Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	)	
	)	Date: April 21, 2008
The Windsor Place,	)	
(CCN: 25-5257),	)	
Petitioner,	)	Docket No. C-05-98
	)	Decision No. CR1775
v.	)	
	)	
Centers for Medicare & Medicaid Services.	)	

DECISION

Petitioner, The Windsor Place, was in violation of 42 C.F.R. §§ 483.20(b)(2)(ii),[1] 483.25(a)(3), and 483.25(c) from September 24, 2004 through October 27, 2004. Petitioner was in violation of 42 C.F.R. §§ 483.10(n) and 483.13(a) from October 25, 2004 through December 21, 2004. Petitioner returned to substantial compliance with all program participation requirements effective December 22, 2004. 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 34 days from September 24, 2004 through October 27, 2004, and $150 per day for the 55 days from October 28, 2004 through December 21, 2004, for a total CMP of $20,150 is reasonable. A DPNA for the period October 27, 2004 through December 21, 2004, is also reasonable. Withdrawal of Petitioner's authority to conduct a Nurse Aide Training and Competency Evaluation Program (NATCEP) was required during the period October 12, 2004 through October 11, 2006. 42 C.F.R. §§ 483.151 and 483.152.

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

I. Background

Petitioner, located in Columbus, Mississippi, is authorized to participate in Medicare as a skilled nursing facility (SNF) and in the Mississippi Medicaid program as a nursing facility (NF). Petitioner was subject to surveys by the Mississippi State Survey Department (the state agency) completed on September 24, 2004, October 22, 2004, and October 28, 2004.

The Centers for Medicare and Medicaid Services (CMS) notified Petitioner by letter dated October 12, 2004, that based on regulatory violations found during the September 24 survey, CMS was imposing a CMP of $350 per day beginning on September 24, 2004, and continuing until Petitioner returned to substantial compliance with program participation requirements; a discretionary DPNA beginning on October 27, 2004, and continuing until Petitioner returned to substantial compliance; termination of Petitioner's provider agreement on March 24, 2005, if Petitioner did not return to substantial compliance before that date; and that Petitioner's authority to conduct a NATCEP was withdrawn. CMS Exhibit (CMS Ex.) 7. CMS notified Petitioner by letter dated December 2, 2004, that based upon the survey completed on October 22, 2004, the CMP was being increased to $550 per day beginning on October 22, 2004. The other remedies previously imposed were unchanged. CMS Ex. 6.

Petitioner requested a hearing by letter dated December 9, 2004. Petitioner denied all findings of deficiency and that there was a basis for the imposition of any enforcement remedy. The request for hearing was docketed as C-05-98 and assigned to me for hearing and decision on December 21, 2004. A Notice of Case Assignment and Prehearing Case Development Order (Prehearing Order) was issued at my direction on December 21, 2004. On March 4, 2005, the case was set for hearing April 25 through 29, 2005.

On October 28, 2004, the state agency completed an annual survey of Petitioner's facility. CMS notified Petitioner by letter dated December 14, 2004,[2] that deficiencies from the prior complaint surveys had been corrected but that new deficiencies were found. CMS advised Petitioner that the CMP continued but that it was reduced to $150 per day beginning October 28, 2004, and the other remedies previously imposed were unchanged. CMS notified Petitioner by letter dated January 18, 2005, that the state agency completed a revisit survey of Petitioner's facility on December 22, 2004, and found that Petitioner had returned to substantial compliance at that time. The accruing CMP and the DPNA

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[2] The December 14, 2004 CMS notice is attached to Petitioner's February 11, 2005, Request for Hearing, Tab A. The December 14 notice was amended by the CMS letter dated December 20, 2004. CMS Ex. 57.

ceased on December 21, 2004, and the termination remedy was rescinded. CMS Ex. 67 Petitioner filed a second request for a hearing by letter dated February 11, 2005, challenging the CMS action based on the October 28, 2004 survey. Petitioner requested that its new appeal be consolidated with C-05-98. The case was docketed as C-05-192, and assigned to me for hearing and decision and a Prehearing Order was issued at my direction on March 2, 2005. On February 18, 2005, CMS filed an opposition to Petitioner's request for consolidation. On March 22, 2005, I issued an order consolidating C-05-98 and C-05-192 for hearing and decision. I also directed the parties to consult and advise me whether they could proceed to hearing on the consolidated case on April 25, 2005, or whether they wished a postponement. On April 12, 2005, the parties proposed that the consolidated case be rescheduled for July 12 through 15, 2005. On April 14, 2005, I issued an order amending the prehearing schedule and a notice of hearing for the consolidated case, setting the case for hearing from July 12 through 15, 2005 in Jackson, Mississippi. On July 8, 2005, CMS moved to reschedule the hearing on grounds that one of its witnesses had been hospitalized. However, I reviewed the witness lists filed by both parties and learned that the hospitalized individual was not listed as a witness by either party. Accordingly, on July 8, 2005, I issued an order denying the CMS request to reschedule the hearing.

A hearing was convened on July 12 and 13, 2005 in Jackson, Mississippi. CMS offered exhibits 1 through 67, which were admitted as evidence. Hearing Transcript (Tr.) 38. CMS also offered CMS exhibits 68 through 77, which were not admitted for reasons discussed in greater detail in the Analysis section of this decision. Tr. 57-62. Petitioner offered exhibits (P. Ex.) 1 through 47, 49 through 60, and 64 through 72. Petitioner exhibits 48, 61, 62, and 63 were withdrawn. Tr. 15-16. Petitioner exhibits 9 through 24, 28 through 47, 49 through 60, 64 through 68, and 70 through 72 were admitted. Tr. 21-25. CMS objected to the admission of Petitioner exhibits 1 through 8, 25 through 27, and 69 on grounds that they had not been authenticated. Petitioner proffered that witnesses would be called to authenticate the exhibits. I deferred ruling upon the admissibility of Petitioner exhibits 1 through 8, 25 through 27, and 69 pending testimony to establish authenticity and relevance. Tr. 18-25. Petitioner did not produce the proffered testimony or reoffer the exhibits for admission and Petitioner exhibits 1 through 8, 25 through 27, and 69 are not admitted. CMS called two witnesses, Surveyors Linda Ward and Karen Baker.[3] My ruling excluding the testimony of three other CMS witnesses is discussed in

[3] Karen Baker was not listed as a witness on CMS's amended witness list filed July 7, 2005. However, Surveyor Baker was listed on two prior CMS witness lists and Petitioner did not object to my receiving her testimony.

detail in the Analysis section of this decision. Tr. 106-21, 161-62. Petitioner elicited testimony from one witness, Gale McDill, Petitioner's dietary manager/kitchen supervisor. The parties submitted post-hearing briefs and reply briefs. (CMS Brief, P. Brief, CMS Reply Brief, P. Reply Brief, respectively.)

II. Discussion

A. Findings of Fact

The following findings of fact are based upon the exhibits admitted. Citations to exhibit numbers related to each finding of fact may be found in the analysis section of this decision if not indicated here.

1. The state agency completed surveys of Petitioner's facility on September 24, October 22, and October 28, 2004.

2. CMS notified Petitioner by letter dated October 12, December 2, and December 14, 2004, that it was imposing enforcement remedies based upon deficiencies found by the state agency during the three surveys of Petitioner's facility.

3. Petitioner requested a hearing on December 9, 2004.

4. CMS determined, based upon a survey completed on October 28, 2004, that deficient practices cited by the survey completed on September 24, 2004 were corrected. CMS Ex. 57, at 2.

5. Petitioner returned to substantial compliance on December 22, 2004, as determined by a revisit survey completed that date.

Findings Related To The Survey Ended September 24, 2004

6. Resident 14 had an annual comprehensive assessment February 3, 2004, that showed that the resident had no pressure ulcers.

7. Resident 14's next comprehensive assessment was dated April 29, 2004 and was triggered by a significant change in status.

8. No significant change comprehensive assessment was done when Resident 14 developed multiple pressure ulcers on her buttocks and left heel in February and March 2004.

9. The pressure ulcer on Resident 14's left buttock worsened to a Stage III by March 8, 2004, the pressure ulcer on her right buttock worsened to a Stage IV by March 15, 2004, and both ulcers on her left heel were Stage II on March 1, 2004.

10. The development of four pressure ulcers impacted more than one area of Resident14's health status.

11. The development of four pressure ulcers was a significant change in Resident 14's health status.

12. Prior to February 2004, Petitioner had a care plan with specific interventions intended to prevent Resident 14 from developing pressure sores.

13. Petitioner has not presented evidence that, prior to the development of pressure ulcers in February 2004, it consistently implemented the interventions of Resident 14's pressure ulcer care plan to prevent development of pressure ulcers.

14. Petitioner has not shown that development of pressure ulcers by Resident 14 was unavoidable.

15. Resident 14 suffered actual harm.

16. Call bells were not accessible to four residents during the period September 14 through 16, 2004.

17. The evidence does not show that Petitioner had a system in addition to a call bell system by which residents in need of assistance with activities of daily living or in case of emergency could summon staff.

18. There was a potential for more than minimal harm when residents were unable to summon staff by use of the call bell system.

Findings Related To The Survey Ended October 28, 2004

19. On October 25, 2004, Resident 22 had a bottle labeled "Cosopt" and a bottle labeled "Betopic," medication administered as eye drops to treat glaucoma.

20. Resident 22 had not, at that time, been assessed as safe to self-administer the medication Cosopt or Betopic via eye drops.

21. The medications Cosopt and Betopic pose the potential for more than minimal harm if not properly administered according to manufacturers' instructions.

22. Petitioner's staff knew that Resident 22 had bottles labeled Cosopt and Betopic not later than October 25, 2004, when a staff member observed the bottles in the presence of the surveyor.

23. Petitioner's assessment of Resident 22 dated October 28, 2004, shows that he was unable to demonstrate the ability to safely store medication in his room.

24. Restraints were used on Residents 1, 5, 7, and 19 on October 26 and 28, 2004.

25. There is no evidence that Residents 1, 5, 7, 19 or the residents' responsible parties were counseled about the use of restraint or the right to refuse restraint.

26. There is no evidence that Petitioner considered less restrictive means to address the medical conditions of Residents 1, 5, 7, and 19.

27. On October 26, 2004, the alternative meat item for the luncheon menu was sliced ham and scraps of meat found on the slicer by the surveyor were from slicing ham for the lunch meal that day.

28. On October 26, 2004, lunch meal service was not complete and it was not yet the time to clean the meat slicer when the surveyor observed meat scraps on the slicer.

29. The evidence does not show that sanitary conditions were not being maintained in Petitioner's kitchen.

B. Conclusions of Law

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

2. CMS has not made a prima facie showing of a violation of 42 C.F.R. § 483.10(f)(1) (Tag F165) as alleged by the surveys completed on September 24 and October 22, 2004.

September 24, 2004 Survey

3. A significant change within the meaning of 42 C.F.R. §§ 483.20(b)(2)(ii) does not require that there be change in more than one area of a resident's health status; what is required is that there be an impact upon more than one area of the resident's health status.

4. Petitioner has not met its burden to show that the development of pressure ulcers by Resident 14 was unavoidable or that Petitioner had another defense.

5. Petitioner was in violation of 42 C.F.R. § 483.20(b)(2)(ii) from September 24, 2004 through October 27, 2004.

6. Petitioner was in violation of 42 C.F.R. § 483.25(c) from September 24, 2004 through October 27, 2004.

7. Petitioner must ensure that residents have accessible a system by which they can summon staff to assist them in emergencies or with activities of daily living.

8. Petitioner was in violation of 42 C.F.R. § 483.25(a)(3) from September 24, 2004 through October 27, 2004.

October 28, 2004 Survey

9. Petitioner was in violation of 42 C.F.R. § 483.10(n) from October 25, 2004 through December 21, 2004.

10. Use of restraints is prohibited except upon a showing of medical necessity.

11. Petitioner has not shown medical necessity for the use of restraints for Residents 1, 5, 7, and 19 because Petitioner has not produced evidence that less restrictive treatment modalities were ineffective.

12. Petitioner has not shown that Residents 1, 5, 7, and 19 or their responsible parties were advised of the residents right to be free of restraint or that the care planning team had concluded restraints were medically necessary.

13. Petitioner was in violation of 42 C.F.R. § 483.13(a) from October 25, 2004 through December 21, 2004.

14. Petitioner has shown by a preponderance of the evidence that it was not in violation of 42 C.F.R. § 483.25(h)(2), contrary to the allegations of the survey that ended on October 28, 2004.

15. Petitioner returned to substantial compliance with all program participation requirements effective December 22, 2004.

16. There is a basis for the imposition of a CMP and a DPNA.

17. A CMP of $350 per day for the 34 days from September 24, 2004 through October 27, 2004, and $150 per day for the 55 days from October 28, 2004 through December 21, 2004, a total CMP of $20,150 is reasonable.

18. A DPNA for the period October 27, 2004 through December 21, 2004, is reasonable.

19. Withdrawal of Petitioner's authority to conduct a NATCEP was required during the period October 12, 2004 through October 11, 2006. 42 C.F.R. §§ 483.151 and 483.152.

20. Petitioner's request for fees pursuant to the Equal Access to Justice Act (EAJA) must be denied as the evidence does not show the agency position was not substantially justified.

C. Issues

The issues in this case are:

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

D. Applicable Law

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

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, 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 per instance CMP that applies whether or not immediate jeopardy is present. 42 C.F.R. §§ 488.408(d)(1)(iv); 488.438(a)(2).

In this case, the state agency withdrew approval of Petitioner to conduct a NATCEP. Pursuant to sections 1819(b)(5) and 1919(b)(5) of the Act, SNFs and NFs may only use nurse aides who have the required training and competency evaluation. Sections 1819(e) and 1919(e) of the Act impose upon the states the requirement to specify what nurse aide training and competency evaluation programs they will approve that meet the requirements established by the Secretary and a process for reviewing and reapproving those programs using criteria set by the Secretary. Pursuant to sections 1819(f)(2) and 1919(f)(2), the Secretary was tasked to develop requirements for approval of nurse aide training and competency evaluation programs and the process for review of those programs. The Secretary promulgated regulations at 42 C.F.R. Part 483, subpart D. Pursuant to 42 C.F.R. § 483.151(b)(2) and (e)(1) a state may not approve and must withdraw any prior approval of a NATCEP offered by a skilled nursing or nursing facility that: (1) has been subject to an extended or partial extended survey under sections 1819(g)(2)(B)(i) or 1919(h)(2)(A)(ii) of the Act; (2) has been assessed a CMP of not less than $5000; or (3) that has been subject to termination of its participation agreement, denial of payment, or the appointment of temporary management. "Substandard quality of care" is identified by the situation where surveyors identify one or more deficiencies related to participation requirements established by 42 C.F.R. § 483.13 (Resident Behavior and Facility Practices), § 483.15 (Quality of Life), or § 483.25 (Quality of Care) that are found to constitute either immediate jeopardy, a pattern of or widespread actual harm that does not amount to immediate jeopardy, or a widespread potential for more than minimal harm that does not amount to immediate jeopardy and there is no actual harm. 42 C.F.R. § 488.301. Extended and partial extended surveys are triggered by a finding of "substandard quality of care" during a standard or abbreviated standard survey

and involve evaluating additional participation requirements. *Id.* A facility is not normally entitled to administrative law judge (ALJ) review of a CMS or state agency level of noncompliance determination (also known as the "scope and severity" determination). The only two exceptions are where the amount of the CMP might be affected and where there was a finding of "substandard quality of care" that led to loss of approval of the facility's nurse aide training and competency evaluation program. 42 C.F.R. § 498.3(b)14.

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, section 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*, 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, 38 (2000), *aff'd, Woodstock Care Center v. Thompson*, 363 F.3d 583 (6th Cir. 2003). The Departmental Appeals Board (the Board) has long held that the net effect of the regulations is that a provider has no right to challenge the scope and severity level assigned to a noncompliance finding, except in the situation where that finding was the basis for an immediate jeopardy determination. *See, e.g.*, *Ridge Terrace*, DAB No. 1834 (2002); *Koester Pavilion*, DAB No. 1750 (2000). Review of a CMP by an ALJ is governed by 42 C.F.R. § 488.438(e).

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 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), *see also*, *Hillman Rehabilitation Center*, DAB No. 1611, at 8 (1997), *aff'd Hillman Rehabilitation Center v. U.S. Dept. of Health and Human Services*, No. 98-3789 (D.N.J. May 13, 1999). To prevail, a long-term care facility must overcome CMS's showing by a preponderance

of the evidence. *Batavia Nursing and Convalescent Center*, DAB No. 1904 (2004); *Batavia Nursing and Convalescent Inn*, DAB No. 1911 (2004); *Emerald Oaks*, DAB No. 1800 (2001); *Cross Creek Health Care Center*, DAB No. 1665 (1998); *Evergreene Nursing Care Center*, DAB No. 2069, at 7-8 (2007).

E. Analysis

1. Petitioner's allegation of conflict of interest and bias on the part of a surveyor is not grounds for relief.

Petitioner alleges that one surveyor involved in the surveys ended September 24 and October 22, 2005, had a conflict of interest due to on-going litigation between her "close, personal friend" and Petitioner's administrator. Petitioner alleges that the surveyor acted inappropriately and unprofessionally and sought revenge through the survey process. Petitioner offered no evidence in support of these serious allegations and requested no specific relief but suggested that I consider them as reflecting negatively upon the surveyor's credibility. P. Brief at 2-3.

It is not necessary to inquire into these allegations against the surveyor. The surveyor's testimony was rejected at trial on other grounds. Further, my review as to the alleged deficiencies is *de novo*. A *de novo* hearing requires that the ALJ make an independent decision, based solely on the evidence which is introduced at the hearing. Thus, I make my decision in this case based on the record made at the hearing independent from the determination of the agency whose action is challenged.

2. Exclusion of CMS documents and testimony was appropriate, but not on the basis of misconduct.

Rarely should an evidentiary ruling on the record in a hearing require discussion in a decision on the merits. However, in this case the exclusion of CMS exhibits 68 through 77 and the testimony of three surveyors[4] was clearly prejudicial to CMS and had the effect of a sanction. Discussion is necessary to clarify that the prejudicial effect was recognized and intended. Discussion is also appropriate as it appears from the post-hearing briefs of CMS that the agency may not have fully understood the rational for the ruling excluding the exhibits and testimony.

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[4] Four surveyors were actually the subject of the ruling, Surveyors McElwain, McNally, Womble, and Yuran. However, Surveyor McNally was hospitalized at the time of hearing and unavailable. Thus, the ruling had the effect of excluding or preventing receipt of the testimony of only the three remaining. Tr. 106.

Pursuant to paragraph A.3 of the Prehearing Order dated December 21, 2004 in C-05-98, CMS had 30 days from the date of that order to disclose its exhibits and witnesses to Petitioner. CMS filed a listing of proposed exhibits and witnesses on January 20, 2005. CMS listed exhibits 1 through 50, five surveyor witnesses and one CMS witness. On February 3, 2005, Petitioner requested subpoenas to obtain documents related to the surveys completed on September 24, 2004 and October 22, 2004, plus a list of persons mentioned or referred to in the statement of deficiency (SOD) from both surveys, other than residents or staff of Petitioner's facility. On February 14, 2005, I issued an order in which I advised CMS that as a party it was subject to sanction for failure to comply with a procedural order, that I was treating Petitioner's request for subpoena[5] as a motion to compel production by CMS, and that CMS had 20 days to respond. On February 18, 2005, CMS filed a response in which it asserted that it had already provided all relevant documents to Petitioner.[6]

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[5] It is not necessary to subpoena documents or testimony from a party to a proceeding where that party is subject to sanction for failure to comply with an order of the ALJ to produce or an order for a representative of a party to appear and testify (specific named witnesses are best subpoenaed, however). Act, §§ 1128A(c)(4), 1819(h)(2)(B)(ii). The distinction between using a subpoena and an order to compel is significant in proceedings under 42 C.F.R. Parts 498 and 1005, because the ALJ has at least limited authority to sanction a party but enforcement of a subpoena must always be through the United States Attorney and the federal district court pursuant to section 205(e) of the Act, a time consuming process at best and not in the best interest of judicial economy.

[6] On June 24, 2005, Petitioner filed a motion for partial summary judgment, the gist of which is that CMS had produced insufficient evidence prehearing to establish a *prima facie* showing of deficiencies alleged in the SOD for the survey ended October 22, 2004 or for two deficiencies cited in the SOD for the survey ended September 24, 2004. Petitioner also argued that CMS should be bound by the results of informal dispute resolution. Pursuant to 42 C.F.R. § 498.17(b) and paragraph A.5.B of the Prehearing Order, CMS had 20 days to respond or until July 14, 2005, two days after the hearing convened. The issues raised by Petitioner's motion for partial summary judgment are fully resolved by this decision on the merits, with one exception. Petitioner argues that CMS is bound by the IDR results that recommended deleting four of the eight examples cited in the SOD dated September 24, 2004, as examples of violation of 42 C.F.R. § 483.10(f)(1) (Tag F165). Petitioner focuses upon the fact that CMS never reviewed the IDR results or expressly accepted or rejected the results. The fundamental problem for Petitioner, however, is that IDR did not recommend deletion of all the examples and/or

(continued...)

On March 22, 2005, I consolidated for hearing and decision Petitioner's first and second requests for hearing, docket numbers C-05-98 and C-05-192. On April 14, 2005, I issued an order amending the prehearing schedule and the notice of hearing. The schedule I adopted was consistent with that recommended by the parties in their proposed scheduling order jointly filed on April 12, 2005. Pursuant to paragraph I.A. of my April 14, 2005 Order Amending Prehearing Schedule and Notice of Hearing (Order and Notice), the parties were to disclose their proposed exhibits and witnesses not later than May 26, 2005. On May 26, 2005, CMS filed its list of proposed exhibits and witnesses. Proposed CMS exhibits 1 through 50 on the CMS lists of January 20 and May 26, 2005 appear to be the same with the exception of CMS exhibit 18 and the difference with that exhibit appears to be a typographical error. The CMS list dated May 26 includes additional proposed CMS exhibits marked 51 through 67. The CMS witness list filed on May 26, 2005, includes one additional surveyor not on the January 20 list.

My Order and Notice dated April 14, 2005, also clearly notified the parties that the hearing would begin on July 12, 2005, three months later. CMS never advised me or Petitioner of any problem with its documentary evidence or witnesses between April 14 and the start of hearing on July 12, 2005, except of course the hospitalized surveyor who was never listed by CMS as a witness. *See* Order Denying Respondent's Request For Rescheduling of Hearing dated July 8, 2005. The problem with the CMS documents arose at hearing when CMS offered nine exhibits, CMS Ex. 68 through 77, that had not been disclosed to Petitioner before the morning of hearing. Tr. 27. Petitioner objected to CMS Ex. 68 through 77 on grounds that Petitioner was prejudiced in the preparation of its defense because the documents were produced late and they are documents that were subject to my order to produce, to which CMS responded that it had already produced everything. Tr. 38-49. Counsel for CMS responded that many of the documents included

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[6](...continued)
the deficiency. Thus, even if I agreed with Petitioner that CMS should not be allowed to present evidence as to four of the eight residents, I must still consider whether the examples of the other residents constitute violations of the regulation. It is the violation of the regulation that is the basis for any enforcement remedy not the individual examples. While Petitioner's "IDR argument" might have been a proper argument for a motion *in limine*, it is not a basis for summary judgment. Furthermore, paragraph A.5.b. of the Prehearing Order dated December 21, 2004, which related to the surveys involved in the motion and was unaffected by my Order of April 14, 2005, required that any motion for summary judgment be filed within 75 days from December 21, 2004. Petitioner's motion was untimely and I do not find good cause to excuse the late filing.

in CMS exhibits 68 through 77 were already in evidence; that Petitioner appeared to have prepared a defense despite not previously receiving copies of CMS exhibits 68 through 77; and the only exhibits not previously disclosed or taken from Petitioner's own records are CMS exhibits 72, 73, 74, 75, and 77. Tr. 49-54.

I ruled that CMS exhibits 68 through 77 would not be received and considered as substantive evidence but that they would remain with the record so they would be available in the event of any appellate review. I explained to the parties on the record that I found production of the significant volume of documents the morning of trial unduly prejudicial to Petitioner. I also explained to counsel that CMS had offered no explanation for the delay in production until the morning of trial. Further, to the extent that CMS admitted that many of the documents were already in evidence or that CMS could call a surveyor as a witness, CMS would suffer no prejudice due to the exclusion of the cumulative evidence. Tr. 57-60.

The second evidentiary problem for CMS arose when CMS filed an amended witness list on July 7, 2005, four calendar days and two working days before trial. The amended witness list included one of the state surveyors listed on the May 26, 2005 CMS witness list, Linda Ward, but listed four other surveyors not listed on either of the prior CMS disclosures. The amended list also included Karen Powers from CMS who was included on both prior CMS disclosures. On July 8, 2005, Petitioner objected on grounds of late disclosure and prejudice and suggested that CMS should be sanctioned based on its failure to comply with my February 14, 2005 order to disclose. At hearing, Petitioner renewed its objection to my receiving testimony from the surveyors not disclosed as witnesses prior to July 7, 2005, Sherry McElwain, Jane or Jan[7] McNally, Donna Womble, and Rich Yuran. Tr. 78-81, 84. Counsel for CMS blamed the state agency for providing the wrong names for the surveyors and argued that Petitioner's staff was aware of the names of the surveyors who had visited the facility. Tr. 81-82, 92. I ruled that I would not consider the testimony of surveyors McElwain, Womble, and Yuran as substantive evidence. Surveyor McNally was not present or available to testify. However, I did offer CMS the opportunity to place the testimony of the three surveyors present on the record as a proffer but subject to cross-examination under oath with the possibility I might reconsider my ruling if Petitioner elected to cross-examine. My rationale, explained in detail on the record, is that Petitioner suffered prejudice in its ability to present a complete defense due to the late disclosure of evidence which CMS or its agent, the state agency, had possessed for long prior to the hearing and disclosure. Tr. 106-12. Despite my

[7] Jane was listed on the CMS amended witness list filed July 7, 2005, but Jan appears at various places in the transcript.

efforts to ensure CMS understood my ruling and remedy,[8] CMS declined to call its witnesses to preserve the record and obtain possible reconsideration of my ruling excluding their testimony in the event Petitioner elected to cross-examine. Tr. 116-20. To the extent that Petitioner has suggested by its objection that CMS should be sanctioned for misconduct, I find no evidence that tends to show conduct that warrants a sanction as I accept the representations of counsel for CMS that the state agency simply failed to provide requested information to counsel for CMS. Tr. 110-11.

3. Petitioner was not in substantial compliance with program participation requirements from September 24, 2004 through December 21, 2004.

The state agency conducted three surveys in this case. The first survey concluded on September 24, 2004, and the results are reported in a SOD of that date. The surveyors allege in the SOD that Petitioner was in violation of 42 C.F.R. §§ 483.10(f)(1) (Tag F165,[9] Scope and Severity (S/S) G[10]); 483.20(b)(2)(ii) (Tag F274, S/S G); 483.25(a)(3)

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[8] Unfortunately, it appears from the CMS brief that my ruling and its impact was not clear to CMS, even after counsel had the opportunity to review the transcript. CMS Brief at 4-5.

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

[10] According to the scope and severity matrix published in the SOM, section 7400E, a scope and severity level of A, B, or C indicates that a deficiency has the potential for no actual harm and has the potential for no more than minimal harm. A scope and severity level of D, E, or F indicates a deficiency that presents no actual harm but has the potential for more than minimal harm that does not amount to immediate jeopardy. A scope and severity level of G, H, or I indicates a deficiency that involves actual harm that does not amount to immediate jeopardy. A scope and severity level of J, K, or L indicates that a deficiency poses immediate jeopardy to resident health or safety.

(continued...)

(Tag F312, S/S E); and 483.25(c) (Tag F314, S/S G). CMS Ex. 2. The second survey was completed on October 22, 2004 and the results are reported in a SOD of that date. It is alleged in the SOD that Petitioner remained in violation of 42 C.F.R. §§ 483.10(f)(1) (Tag F165, S/S I). No other deficiencies are alleged in the SOD dated October 22, 2004. CMS Ex. 3. The results of the third survey are reported in a SOD dated October 28, 2004, the date the survey was completed. The third survey was both an annual recertification survey and a revisit survey to the prior complaint surveys that ended on September 24 and October 22, 2004. The revisit survey concluded that all deficiencies cited by the prior complaint surveys were corrected. CMS Ex. 57, at 2. In the October 28, 2004, SOD the surveyors allege the following new violations: 42 C.F.R. §§ 483.10(n) (Tag F176, S/S D); 483.13(a) (Tag F221, S/S E); 483.35(h)(2) (Tag F371, S/S F); and 483.75(l)(1) (Tag F514 S/S B).[11] CMS Ex. 21. A revisit survey completed on December 22, 2005, determined that Petitioner had returned to substantial compliance with all program participation requirements effective December 22, 2004. CMS Ex. 67.

I conclude after review of all the evidence admitted and consideration of the parties arguments, that:

> (a) Petitioner was not in substantial compliance with program participation requirements from September 24, 2004 through October 27, 2004, based upon violations of 42 C.F.R. §§ 483.20(b)(2)(ii) (Tag F244), 483.25(a)(3) (Tag F312); and 483.25(c) (Tag F314);
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> (b) CMS has not made a *prima facie* showing that Petitioner was in violation of 42 C.F.R. § 483.10(f)(1) (Tag F165) as alleged by the surveys completed on September 24 and October 22, 2004;

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[10](...continued)
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.

[11] Because the alleged violation of 42 C.F.R. § 483.75(l)(1) (Tag F514) is cited at a scope and severity of B, the surveyors did not find that there was a potential for more than minimal harm, the alleged deficiency does not amount to an allegation of substantial noncompliance, it may not be the basis for an enforcement remedy, and it is not subject to my review.

(c) Petitioner was not in substantial compliance with program participation requirements from October 25, 2004 through December 21, 2004, based upon violations of 42 C.F.R. §§ 483.10(n) (Tag F176) and 483.13(a) (Tag F221); and

(d) Petitioner returned to substantial compliance with all program participation requirements effective December 22, 2004.

a. CMS has failed to make *prima facie* showing of a violation of 42 C.F.R. § 483.10(f)(1) (Tag F165, S/S G) (September 24 and October 22, 2004 surveys).

Tag F165 is cited on both the September 24 and October 22, 2004 surveys, and it is the only violation cited on the October 22 survey. The regulation requires that a facility protect and promote a resident's right to "(v)oice grievances without discrimination or reprisal." 42 C.F.R. § 483.10(f)(1).

It is alleged in the September 24, 2004 SOD, that the facility failed to ensure that residents could report grievances without discrimination or reprisal. Illustrative examples are cited regarding Residents 1, 2, 3, 6, 7, 8, 9, and 14. CMS Ex. 2, at 1. CMS recognized in its notice letter dated December 2, 2004, that IDR deleted the examples cited related to Residents 3, 7, 8, and 9. CMS Ex. 6, at 2. The same deficiency was cited on the October 22, 2004 survey. It is alleged in the October 22 SOD that Petitioner failed, as to all 125 residents of the facility, to "enable residents, concerned family members, and or/responsible parties to voice grievances without fear of reprisal." CMS Ex. 3, at 1. It is alleged in the SOD, that some residents "did not feel" grievances were resolved; some residents "felt intimidated by facility staff and feared repercussions;" and some reported that after complaints were made by residents or their representatives during the last survey, Petitioner's staff attempted to discuss with them what was said to the state agency personnel, told them if they were not happy they could find another facility, and/or asked for a taped interview denying prior allegations. CMS Ex. 3, at 2.

At the hearing CMS sought to introduce surveyor testimony of residents' complaints regarding their inability to voice grievances without fear or reprisal. Tr. 98-106, 116. For the reasons stated in section E. 2. above, surveyors McElwain, Womble, and Yuran were not permitted to testify, and their surveyor notes were excluded. In any event, even if I had allowed the surveyor testimony and notes this evidence is problematic. First, counsel for CMS agreed with me that the surveyor notes do not include complete statements of complaining residents and family members but rather just notes the surveyors made during interviews. Tr. 98-99. Second, the SOD contains nothing but conclusions and the surveyors' version of what they think they heard. Third, the surveyors failed to actually

record what questions were asked of the residents and what answers were given. The hearsay evidence that is at issue here is unverified and unreliable. It is not possible to discern whether the surveyors accurately reported the statements that are recited in the survey report, or whether the statements are unbiased and otherwise credible. Thus, CMS did not establish even a *prima facie* case that Petitioner failed to comply with 42 C.F.R. § 483.10(f)(1). Of course, CMS could have taken steps at the hearing to prove that the assertions in the survey report are reliable. For example, CMS might have called as witnesses members of the residents' families to testify regarding the allegations, but they were not called.

b. Petitioner violated 42 C.F.R. § 483.20(b)(2)(ii) (Tag F274, S/S G) (September 24, 2004 survey).

The regulation requires that a facility must complete a comprehensive assessment of a resident within 14 calendar days "after the facility determines, or should have determined, that there has been a significant change in the resident's physical or mental condition." 42 C.F.R. § 483.20(b)(2)(ii).

It is alleged in the September 24, 2004 SOD, that Petitioner failed to conduct a comprehensive assessment of Resident 14 within 14 days after the resident experienced a major decline in her condition as evidenced by the development of pressure ulcers. CMS Ex. 2, at 6. The surveyor alleges more specifically based upon review of Petitioner's clinical records for Resident 14, that Resident 14 developed four pressure sores between February 12, 2004 and February 27, 2004. Petitioner's clinical records show the development of the four pressures sores between February 12 and 27, 2004. However, Petitioner's staff did not do a significant change assessment at that time. Petitioner's staff did not do a comprehensive assessment of any kind until April 29, 2004. CMS Ex. 2, at 7-9.

Petitioner correctly points-out that the surveyor that cited this deficiency did not appear and testify at hearing. P. Brief at 8. Although not noted by Petitioner, CMS also offered no documents in support of this deficiency citation other than the allegations in the SOD. Petitioner argues that Surveyor McElwain who conducted the September 2004 survey was biased against Petitioner and that her observations recorded in the SOD are unreliable and should not be considered. P. Brief at 9.[12] However, Petitioner's clinical records for

[12] Petitioner argument extends to all the deficiencies cited by the September 24, 2004, as Surveyor McElwain was the only surveyor involved in that survey. Petitioner's suggestion that CMS did not make Surveyor McElwain available to testify is a

(continued...)

Resident 14 admitted at hearing as P. Ex. 23 and 72 are consistent with the surveyor's reported observations in the SOD showing that they are, in fact, reliable and worthy of my consideration. Furthermore, Petitioner does not deny the specific observations upon which the deficiency turns, but defends upon different grounds. I conclude that the observations of the surveyor set forth in the SOD are sufficiently reliable to satisfy the CMS prima facie showing of a violation and to put Petitioner to its proof to show substantial compliance or that it has an affirmative defense.

Resident 14 was admitted to Petitioner's facility on March 11, 2002, when she was 79 years old. Her admission Minimum Data Set (MDS) shows she suffered from cardiac dysrhythmias, hypertension, Alzheimer's disease, Aphasia, a history of cardiovascular accident (CVA), dementia other than Alzheimer's, seizure disorder, dysphagia, and organic brain syndrome. P. Ex. 23, at 72. She was fed by feeding tube. P. Ex. 23, at 73. Petitioner does not dispute the allegations in the September 24, 2004 SOD, that Resident 14 had an annual comprehensive assessment February 3, 2004, which showed that the resident had no pressure ulcers. Petitioner does not dispute the allegation of the September 2004 SOD that the resident's next comprehensive assessment was dated April 29, 2004, and was triggered by a significant change in status. Petitioner also does not dispute that no significant change comprehensive assessment was done when the resident developed multiple pressure ulcers in February 2004. Rather Petitioner argues that the development of pressure ulcers was not a "significant change" because it did not impact two or more areas of Resident 14's health. P. Brief at 23-25; P. Reply at 9. Petitioner's argument is without merit.

Resident 14's Decubiti Reports' document the development of four pressure sores in February and March 2004. On February 17, 2004, she was noted to have a Stage II ulcer on her left buttock. P. Ex. 23, at 1. The ulcer worsened to a Stage III by March 8, 2004, described as being one centimeter by one centimeter and 0.8 centimeters deep with moderate drainage. P. Ex. 23, at 1. Resident 14 was noted to have a Stage II ulcer on her right buttock on February 17, 2004. The ulcer on the right buttock worsened to a Stage IV ulcer as of March 15, 2004, described as being six by five centimeters and six centimeters deep with tunneling. P. Ex. 23, at 2. On February 27, 2004, it was observed that Resident 14 had developed two ulcers on her left heel, one on the inner part and the other on the outside part. Both ulcers on the left heel are noted to be Stage II on March 1, 2004. P. Ex. 23, at 58-59.

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[12](...continued)
mischaracterization. P. Brief at 8, fn. 10. CMS argued strongly for Surveyor McElwain to be permitted to testify. However, it was Petitioner's motion to prevent her testimony that I sustained.

The development of pressure ulcers at Stage II or higher, when no ulcers were previously present, indicated a significant change in Resident 14's physical condition, requiring Petitioner to conduct a comprehensive assessment of Resident 14. CMS policy is that emergence of a Stage II or higher ulcer when no ulcers at Stage II or higher previously existed, is a significant change requiring a comprehensive assessment. P. Ex. 35, at 2 (SOM, App. PP, Tag 274). Petitioner argues that the development of the pressure sores was not a significant change that would trigger the need for a comprehensive assessment, and that a "significant change" means that there must be a change in more than one area of the resident's health status. P. Brief at 23-24. Petitioner's argument is based upon a misunderstanding of the plain language of the regulation and a misreading of the decision of another ALJ in *Britthaven of South Louisville*, CR1053 (2003). "Significant change" is defined by the regulation as

> [A] major decline or improvement in the resident's status that will not normally resolve itself without further intervention by staff or by implementing standard disease-related clinical interventions, that has an impact on more than one area of the resident's health status and requires interdisciplinary review or revision of the care plan, or both.

42 C.F.R. § 483.20(b)(2)(ii).

The decision of the ALJ in *Britthaven of South Louisville* adds nothing to our understanding of what is or is not a significant change. In that case, the petitioner conceded it had not timely done comprehensive assessments for five residents. However, the ALJ found that CMS failed to prove that a one or two day delay in performing assessments of the five residents resulted in the potential for more than minimum harm. *Britthaven of South Louisville,* at 15. Contrary to the suggestion of Petitioner, the ALJ did not conclude or even suggest that in order to trigger the requirement for a comprehensive assessment there must be "change in more than one area of health status." P. Brief at 24. Furthermore, an appellate panel of the Departmental Appeals Board (Board) commented in *Willow Creek Nursing Center*, DAB No. 2040 (2006), that the drafters of 42 C.F.R. § 483.20 intended that a facility be responsible for assessing in response to acute or emergent problems, citing 62 Fed. Reg. 67174, 67193 (Dec. 23, 1997). *Id.*, fn. 5. The examples the Board listed were respiratory distress and fever but that list was clearly not exhaustive and did not by implication exclude pressure ulcers as a "significant change."

The plain language of the regulation is inconsistent with the interpretation Petitioner advocates which is clear when the elements of the definition are broken out. The definition provides that a significant change is:

> 1. A major decline or major improvement in the resident's status;
>
> 2. That will not normally resolve itself without
> – further intervention by staff or
> – by implementing standard disease-related clinical interventions;
>
> 3. That has an impact on more than one area of the resident's health status, and;
>
> 4. That requires interdisciplinary review or revision of the care plan, or both.

42 C.F.R. § 483.20(b)(2)(ii) (emphasis added).

The definition does not require a "change" in more than one area of the resident's health status. Rather, the first element requires a change which can be either a major decline or a major improvement in the resident's status, and is not limited to either physical or mental status. Certainly, the appearance of pressure ulcers in February 2004 was a major decline in Resident 14's physical status as she had no ulcers reported earlier that month.

The second element requires that the decline not normally resolve itself without staff intervention or implementing standard interventions. Petitioner presents no evidence suggesting that the resident's ulcers, which Petitioner does not dispute were worsening during February and March 2004, would resolve without staff intervention or by application of some "standard disease-related clinical interventions."

The third element of the regulatory definition is that the major decline or improvement have impact on more than one area of the resident's health status, not that there be a "change" in more than one area. It is fair to say that pressure ulcers of the type that Resident 14 was suffering from are painful. Pain of this sort can often have a serious adverse impact on sleep and emotional status.[13] Very often pressure sores of the type Resident 14 suffered require special treatment including wrapping or packing, possible antibiotic interventions, dietary changes, monitoring, and other special therapies and interventions some of which were implemented by Petitioner once the ulcers developed in

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[13] Nurses Notes from the period generally note that the nurses observed no distress. I note, however, that this resident's ability to communicate and be understood was limited from her admission. P. Ex. 23, at 105. Furthermore, it is recorded that on May 10, 2004, the resident's daughter specifically expressed concern about signs that the resident was suffering pain. P. Ex. 23, at 310.

this case. No doubt there are other impacts that are better left to the experts to describe. Petitioner has presented no evidence that the development of the pressure sores did not impact multiple areas of the resident's health status. To the contrary, the nursing notes and dietary progress notes presented by Petitioner clearly show that Petitioner's staff recognized that the development of pressure sores impacted more than one area of the resident's health, including her skin integrity and nutritional needs. P. Ex. 23, at 271, 274-75, 479.

The fourth element requires interdisciplinary review and/or revision of the care plan. There can be no dispute that the development of multiple pressure sores as in this case is serious and requires the interdisciplinary team to determine the cause, including all contributing factors, and then develop interventions to address the prevention of additional ulcers and the treatment of existing ulcers.

The resident developed four pressure sores in February and March 2004. The development of the pressure sores marked a significant change in her health status as she had no prior recorded pressure sores. Petitioner failed to do a significant change assessment for the resident. I have no difficulty finding that the worsening of the wounds constituted actual harm. Accordingly, I conclude Petitioner violated 42 C.F.R. § 483.20(b)(2)(ii) in the case of Resident 14. The evidence does not show that this deficiency was corrected prior to the revisit survey completed on October 28, 2004. CMS Ex. 57, at 2.

c. Petitioner violated 42 C.F.R. § 483.25(c) (Tag F314, S/S G) (September 24, 2004 survey).

The quality of care requirement includes the requirement that a facility ensure that a resident who enters the facility without a pressure sore does not develop one unless clinically unavoidable and that a resident entering with a pressure sore receives care and services necessary for healing, to prevent infection, and to prevent other sores from developing. 42 C.F.R. § 483.25(c).

I have already discussed under Tag F274 the unfortunate case of Resident 14. Although the surveyors' allegation may not be a model of clarity, it is clear that she alleges Petitioner violated the regulation because it failed to prevent the development of pressure ulcers by Resident 14. There is no question that Resident 14 had no pressure sores noted during her assessment recorded on her MDS dated February 3, 2004. Thereafter, in February and March 2004, she developed four pressure ulcers. P. Ex. 23, at 1-2, 58-59; P. Ex. 72, at 24. There is no dispute by Petitioner that the ulcers worsened during early

March 2004. P. Ex. 23, at 1-2, 58-59. CMS has made a *prima facie* showing of a violation of 42 C.F.R. § 483.25(c). *Clermont Nursing and Convalescent Center*, DAB No. 1923, at 8-10 (2004). I note that a *prima facie* showing under Tag F314 is a low threshold for CMS and the burden for Petitioner to show unavoidability is great.

Resident 14 was admitted to Petitioner's facility in March 2002. P. Ex. 23, at 64. She was assessed as at risk for pressure ulcers due to impaired bed mobility and incontinence. P. Ex. 23, at 92. Her care planned interventions included: weekly skin assessment by a nurse; checks every two hours and as necessary to ensure her linens were not soiled and she was to be given good perineal care; signs and symptoms of skin break down such as redness, blisters, and skin discoloration were to be reported to the charge nurse; she was to be turned and repositioned every two hours; she was to have lotion applied to all extremities two times per day; her bed side-rails were to be up for mobility and safety; and staff was to report any bruising due to coumadin therapy. P. Ex. 23, at 98, 122, 142. Resident 14 also had care plans for nutrition and hydration due to her feeding tube (P. Ex. 23, at 97, 121, 141) and bowel and bladder incontinence, which subsequently changed due to use of an indwelling catheter (P. Ex. 23, at 96, 120, 140). An assessment for pressure ulcers dated April 30, 2002, noted that she was at risk for ulcers due to impaired mobility and bowel incontinence; that her skin was then intact; that she could not turn herself; that adequate fluid and calories would be provided by her feeding tube; and that a nurse would do a weekly skin assessment. P. Ex. 23, at 173. Her care plan was updated about April 30, 2002, to include Lotrisone cream being applied to her coccyx twice a day due to yeast but this intervention was deleted September 3, 2002. P. Ex. 23, at 179, 199, 219. An update to her pressure ulcer care plan around February 25, 2003, shows that an air mattress was added to her bed. P. Ex. 23, at 239, 261, 267. Between March 2002 and September 2002 she was assessed as being at mild risk for developing pressure sores. P. Ex. 23, at 61. However, in February 2003 and again in February 2004, she was assessed as being at high risk for pressure sores. P. Ex. 23, at 6. Resident 14 was a very vulnerable resident who was totally dependent upon staff for activities of daily living and mobility, and she had to be fed through a feeding tube. P. Ex. 23, at 71-72, 259. Review of physician's orders from May 2002 to February 2004, does not reveal any orders that indicate that Resident 14 suffered any pressure ulcers during that period but, she was treated for a skin tear to her right elbow in February 2003. P. Ex. 72, at 1-8. Similarly, review of the other clinical records provided by Petitioner show no evidence that the resident had pressure ulcers prior to February 2004. P. Exs. 23, 72.

Resident 14's condition changed beginning about February 8, 2004. A Nurses Notes entry from February 8, 2004, shows that despite her urinary catheter the pad under the resident was wet with urine, the catheter was replaced and it was noted that her urine had a strong, foul odor. Her urine was noted later the same day to include sediment and it was dark

amber in color. Her urine was noted to be decreased in amount, tea color, and with a foul odor on February 9, 2004, and a urinalysis was ordered. P. Ex. 23, at 270. A note from February 10, 2004, indicates the resident was possibly suffering a urinary tract infection (UTI) and the urine sample was obtained and sent to the laboratory. On February 11, 2004, notes show that the urinalysis results were received and the physician ordered a antibiotic. P. Ex. 23, at 269. A Physician's Orders sheet reflects that on February 12, 2004 at 3:15 p.m., Dr. Brett Brown issued orders for treatment of blister areas on the resident's right and left buttocks. P. Ex. 72, at 24. A Nurses Notes entry dated February 14, 2004, documents that on February 12, 2004, a nurse found a small blister on the resident's buttocks , the area was cleaned and dressed, a physician's order was received, and staff was instructed to keep the resident off her buttocks with pillows for support. P. Ex. 23, at 272. Notes from February 14 and 15, 2004, show that the resident continued to be turned and repositioned and that she continued on antibiotic for an UTI. P. Ex. 23, at 273. Nurse Notes entries from February 16, 2004, show that the resident continued to be treated for ulcers on her buttocks and that pressure ulcers were noted on her left heel. New interventions implemented on February 16, 2004 according to the nurse notes included: implementation of standing dietary orders and a dietary assessment; addition of a low air loss mattress; addition of heel elevators or protectors; and the addition of multivitamin, vitamin C, and zinc. P. Ex. 23, at 271, 274-75. Dietary Progress Notes show the registered dietician was actually notified by facsimile on February 18, 2004, her recommendations were received on February 20, 2004, and her recommendations were approved on February 23, 2004. P. Ex. 23, at 479. A Nurses Notes entry dated February 27, 2004, records two new blister areas to the resident's left heel. P. Ex. 23, at 281. A facsimile to the physician dated March 6, 2004, shows that staff reported that the ulcers on the resident's coccyx were not healing. P. Ex. 23, at 286. Facsimiles to the physician March 15, 2004, show staff reported worsening of the buttocks ulcers to Stage III and they requested a surgical consult to debride and open the wound, which the doctor approved. P. Ex. 23, at 290-91. On March 17, 2004, staff requested and the physician ordered daily whirlpool baths with vinegar. P. Ex. 23, at 293-94. Nurses Notes entries from April 21, 2004, show that the resident was again placed on antibiotic for an UTI. P. Ex. 23, at 301.

Petitioner's records for Resident 14 show that she developed four pressure sores in February and March 2004. On February 17, 2004, she was noted to have a Stage II ulcer on her left buttock. P. Ex. 23, at 1. The ulcer worsened to a Stage III by March 8, 2004, described as being one centimeter by one centimeter and 0.8 centimeters deep with moderate drainage. P. Ex. 23, at 1. Resident 14 was noted to have a Stage II ulcer on her right buttock on February 17, 2004. The ulcer on the right buttock worsened to a Stage IV ulcer as of March 15, 2004, described as being six by five centimeters and six centimeters deep with tunneling. P. Ex. 23, at 2. On February 27, 2004, it was observed that Resident 14 had developed two ulcers on her left heel, one on the inner part and the other on the outside part. Both ulcers on the left heel are noted to be Stage II on March 1, 2004. P. Ex.

23, at 58-59. Petitioner's records show that staff did intervene to treat Resident 14's pressure sores, the registered dietician was consulted and issued orders, and the resident's physician was consulted and he issued orders. The evidence records that interventions ordered were implemented and monitored. P. Exs. 23; 72; P. Brief, App. B. Petitioner's records also show that the ulcers were largely resolved by May 18, 2004. P. Ex. 23, at 1-2, 57-60.

The evidence shows Petitioner assessed Resident 14 to be at risk from the date of her admission; that Petitioner had a care plan to prevent pressure sores from the date of her admission; and that Petitioner did implement interventions once ulcers developed. The evidence does not show, however, that Petitioner was actually following its care plan to prevent the development of ulcers in January and February 2004, prior to presentation of the ulcers on or about February 12, 2004. Petitioner offered no records or other evidence to show Resident 14 was being turned as planned, that she was being checked for incontinence as planned, that she was being assessed by a nurse as planned, or that lotion was being applied, all as planned for the prevention of ulcers from the time of her admission. Following its plan of care for pressure sores may have been all the more important given that the resident had an indwelling catheter that leaked and her health was compromised by the UTI.

Furthermore, as discussed under Tag F274, the development of the pressure sores should have triggered a comprehensive assessment because the development of the sores was a significant change in her status. The evidence shows that Petitioner's nursing staff, the treating physician, and registered dietician were all involved in the treatment of the pressures sores. However, the record shows that they did not do a comprehensive assessment and then develop a plan to address the ulcers and impact upon her diet and other areas of her health. Rather there was a piecemeal approach to treatment once the sores presented. Petitioner's failure to comprehensively assess the resident's condition was an omission of an essential step necessary for the prompt and proper treatment of Resident 14's condition.

Petitioner argues that it did all it could to prevent the pressure ulcers and that I should conclude they were unavoidable. P. Brief at 24-25. Petitioner points to the statements of Petitioner's physician to the resident's daughter that are recorded in a Nurses Notes entry on February 23, 2004. Dr. Brown reportedly told the disgruntled daughter of Resident 14 that, ". . . the natural process of aging, late effects of old CVA, advanced dementia et., state of immobility lead to progression of common problems . . . 24 hr/day one on one care can not guarantee that one might not get skin breakdown . . . ." P. Brief at 28; P. Ex. 23, at 278-279. Petitioner did not call Dr. Brown to testify at trial so that the basis for his

opinions could have been explored. I give Dr. Brown's statements as recorded in the Nurses Notes little weight as to the issues before me as there was no opportunity to explore the basis for his opinions and the statements were made in a significantly different context than at a hearing under oath.

I conclude that Petitioner has failed to establish that the pressure sores were unavoidable or that Petitioner could not have implemented other interventions that might have prevented the development and worsening of the ulcers. Petitioner did not show it was following its pressure ulcer plan of care for the resident prior to the development of the ulcers and Petitioner did not do the comprehensive assessment required when ulcers developed. Accordingly, Petitioner violated 42 C.F.R. § 483.25(c). The development and worsening of the ulcers was actual harm. The evidence does not show that this deficiency was corrected prior to the revisit survey completed on October 28, 2004. CMS Ex. 57, at 2.

d. Petitioner violated 42 C.F.R. § 483.25(a)(3) (Tag F312, S/S E) (September 24, 2004 survey).

The general quality of care requirement is that a facility must ensure that it provides and each resident receives the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care. 42 C.F.R. § 483.25. For residents who cannot do their own activities of daily living, the facility must, in accordance with the comprehensive assessment and plan of care, ensure that the resident receives the services necessary to maintain good nutrition, grooming, personal hygiene, and oral hygiene. 42 C.F.R. § 483.25(a)(3).

It is alleged in the September 24, 2004 SOD that Petitioner violated this requirement because in five residents' rooms call bells were out of reach of the resident or were not timely answered.

One allegation was that it took 12 minutes to respond to a call bell. CMS Ex. 2, at 10. CMS has presented no evidence of an industry or other applicable standard by which I might judge whether 12 minutes is too long or not. Therefore, CMS has not made a *prima facie* showing of a violation as to that incident.

The other four examples allege that the surveyor observed the call bells were not accessible to the residents at a specific time on a specific date. Petitioner does not deny that the call bells were not accessible as the surveyor observed.[14] Rather Petitioner argues that there is no evidence that any of the residents were "malnourished, hungry, dirty, ungroomed, or in need of oral or personal care." P. Brief at 25. Petitioner argues that the observation of the surveyor that the call bells were inaccessible to residents, is not appropriately charged as a violation of 42 C.F.R. § 483.25(a)(3). P. Brief at 25; P. Reply at 10. The undisputed fact that the call bells were inaccessible to residents in four rooms due to the location of the call bell and the impairments of the residents might be charged as a violation of other regulatory provisions. Nevertheless, there is clearly a common sense relationship or nexus between the accessibility of call bells and the facilities obligation to ensure a resident who, for example, cannot toilet him or herself receives assistance with toileting and associated personal care. The same is true for a resident who requires a drink, a snack, a nose wiped, drool wiped, a tear wiped, or clothing readjusted. The purpose of the regulation is clear: Petitioner must ensure the care needs of its residents are met and, in the case of those who cannot meet their own care needs, there must be a system by which staff can be summoned. The system that is commonly used is the call bell. Petitioner has presented no evidence that it had some other system in place for residents who required care to summon staff for assistance. The potential for more than minimal harm to a resident who cannot summon staff is clearly present.

Accordingly, I conclude that Petitioner violated 42 C.F.R. § 483.25(a)(3). The evidence does not show that this deficiency was corrected prior to the revisit survey completed on October 28, 2004. CMS Ex. 57, at 2.

e. Petitioner violated 42 C.F.R. § 483.10(n) (Tag F176, S/S D) (October 28, 2004 survey).

This regulation allows a resident to self-administer drugs if the interdisciplinary team, as defined by 42 C.F.R. § 483.20(d)(2), has determined that this practice is safe. I find that Petitioner violated 42 C.F.R. § 483.10(n) by allowing Resident 22 to possess drugs that he might attempt to self-administer, because Petitioner did not first determine it was safe for Resident 22 to possess or self-administer the drugs.

[14] I find that the observations recorded in the SOD were credible absent specific denials by Petitioner. I note that Surveyor McElwain was not permitted to testify as I granted Petitioner's motion to exclude her on grounds other than credibility.

According to the SOD dated October 28, 2004, a surveyor saw two bottles of "glaucoma eye drops" labeled "Cosopt and Betopic" on Resident 22's beside table about 5:00 p.m. on October 25, 2004. CMS Ex. 21, at 1; P. Ex. 46, at 1. The SOD recites that the resident told the surveyor that he needed the drops everyday. The medication administration nurse was present observing, did not object, and the drops remained in the room when the surveyor and nurse departed. The surveyor could not find a physician order for either medication in the resident's file or an assessment that the resident was safe to self-administer the medication. CMS Ex. 21, at 1; P. Ex. 46, at 1. Thus, the surveyor cited Petitioner for violation of the regulation.

Petitioner does not deny the allegations that Resident 22 had the eye drops and that he had not been assessed safe to do self-administration. However, Petitioner argues that CMS has not proven that the glaucoma eye drops have the possibility of being harmful to Resident 22, or that the resident actually self-administered the drops. P. Brief at 29-30.

The evidence is convincing that the prescription drug eye drops Betopic and Cosopt, if not taken according to manufactures' directions, may be harmful. Both these drugs work by reducing intra ocular pressure in the eye. CMS Ex. 62, at 1; CMS Ex. 63, at 1. CMS Exs. 62 and 63 are the manufactures' product guide for these two drugs and they list several warnings and indications of potential harm to patients if these drugs are taken improperly or not properly handled. For example, for the drug Cosopt the guide states, "[p]atients should be instructed that ocular solutions, [such as Cosopt] if handled improperly, can become contaminated by common bacteria known to cause ocular infections. Serious damage to the eye and subsequent loss of vision may result from using contaminated solutions." CMS Ex. 63, at 5. The information for Betopic warns of possible severe respirator and cardiac reactions and anaphylactic reaction, all of which are life threatening according to the manufacturer's warnings. CMS Ex. 62, at 1. CMS has proven that the drugs Betopic and Cosopt, if improperly taken or handled have the possibility of being harmful to Resident 22.

Petitioner also argues that CMS has not shown that Resident 22 self-administered the drugs, and that Petitioner was not aware that drugs were in Resident 22's room. P. Brief at 30. The regulations do not require that CMS show that Petitioner was aware that drugs were present in Resident 22's room in order to make a *prima facie* case. Nevertheless, the SOD reveals that Petitioner's staff had knowledge of the medications at the bedside of Resident 22. P. Ex. 46, at 2. Petitioner has not introduced any testimony or any other evidence to refute that staff had knowledge at the very latest when the nurse was in the resident's room with the surveyor. Whether or not Resident 22 actually self-administered

is not the issue either. The point of the regulation is clear, a resident ought not have medication unless the resident has been assessed safe to self-administer. Petitioner admits it did not do the assessment. Petitioner's defense of ignorance, given that the bottles were in plain view on the bedside table, is simply not credible.

In this case, Petitioner failed to ensure that an assessment to determine whether the resident was safe to self-administer was done before the resident was allowed to have the medication, unsecured on the bed-side table in his room. After the October survey began and the survey team pointed out this deficiency, Petitioner's staff conducted an assessment of Resident 22 for self-administration of medication. P. Ex. 51, at 3. The assessment dated October 28, 2004, shows that Resident 22 was unable to demonstrate secure storage for medication kept in his room. Thus, even if Resident 22 was assessed able to self-administer, the drugs should not have been unsecured in his room where other resident's might abuse them.

I conclude that Petitioner was in violation on October 25, 2004, when the surveyor observed the medication on the resident's bedside table. The medications Cosopt and Betopic pose the potential for more than minimal harm if not properly handled or administered by a resident. The evidence does not show that Petitioner corrected this deficiency prior to December 21, 2004, the date found by CMS.

f. Petitioner violated 42 C.F.R. § 483.13(a) (Tag F221, S/S E) (October 28, 2004 survey).

This regulation provides that a resident has the right to be free from any physical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms. 42 C.F.R. § 483.13(a). The plain language of this regulation imposes upon a facility a heavy burden to show that any use of restraint, be it chemical or physical, in contravention of the resident's right to be free of such restraint, is warranted by the resident's medical symptoms. In *Cross Creek*, the Board interpreted the Act (§§ 1819(c)(1)(A)(ii) & 1919(c)(1)(A)(ii)) and the regulation (42 C.F.R. § 483.13(a) to prevent restraints from being used if they are not medically necessary. *Id.* at 10-12. The CMS interpretation of the regulation is that each resident should be able to attain and maintain the highest practicable well-being in an environment where use of restraints for discipline or staff convenience is prohibited and where restraints are only used for treatment of symptoms that warrant restraints. P. Ex. 34 (SOM App. PP, Tag 221). It is fundamental that Petitioner must know and must be able to show that it knew whether or not restraints were necessary for treatment of a resident's condition. Further, Petitioner must reasonably determine and must be able to show that restraints are being used in the most minimally restrictive manner necessary to treat the resident's medical condition. In order for Petitioner to make the required showing, it must have some evidence that

appropriate assessments were done and that the care planning team engaged in the necessary decision-making. CMS specifies in the SOM that prior to using restraints a facility must determine the specific medical symptom that necessitates the use of restraints, how the restraints effectively treat the symptoms, how the resident's safety is protected, and how the resident will be assisted in attaining or maintaining the highest level of well-being. Medical symptoms, assessments, and care plans must all be documented and a physician order is required, but an order alone is insufficient evidence of the need for restraint. The resident or the responsible party must be fully informed to include the condition or conditions that trigger consideration of restraining the resident, risks and benefits, and alternatives. P. Ex. 34, at 2-3 (SOM App. PP, Tag 221). Petitioner's policy on use of restraints is not inconsistent with the CMS guidance in the SOM, although not as detailed. Petitioner's policy provides that restraints are not to be used for convenience or as discipline, an assessment is required, a physician's order is required, the reason for and type of restraint and doctor's order must be in the medical record, and the resident or the responsible party must be counseled or educated on the use of restraints. Petitioner lists as examples of devices that are restraints: a Merriwalker; a lap buddy; a lap or waist belt; side rails; and a roll belt. CMS Ex. 58.

The SOD alleges generally that the facility failed to properly assess, care plan, and document the use of restraints for Residents 1, 5, 7, 14[15], 17, and 19, and failed to inform the residents and/or responsible parties of their rights and options regarding the use of restraints.[16]

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[15] CMS did not provide information to support an allegation of noncompliance for Resident 14. Tr. 67. Therefore, I consider the allegations of noncompliance with Tag F221 regarding Resident 14 to be withdrawn.

[16] The general allegation from the SOD (CMS Ex. 21, at 4) is sufficient notice to Petitioner to prepare to defend all aspects of the imposition of restraints as to the residents discussed in the survey. The surveyor's allegation of specific omissions in the case of individual residents should not be viewed as narrowing or limiting Petitioner's obligation or burden to show that restraints were properly imposed. Surveyors, after all, are not attorneys and their skill in drafting legal documents should not impede enforcement of the Act and regulations for the benefit of long-term care residents and the long-term care industry except where the notice provided is so insufficient that one cannot reasonably be expected to prepare to defend.

Petitioner argues that CMS has failed to show that Petitioner used restraints on residents for disciplinary or convenience purposes. Petitioner is in error regarding what is required for CMS to make a *prima facie* showing of a violation. According to the Board, it is sufficient when restraints are used, for CMS to show that a facility lacks documentation of medical necessity or there is credible evidence of improper purpose. *Cross Creek*, at 16. Petitioner does not contest that restraints were being used on Residents 1, 5, 7, and 19 as alleged by the surveyors. Petitioner also does not deny the surveyor's allegation that the documents described in the SOD were not produced during the survey. P. Brief at 30-32. CMS does not argue that there is evidence of any improper purpose for the use of restraints in the case of these four residents. Tr. 199; CMS Brief at 17-22. The evidence is sufficient here to put Petitioner to its proof. In this case, Petitioner fails to satisfy its burden as to four of the residents cited as examples by the survey.

(1) Resident 1:

The surveyor alleges the resident was observed on October 28, 2004, with one side rail up and the nurse entered the room and raised the other side rail. There was a physician's order for both side rails to be up while the resident was in bed. The surveyor alleged that there was no documentation of consent for the use of restraint, no documentation that the use of restraint had been discussed with the resident or the responsible party, the use of restraint was not documented on the care plan, and it was not documented on the certified nurse assistant (CNA) instructions.

The evidence shows that on August 17, 2004, the resident's doctor ordered that both side rails on the resident's bed be up for safety and mobility. P. Ex. 52, at 1-2. The resident's care plan showed that he was at risk for falls due to gait impairment and decreased safety awareness and among the interventions ordered and still in effect at the time of the survey was the use of side rails for safety and mobility when in bed and the use of the Merriwalker when the resident was up. CMS Ex. 51, at 25. The resident did not sign the care plan. CMS Ex. 51, at 32.

Contrary to the allegations of the SOD, there is evidence that both forms of restraint, side rails and use of the Merriwalker, are listed in the care plan. The surveyor does not allege any deficiency based upon the Merriwalker, so I will not consider it further. The care plan is evidence that there was some assessment of the need for use of side rails by the treatment team. There is also a doctor's order for the use of the side rails. There is also evidence that the resident and a family member was invited to attend and attended the care plan conference.

Petitioner fails to carry its burden in the example of Resident 1 because Petitioner has not shown that the resident or the responsible party was counseled regarding the use of restraints as required by Petitioner's policy and SOM, including the right to refuse restraints. The fact that a resident and/or family was present at a care plan conference, and that the inference that the care plan was discussed during the conference, is not evidence that Petitioner's staff advised the resident or responsible party of the right to refuse restraints or that other less restrictive methods were considered and rejected. There is also no evidence from counseling the resident or responsible party, the care plan, or the doctors order that shows Petitioner considered whether Petitioner's medical condition could have been accommodated by less restrictive means, for example the use of alarms or a low bed to minimize or eliminate the risk for falls. In the absence of some evidence that Petitioner considered less restrictive means, it is not possible to conclude that restraint was medically necessary. Accordingly, Petitioner violated 42 C.F.R. § 483.13(a) in the case of Resident 1.

(2) Resident 5:

The surveyor observed the resident on October 26, 2004, lying in bed with both side rails up. The surveyor alleged there was no documentation that use of restraint had been discussed with the resident or the responsible party and no documentation on the care plan.

On August 16, 2004, Resident 5's doctor ordered that her side rails on both sides of her bed be up for safety and mobility, due to her decreased mental status. P. Ex. 53, at 1. Contrary to the surveyor's allegation, the resident's care plan reflects that the resident was at risk for falls and, among other interventions, her side rails were to be up for safety and mobility.[17] Petitioner also produced the signature page for the care planning conference, which shows the resident did attend. P. Ex. 53, at 3. However, the doctor's order and the signature sheet for the care planning do not show that the resident was ever advised that she had the right to refuse restraint or that other less restrictive interventions has been considered and rejected by Petitioner and/or the resident's doctor as ineffective to address her medical condition. Accordingly, as in the case of Resident 1, Petitioner has not shown it complied with the resident's right to be free of restraint except when medically necessary.

[17] The fact that the doctor or Petitioner states that side rails are to be up for "safety and mobility" does not minimize the fact that the side rails are restraints because they do restrict freedom of movement, even though they may also have ancillary benefit for some activities of daily living.

(3) Resident 7:

The surveyor observed the resident on October 26, 2004, lying in bed with both side rails up. The surveyor alleged that there was no signed consent for the use of restraints, there was no documentation that the use of restraint had been discussed with the resident and/or responsible party, and no documentation of assessment of the least restrictive means.

Resident 7's admission assessment shows that she was to have both side rails on her bed up. P. Ex. 54, at 1, 3, 4, and 6. She attended her care planning conference on September 24, 2004, and her care plan included the intervention of keeping both side rails up due to her risk for falls. P. Ex. 54, at 7-8. For this resident Petitioner produced a document entitled "Side Rail Rational Screen," which shows Petitioner made some assessment of the need for side rails. However, as alleged in the SOD there is no evidence that the resident was ever counseled that she had a right to refuse restraint or whether or not less restrictive interventions had been considered and rejected by Petitioner as insufficient to meet the resident's medical needs. The surveyor specifically alleged for this resident that Petitioner failed to determine whether less restrictive means would have been all that were necessary to meet the resident's medical needs. Petitioner has provided me no evidence that it assessed less restrictive means and has thus failed to establish medical necessity for the restraint imposed.

(4) Resident 17:

The surveyor observed the resident on October 28, 2004, sitting in a wheelchair but the surveyor does not allege that any restraint was observed in use. Thus, I give no further consideration to the example of this resident.

(5) Resident 19:

The resident was observed on October 28, 2004, sitting in a wheel chair with a roll belt on. The surveyor alleged in the SOD that there was no evidence the family was informed of the use of the restraint.

Resident 19 was assessed for the use of a roll belt in bed on September 28, 2004. The resident had problems with safety awareness and confusion and reportedly he would attempt to climb over the bed side rails. P. Ex. 57, at 1. He was also assessed for the use of a lap buddy when up in his wheelchair, but that was changed to a lap belt on October 5, 2004, because he could remove the lap buddy. P. Ex. 57, at 2-3, 7. The use of a lap belt and then a "waist belt" while the resident was up in his wheel chair and side rails while in bed are interventions in his care plan. P. Ex. 57 at 6-7. The pages of the care plan provided by Petitioner do not list the use of a roll belt while the resident was in bed.

Petitioner presented evidence that the resident attended his care planning conference on October 11, 2004.

Petitioner has not shown that the resident or the responsible party was counseled regarding the use of restraints as required by Petitioner's policy and the SOM, including the right to refuse restraints. There is no evidence from counseling the resident or responsible party, the care plan, or the doctors order that shows Petitioner considered whether Petitioner's medical condition could have been accommodated by less restrictive means, for example the use of alarms or a low bed to minimize or eliminate the risk for falls from bed or a personal alarm while the resident was up in his wheelchair. In the absence of some evidence that Petitioner considered less restrictive means, it is not possible to conclude that restraint was medically necessary.

Based upon four of the five examples cited during the survey, I conclude that Petitioner was in violation of 42 C.F.R. § 483.13(a). There was the potential for more than minimal harm due to the use of restraints when less restrictive means may have been adequate. The evidence does not show that Petitioner corrected this deficiency prior to December 22, 2004, the date found by CMS.

g. Petitioner established by a preponderance of the evidence that it was in substantial compliance with 42 C.F.R. § 483.35(h)(2) (Tag F371, S/S F) (October 28, 2004).

This regulation requires a facility to store, prepare, distribute and serve food under sanitary conditions. 42 C.F.R. § 483.35(h)(2). The SOD alleges that Petitioner failed to maintain the meat slicer in a sanitary condition by failing to follow the facility policy to clean and sanitize the meat slicer after each use. CMS Ex. 21, at 7. Specifically, the survey team alleges that during the October survey, food residue (ham) was observed on the blade of a meat slicer and on the base of the blade. Tr. 129-135; CMS Ex. 21, at 7. According to the SOD the facility's food safety policy indicates that the meat slicer was to be cleaned and sanitized by Petitioner's kitchen staff after each use. CMS Ex. 21, at 7-8.

Gale McDill, Petitioner's dietary manager, testified that the surveyor observed the food residue on the meat slicer in the middle of the lunch service on October 26, 2004, at approximately 12:15 p.m. in the afternoon. Tr. 228. Ms. McDill testified that ham was the substitute menu item for lunch and that ham had been sliced. She further testified that the facility's policy means the meat slicer is cleaned at the end of the shift, which was at 1:00 p.m., and that the meat slicer had not yet been cleaned at the time it was observed because lunch was not over. Tr. 228-229.

I find Ms. McDill's testimony to be credible, reasonable, and unrebutted. In the normal course of using a meat slicer to slice ham, it is reasonable that some pieces of the ham might remain on the blade or fall to the base of the slicer. The surveyor observed what she believed to be pieces of dry meat on the base of the meat slicer at 12:15 p.m., before the lunch shift had ended at 1:00 p.m., and before the facility was required to clean the meat slicer under its policy. It is not reasonable to interpret the facility policy to require that the meat slicer be cleaned before the end of the meal service, which was still on going according to the surveyor. Tr. 130-131. Surveyor Ward testified that brownish chunky particles appeared to be very hard and she inferred that they were old and present for longer than the meal service. Tr. 129, 132, 134, 142-43. Surveyor Ward admitted in response to my questions that she never actually touched the residue on the meat slicer but only imagined how hard it must have been. Tr. 148-49. Although Surveyor Ward was generally credible, her conclusion that the meat residue was hard and old is not supported by the evidence and not credible. I find Ms. McDill's testimony to be more weighty. Therefore, I conclude that Petitioner has established by a preponderance of the evidence that it was in compliance with 42 C.F.R. § 483.35(h)(2).

4. Petitioner's Request for EAJA Fees is Denied.

Petitioner requests an award of its attorney fees without specifically referring to EAJA, 5 U.S.C. § 504(a), however that is the only authority for such an award in a case of this type. P. Reply Brief at 19. Although Petitioner's request for attorney's fees pursuant to EAJA is premature, the request must be denied as Petitioner is not the prevailing party in this case and the CMS position was substantially justified.

The purpose of EAJA is to enable a qualified applicant who has successfully litigated against an agency of the federal government to obtain attorney's fees and associated costs and expenses where the agency's position in the case was not substantially justified. 5 U.S.C. § 504(a)(1). EAJA specifies that fees and associated costs will be denied if the position of the agency was substantially justified. The clear intent of EAJA is to require the government to pay fees and costs only in the circumstances where its action reflected in the administrative record, viewed from the perspective of hindsight, is unreasonable. *See, Park Manor Nursing Home*, DAB No. 2005 (2005), *pet. review denied*, *Park Manor, LTD. V. U.S. Department of Health and Human Services*, 495 F.3d 433 (7th Cir, 2007). Even if Petitioner was considered the prevailing party as to the October 22, 2004 survey, the position of the agency was substantially justified. The factual allegations in that survey, based upon statements received by the surveyors, provided a reasonable basis for the allegation of a regulatory violation.

In this case, the position of CMS clearly was justified and not unreasonable, and CMS prevailed on most of its deficiency allegations. Therefore, the criteria for an award of attorney's fees in this case under the EAJA are not met, and as such must be denied.

5. A CMP of $350 per day from September 24, 2004 through October 27, 2004 and $150 per day from October 28, 2004 through December 21, 2004, a total CMP of $20,150; and a DPNA for the period October 27, 2004 through December 21, 2004 are reasonable enforcement remedies and withdrawal of Petitioner's authority to conduct a NATCEP was required as a matter of law.

Petitioner, was in violation of 42 C.F.R. §§ 483.20(b)(2)(ii), 483.25(a)(3), and/or 483.25(c) from September 24, 2004 through October 21, 2004. Petitioner was in violation of 42 C.F.R. §§ 483.10(n) and 483.13(a) from October 25, 2004 through December 21, 2004. Petitioner returned to substantial compliance with all program participation requirements effective December 22, 2004. There is a basis for the imposition of a CMP and a DPNA.

If a facility is not in substantial compliance with program requirements, CMS has the authority to impose one or more of the enforcement remedies listed in 42 C.F.R. § 488.406, including a DPNA and a CMP. CMS may impose a CMP for the number of days that the facility is not in compliance or for each instance that a facility is not in substantial compliance. 42 C.F.R. § 488.430(a). There are two ranges for per day CMPs. 42 C.F.R. §§ 488.408, 488.438. The upper range of CMP, 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).

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 based on Petitioner's compliance history or financial condition. There is no evidence showing that Petitioner has a history of noncompliance. Petitioner has not provided any evidence to show that its financial condition precludes it from paying the CMP.

I have determined that CMS failed to make a *prima facie* showing with respect to the October 22, 2004 deficiency allegation (Tag F165). Therefore, CMS has no basis to impose an increased CMP of $550 per day from October 22 through 27, 2004.

The deficiencies upheld from the September 24, 2004 survey were all corrected as determined by the revisit survey of October 28, 2004. The scope and severity levels of the September 24, 2004 survey were cited at G and I, which would permit a CMP between $50 and $3000 per day. The $350 CMP which CMS determined to impose is at the low end of the penalty range and quite reasonable given the widespread nature of the deficiencies, actual harm suffered by some of the residents, and Petitioner's culpability. Similarly, a CMP of $150 per day from October 27, 2004 until the deficiencies were corrected effective December 22, 2004, is reasonable. Petitioner did not demonstrate it had remedied all the deficiencies earlier than December 22, 2004, except as noted above. CMS has broad discretion to impose a DPNA; which it did reasonably for the reasons already noted, effective October 27, 2004 until the deficiencies were corrected on December 22, 2004.

A CMP of $350 per day for the 34 days from September 24, 2004 through October 27, 2004, and $150 per day for the 55 days from October 28, 2004 through December 21, 2004, for a total CMP of $20,150 is reasonable. A DPNA for the period October 27, 2004 through December 21, 2004, is also reasonable. Withdrawal of Petitioner's authority to conduct a NATCEP was required during the period October 12, 2004 through October 11, 2006. 42 C.F.R. §§ 483.151 and 483.152.

III. Conclusion

For the foregoing reasons, I conclude that there is a basis for the imposition of a CMP, and a CMP of $350 per day for the period September 24, 2004, through October 27, 2004 and $150 per day CMP for the period October 28, 2004 through December 21, 2005, for a total CMP of $20,150, is reasonable. A DPNA from October 27, 2004 to December 21, 2004 is reasonable.

/s/
Keith W. Sickendick
Administrative Law Judge