Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:	
	Date: September 29, 2008
Community Northview Care Center (CCN: 15-5718),	
Petitioner,	Docket No. C-06-339
	Decision No. CR1848
v.	
Centers for Medicare & Medicaid Services.	

DECISION

Petitioner, Community Northview Care Center, was in substantial compliance with program participation requirements during the survey conducted January 3 through 6, 2006. A mandatory denial of payment for new admissions (DPNA)[1] was not triggered on February 21, 2006.

I. Background

Petitioner, is a long-term care facility authorized to participate in the Medicare program as a skilled nursing facility (SNF) and in the State of Indiana Medicaid program as a

[1] Section 1819(h)(2)(D) of the Social Security Act (Act) is implemented by 42 C.F.R. § 488.417(b)(1), which requires that the Centers for Medicare and Medicaid Services (CMS) or the state deny payment for all new admissions when a facility has not returned to substantial compliance three months after the last day of the survey that identifies noncompliance. CMS and the state exercise no discretion with regard to imposing the mandatory DPNA. The mandatory DPNA must be distinguished from the optional DPNA which CMS is granted discretion to impose as an enforcement remedy pursuant to 42 C.F.R. § 488.417(a).

nursing facility (NF). On January 3 through 6, 2006, Petitioner was subject to a complaint and revisit survey by the Indiana State Department of Health (state agency). The survey resulted in a Statement of Deficiencies dated January 6, 2006 (SOD) in which it is alleged that Petitioner was found to be in violation of 42 C.F.R. §§ 483.25(m)(1)[2] (Tag F332[3], scope and severity (S/S)[4] D) and 483.30(a) (Tag F353, S/S E). Joint Stipulation. Petitioner was notified by the state agency by letter dated January 18, 2006 that, pursuant to its delegation of authority from CMS, the state was requiring that Petitioner conduct directed in-service training covering medication administration effective February 17, 2006. The state agency also advised Petitioner that a mandatory DPNA would be triggered effective February 21, 2006. CMS Exhibit (CMS Ex.) 1.

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[2] References to the Code of Federal Regulations (C.F.R.) are to the version in effect at the time of the survey unless otherwise indicated.

[3] 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 Dep't of Pub. Welfare v. Sullivan*, 934 F.2d 853 (7th Cir. 1991); *Northwest Tissue Ctr. v. Shalala*, 1 F.3d 522 (7th Cir. 1993). Thus, while the Secretary of the Department of Health and Human Services (the Secretary) may not seek to enforce the provisions of the SOM, he may seek to enforce the provisions of the Act or the regulations as interpreted by the SOM.

[4] Scope and severity levels are used by CMS and a state when selecting remedies. The scope and severity level is designated by an alpha character, A through L, selected by CMS or the state agency from the scope and severity matrix published in the SOM, Chap. 7, § 7400E. A scope and severity level of A, B, or C indicates a deficiency that presents no actual harm but has the potential for minimal harm. Facilities with deficiencies of a level no greater than C remain in substantial compliance. 42 C.F.R. § 488.301. A scope and severity level of D, E, or F indicates a deficiency that presents no actual harm but has the potential for more than minimal harm that does not amount to immediate jeopardy. A scope and severity level of G, H, or I indicates a deficiency that involves actual harm that does not amount to immediate jeopardy. Scope and severity levels J, K, and L are deficiencies that constitute immediate jeopardy to resident health or safety. 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, Chap. 7, § 7400E.

Petitioner requested a hearing by an administrative law judge (ALJ) by letter dated March 22, 2006, challenging the findings of the January 6, 2006 SOD and enforcement remedies based thereon. The case was assigned to me for hearing and decision on April 4, 2006, and a Notice of Case Assignment and Prehearing Case Development Order (Prehearing Order) was issued at my direction on that date.

On June 22, 2006, CMS filed a motion for summary affirmance, which I construed to be a motion to dismiss, a brief in support of its motion for summary affirmance (CMS Motion), and a motion to stay proceedings pending my ruling upon its motion.[5] On July 12, 2006, Petitioner filed a brief in opposition to the CMS motion for summary affirmance. On July 14, 2006, Petitioner filed a motion for summary judgment. On July 28, 2006, Petitioner filed its brief in support of its motion for summary judgment with exhibits. On August 3, 2006, CMS filed a motion opposing Petitioner's motion for summary judgment. On August 17, 2006, CMS filed a brief in opposition to Petitioner's motion for summary judgment. On September 20, 2006, I issued an order denying the CMS motion to dismiss and Petitioner's motion for summary judgment.

On January 9 through 11, 2007, I convened a hearing in Indianapolis, Indiana. CMS offered and I admitted as evidence CMS exhibits 1 through 19, 21 through 23, 25 through 27, 29 (except for pages 2, 3, 10 and 11), 30 through 32,[6] 46 and 47, 53 and 54, 56 through 58, 69 through 73, 75, 77 through 80, 84, 95, 97 page 6, 101, 104 and 105, 107, and 116. CMS withdrew CMS exhibits 33 through 45, 48 through 52, 55, 59 through 68, 74, 76, 85 through 94, 96, 98 through 100, 102 and 103, 106, 108, and 110 through 113. Tr. 96-98, 436, 670. Petitioner offered and I admitted Petitioner's exhibits (P. Ex.) 1 through 16, 18, and 19. Tr. 128-29, 568, 582, 651, 725.CMS presented the testimony of Surveyor Jackie Wolfgang, Registered Nurse (R.N.); Surveyor Donna Smith, R.N.; and Surveyor Ginger McNamee, R.N. Petitioner presented the testimony of Donald Gatlin, Petitioner's accountant; Denise Smith, R.N., Petitioner's Director of Nursing (DON); Glenn Burke, Petitioner's Administrator; and Peggy Trueblood, Petitioner's Assistant DON. The parties submitted post hearing briefs on March 15, 2007 (CMS Brief and P. Brief, respectively), CMS submitted a post hearing reply brief on May 15, 2007 (CMS Reply), and Petitioner submitted a post hearing reply brief on May 16, 2007 (P. Reply).

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[5] None of the exhibits filed by the parties with their motions were admitted as evidence. Rather, the parties had the opportunity to offer the exhibits at the hearing.

[6] The transcript at page 96, line 19 and page 98, line 5 should be corrected by the addition of CMS exhibit number 32, to show that exhibit was admitted as evidence.

II. Discussion

A. Findings of Fact

The following findings of fact are based upon the exhibits admitted, the testimony at hearing, and the stipulations of the parties. 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. Petitioner was subject to four surveys by the state agency that concluded on November 21, 2005, January 6, 2006, February 13, 2006, and March 3, 2006, each of which found that Petitioner was not in substantial compliance with program participation requirements.

2. The running of the three month period that triggered the mandatory DPNA in this case began on November 21, 2005, the last day of the survey when Petitioner was first found not in substantial compliance.

3. The January 6, 2006 survey was a revisit survey following-up the November survey, and a complaint investigation.

4. Deficiencies from the November 21, 2005 survey were found to be corrected as of the January 6, 2006 survey, except the surveyors concluded that Petitioner continued not to be in substantial compliance due to continuing violation of 42 C.F.R. § 483.25(m)(1) (Tag F332).

5. CMS elected not to proceed at hearing on the alleged violation of 42 C.F.R. § 483.25(m)(1) (Tag F332).

6. The surveyors also found Petitioner was in violation of 42 C.F.R. § 483.30(a) (Tag F353), during the survey that ended on January 6, 2006. CMS Ex. 4, at 6.

7. The surveyors concluded that Petitioner's violation of 42 C.F.R. § 483.30(a) (Tag F353) posed a risk of more than minimal harm for Petitioner's residents. CMS Ex. 4, at 6.

8. The state agency advised Petitioner that a "mandatory" DPNA would be effective February 21, 2006, and remain in effect until Petitioner was found to be in substantial compliance or its provider agreement was terminated. CMS Ex. 1, at 1-2.

9. Petitioner requested a hearing by letter dated March 22, 2006, in which Petitioner requested a hearing as to the findings and conclusions stated in the Statement of Deficiencies (SOD) dated January 6, 2006, and the remedies imposed, the mandatory DPNA and directed in-service training of which the state agency notified Petitioner by its letter of January 18, 2006.

10. Petitioner waived its right to hearing on remedies imposed based upon findings from the surveys completed on February 13 and March 3, 2006.

11. There is no notice that CMS imposed a discretionary DPNA based upon any of the findings and conclusions of any of the surveys in the survey cycle.

12. The evidence does not show any failure by Petitioner to deliver a care planned care or to meet a resident's care planned need.

13. The evidence does not show that insufficient staffing at Petitioner's facility posed an unreasonable threat that Petitioner would fail to meet a resident's care planned need.

14. The evidence does not show that any resident was exposed to the risk of more than minimal harm due to insufficient staffing at Petitioner's facility.

B. Conclusions of Law

1. Petitioner did not waive its right to a hearing on the deficiencies alleged by the survey completed on January 6, 2006 and the enforcement remedies based upon those deficiencies.

2. I have jurisdiction to hear and decide this case.

3. I have no authority to review CMS's selection of remedies because CMS's choice of remedy is not subject to appeal and review. 42 C.F.R. § 488.408(g)(2).

4. CMS did not make a prima facie showing of a violation of 42 C.F.R. § 483.25(m)(1) (Tag F332).

5. CMS did not make a prima facie showing that Petitioner violated 42 C.F.R. § 483.30(a) (Tag F353).

6. CMS did not make a prima facie showing that Petitioner was not in substantial compliance with program participation requirements on January 6, 2006.

7. Petitioner was in substantial compliance during the survey conducted January 3 through 6, 2006, which stopped the running of the three month period that began November 21, 2005, and the mandatory DPNA was not triggered effective February 21, 2006.

8. The survey that ended on January 6, 2006, did not provide a basis for the imposition of an enforcement remedy.

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

The statutory and regulatory requirements for participation by a long-term care facility are found at sections 1819 (SNF) and 1919 (NF) of the Act and at 42 C.F.R. Part 483. Section 1819(h)(2) of the Act vests the Secretary with authority to impose enforcement remedies against a SNF for failure to comply substantially with the federal participation requirements established by sections 1819(b), (c), and (d) of the Act.[7] Pursuant to 1819(h)(2)(C), the Secretary may continue Medicare payments to a SNF not longer than six months after the date the facility is first found not in compliance with participation requirements. Pursuant to 1819(h)(2)(D), if a SNF does not return to compliance with participation requirements within three months, the Secretary must deny payments for all individuals admitted to the facility after that date – commonly referred to as the mandatory or statutory DPNA. In addition to the authority to terminate a noncompliant SNF's participation in Medicare, the Act grants the Secretary authority to impose other enforcement remedies, including a discretionary DPNA, civil money penalties (CMP),

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

appointment of temporary management, and other remedies such as a directed plan of correction. Act § 1819(h)(2)(B).

The Secretary has delegated to CMS and the states the authority to impose remedies against a long-term care facility that is not complying substantially with federal participation requirements. "*Substantial compliance* means a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm." 42 C.F.R. § 488.301 (emphasis in original). A deficiency is a violation of a participation requirement established by sections 1819(b), (c), and (d) of the Act or the Secretary through his regulations at 42 C.F.R. Part 483, Subpart B. Facilities that participate in Medicare may be surveyed on behalf of CMS by state survey agencies in order to determine whether the facilities are complying with federal participation requirements. 42 C.F.R. §§ 488.10-488.28, 488.300-488.335. The regulations specify the enforcement remedies that CMS may impose if a facility is not in substantial compliance with Medicare requirements. 42 C.F.R. § 488.406.

The Act and regulations make a hearing before an ALJ available to a long-term care facility against which CMS has determined to impose an enforcement remedy. Act § 1819(h)(2)(B)(ii) (incorporating Act § 1128A(c)(2)); 42 C.F.R. §§ 488.408(g); 498.3(b)(13). The hearing before an ALJ is a *de novo* proceeding. *Anesthesiologists Affiliated, et al*, DAB CR65 (1990), *aff'd*, 941 F.2d 678 (8th Cir. 1991); *Emerald Oaks*, DAB No. 1800, at 11 (2001); *Beechwood Sanitarium*, DAB No. 1906 (2004); *Cal Turner Extended Care*, DAB No. 2030 (2006)*; The Residence at Salem Woods*, DAB No. 2052, (2006). A facility has a right to appeal a "certification of noncompliance leading to an enforcement remedy." 42 C.F.R. § 488.408(g)(1); *see also* 42 C.F.R. §§ 488.330(e) and 498.3. However, the choice of remedies by CMS or the factors CMS considered when choosing remedies are not subject to review. 42 C.F.R. § 488.408(g)(2). A facility may only challenge the scope and severity level of noncompliance found by CMS if a successful challenge would affect the range of the CMP that could be imposed by CMS or impact upon the facility's authority to conduct a nurse aide training and competency evaluation program. 42 C.F.R. §§ 498.3(b)(14) and (d)(10)(i). 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 subject to 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, *i.e.*, CMS must show a violation of a participation requirement, statutory or regulatory, and that the violation posed more than minimal harm to a resident or residents. "*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); s*ee also Hillman Rehabilitation Center*, DAB No. 1611, at 8 (1997), *aff'd, Hillman Rehabilitation Center v. U.S. Dep't Health & Human Services*, No. 98-3789 (GEB) (D.N.J. May 13, 1999). To prevail, a long-term care facility must overcome CMS's showing by a preponderance of the evidence. *Evergreene Nursing Care Center*, DAB No. 2069, at 7-8 (2007); *Emerald Oaks*, DAB No. 1800 (2001); *Cross Creek Health Care Center*, DAB No. 1665 (1998); *Hillman Rehabilitation Center*, DAB No. 1611.

E. Analysis

1. Petitioner did not waive its right to a hearing on the deficiencies alleged by the survey completed on January 6, 2006 and the enforcement remedies based upon those deficiencies, and I have jurisdiction to hear and decide this case.

On June 22, 2006, CMS moved to dismiss Petitioner's request for hearing. The CMS theory was that Petitioner waived its right to a hearing as to the deficiencies alleged by the survey completed on January 6, 2006, and the enforcement remedies based on those deficiencies. CMS argued that the waiver occurred because Petitioner accepted, pursuant to 42 C.F.R. § 488.436, a 35 percent reduction in a civil money penalty (CMP) that was based upon the findings of a subsequent survey completed on February 13, 2006. The regulation provides for the payment of a reduced CMP in exchange for Petitioner waiving its right to hearing. On September 20, 2006, I issued an Order in which I denied the CMS motion to dismiss for reasons discussed in detail in that order.

CMS argues in its Prehearing Brief that I do not have jurisdiction to consider and decide the request for hearing because Petitioner waived its right to a hearing for a 35 percent reduction of the CMP imposed based on the February 13, 2006 survey findings. CMS advances an argument similar to that advanced in its motion to dismiss. CMS recognizes that Petitioner's waiver of hearing was in exchange for a 35 percent reduction of the CMP that was based on deficiencies cited during the February 2006 survey. CMS argues, however, that the mandatory DPNA was triggered by a three month period of noncompliance, and part of the three month period of noncompliance was based on the finding of continued noncompliance of the February 2006 survey. CMS reasons that because Petitioner waived a hearing as to the findings and remedies of the February 2006 survey, Petitioner waived review as to the mandatory DPNA, and all findings of

noncompliance that caused the continued running of the three-month period of noncompliance that triggered the mandatory DPNA. CMS also argues that, even if I conclude that the mandatory DPNA was not triggered, CMS could have imposed a discretionary DPNA based on the February 2006 survey findings. Counsel for CMS does not assert CMS did act to impose a discretionary DPNA or offer any explanation for why CMS did not do so, if CMS officials believed that a discretionary DPNA was appropriate. CMS Prehearing Brief at 1-2. In its post hearing brief, CMS acknowledges that its motion to dismiss was denied. However, CMS asserts for purposes of appeal that even if Petitioner shows it returned to substantial compliance at the time of the survey that ended January 6, 2006, CMS had the authority pursuant to 42 C.F.R. § 488.417(a) to impose a discretionary DPNA based on the November 2005 and February 2006 findings of noncompliance, neither of which is challenged by Petitioner. CMS Brief at 2, n.1; CMS Prehearing Brief at 2, n.1. CMS does not address why CMS did not elect to impose a discretionary DPNA. CMS advocates that I should treat the mandatory DPNA as though it was a discretionary DPNA. However, as noted in virtually every ALJ decision under 42 C.F.R. Part 498, the choice of remedies by CMS or the factors CMS considered when choosing remedies are not subject to my review. 42 C.F.R. § 488.408(g)(2). Furthermore, it is not within my authority to substitute my judgment for that of CMS, particularly with regard to the appropriate enforcement remedy to be imposed. My authority is limited to deciding whether there is a basis for the imposition of the enforcement remedy chosen by CMS and whether the remedy is reasonable. I further note that pursuant to 42 C.F.R. § 498.30, CMS could have reopened and revised its decision regarding the appropriate enforcement remedies at anytime within 12 months and could have requested a remand for that purpose either with or without consent of Petitioner pursuant to 42 C.F.R. §§ 498.56(d) or 498.78. CMS never reopened and revised its determination; never gave Petitioner notice of any change in remedies consistent with the notice requirements of 42 C.F.R. §§ 498.20 or 498.32; and CMS never asserted before me that a determination was made by the state agency or CMS that a discretionary DPNA was imposed based on any of the surveys in the survey cycle.

I have reviewed the arguments of CMS in its prehearing and post hearing briefs. I conclude that the rationale for denying the CMS motion to dismiss was correct when I issued the Order denying that motion on September 20, 2006. I further conclude that the rationale remains correct and supportive of my decision that Petitioner did not waive its right to a hearing as to the January 2006 deficiency findings and related enforcement remedies. For the benefit of any appellate review, I repeat the rationale in this decision.

There is no dispute that Petitioner was subject to four surveys by the state agency that concluded on November 21, 2005, January 6, 2006, February 13, 2006, and March 3, 2006.[8] Each of the four surveys concluded that Petitioner was not in substantial compliance with program participation requirements, *i.e.*, there were regulatory or statutory violations and a risk for more than minimal harm to Petitioner's residents. CMS does not assert and I have not received any evidence that Petitioner was notified of the imposition of any enforcement remedies based on the deficiency findings from the November 21, 2005 survey. However, November 21, 2005 started the running of the three-month period that triggered the mandatory DPNA. CMS Motion at 3-4; CMS Prehearing Brief at 2-3. The January 6, 2006 survey was a revisit survey following-up the November survey, and a complaint investigation. During the January survey, the surveyors found continuing noncompliance with 42 C.F.R. § 483.25(m)(1) (Tag F332), but the other violations from the November 2005 survey were not cited again and were apparently determined to have been corrected. The surveyors found a new violation of 42 C.F.R. § 483.30(a) (Tag F353). CMS Ex. 4; CMS Motion at 4; CMS Prehearing Brief at 3. The state agency sent Petitioner a letter dated January 18, 2006, which advised Petitioner of the findings of noncompliance by the November 2005 and January 2006 surveys. The state agency advised Petitioner that it imposed, pursuant to a delegation of authority from CMS, the remedy of directed in-service training effective February 17, 2006 for all nursing staff regarding facility policy and procedures for medication administration. The state agency advised Petitioner that a "mandatory" DPNA would be effective February 21, 2006, and remain in effect until Petitioner was found to be in substantial compliance or its provider agreement was terminated. The state agency also advised Petitioner that it would recommend to CMS that Petitioner's provider agreement be terminated on May 21, 2006, if Petitioner did not return to substantial compliance before that date. CMS Ex. 1, at 1-2. Petitioner requested a hearing by letter dated March 22, 2006. Petitioner specifically requested a hearing as to the findings and conclusions stated in the Statement of Deficiencies (SOD) dated January 6, 2006, and the remedies imposed, the mandatory DPNA and directed in-service training of which the state agency notified Petitioner by its letter of January 18, 2006. Petitioner specifically listed and discussed the two deficiency findings from the January 2006 survey. Request for Hearing.[9]

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[8] Petitioner was subject to a fifth survey on April 26, 2006, that determined that Petitioner returned to substantial compliance with program participation requirements effective April 26, 2006. CMS Ex. 3.

[9] The parties stipulated that only the January 2006 survey findings are at issue before me. Joint Stipulation of Facts, filed July 19, 2006.

The state agency conducted a complaint survey of Petitioner's facility that concluded on February 13, 2006, and Petitioner was found not to be in substantial compliance. The state agency conducted another revisit survey and complaint investigation on March 3, 2006, and concluded that Petitioner remained out of substantial compliance. CMS Ex. 2, at 1-2; CMS Motion at 4; CMS Prehearing Brief at 3. CMS advised Petitioner of the results of the February 2006 survey in its letter dated April 11, 2006. CMS advised Petitioner that surveyors found during the February 2006 survey that Petitioner's violations of 42 C.F.R. §§ 483.13(b)(1)(i) (Tag F223) and 483.13(c) (Tag F226) posed immediate jeopardy to patient health and safety beginning January 25, 2006, and continuing to February 10, 2006. CMS advised Petitioner that the March revisit found continuing noncompliance. CMS noted that the state agency had imposed directed in-service training effective February 17, 2006, and the mandatory DPNA that was effective February 21, 2006, and that the state had advised Petitioner of the right to appeal those remedies and the alleged deficiencies upon which they were based. CMS stated that the mandatory DPNA was required by sections 1819(h)(2)(D) and 1919(h)(2)(C) of the Act and 42 C.F.R. § 488.417(b) and that it would remain in effect until Petitioner returned to substantial compliance. CMS advised Petitioner that it was imposing two per instance CMPs totaling $5000 for the violations found by the February 2006 survey. CMS Ex. 2, at 1-3. The CMS letter advised Petitioner that the CMP would be reduced by 35 percent if Petitioner filed a written waiver of its right to a hearing. CMS also advised Petitioner of the right to request a hearing. CMS stated that the state agency had previously notified Petitioner of "appeal rights for noncompliance found during the November 21, 2005, November 28, 2005 and January 6, 2006 surveys that resulted in the imposition of the denial of payment for new admissions and the directed in-service training."[10] CMS Ex. 2, at 4. CMS continued:

> This formal notice imposed a civil money penalty for noncompliance cited during the February 13, 2006 survey. If you disagree with the finding of noncompliance which resulted in this imposition and the continuation of the denial of payment for new admissions, and the finding of SQC [substandard quality of care] which resulted in the loss of NATCEP [Nurse Aide Training and Competency Evaluation Program] approval, you or your legal representative may request a hearing before an administrative law judge . . . .

CMS Ex. 2, at 4. This language clearly indicates the CMS position, at the time, that a right to request a hearing was triggered by the state agency notice of enforcement remedies dated January 18, 2006 (CMS Ex. 1) and that a separate right to request a

[10] The November 28, 2005 survey was a fire safety inspection that is not at issue.

hearing was triggered by the CMS letter dated April 11, 2006 (CMS Ex. 2). The CMS position, evidenced by the April 11, 2006 notice, is consistent with the usual CMS position that the notice of imposition of separate enforcement remedies based upon separate surveys, even within the same survey cycle, triggers separate rights to review by an ALJ. There is no dispute that by letter dated May 31, 2006, Petitioner waived its right to a hearing to receive the 35 percent reduction of the CMP as provided by 42 C.F.R. § 488.436, and that Petitioner included a check for $3250, which is 65 percent of $5000. CMS has never denied that it negotiated the check and thereby accepted the offered compromise.

I find unpersuasive the CMS arguments that Petitioner's May 31, 2006 payment and waiver not only waived Petitioner's right to a hearing on the February 2006 survey and the CMPs based on that survey, but also caused a waiver of Petitioner's right to a hearing on the January 2006 deficiencies and the remedies based on or triggered by that survey. Also, I find no merit to the CMS arguments that allowing Petitioner to proceed with its request for hearing on the January survey would subvert the purpose of 42 C.F.R. § 488.436, or that there is no remedy I can grant on the request for hearing from the January 2006 survey.

Petitioner was subject to at least four separate surveys by the state agency that resulted in deficiency findings. Pursuant to 42 C.F.R. § 488.408(g), a facility may appeal a certification of noncompliance that leads to an enforcement remedy. The January survey and certification of noncompliance for which Petitioner has requested a hearing resulted in enforcement remedies, *i.e.*, the state agency notice of a mandatory DPNA, effective on February 21, 2006[11] and directed in-service training. The findings of noncompliance from the January survey resulted in the imposition of enforcement remedies specified under 42 C.F.R. § 488.406, and that constitutes an "initial determination" within the meaning of 42 C.F.R. § 498.3(b)(13). There is no question that the "initial determination" to impose a remedy, except the state monitoring remedy, triggers the right to request a hearing. *See* 42 C.F.R. §§ 498.3 and 498.5. CMS has never argued that Petitioner did not have a right to request a hearing related to the January survey.

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[11] In this case, the three month period began to run on November 21, 2005, the last day of the November 6, 2005 survey. The state agency notice of January 18, 2006, advised Petitioner that, due to a finding of noncompliance from the January survey, the mandatory denial would be effective February 21, 2006. Had Petitioner been found to have returned to substantial compliance during the January survey, the mandatory DPNA would not have been effective February 21, 2006, as the three-month period would have been broken.

The February complaint investigation resulted in the conclusion by the state agency that Petitioner was not in substantial compliance with program requirements. The per instance CMPs imposed were specifically based upon deficiencies found only during the February survey. The surveyors found that the deficiencies identified during the February survey posed immediate jeopardy to Petitioner's residents beginning on January 25, 2006. CMS Ex. 2, at 2-3. The February survey triggered a separate right to request a hearing to challenge the initial determination to impose enforcement remedies based upon the deficiencies identified during that survey. CMS has never argued that Petitioner did not have a right to request a hearing related to the February survey. Further, Petitioner does not dispute that it waived its right to a hearing as to the February survey and the remedies related to that survey by accepting and paying the reduced CMP in accordance with 42 C.F.R. § 488.436. I also note that Petitioner waived its opportunity to challenge the CMS determination that there was immediate jeopardy due to the deficiencies cited on the February survey beginning on January 25, 2006.

The January and February surveys were separate surveys with different deficiency findings and different enforcement remedies involved. There is no question that notice of the findings and proposed remedies for each survey was a separate "initial determination" that triggered a right to request a hearing by an ALJ. The fact that the two surveys were part of the same survey cycle is of no consequence given the facts of this case. CMS incorrectly relies upon the decision of an ALJ in *Casa Del Sol Senior Care Center v. CMS*, DAB CR1418 (2006), which is easily distinguished from the present case. In *Casa Del Sol*, not only did the ALJ not specifically address the issue raised by CMS in this case, the DPNA and CMP in that case arose from a single survey. CMS is also incorrect when it asserts that by allowing Petitioner to proceed based upon its request for hearing on the February survey, CMS is deprived of the benefit contemplated by 42 C.F.R. § 488.436 – clearly that is not the case. CMS has received partial payment on the CMPs imposed based on the February survey without the need to litigate whether or not the deficiencies cited on the February survey actually provided a basis for the imposition of those CMPs and whether or not the CMPs were reasonable. Finally, CMS is in error in asserting that, if I should decide that Petitioner's case is meritorious and that the deficiencies cited on the January survey are unsupported, I can fashion no remedy. CMS recognized in its brief on its motion, that if there had there been no deficiency findings on the January survey, the three month period triggered by the November survey would have been stopped as of the date of the January survey and the mandatory DPNA under 42 C.F.R. § 488.417(b)(1) would not have gone into effect on February 21, 2006. CMS Motion at 14.

I conclude that Petitioner's waiver of its right to hearing as to the CMPs based upon the findings of deficiency from the February 2006 survey, did not result in a waiver of Petitioner's right to hearing to challenge the findings of the January 2006 survey that

continued the running of the three-month period that triggered the mandatory DPNA on February 21, 2006. Petitioner has a right to a hearing to challenge the basis for the imposition of the mandatory DPNA and I have jurisdiction.

2. CMS did not make a prima facie showing of a violation of 42 C.F.R. § 483.25(m)(1) (Tag F332).

In the SOD dated January 6, 2006 for the survey that ended on that date, the surveyors cited Petitioner for only two alleged deficiencies: violation of 42 C.F.R. § 483.25(m)(1) (Tag F332) at a scope and severity of D, and violation of 42 C.F.R. § 483.30(a) (Tag F353) at a scope and severity of E. CMS advised me in its prehearing brief and confirmed at hearing that it would not proceed upon Tag F332 (42 C.F.R. § 483.25(m)(1) that alleged medication errors. CMS Prehearing Brief at 16, n.2; Tr. 19. CMS advised me that it would still rely upon findings and allegations under Tag F332 in support of its prima facie showing that Petitioner was in violation of 42 C.F.R. § 483.30(a) (Tag F353). CMS Prehearing Brief at 16, n.2.

Accordingly, I conclude that CMS has failed to make a prima facie showing of a violation of 42 C.F.R. § 483.25(m)(1) (Tag F332) due to its election not to proceed upon that violation at hearing.

3. CMS did not make a prima facie showing that Petitioner violated 42 C.F.R. § 483.30(a) (Tag F353).

The regulation at issue requires:

> The facility must have sufficient nursing staff to provide nursing and related services to attain or maintain the highest practical physical, mental, and pyschosocial well-being of each resident, as determined by resident assessments and individual plans of care.
>
> (a) *Sufficient staff.* (1) The facility must provide services by sufficient numbers of each of the following types of personnel on a 24-hour basis to provide nursing care to all residents in accordance with resident care plans:
>
> > (i) Except when waived under paragraph (c) of this section, licensed nurses; and
> >
> > (ii) Other nursing personnel.

> (2) Except when waived under paragraph (c) of this section, the facility must designate a licensed nurse to serve as a charge nurse on each tour of duty.

42 C.F.R. § 483.30(a).

The Guidance to Surveyors, SOM, App. PP, Tag F353, instructs surveyors:

> [T]he determining factor in sufficiency of staff (including both numbers of staff and their qualifications) will be the ability of the facility to provide needed care for residents. A deficiency concerning staffing should ordinarily provide examples of care deficits caused by insufficient quantity and quality of staff. If, however, inadequate staff (either the number or category) presents a clear threat to residents reaching their highest practicable level of well-being, cite this as a deficiency. Provide specific documentation of the threat.

The Board addressed 42 C.F.R. § 483.30(a) in *Carehouse Convalescent Hospital*, DAB No. 1799 (2001) and in *Westgate Healthcare Center*, DAB No. 1821 (2002). In *Carehouse*, the Board upheld the ALJ decision that CMS failed to make a prima facie showing that Petitioner was not in substantial compliance with 42 C.F.R. § 483.30(a) (Tag F353). *Carehouse*, at 39-40. The Board commented that the essence of a deficiency under Tag F353 is the link or nexus between a facility's failure to deliver appropriate care and the number of staff the facility provided to deliver care to its residents. The Board declined to comment upon when quality of care issues give rise to an inference of insufficient numbers of nursing staff. *Id.* The Board did not address whether the number of staff on duty might give rise to an inference of poor quality of care, the principal theory advanced by CMS in this case.[12]

In *Westgate*, a different appellate panel of the Board writing less than four months after the *Carehouse* decision, stated that "compliance with the federal **staffing** requirement at 42 C.F.R. § 483.30(a)(1) is determined by whether the numbers of staff are sufficient to meet residents' needs, as determined by resident care plans and, therefore, [Petitioner's] compliance with a minimum resident to staff ratio in state law is irrelevant; . . . ." *Westgate*, at 2 (emphasis added). The Board subsequently explains in the decision, that

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[12] For reasons discussed in more detail hereafter, the complaints of various staff members interviewed by the surveyors are not considered to be credible evidence of specific instances of failure to deliver care. Further, as discussed hereafter, the surveyors failed to identify any specific instance of a failure to deliver care.

compliance with a staffing ratio established by state law may or may not be relevant depending upon the basis for the state staffing ratio and how it relates to the federal staffing requirement. The appropriate level for staffing under the federal regulation is determined based upon the needs of the residents. The Board noted that Westgate did not base its staffing-level on resident needs but relied only upon the state required staffing ratio. *Id.* at 11. The Board commented upon the decision in *Carehouse*, that that decision "stand[s] for the proposition that CMS may not rely on resident outcomes alone, without showing a nexus to the sufficiency of staff . . . ." *Id.* at 14. The Board rejected an argument that the ALJ was "required to find that additional staff would have prevented incidents in which residents were harmed" and stated that:

> CMS need only show that the numbers of staff were not sufficient to meet the residents' needs as shown in their care plans. CMS may accept as sufficient a staffing level that might not be able to prevent every incident such as those cited, as long as the facility has that staff that is reasonably expected to be needed in order to fulfill the resident's needs, for example, by reducing the number and severity of such incidents to the extent practicable. The requirement is for the highest practicable level of well-being that can be attained or maintained.

Id. at 15 (emphasis in original).

Based upon the language of 42 C.F.R. § 483.30(a)(1) and the Board's decision in *Carehouse and Westgate*, CMS makes a prima facie showing that Petitioner was not in substantial compliance with the regulation if CMS shows that (1) resident needs as identified in their care plans are not met or may not be met; (2) the inability or failure to meet needs of the residents was due to insufficient staffing; and (3) the failure to meet resident care planned needs posed the risk for more than minimal harm. Further, meeting or exceeding a state mandated staffing ratio is not an absolute defense for Petitioner, but may constitute some evidence that staff was sufficient. The Board indicated by the quoted language from *Westgate* that a rule of reasonableness is to be applied, *i.e.*, what staffing is reasonably necessary to meet expected resident needs rather than to avoid all adverse incidents or outcomes.

The parties were advised in the Prehearing Order and at hearing (Tr. 3), and have not disputed, that CMS has the burden of going forward with the evidence to establish a prima facie case that Petitioner was not in substantial compliance with a program participation requirement that provides a basis for the imposition of an enforcement remedy. "*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).

> CMS has the burden of coming forward with evidence related to disputed findings that is sufficient (together with any undisputed findings and relevant legal authority) to establish a prima facie case of noncompliance with a regulatory requirement. If CMS makes this prima facie showing, then the SNF must carry its ultimate burden of persuasion by showing, by a preponderance of the evidence, on the record as a whole, that it was in substantial compliance during the relevant period.

Evergreene Nursing Care Center, DAB No. 2069, at 7 (2007) (citations omitted); *Bradford County Manor*, DAB No. 2181, at 3 (2008). Mere allegations and speculation are not sufficient to satisfy the requirement to establish a prima facie case when disputed. Whether CMS makes a prima facie showing is determined by review of the credible evidence CMS presents to establish each element necessary to show that a facility is not in substantial compliance with a statutory or regulatory requirement of participation. To establish a prima facie case of substantial noncompliance, the required basis for imposition of an enforcement remedy, CMS must show that the participation requirement was violated and that one or more residents suffered or were exposed to a risk for more than minimal harm. Petitioner disputes the factual basis for the CMS prima facie case. Petitioner preserved its argument that CMS failed to make a prima facie case that Petitioner was not in substantial compliance with the participation requirement established by 42 C.F.R. § 483.30(a) by requesting summary judgment on that basis and by motion at the conclusion of the CMS case-in-chief for a judgment that CMS failed to make a prima facie showing. *Jennifer Matthew Nursing & Rehabilitation Center*, DAB No. 2192 (2008), at 20, n.12; *see* Petitioner Community Northview Care Center's Memorandum in Support of Its Motion for Summary Judgment at 2, 22-30; Tr. 512.[13] CMS argues in its post hearing brief that the evidence shows Petitioner was often understaffed compared to its determination of required staffing and at times had less than half the staff working that Petitioner deemed necessary. CMS argues that, due to being

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[13] As discussed in some detail in my ruling on the motion for summary judgment, the requirement to view the evidence in a light most favorable to CMS, the nonmovant, precluded a ruling in Petitioner's favor at that time. Order Denying Respondent's Motion to Dismiss for Lack of Jurisdiction; Denying Petitioner's Motion for Summary Judgment; and Directing the Parties to File Notice of Potential Conflicts, dated September 20, 2006, at 7-9. The transcript reflects that I denied Petitioner's motion for judgment. My statement that I denied the motion for judgment is incorrect and the context indicates that I declined to issue a decision from the bench and rather deferred ruling upon the motion until the decision on the merits of the case. Tr. 512. The parties understanding that the issue was preserved is reflected by their extensive arguments in post hearing briefing about whether CMS made a prima facie showing.

understaffed, Petitioner failed to provide good perineal care for its residents, failed to check its incontinent residents frequently enough, gave nurse aides unreasonable assignments that could not be completed during an eight-hour shift, Petitioner's staff did not answer call lights timely, and Petitioner's staff routinely administered medications late. CMS Brief at 18-19. During the hearing, counsel for CMS agreed with my characterization that the CMS theory is that Petitioner's residents had assessed needs and that Petitioner's level of staffing was not sufficient to provide for the needs of the residents present at the time of the survey and during December 2005. Counsel for CMS agreed that there were no specific deficiencies in the delivery of care or services cited by the surveyors, but CMS was proceeding based upon its understanding of prior Board decisions that it is not necessary to cite a quality of care deficiency in order to allege insufficient staffing. Tr. 41-44. My understanding is that CMS advocates that I should compare the assessed needs of residents with the number of staff on duty and infer or determine that staff was insufficient to meet the needs of the residents without evidence of a specific failure of Petitioner to meet a care planned need of a resident and without evidence of the specific care planned needs of the residents. CMS cites to no authority for this approach or case where such approach has been accepted by the Board.

I conclude based upon my review of the facts as summarized hereafter, that CMS has failed to show any failure by Petitioner to deliver a care planned care or to meet a resident's care planned need. I conclude based upon my review of the facts, that CMS has failed to show that insufficient staffing by Petitioner posed an unreasonable threat that Petitioner would fail to meet a resident's care planned need. I conclude based upon my review of the facts, that CMS has failed to show that any resident was exposed to more than minimal harm due to insufficient staffing at Petitioner's facility. I conclude that CMS has failed to make a prima facie showing of a violation of 42 C.F.R. § 483.30(a)(1) (Tag F353).

(a) Findings and conclusions from the SOD.

The surveyors allege in the SOD that Petitioner violated the regulation because Petitioner failed to:

> [E]nsure nursing staff were allowed sufficient time to get their assigned residents to scheduled meal times, to set up room trays, to feed residents who require assistance, to provide personal hygiene and grooming on a daily basis, and failed to ensure residents were checked for incontinence regularly while in bed, as evidenced by nursing staff padding the resident's beds with more than 2 cloth incontinence pads, for 3 of 4 days of the survey. The facility also failed to ensure nursing staff were able to

> complete medication passes in the allotted time allowed to pass medications for 2 of 4 days of the survey.

CMS Ex. 4, at 7. The surveyors allege three numbered examples in the SOD to show the existence of the alleged regulatory violation: (1) a strong smell of urine was noted each morning of the survey and the surveyors observed multiple incontinence pads on multiple beds; (2) the surveyors observed that medications were not given at the right time; and (3) the surveyors received complaints from residents, residents' family members, and staff that there was insufficient staff, resulting in unanswered or delayed response to call lights, missed or inadequate cares such as oral or perineal, and delayed or late delivery of meal trays. The surveyors allege under example 1 that when they arrived at the facility on January 3, 2006 at 9:30 a.m. there was a strong odor of urine. During the morning of January 3, 2006, the surveyors allege they observed three instances where residents (Residents SSS, DDD, XXX, and QQQ) had three cloth incontinence pads on their beds, but none were alleged to be wet. CMS Ex. 4, at 7-8. The surveyors allege that on January 4, 2006, they smelled urine; they observed Resident XXX's bed with three incontinence pads, the top two wet (CMS Ex. 23, at 7 reflects that Resident XXX (CMS Ex. 8, at 1) was not in bed when the observation was made); they observed Resident V's bed was stripped and there were two wet incontinence pads; and they observed that Resident V's roommate was in bed lying on three incontinence pads, which they did not allege were wet. CMS Ex. 4, at 8-9. The surveyors allege that on January 5, 2006, they smelled urine; they observed seven instances of three or four incontinence pads on a resident's bed (Resident AAAA, RRR, J, XXX, PP, MMM, HHH) and none were alleged to be wet. CMS Ex. 4, at 9-10. The surveyors also allege that they were told by nursing staff members that multiple incontinence pads were often used for residents who were really incontinent and staff found wet incontinence pads. CMS Ex. 4, at 10-11.

Under example 2, the surveyors allege they observed medication passes on January 3 and 4, 2006. On January 3, 2006, they observed: three medications given at 10:00 a.m. but the Medication Administration Record (MAR) indicated that the medications were to be given at 9:00 a.m.; seven medications given at 10:45 a.m. that the MAR showed should have been given at 9:00 a.m.; and one medication was given at 11:00 a.m. that was supposed to be given at 9:00 a.m. On January 4, 2006, the surveyors allege that they observed: five medications given at 10:35 a.m.[14] that should have been given at 9:00 a.m.; seven medications given at 10:30 a.m. that should have been given at 9:00 a.m.; 13 medications given at 10:45 a.m. that should have been given at 9:00 a.m. CMS Ex. 4, at

[14] The SOD actually states "10:30 p.m." but it is clear from the context that there was a typographical error and the time should have read "10:30 a.m." and the surveyor agreed. CMS Ex. 4, at 12; Tr. 453.

12. A staff member complained to the surveyors that medications ran late most mornings for the last one to two weeks because staff responsible to deliver medication were being called away to assist with meals. The DON told the surveyors that a new dining program had been implemented on December 21, 2005, that was causing medications to be passed late and she had not resolved the problem yet. CMS Ex. 4, at 12-13.

Example 3 lists ten complaints the surveyors received while doing interviews in the facility, including two from family members, three from residents, and five from staff.

The surveyors do not specifically allege that they observed actual harm or that the conditions they observed or heard about were likely to cause more than minimal harm. Thus, the surveyors do not allege in the SOD how any of the examples cited pose the potential for more than minimal harm. However, the surveyors cited the deficiency at a scope and severity of E (CMS Ex. 4, at 6), which means they determined that there was a pattern of deficiencies that caused no actual harm but had the potential for causing more than minimal harm. Tr. 299. The surveyors testified at hearing regarding their conclusions about the potential for harm.[15] Surveyor Wolfgang testified the surveyors concluded that Petitioner did not have sufficient staff; that there was a risk for increased falls when residents tried to get up when their call bells were not answered; potential for skin breakdown when incontinence incidents occurred that were not promptly cleaned-up; and dignity and environment problems because of odors. Tr. 228-30. Surveyor McNamee testified that the surveyors concluded that Petitioner did not have sufficient staff to deliver care that resident's needed. Tr. 477. She testified that there was the potential for more than minimal harm for Petitioner's residents due to the potential for increased falls if residents did not receive prompt care and tried to walk on their own; skin break down due to inadequate perineal care; general discomfort and indignity from

[15] The SOD in this case fails to allege the elements of a prima facie case because the findings and conclusions of the surveyors do not address either specific examples of failure to deliver care planned cares or an unreasonable risk of such failure, or the potential for more than minimal harm. Thus, there is a significant issue regarding the adequacy of the SOD as a notice document. Petitioner preserved the issue by its motion for summary judgment and objections at hearing. However, given my decision I conclude it is not necessary to specifically address the adequacy of SOD to give Petitioner the required notice of what Petitioner had to defend. CMS also argues that staffing levels in December 2005 were not sufficient. The surveyors did not specifically allege a deficiency related to staffing in December 2005. The CMS attempt to amend the SOD to include additional grounds for a deficiency finding at hearing also creates a significant notice issue. However, I again find it unnecessary to address that specific issue given my decision in this case.

lying on a wet incontinence pad. However, she admitted in response to my question that the surveyors found no evidence of such adverse results or negative outcomes at Petitioner's facility. Tr. 474-77.

(b) CMS arguments.

In its prehearing brief, CMS describes the assessments of 20 of Petitioner's residents based on clinical records obtained by the surveyors during the survey. CMS Prehearing Brief at 6-13. CMS only mentions care plans for three residents: Alice T's care plan required that she be toileted and turned every two hours; Thelma V's care plan required that she be turned every two hours; and Treva E's care plan required that she be toileted and turned every two hours. CMS Prehearing Brief at 9-10. CMS does not allege that the surveyors observed or determined from records review that Alice T., Thelma V., or Treva E. were not turned or toileted as required by their care plans. CMS does not specifically allege in its prehearing brief that any assessed or care planned need of any of the 20 described residents was not met.

CMS alleges that Resident AAAA's son told surveyors that Petitioner's "staff take a long time to get things done because they have to care for so many residents" and that "staff do not show up to work their shifts." CMS Prehearing Brief at 8 (citing surveyor notes at CMS Ex. 21, at 3); *see* CMS Brief at 13. The surveyor notes do not reflect the actual questions asked or the answers of the resident's son. The notes do include some statements contained within quotations, but there is no indication that the declarant ever saw what the surveyor recorded or agreed it was an accurate summary of what he said. CMS did not introduce as evidence any written statement of the resident's son that shows he understood that he was obliged to respond truthfully to the surveyors. The evidence does not reveal how Resident AAAA's son knew that staff did not show for work, what things took a long time or why his perception of how long things took should be given any weight, or the basis for his opinion that the time it took to get things done was impacted by the number of staff or residents. The surveyor notes were made by the surveyor during the course of her duties as an investigator and there is no assurance that the contents of the notes were not affected by her perceptions as an investigator, *i.e.*, what is recorded is the investigator's perception of responses to questions the investigator asked to which I am not privy and in a context that is not captured in the investigators notes. My concern about possible investigator bias applies to all the surveyors' recordings and recollections of complaints by staff and residents in this case. Hearsay is clearly admissible in this administrative proceeding. However it is necessary in this proceeding to determine whether such hearsay is credible and whether it has probative value. Absent some indicia of reliability, I do not find credible the surveyor's recollection of the out-of-court statement of Resident AAAA's son, and I do not consider it probative evidence. Even if I found the statement of AAAA's son to be credible, I note

that the surveyor did not record that Resident AAAA's son stated that the resident was denied any care.

CMS alleges in its prehearing and post hearing brief that Resident PPP's daughter told a surveyor that Petitioner never has enough staff, that the resident is left in wet incontinence briefs for long periods, and that contributed to urinary tract infections (UTIs) and skin breakdown for her mother since moving to Petitioner's facility. CMS Prehearing Brief at 8-9 (citing CMS Ex. 21, at 6); CMS Brief at 13; Tr. 170-71. CMS has produced no statement of Resident PPP's daughter, only the surveyor notes and testimony that do not reflect questions and answers, the context of the interview, or that Resident PPP's daughter understood she needed to be truthful in responding. The surveyor notes indicate that Resident PPP's daughter told her that Petitioner has two staff, one on each hallway during each shift. Her statement is unclear in that it does not specify the category of staff or to which shifts she refers and is inconsistent with other evidence CMS presented that shows Petitioner had more staff on duty each shift through the months of December 2005 and January 2006. CMS Ex. 32. The surveyor notes do not indicate how long Resident PPP's daughter observed that her mother was left in wet briefs or why she thought the period was too long, but the notes do indicate that the resident had no brief changes all morning without clarifying whether the briefs were wet the entire period. CMS Ex. 21, at 6. There is no evidence of the basis for the daughter's opinion that her mother being in a wet brief for an unspecified period contributed UTI's or skin breakdown or that she was qualified to make such a judgment. The surveyor notes do not show that the daughter alleged that any other need of Resident PPP was not met or not met promptly enough to suit her. CMS Ex. 21, at 6. I do not find the surveyor's recording of the out-of-court statement of Resident PPP's daughter to have sufficient indicia of reliability to be given probative value.

CMS alleges in its briefs that the husband of Resident OO reported to a surveyor that he thought Petitioner was always short-staffed on weekends. CMS Prehearing Brief at 14; CMS Brief at 12-13. The surveyor notes of the conversation with Resident OO's husband are not considered probative. I have no evidence of the context, the questions or answers, or whether the husband understood he needed to tell the truth. The surveyor notes do not give a clue as to the basis for the opinion of the husband that Petitioner operated short-staffed on the weekend or that scheduled staff did not come to work. Although surveyor notes indicate he also told surveyors that staff do not answer call lights, the notes do not show that his wife's call light was not answered or how he knew that lights were not answered. He also reportedly stated that the wait at meal time was 30 minutes to one hour, but there is no indication that he felt that was bad or good. CMS Ex. 22, at 7. His complaints about food service are inconsistent with the findings of the surveyors. CMS Ex. 10, at 3. Surveyor McNamee testified that when she interviewed the husband of Resident OO, she learned that he was at the facility from before lunch until after supper;

he told her that sometimes staff did not answer call lights for 30 minutes to an hour during mealtimes and he knew that because he checked his watch. She testified he gave her only one example of when this happened and that was when, after returning from meals, he wanted assistance in helping his wife lie down. She testified that he told her that delayed response to call lights was not a daily problem but occurred a few times per week. Tr. 468-73. Surveyor McNamee also testified that she did not recall Petitioner's call light system including an intercom system to permit staff to communicate with a resident without going to the room. Tr. 470. Her testimony is inconsistent with the notes of Surveyor Wolfgang from January 5, 2006, at 10:06 a.m., which show that Surveyor Wolfgang heard an intercom used. CMS Ex. 21, at 5.

In its post hearing brief, CMS alleges that Resident LLLL told surveyors that her roommate had to wait in the bathroom 45 minutes for staff to respond to the call light and she knew how long it took because she had taken Milk of Magnesia and had to wait. CMS Brief at 13. CMS also argues that Resident Y complained because staff forgot to take her off the bedpan and sometimes gave her coffee rather than tea and then she had to wait until after the meal for her tea. CMS Brief at 13-14. Assuming both Resident LLLL and Y were capable of understanding and responding to questions, I have no evidence of the actual questions or their answers. The wait to use the bathroom after taking Milk of Magnesia may just seem to last an eternity and there is no indication that Resident LLLL actually looked at a clock when the call light was activated or when staff responded. Resident Y is not reported to have said how long she was left on the bedpan or how long she had to wait for her tea. There is no indication either resident understood that they needed to tell the truth or were even capable of understanding the truth. The surveyors do not allege that Resident LLLL's roommate or Resident Y were actually denied a care planned care.

CMS argued in its prehearing brief and post hearing brief that the DON told surveyors that aides usually care for no more than ten residents and the usual staffing was four to five nurse assistants on both the Dogwood and Rosewood wings of the facility during the day shift. CMS Prehearing Brief at 13 (citing CMS Ex. 21, at 8; CMS Ex. 22, at 8; CMS Ex. 23, at 18); CMS Brief at 7. Surveyor Wolfgang testified that the DON told her that CNAs (Certified Nurse Assistants) never had to care for more than 10 residents during the day shift. Tr. 186-87. Surveyor Wolfgang's assertion that the DON said CNAs never had more than 10 residents is inconsistent with the CMS assertions in its brief that the DON said CNAs usually have no more than 10 residents. Her testimony is inconsistent with the SOD in which the surveyors state that they were told by the DON that she liked to have a staffing ratio of one CNA to 10 residents but sometimes CNAs had to handle more residents. CMS Ex. 4, at 18. Her testimony is also inconsistent with her notes of her conversation with the DON that reflect that the DON said CNAs usually have no more than 10 residents. I find the statement from the SOD to be the more credible

version of the DON's out-of-court statement as that version was made closer in time to the interview of the DON than either the CMS briefs or Surveyor Wolfgang's testimony. I also note that the surveyor's testimony in this regard reflected a tendency to overstatement or exaggeration that reflects poorly upon her credibility, adding to my concern that investigator bias affected surveyor recording and recollection of statements of residents and staff.[16] I also note that Surveyor Wolfgang expressed at least one opinion during testimony for which she was unable to articulate a credible basis upon my inquiry, further damaging her credibility. Tr. 223-26.

The surveyors make no allegations in the SOD regarding December 2005 or specific numbers of staff that worked on any date or shift. However, CMS argues in its prehearing brief based upon CMS Ex. 33, that for various shifts on specific dates in December 2005, fewer nurse aides worked than would have been necessary for a ratio of ten to one, the DON's preferred ratio. CMS Prehearing Brief at 13-14. CMS Ex. 33, which CMS characterizes as a document reflecting hours worked by type of employee for each shift at Petitioner's facility for the period December 1 through 24, 2005, was withdrawn by CMS and not admitted as evidence. Hence, the CMS analysis based on CMS Ex. 33 is not considered further as it is not based on evidence of record. CMS presents a similar analysis in its post hearing brief based on evidence admitted at hearing. CMS concluded that for shifts worked between December 1 through December 24, 2005, and on January 2, 2006, "fewer aides than [Petitioner] identified as needed worked 64% of the shifts on Rosewood and more than 40% of the shifts on Dogwood." CMS Brief at 9. CMS provides tables showing, and an explanation for, its calculations. CMS Brief at 9-11. Although Petitioner disputes the calculations and what they might represent, for purposes of determining whether CMS made a prima facie showing I accept the information as presented and that the evidence shows that at times Petitioner operated with fewer staff than the DON preferred. However, that evidence does not show that any resident was denied care as a result and I draw no inference based on this evidence that the level of staffing posed an unreasonable risk that care planned care would not be delivered.

CMS argues in its briefs that three nurse aides complained to surveyors about having too many residents and not being able to get their work done and that a nurse reported that staff frequently call-in that they cannot work. CMS Prehearing Brief at 13-14; CMS

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[16] Surveyor Wolfgang also testified that in her opinion it takes the same number of staff to care for residents during the night shift as during the day shift. Tr. 166-67. However, on cross-examination she agreed that meals are not served during the night shift, showers are not given during the night shift, and residents are usually sleeping. Tr. 280.

Brief at 12. According to the surveyor notes, both CNA Chapin and CNA Price complained that the nurses on shift do not do anything. CMS Ex. 21, at 5, 6.[17] The surveyors only record a summary of their conversations with staff, the questions asked, specific answers, and the context are not indicated in surveyor notes. CMS Ex. 21, at 5, 6; CMS Ex. 22, at 8; CMS Ex. 23, at 8. There are no written statements prepared or adopted by the interviewed staff members and there is no indication that they saw the surveyors' summary of their interview or agreed with the summary. The surveyor notes show that CNA Chapin reported that meal trays sometimes sat for 20 minutes before residents were fed, that she had found four to six wet pads on wet sheets at times, she was not able to get her work done, and she did not have time to provide oral care. CMS Ex. 21, at 5. CNA Chapin is not reported to have stated that residents were not fed, that the food was not palatable, that there were complaints about the food, or incidents of food poisoning, and there is no evidence that she was asked such questions. The surveyors cited no deficiencies related to the quality of food or feeding practices and they do not report that they observed such deficiencies. In fact, the surveyors specifically determined unsupported a complaint about the food and meal service. CMS Ex. 10, at 3. CNA Chapin did not state that residents were not provided timely perineal care or that any residents showed signs or symptoms related to inadequate perineal care following incontinence episodes. Surveyor Wolfgang testified that CNA Chapin told her that she was able to keep her residents dry, but she could not recall anything other than that regarding perineal care. Tr. 303. Although CNA Chapin complained that she did not have time to get her work done, she did not say she did not do her work or that any residents were actually deprived of appropriate oral care. The evidence does not show that she was asked such questions by the surveyors. The evidence does not show that the

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[17] An admission of a party opponent is not hearsay. The issue that must be resolved to determine whether a party's agent's or servant's statements amount to an admission of the party is whether the agent or servant made statements concerning a matter within the scope of the agency or employment. Fed. R. Evid. 801(d)(2)(D). In administrative proceedings such as this, hearsay is admissible if authentic and relevant. A significant factual inquiry could be made to determine whether any of Petitioner's staff who spoke with surveyors were acting within the scope of their employ. Certainly staff has a duty to respond to questions of surveyors and that may be determined to be within the scope of employment. However, if staff lies or misrepresents, then arguably they are not responding within the scope of employment. In this case it is not necessary to resolve whether the statements of staff amounted to admissions. I do not treat the statements as hearsay but rather conclude that the recording of the surveyors' perception of their statements is not reliable or does not amount to a statement that any resident was denied a care planned care.

surveyors observed inadequate perineal care during the three days of the survey or identified such from residents' clinical records.

CNA Price stated that she was not able to get work done during a shift, but the surveyor notes do not show what work she was unable to get done or that she alleged that any resident was denied care planned cares. She did not know why the night shift padded the bed so much, but was willing to speculate it was because residents were not checked every two hours. The surveyor notes indicate she said there was not enough time to feed residents so she fed as fast as possible and went to the next resident. The surveyor quoted her as saying it was known that there was weight loss but they were doing the best they could. CMS 21, at 6-7. I note that the surveyors make no allegation that they observed or determined that there were any instances of unplanned weight loss and CMS points to no evidence of any unplanned weight loss.

CMS refers in its prehearing brief to a statement of Licensed Practical Nurse (L.P.N.) Donna Gray to the effect that staff frequently call-in to report they are not coming to work. CMS Prehearing Brief at 14. CMS does not mention in its prehearing brief that surveyor notes show that L.P.N. Gray also told surveyors that while staff has too much to do, they give good care and get the job done even though they are rushed. CMS Ex. 22, at 8. The surveyor notes do not indicate whether the L.P.N. was the charge nurse and referring to accomplishing all the work on her assigned unit or just her specific assignments, however Surveyor Wolfgang testified that she was asking L.P.N. Gray specifically whether she was able to get her work done by the end of the shift. Tr. 310. Of course, Surveyor Wolfgang could not credibly testify as to whether L.P.N. Gray actually understood the question or that it was limited as Surveyor Wolfgang intended. CMS does not mention that surveyor notes show that CNA Clarkson told surveyors that she was not aware of a problem with staff getting things done. CMS Ex. 22, at 8. CMS does not mention that surveyor notes show that L.P.N. Siscoe (or possibly Discoe) told surveyors that she had no problem getting work done by the end of the shift. CMS Ex. 21, at 6.

CNA Goins reportedly complained that Petitioner is always short-staffed. CMS Prehearing Brief at 14; CMS Brief at 12; CMS Ex. 23, at 8. Surveyor notes do not show she identified any resident that was denied care planned care. CMS Ex. 23, at 8. However, the notes do indicate that CNA Goins told the surveyors that no showers were given the weekend before the survey, which CMS represents was the New Years holiday weekend. Assuming showers were actually scheduled for that weekend, CNA Goins did not indicate that showers were not provided before or after the weekend to accommodate scheduling, but the notes clearly do not show she told the surveyors that any resident was denied a shower. CMS Ex. 23, at 16. Furthermore, CMS makes no allegation and cites

no evidence that any resident suffered harm or was at risk for harm because the resident was not showered on the New Years holiday weekend.

CMS argues that during the survey on Thursday, January 6, 2006, 19 residents were scheduled to be given showers and that at the end of her shift, the shower aide still had two showers to give despite having worked her shift without taking her breaks. CMS Brief at 16-17. Surveyor Smith testified that the allegation was included in the SOD (CMS Ex. 4, at 17-18) to "establish the CNAs responsibilities as far as giving showers and how much time it would take to do a good job." Tr. 368. CMS does not mention in its brief that Surveyor Smith testified that the CNA assigned to give showers that day did complete all the showers, although she had to work overtime to do so.[18] Tr. 370.

CMS argues in its post hearing brief that "surveyors witnessed call lights that went unanswered for more than 15 minutes." CMS Brief at 17. However, the evidence does not show that the surveyors witnessed more than one instance where a call light was illuminated for 15 minutes or more. CMS Ex. 23; Tr. 387-91, 414-19. The one instance discussed by CMS and reflected in the surveyor worksheet involved Room 216, where Surveyor Smith noted the light already illuminated on January 3, 2006 at 7:02 a.m. and it was turned-off at 7:17 a.m. CMS Ex. 23, at 7. However, Surveyor Smith admitted during my questioning of her that she had no idea when the light was turned-on, who activated the light, or why the light was activated. Tr. 418-19. Surveyor Smith only observed the light on and then turned off after 15 minutes. She did not investigate why the light was on. She did not determine whether a service was needed that had been delivered and the light was simply not cancelled. She did not testify whether any resident was even in the room during her observations or that a resident was deprived of care.

CMS made two assertions in it prehearing brief regarding meals and feeding in support of its argument that Petitioner was short-staffed: (1) a surveyor observed CNA Price ask Resident D if he was going to eat, she walked away, and a nurse came 10 minutes later and fed the resident a few bites; and (2) Resident Y complained that she did not get the correct drink with her meal and when she asked for a new drink, it came after the meal was completed. CMS Prehearing Brief at 15-16 (citing CMS Ex. 21, at 1; CMS Ex. 22, at 7). As already noted, the surveyors found unsubstantiated a complaint about food and meal service. CMS Ex. 10, at 3. CMS does not state in its brief whether it considers that either incident reflects a failure to provide a care planned care; suggest that either resident suffered harm as a result; or explain how the observations could support an inference that

[18] The surveyor did not ask whether the CNA was paid overtime, but that is not relevant to the issues before me. Tr. 370.

a care planned need was not met or at risk for not being met with a risk for more than minimal harm to any resident.

(c) Surveyor testimony.

All three of the surveyors involved in the January 2006 survey testified.

(1) Urine Odor.

One of the complaints that the surveyors were investigating during the January survey involved the use of incontinence pads during the 10:00 p.m. to 6:00 a.m. shift. The anonymous complaint was that during the night shift when a resident had an episode of incontinence, incontinence pads were stacked on the bed instead of changing the bed. The complainant also alleged that the residents who had episodes of incontinence were not "washed up" until their day for a shower. CMS Ex. 10, at 4. In its post hearing brief, CMS argues that Petitioner used more than two incontinence pads for residents when staff were unable to check residents often enough and provide prompt incontinence care due to insufficient staff. CMS Brief at 14. CMS also argues that there was a "pervasive odor of urine on a least three mornings of the survey." CMS Brief at 15, 19. CMS attributes the odor to Petitioner's failure to provide timely and good perineal care to incontinent residents, which CMS argues was due to insufficient staffing. The surveyors allege in the SOD that there was a strong urine odor in both hallways of the Rosewood unit at 9:30 a.m. on January 3, 2006; 8:00 a.m. on January 4, 2006; and 9:00 a.m. on January 5, 2006. CMS Ex. 4, at 7-8. Surveyor Smith indicates in her notes that there was a smell of urine at 6:55 a.m. on January 4, 2006, between room 107 and 108 in the hall, but her note also indicates staff picked-up linen off the floor and bagged it. The surveyor does not state whether the linen was soiled or the perceived source of the urine smell, or whether the urine smell abated when the linen was bagged. CMS Ex. 23, at 7. Surveyor McNamee indicated in her notes for January 4, 2006, at 8:38 a.m. that there was a urine odor between room 308 and 310. CMS Ex. 22, at 1. Surveyor Wolfgang recorded in her surveyor notes that on January 4, 2007, at 8:10 a.m. there was a strong odor of urine in room 106 and emanating into the hall and she noted two wet pads and soiled linens in the shower chair in the room. CMS Ex. 21, at 2. Surveyor Wolfgang testified that there was a strong odor of urine throughout one wing of the facility, the Rosewood wing, in the hall and some of the rooms several mornings of the survey. Tr. 147-48. On cross-examination she admitted that her notes do not reflect that she perceived that the odor of urine was throughout the facility but she did make a note that there was odor in the hall near one resident's room. Tr. 239-40. She also agreed that she did not document a urine odor during the morning of January 3, 2006. Tr. 247. On redirect examination she testified that the odor of urine was so prevalent on the Rosewood wing she knew she was never going to forget it. Tr. 298. Surveyor Smith testified that there were urine odors on

at least one morning but if she thought something was unusual she would have made a note in her surveyor worksheet. Tr. 413. Her notes reflect that she only smelled urine between rooms 107 and 108 in the hall on January 4, 2006, at 6:55 a.m. CMS Ex. 23, at 7. The surveyors did not testify about the duration of the odor, whether it abated after a period, or whether it was always present.

(2) Incontinence pads.

The surveyors inferred from the fact that staff placed more than two incontinence pads on some beds, that residents were not checked and turned regularly and were not provided timely perineal care. Surveyor Wolfgang testified that she observed more than two incontinence pads stacked on many beds and, in her opinion, the standard of care is that no more than one or two pads should be used. Tr. 148-51. However, she did not testify whether the use of three pads for residents assessed as incontinent might be appropriate in a facility such as Petitioner where the decision was made that it was better to place the resident on pads without incontinence briefs rather than with incontinence briefs with two pads. Tr. 149. She testified that she did see staff use incontinence pads to lift residents. Tr. 154. She testified that she was told by unspecified staff that pads were stacked on beds and removed as they became wet and they would find three to four incontinence pads on the beds after the night shift. Tr. 169. She did observe and record in the SOD her observation of Resident B in his room in his wheelchair, his bed had been stripped and two wet incontinence pads and a wet sheet were on the shower chair in the center of his room. Tr. 159-160. She testified that in her experience staff used three or more incontinence pads for their own convenience, possibly because there was not enough staff. Tr. 173. She concluded in this case that more than two pads were being used because staff was not able to get back to their residents often enough. Tr. 174. In her surveyor notes she recorded that she observed as many as four incontinence pads on beds. CMS Ex. 21, at 6. On cross-examination she agreed that she never saw six pads in use, but she could not recall if she saw five pads without consulting her surveyor notes. She could not remember whether any of the other two surveyors reported seeing more than three pads in use. Tr. 241-43. She agreed on cross-examination that the fact a resident was found incontinent in the morning did not support an assumption that the resident was not properly checked during the night. Tr. 246. She testified that no observations were made by the surveyors during the night shift even though the allegations about use of multiple pads and failure to check and clean residents related to the night shift. According to Surveyor Wolfgang they had enough information from their observations during the first two shifts. Tr. 283. In response to my questions she admitted that she had not observed that night staff was stacking three or four pads and removing them when they were soiled, rather her information in that regard was based solely on what she was told in interviews. Her understanding, based on her interviews, was that staff would stack pads and remove them when they became wet or soiled without providing perineal care

for the resident. However, she could not remember whether she ever found a resident on a wet pad and she could not recall whether either of the other surveyors had. Tr. 288-90. On further inquiry she explained that surveyors deliberately went from room to room checking residents to determine what had been done and, while they found beds with multiple pads, she did not believe that they found any resident on wet pads or that had not been provided perineal care, although she could not speak for the other surveyors on the last point. Tr. 290-92. She testified that there were no staffing issues cited on the November 2005 or February 2006 surveys. Tr. 284. The parties also stipulated that Petitioner was not cited for insufficient staff during November 2005 or February 2006 surveys. Tr. 124-25, 284.

Surveyor Smith testified that she observed three or more incontinence pads on beds. Tr. 322. However, on cross-examination she admitted she never saw more than three pads on any bed. She testified that her note at CMS Ex. 23, at 7 for Room 114, Resident R, reflects that she saw three pads (Tr. 397) and she testified that she did not see more than three pads on any bed. Tr. 401. Surveyor Smith's overstatement or exaggeration on direct examination that she saw three or more pads when in fact she had to admit on cross-examination that she did not see more than three pads reflects badly upon her credibility. She testified that she used to teach CNAs not to use more than two pads. Tr. 325. However, she did not testify whether the use of three pads for residents assessed as incontinent might be appropriate in a facility such as Petitioner where the decision was made that it is better to place the resident on pads without incontinence briefs rather than with incontinence briefs with two pads. Tr. 323-24. She assumed that because staff was using four pads they were not checking and turning residents, however she admitted that she did not make any observations that residents were not being checked and turned, only that incontinence pads were being used. Tr. 380-81.

Surveyor McNamee testified that had she observed more than three pads on any bed or smelled an odor on the Dogwood unit, she would have noted that in her surveyor notes. Tr. 483-484. Her notes indicate a urine odor between rooms 308 and 310. CMS Ex. 22, at 1. Her notes do not indicate that she ever observed more than three incontinence pads on any bed. CMS Ex. 22.

Surveyor Wolfgang admitted that the presence of an odor of urine is not necessarily a deficiency. However, she testified that the odor of urine, if it was present often, offended the dignity of the residents. Tr. 160-161. She testified that the use of multiple incontinence pads and failure to keep the residents clean and dry and to turn them created a risk for skin problems and urinary tract infections, and failure to regularly check the residents every two hours created the risk that residents would attempt to get out of bed alone and fall. Tr. 151-52, 228-29. Surveyor Smith testified that a resident lying on more than two incontinence pads might adversely affect the resident's skin. She testified that

resident dignity was affected due to the odor of wet pads. Tr. 326, 329. She testified that the risks of insufficient staffing, include risk for falls, skin breakdown, and negative impact upon the dignity of the residents. Tr. 376-77. She testified that her opinion was based on the use of multiple incontinence pads and her inference or conclusion based on the use of multiple pads that residents were not turned and checked often enough. Tr. 380-81. Surveyor McNamee testified that the potential for harm due to insufficient staffing was an increased risk for falls, skin breakdown, increased UTIs, increased behaviors, and negative impact upon resident dignity. However, she testified that the surveyors did not observe any of the adverse events or results that she listed and she hoped that the surveyors intervened in time to prevent adverse results. Tr. 476-77. On cross-examination Surveyor McNamee admitted she had not determined whether any residents required turning, that no observations were made of the night shift, and no findings were made by the surveyors that any care plan was not met for any resident. Tr. 491-95. She testified that sufficiency of staffing was not an issue during the November 2005 or February 2006 surveys because residents were receiving care and the state had received no complaint regarding staffing and so the surveyors did not investigate staffing-level. Tr. 499-500.

Surveyor Wolfgang testified that the Administrator and DON told her that residents are to be checked every two and a half hours to three hours during the night shift. Tr. 163-64. Surveyor Smith testified that the DON stated the policy was that residents were to be checked every three hours during the night. She opined that the standard for incontinent residents was to check every two hours and a heavy wetters should be checked more frequently. Tr. 330-31. Surveyor McNamee testified that in her experience three bed checks would be done during an eight-hour night shift. Tr. 452. I note that according to Surveyor McNamee bed checks would have been done an average of once every 2.67 hours rather than every two hours. The surveyors' testimony is also inconsistent with the SOM which does not specify a fixed frequency for checking residents but reflects that the frequency for checking is case specific, *e.g.*, residents who are unable to call for help should be checked frequently, for example each half hour (SOM, App. PP, Tag F354); residents with a newly inserted gastric tube should be checked every two to four hours (SOM, App. PP, Tag F322); and no frequency for checking is specified for residents who suffer incontinence (SOM, App. PP, Tag F315).[19] The surveyors are not clear whether the DON and Administrator were suggesting that every resident must be checked every

[19] A more recent version of the SOM includes a lengthy discussion of urinary incontinence and indicates that residents who suffer urinary incontinence should be checked on a schedule based on the resident's voiding pattern, accepted standards of practice, and incontinence product manufacturer's recommendations. SOM, App. PP, Tag F315 (Rev. 36, Aug. 1, 2008).

two and a half to three hours, whether that was for all residents or just the incontinent residents, whether it was an average frequency, or how it was determined. Surveyor McNamee's testimony regarding the frequency with which she checked residents is not inconsistent with checking residents on average every two and a half to three hours. The surveyors did not cite any instance where a resident was not turned according to a turning schedule or toileted every two hours. The surveyors were unable to verify allegations that dry pads were placed on wet or soiled sheets to avoid linen changes. The surveyors did not allege that checking the residents as indicated by the Administrator and DON violated program quality of care requirements.

(3) Medication pass.

Surveyor Wolfgang testified that she was told by the Administrator and DON that facility policy established the times for medication pass as 9:00 a.m., 1:00 p.m., 5:00 p.m., and 9:00 p.m. and up to one hour before or after those times, but she saw staff administering medications more than one hour after the established time. She testified that she was told by a staff member that she was delivering medication late because staff had to stop delivering medications to pass meal trays. Tr. 174-78. She testified that she was not told that medication pass times had been changed. Tr. 300. However, according to Surveyor Smith's notes, during a meeting attended by the DON and all three surveyors at 3:04 p.m. on January 4, 2006, the DON told them that she changed medication pass times to get the medication pass done before meals as suggested by a Qualified Medication Aide (Q.M.A.). CMS Ex. 23, at 14. Surveyor McNamee testified that she observed a Q.M.A. administering her 9:00 a.m. medications at 10:35 a.m. and, when she asked, the Q.M.A. told her she was late because she had to stop and work in the dining room. Tr. 453-54. Surveyor McNamee testified that it is nursing standard that you must administer medications within an hour of the scheduled time. Tr. 454. Surveyor McNamee testified that the DON told her she recognized there was a problem with the time required to pass medication due to a change in meal times and she had not resolved the problem yet. Tr. 455-57. Surveyor McNamee admitted that there was no risk for harm associated with administering late any of the medications that she observed were given late. Tr. 457-65; CMS Ex. 22, at 2.

> (d) CMS has failed to present credible evidence that residents were denied a care planned care, were at risk of being denied care due to insufficiency of staff, or were at risk for more than minimal harm.

In this case, as in *Carehouse*, CMS has failed to make a prima facie showing of a violation of 42 C.F.R. § 483.30(a). To establish a prima facie case of a violation of 42 C.F.R. § 483.30(a)(1) (Tag F353), CMS must allege and present evidence that Petitioner did not do what the regulation requires. Ideally, the SOD should allege the elements of a

prima facie case to ensure Petitioner has notice of what it must defend. The SOD may, in some cases, constitute prima facie evidence required to make a prima facie showing or case, but if not, then CMS has to produce some evidence. The evidence CMS produces must be credible and amount to more than mere allegations or speculation of the surveyors. CMS must also allege and show as part of its prima facie case that the violation posed more than minimal harm because only then is an enforcement remedy allowed or triggered as in the case of a mandatory DPNA.

CMS fails to make a prima facie showing in this case because the evidence does not show that any of Petitioner's residents were denied a care planned care or service. The surveyors do not identify any resident who was denied a care or service in the SOD or in their testimony. The surveyors do not identify an unreasonable risk that Petitioner's residents would be denied a care or service. I do not consider the extra-record statements of family and staff to be reliable for reasons already discussed, and even if considered reliable evidence, they do not show that residents were denied care. The evidence does not verify reports to surveyors that multiple incontinence pads were used rather than cleaning resident's during incontinence episodes. Although Surveyor Wolfgang observed four incontinence pads on some beds, there is no reliable evidence that the pads were used as she or the other surveyors speculated to avoid cleaning a resident after an episode of incontinence. The surveyors' concern that residents were not being turned is nothing more than speculation. Other than the fact that the surveyors observed more than two pads but no more than four pads on beds, there is no credible evidence that suggests residents were not turned or checked in accordance with their care plans. The surveyors admit that call lights were answered, even though in one case a light was observed to be on for 15 minutes, but the surveyor did not investigate why and had no idea if the room was even occupied at the time. The surveyors did not observe or gather any credible evidence that anyone was denied oral care, a shower, food, or medication or that any resident suffered unplanned weight loss. While some medication may have been delivered 35 minutes or more later than facility policy provided, the surveyor admitted that there was no harm due to the late delivery. Furthermore, there is no evidence presented by CMS that the late delivery of any medication was in violation of physician order or manufacturer's instructions. The surveyors expressed concern that urine odors could offend the dignity of residents, but they did not testify that the odor rose to that level in this case or assert that resident dignity was actually offended based upon their observations. The surveyors identified no residents who were not maintained clean and dry. The surveyors and CMS do not allege that the facility practice of placing resident's on incontinence pads without incontinence briefs is not an acceptable intervention.

4. There is no basis for an enforcement remedy and a mandatory DPNA was not triggered.

I conclude that Petitioner was in substantial compliance with program participation requirements during the survey conducted January 3 through 6, 2006. Accordingly, there is no basis for the imposition of an enforcement remedy. Furthermore, because Petitioner was in substantial compliance, the running of the three month period that began November 21, 2005 was stopped, and the mandatory DPNA was not triggered effective February 21, 2006.

III. Conclusion

For the foregoing reasons, I conclude that Petitioner was in substantial compliance during the survey conducted January 3 through 6, 2006, which is within three months of the November 21, 2005 survey. Accordingly, the running of the three month period established by Act § 1819(h)(2)(D) and 42 C.F.R. § 488.417(b)(1) was interrupted and the mandatory DPNA was not triggered on February 21, 2006.

/s/
Keith W. Sickendick
Administrative Law Judge