, and, whether it was a slip hazard or a drowning hazard, the fact it was present is sufficient to put Petitioner to its proof.

Petitioner contends that all facility-provided scissors are blunt-end. Petitioner Brief at 13. This does not eliminate the possibility that sharp scissors belonging to a resident may have been present. Even if the scissors were blunt-ended, however, CMS contends that Petitioner has failed to show that they could not be used to inflict more than minimal harm if used by a resident to poke or stab him or herself or another resident. CMS Brief at 24. Petitioner has also not shown that blunt-end scissors could not be used for cutting fingers, ears, noses, or otherwise causing wounds.

Petitioner's argument that the uric acid eliminator belonged to a resident (P. Brief at 13) is no defense. Ms. Cain testified that the substance is not provided by the facility. Tr. 661. Petitioner argues, based on Ms. Cain's testimony, that the substance must have been the property of a resident and left there by the resident. P. Brief at 13. Petitioner never explains how this relieves it of the responsibility to ensure its residents are not subject to the accident hazard such a substance poses to its vulnerable residents. I reject Petitioner's suggestion that its regulatory obligation to permit residents to have personal property supercedes its obligation to ensure a safe environment as free as possible of accident hazards. Petitioner has not shown that the substance was not hazardous, that it took reasonable steps to ensure its presence in the facility presented no hazard or to protect its residents from the hazard if it could not be eliminated, or that it was unreasonable for Petitioner to know the substance was present or that it posed a hazard.

The same analysis must be applied to the pool of water in the shower room. Petitioner does not deny it was present. It is common knowledge that water on the floor poses a slip hazard. Petitioner's argument that the pool was caused by a resident's recent shower is no defense. Petitioner has not shown the water did not pose a hazard, that it took reasonable steps to eliminate or mitigate the hazard, or that it was not reasonable for it to know the pool of water was present or that it posed a hazard.

Accordingly, I conclude that Petitioner violated 42 C.F.R. § 483.25(h)(1). No violation of this regulation was alleged by the survey completed on March 12, 2003, and I presume Petitioner corrected the deficiency by the date of that survey.

6. Petitioner violated 42 C.F.R. § 483.25(h)(2) (Tag F 324).

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 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 F 324; *Woodstock Care Center*, DAB No. 1726, at 4.

The surveyors allege in the January SOD that on December 28, 2002, Resident 4 was found outside the facility on an asphalt surface with her head bleeding. The surveyors concluded that the resident exited a facility door in her wheel chair, toppled down a set of wooden steps and fell onto the asphalt. The surveyors allege that Petitioner failed to provide the supervision necessary to prevent the accident. CMS Ex. 1, at 7-8.

Petitioner does not deny that Resident 4 fell on December 28, 2002, and injured her forehead. Nurse's notes dated December 28, 2002, at 3:30 p.m, show that the resident was found on the ground outside a facility door at the back of the building. Resident 4 was found lying on her right side, strapped in her wheelchair by a soft-belt. There was a small pool of blood under her head on the asphalt but she was conscious and talking. P. Ex. 7, at 489.

In *Alden*, the Board defined a prima facie showing of a violation of 42 C.F.R. § 483.25(h)(2) as follows:

> A prima facie case of noncompliance with this requirement would correspondingly be made if CMS presented evidence to show that a facility failed to provide adequate supervision and/or assistance devices to reduce the foreseeable risk of an accident to the highest practicable degree. If CMS set out such evidence, the burden shifts to the facility to rebut the evidence or present other evidence showing substantial compliance.

Alden, at 10-11. Thus, the required elements of the CMS prima facie case as recently defined are: (1) CMS must show the facility failed to provide adequate supervision and or assistance devices to reduce to the highest practicable degree a foreseeable risk of an accident; and (2) CMS must show that there was a foreseeable risk of an accident. The occurrence of an accident may or may not be evidence of the adequacy of the supervision or assistance device. *Alden,* at 5-6. I suppose the occurrence of an accident may or may not be evidence that there was a potential risk for an accident also. In this case, I conclude that CMS has satisfied the heavy burden imposed by the Board's decision in *Alden*. There is no question the accident occurred and, as the evidence discussed hereafter shows, it was foreseeable. Further, the evidence, taken as a whole, shows that Petitioner's provision of supervision and assistance devices was not adequate. Thus, the burden "shifted" as contemplated by the Board in *Alden*, and Petitioner had to rebut the CMS case or otherwise show it was in substantial compliance. Petitioner failed to satisfy its burden.

Resident 4's MDS, with an assessment reference date of December 19, 2002, shows that she was a 92-year-old female. The MDS shows that her ADL status was affected by a hip fracture, depression and allergies. The MDS also shows that she had both short and long-term memory deficits. She was moderately impaired for decision-making, she had periods of restlessness, and her mental function varied over the course of a day. She required limited to extensive assistance with all activities of daily living. She required assistance maintaining her balance standing or sitting. A wheelchair was her primary means of locomotion and she could wheel herself. She was incontinent of both bowel and bladder. She was assessed as having fallen within the past 31 to 180 days and she had a hip fracture and another fracture in the last 180 days. She was reported as requiring use of full bed rails and a trunk restraint. P. Ex. 7, at 347-55. An undated diagnosis form includes diagnoses of syncope, mini-strokes, atrial fibrillation, short-term memory loss, UTI, incontinence, osteoarthritis, recurrent bowel obstructions, history of fracture of the spine, femur and wrist, dehydration, dysphasia, and anorexia. P. Ex. 7, at 422.

Resident 4 was consistently assessed by Petitioner as being at risk for falls from February through December 2002. P. Ex. 7, at 45, 445, 451; CMS Ex. 13, at 41-42. A wandering/elopement risk assessment dated November 18, 2002, indicates that risk existed based on senile dementia, cognitive impairment, history of previous wandering, she self-propelled her wheel chair at times, she performed repetitive tasks, talked of leaving the facility, had a history of panic attacks, and a lack of safety awareness. CMS Ex. 13, at 42; P. Ex. 7, at 637-38. I find nothing in the clinical records of Resident 4 that Petitioner care planned interventions to minimize the risk of accidents secondary to the residents foreseeable attempts to leave the facility, i.e., elope.

CMS offered Petitioner's records as evidence which show that Resident 4 suffered falls on April 30, 2002 (two falls in room and bathroom), May 3, 2002 (bathroom), September 1, 2002 (activity room), September 21, 2002 (room), November 16, 2002 (escaped through kitchen door and fell), November 30, 2002 (bathroom), December 28, 2002 (outside the back door to the laundry room), January 6, 2003 (room), January 7, 2003 (room), and January 17, 2003 (room). CMS Ex. 13, at 26-36. When Resident 4 fell on September 21, 2002, she suffered a fractured right wrist and hip. CMS Ex. 13, at 30. Other falls involved abrasions, contusions, or no injuries at all. Petitioner provided additional documents from the resident's clinical record reflecting these falls. P. Ex. 7, at 34, 437, 439, 489-91, 514, 538, 594, 595, and 634.

Petitioner's records reflect fall prevention interventions following the September fall that resulted in a fractured hip and wrist. On September 26, 2002, when Resident 4 returned from the hospital following treatment for her hip and wrist fractures resulting from the September 21, 2002 fall, Dr. Tilley ordered use of a soft belt while Resident 4 was up in her wheelchair and a roll belt while she was in bed. CMS Ex. 13, at 37. Nurse's notes indicate a soft roll belt was being used with both side rails up after Resident 4 returned from the hospital on September 26, 2002. P. Ex. 7, at 594. In an assessment dated September 27, 2002, the occupational therapist recommended that the following interventions be applied: 1) side rails up and roll belt while in bed; and 2) soft belt when up in wheelchair. CMS Ex. 13, at 39A. On October 14, 2002, Dr. Tilley renewed the order to use a lap belt while the resident was in her wheelchair and a roll belt while she was in bed to prevent falls. P. Ex. 7, at 384, 435; CMS 13, at 38. A fall risk care plan dated October 15, 2002, identified Resident 4 as at risk due to poor eye sight, her requirement of extensive assistance, fracture of hip and wrist, and her pain medications. Interventions included keeping call bell in reach and encouraging use; keeping bed at lowest level; keeping bed rails up; keeping room clutter free; keeping room well lighted; monitoring, supervising, and assisting all transfers; obtaining assistive devices as indicated; assessing and evaluating history of previous falls; assessment by occupational therapy; additional approaches as needed; and assist with ADLs. CMS Ex. 13, at 128. A care plan dated December 18, 2002, recognizes that Resident 4 "falls occasionally if unsteady when ambulating" and the intervention is that she be restrained in chair if not ambulating. CMS Ex. 13, at 136; P. Ex. 7, at 449. Resident 4's clinical record shows that she was capable of releasing or slipping under the belt in her wheelchair and bed. P. Ex. 7, at 514, 541; CMS 13, at 32, 33, 35, 36.

In the clinical records provided to me, the first indication of the resident's tendency to wander and her desire to elope was in October 2002. A nurse's note dated October 23, 2002, states that a certified nurse assistant (CNA) reported that Resident 4 was more confused, trying to find her husband and trying to get out of the facility. The nurse noted that she would continue to monitor. P. Ex. 7, at 584. An undated care plan shows that the resident was assessed as at risk for wandering due to cognitive impairment and her ability

to self-ambulate in her wheelchair. Interventions were to monitor the resident's baseline mental status, document any changes, and notify the director of nursing (DON) and physician; do laboratory testing as ordered; use behavior monitoring form; contact DON and administrator if resident is not "redirectable;" institute an updated care plan if resident deemed a wanderer. CMS Ex. 13, at 126. This care plan did not address the risk for elopement.

An incident/accident report dated November 16, 2002, shows that at about 5:00 p.m. on that date the resident "wandered" through the kitchen and "tried to escape." CMS Ex. 13, at 31. A nurse's noted dated November 16, 2002, at 5:00 p.m., provides more detail. According to the note, Resident 4 was found on the ground outside the kitchen door with her wheelchair turned on its right side. Resident 4 released her soft chair restraint at the time of the fall. She suffered a bruise on her forehead. P. Ex. 7, at 541. A wandering behavior care plan dated November 16, 2002, refers to one episode of wandering behavior. Interventions are to ensure the resident is dressed appropriately; provide well fitting shoes; avoid restraints; use soft belt while in wheelchair and roll belt while in bed with side rails; use consistency in placement of objects; encourage regular exercise; monitor whereabouts on a regular schedule; one-on-one observation if necessary; and observe for nonverbal signs. CMS 13, at 129. This care plan does not specifically address elopement. A nurse's note dated November 25, 2002, included the comments that the resident was at risk for injury due to wandering behavior and stated that her whereabouts should be monitored on a regular schedule, one-on-one observation should be used if necessary, and she should be observed for verbal cues. CMS Ex. 7, at 521-22. Nurse progress notes dated December 2 and 24, 2002, include the entry that a problem behavior for the resident was her attempting to leave the facility. P. Ex. 7, at 509, 619. A nurse's daily charting form dated December 10, 2002, shows that the resident attempted to leave the facility that morning. P. Ex. 7, at 487. A care plan dated December 18, 2002, indicates that the resident wanders into unsafe areas, and the planned intervention is to check her whereabouts frequently. CMS Ex. 13, at 136; P. Ex. 7, at 449. Nurse's notes show that on December 21, 2002, Resident 4 made two attempts to leave the facility through the activity room doors. CMS Ex. 13, at 48.

There is evidence that Petitioner initiated monitoring of Resident 4's activities every half-hour beginning on November 17, 2002, and continuing to January 2, 2003, the day prior to her transfer to Petitioner's secure unit. CMS Ex. 13, at 65-113. On January 3, 2003, the monitoring sheet is not initialed from 7:00 a.m. through 2:30 p.m., but reflects the transfer at 4:30 p.m. CMS Ex. 13, at 114. A nurse's note dated January 3, 2003, at 4:20 p.m., reports that Resident 4 was moved to the secure unit due to continued attempts to exit the facility. CMS Ex. 13, at 50.

The resident was reassessed on January 3, 2003, whether before or after entering the secured unit is not clear, and the same interventions, i.e., side rails and roll belt in bed, and soft belt in wheelchair, were continued. CMS Ex. 13, at 40. In the secure unit the resident fell on January 6, January 7, and January 17, 2003, and it was noted that the she was able to release the restraint and apparently fell when attempting to transfer herself without assistance. CMS Ex. 13, at 32, 35, 36. A nurse's progress note dated January 10, 2003, notes Resident 4 fell three times during the past week in the secure unit even with restraints. P. Ex. 7, at 616.

Resident 4 was clearly at risk for falls and this was clearly known to Petitioner. Despite Petitioner's interventions, the resident continued to fall. Petitioner's staff knew or should have known not later than October 23, 2002, when a CNA reported same to a nurse, that Resident 4 was wandering and trying to get out of the facility. Although there is evidence, Petitioner care planned to address the wandering behavior, I see no evidence that Petitioner ever addressed the elopement risk and the risk for accidental harm related to elopement. On November 16, 2002, the resident clearly attempted to elope and Petitioner did nothing to address that risk. Petitioner cannot argue that after that date there was not a foreseeable risk the resident would try to leave again. Petitioner's staff clearly recognized the risk. Petitioner's records show that twice on December 21, 2002, the resident tried to leave through the activity room door. On December 28, 2002, the resident fell out of the laundry room door, whether she was trying to elope is not clear, but her intent is not important. What is clear is that she was not supposed to be going out of the laundry door and the risk of harm associated with such an exit from the facility was proven by the accident she had, i.e., tipping over her wheelchair and crashing her head into the asphalt pavement.

The evidence clearly shows that Petitioner's interventions to deal with the resident's falls, her wandering, and her exit seeking behavior, were not adequate to prevent accidental injury, not once but repeatedly. Once CMS has established a prima facie case of non-compliance, the burden then shifts to Petitioner to demonstrate that it did what was reasonable to protect this vulnerable resident. Petitioner has not satisfied its burden. Despite continued falls and attempted exits, the record does not show that Petitioner attempted to use interventions such as bed and chair alarms, exit alarms, or one-on-one observation.[15]

I conclude that Petitioner violated 42 C.F.R. § 483.25(h)(2).

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[15] Although mentioned as an intervention, there is no evidence it was ever done.

7. The remaining deficiencies alleged based on the March 2003 survey are without merit.

a. Petitioner did not violate 42 C.F.R. § 483.13(c) (Tag F 224).

The regulation requires that a facility "develop and implement written policies and procedures that prohibit mistreatment, neglect, and abuse of residents and misappropriation of resident property." 42 C.F.R. § 483.13(c). Subsection (1) of the regulation specifies that the facility must: (a) "[n]ot use verbal, mental, sexual, or physical abuse, corporal punishment, or involuntary seclusion;" (b) not employ people who have been convicted of abusing, neglecting or mistreating residents or that have been listed in the nurse aide registry for abuse, neglect, mistreatment, or misappropriation; and (c) report any action by a court against an employee that indicates unfitness to be a nurse aide or a member of a facility staff.

The surveyors for the survey ended on March 12, 2003, allege in the SOD that Petitioner violated the regulation because a newly hired licensed practical nurse (LPN) was not properly oriented before beginning work on Petitioner's secure unit. The surveyors alleged specifically that "the facility failed to follow policies and procedures that prohibited the neglect of Resident 1," because Petitioner failed to ensure the new LPN was properly oriented. CMS Ex. 23, at 1.

The specific failures of the LPN that are alleged to amount to neglect are not readily apparent from this poorly drafted allegation. The surveyors allege that Resident 1 was admitted to the facility on February 5, 2003, with diagnoses that included paranoid schizophrenia, senile dementia, depression, and hypertension. On February 8 and 9, 2003, she was suffering from delusions and hallucinations and manifesting other erratic behavior. She attacked a CNA who attempted to assist her, closing him in her bathroom at around 2:25 a.m. The CNA reported hearing a noise and upon exiting the bathroom, found the resident on the floor. The LPN entered at some point and also saw the resident on the floor. When the CNA attempted to assist the resident, she attacked him again and the LPN instructed the CNA to leave the room. The surveyors found nurses notes that show that the resident was assessed as having a cut behind the right ear and a cut on a finger on the right hand. CMS Ex. 23, at 1-3.

The surveyors allege the following errors as violations, attributable according to the surveyors, to the LPN:

> (1) There was no documentation that the resident was assessed again between 2:25 a.m. and 8:00 a.m. on February 3, 2003, at which time she complained of pain in her arm which was subsequently determined to be a fracture (CMS Ex. 23, at 2, 3);

(2) The incident report completed on February 9, 2003, at 8:45 a.m., does not show notification of the physician (CMS Ex. 23, at 2);

(3) No vital signs were recorded at 2:25 a.m. on February 9, 2003, and vital signs are recorded only one time in the next 24 hours (CMS Ex. 23, at 3).

The surveyors assume that the resident fell about 2:25 a.m. on February 9, 2003. The surveyors imply, without specifically alleging, that a cut behind the resident's right ear and a cut on a finger on the right hand were due to the fall. The surveyors also assume that the wrist fracture identified around 8:00 a.m. on February 9, 2003, was the result of the assumed fall earlier that morning. Based on these assumed facts, the surveyors allege that the LPN violated facility policy because he did not do another assessment and document monitoring of the resident between 2:25 a.m. and 8:00 a.m. The surveyors also allege that the LPN violated Petitioner's policy by not notifying the resident's physician. CMS Ex. 23, at 2-3. The surveyors attribute the alleged violation to Petitioner because Petitioner allegedly did not orient the LPN prior to him assuming duties.

My understanding is that CMS is not alleging that Petitioner did not have the policy required by the regulation. In fact, the surveyors cite the existence of the policy. My understanding is that the gist of the allegation is that Petitioner violated the regulation because it failed to implement its policies to prevent neglect and/or abuse, by this alleged one time failure to follow the policy which the surveyors admit Petitioner had. Further, the application of the regulation and Petitioner's policy is triggered in this case by the surveyor's assumption that the resident fell, even though there is no contemporaneous evidence of a fall other than that she was sitting on the floor when observed by the CNA and LPN.[16] CMS Ex. 27, at 6.

Even if I were to conclude that the resident fell as alleged by the surveyors, I would not find this one time violation of Petitioner's neglect/abuse/accident/incident policy as evidence that Petitioner failed to implement the policy required by the regulation. Several facts impact my decision. The LPN was clearly new. The LPN did actually assess the

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[16] CMS expended considerable energy in adducing evidence and arguing in its reply brief that Petitioner failed to do all that was reasonable to prevent the fall. CMS's argument is more akin to arguing that Petitioner failed to supervise and assist or properly assess and care plan than a violation of Tag F 224. The surveyors did not allege that Petitioner failed to properly assess and care plan (42 C.F.R. § 483.20(b) or (k)) or to supervise and assist to prevent accidents (42 C.F.R. § 483.25(h)(2)). Petitioner was not given notice of any such violations identified on the March 2003 survey by the SOD or any State or CMS notices of alleged violations. It is too late at hearing or post hearing for CMS to attempt to amend the SOD to add new alleged violations.

resident -- the resident told him the cut on the ear was a scratch that she caused, she had a slight cut on her finger on her right hand, he checked her ROM and found no broken bones of any type. CMS Ex. 27, at 6-7. The incident was investigated on the morning of February 9, 2003, after it was learned that the resident had a more extensive injury, a possible fracture of her wrist. The evidence shows her treating physician was notified at 8:45 a.m. CMS 27, at 13-14. The evidence shows that despite a delay of approximately six hours between 2:25 a.m. and 8:00 a.m. on February 9, 2003, the omissions of the LPN were quickly corrected by Petitioner's staff and its policy was followed.

I conclude that there was no violation of 42 C.F.R. § 483.13(c) (Tag F 224).

b. CMS failed to make a prima facie case that Petitioner was out of substantial compliance with 42 C.F.R. § 483.25(j) (Tag F 327).

The regulation provides:

> Hydration. The facility must provide each resident with sufficient fluid intake to maintain proper hydration and health.

42 C.F.R. § 483.25(j). The regulation does not specify how a facility is to provide the proper hydration it requires only that a facility provide "sufficient fluid intake." The SOM states that the intent of the regulation is to assure that a resident receives a sufficient amount of fluids based on individual needs to avoid dehydration. Sufficient fluids is defined as a sufficient amount to avoid dehydration. The SOM sets out the investigative protocol for surveyors with regard to hydration, but does not require facilities to monitor resident input and output. SOM App. PP at 109-110.

The surveyors allege that Petitioner failed to ensure that a resident identified as at risk for dehydration was: (1) thoroughly assessed; and (2) "provided sufficient fluids to maintain proper hydration to prevent impactions and the decline of a pressure sore." CMS Ex. 23, at 7. The SOD fails to allege a violation because the surveyors never allege that the resident was dehydrated.

The surveyors attempt to establish this deficiency by showing that Petitioner failed to adequately document that Resident 6[17] received the necessary services to ensure proper fluid intake. For example, the surveyors allege that there was a lack of documented evidence that the resident consumed a dietary liquid supplement, and that the facility failed

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[17] Resident 5 on the January survey and the resident considered under Tag 314 related to her pressure sores.

to consistently monitor and document the resident's fluid intake. The surveyors also point to development of fecal impaction and a decline in the Resident's pressure sores as evidence that Resident 6 was not receiving sufficient hydration. CMS. Ex. 23, at 7-11.

CMS fails to make a prima facie showing that the example of Resident 6 is a violation of 42 C.F.R. § 483.25(j), because CMS presented no evidence that Resident 6 was dehydrated. CMS's reliance upon lack of documentation of intake and output, lack of documentation of consumption of supplements, fecal impaction, and development or worsening of pressure sores, is misplaced. CMS wants me to infer that Resident 6 was not properly hydrated because the facility could not document that Resident 6 was receiving fluids and the resident experienced a health decline in areas that can be related to hydration. However, that is an inference I will not draw given the resident's complicated clinical condition and the fact that CMS points to no evidence that Resident 6 was dehydrated during the March survey.

c. CMS failed to make a prima facie case that Petitioner was out of substantial compliance with 42 C.F.R. § 483.75(j) (Tag F 502).

The regulation requires a facility to "provide or obtain laboratory services to meet the needs of its residents." 42 C.F.R. § 483.75(j). The regulation also provides that the facility is responsible for the quality and timeliness of the services, whether or not the services are provided at the facility. The SOM, under Tag F 502, explains that the intent of this provision is to assure that laboratory services are accurate and timely reported in order to maximize the utility of laboratory test results for prompt diagnosis, treatment, prevention, and assessment.

The surveyors allege in the SOD that Petitioner failed to obtain a monthly physician ordered albumin level for Resident 6 in January of 2003. An albumin level was taken for Resident 6 on February 3, and again on February 19, "because that was the scheduled day for monthly lab draws."CMS Ex. 23, at 12. The surveyors allege in a second example that Resident 2 had a protime level done on February 14 and 19, 2003, twice within a one week period. *Id.*

Neither example alleged by the surveyors suggests that services provided by the laboratory were not timely and accurate. The allegations are that Petitioner's staff failed to obtain and submit a sample for one resident and obtained two samples for another resident. Even if the allegations are true, CMS has failed to make out a prima facie case. There is no allegation and no evidence that when samples were drawn and submitted the laboratory test results were not accurate and timely reported.

8. The amount of the CMP imposed by CMS is reasonable.

I must consider whether the amount of the civil money penalty imposed is reasonable, applying the factors listed in 42 C.F.R. § 488.438(f). *Emerald Oaks*, DAB No. 1800, at 10 (2001); *CarePlex of Silver Spring*, DAB No. 1683, at 16-17 (1999); *Capitol Hill Community Rehabilitation and Specialty Care Center*, DAB No. 1629 (1997). In reaching a decision on the reasonableness of the CMP, I may not look into CMS's internal decision-making process. Instead, I consider whether the evidence presented on the record concerning the relevant regulatory factors supports a finding that the amount of the civil money penalty is at a level reasonably related to an effort to produce corrective action by a provider with the kind of deficiencies found and in light of the other factors involved (financial condition, facility history, and culpability). I am neither bound to defer to CMS's factual assertions, nor free to make a wholly independent choice of remedies without regard to CMS's discretion. *Community Nursing Home*, DAB No. 1807, at 25 (2002); *CarePlex*, DAB No. 1683 (1999), at 11.

The regulations provide that CMP's ranging from $50 to $3000 per day may be imposed to remedy noncompliance that does not rise to the level of immediately jeopardizing the health and safety of a facility's residents. 42 C.F.R. § 488.438(a)(1)(ii). Determination of the actual amount of a penalty within this $50 to $3000 range depends on evidence relating to factors that are described at 42 C.F.R. §§ 488.438(f) and 488.404 (incorporated by reference into 42 C.F.R. § 488.438(f)(3)). These factors may include: the seriousness of a facility's noncompliance; its compliance history; its culpability; and its financial condition.

CMS seeks to impose a CMP of $350 per day from January 24, 2003 through March 11, 2003, and $50 per day from March 12, 2003 through May 22, 2003. CMS also imposed a DPNA effective March 10, 2003. Petitioner denied any deficiencies existed and did not argue that substantial compliance was achieved at any earlier date than alleged by CMS. Thus, the duration of the enforcement remedy has not been placed in issue. Furthermore, the CMP from March 12, 2003 through May 22, 2003, is set at $50, the lowest amount authorized when a basis exists for imposing a CMP. 42 C.F.R. § 488.438(a)(ii). When I have found a violation that provides a basis for the imposition of a CMP, I cannot reduce the CMP imposed by CMS to zero. 42 C.F.R. § 488.438(e). I have found that Petitioner was in violation of 42 C.F.R. § 483.25(c) with regard to treatment of Resident 5/6 for pressure sores during the March survey and there is a basis for the imposition of a CMP. Thus, I can provide Petitioner no remedy regarding the $50 CMP, even if I were inclined to do so. Given the egregious nature of the violation my inclination would be to impose a more significant CMP to encourage regulatory compliance, particular in cases such as that of Resident 5/6.

Thus the CMP that requires my careful consideration is the $350 per day CMP from January 24 through March 11, 2003. In determining whether the amount of the CMP is reasonable, the following factors specified at 42 C.F.R. § 488.438(f) must be considered: (1) the facility's history of non-compliance, including repeated deficiencies; (2) the facility's financial condition; (3) the seriousness of the deficiencies as set forth at 42 C.F.R. § 488.404; and (4) the facility's degree of culpability. Neither party has contended that a penalty amount should be impacted by Petitioner's compliance history or financial condition. There is no evidence showing that Petitioner has a history of noncompliance other than during this survey cycle. Petitioner has not provided any evidence to show that its financial condition precludes it from paying the proposed CMP totaling $20,050. Petitioner was culpable. Petitioner failed to provide the necessary treatment and services to promote healing of Resident 3's pressure sores; failed to prevent Resident 5/6's pressure sores from worsening from Stage II to Stage IV (and was unable to demonstrate that the decline was clinically unavoidable); failed to review and update care plans for three residents to reflect needed care for pressure sores; failed to ensure that the residents' environment remained free of accident hazards by allowing a potentially hazardous chemical and scissors to be left in a common bath area; and failed to provide Resident 4 with adequate supervision and assistance devices to prevent accidents. The sum of $350 per day is modest considering the actual harm caused multiple residents. It comprises slightly more than 10 percent of the maximum allowable CMP amount for non-immediate jeopardy level penalties. The $50 per day CMP is the lowest level the regulations allow, which I may not reduce since I have found that there is a basis for the CMP.

III. Conclusion

For the foregoing reasons, I conclude that there is a basis for the imposition of a CMP and a DPNA. I further conclude that a CMP of $350 per day for the 47 days from January 24, 2003 through March 11, 2003, and $50 per day for the 72 days from March 12, 2003 through May 22, 2003, for a total CMP of $20,050, is reasonable. A DPNA from March 10, 2003 to May 22, 2003 is also reasonable.

/s/ Keith W. Sickendick
Administrative Law Judge