Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

The Windsor Place,
(CCN: 25-5257),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-09-115 (On Remand)

Decision No. CR2093

Date: March 16, 2010

DECISION ON REMAND

Petitioner, The Windsor Place, was not in violation of 42 C.F.R. § 483.13(a)[1] from October 25, 2004 through December 21, 2004. A civil money penalty (CMP) of $75 per day from October 28, 2004 through December 21, 2004, based on the previously affirmed violation of 42 C.F.R. § 483.10(n), is reasonable.

I. Background

Petitioner, located in Columbus, Mississippi, is authorized to participate in Medicare as a skilled nursing facility (SNF) and in the Mississippi Medicaid program as a nursing facility (NF). Petitioner was subject to surveys by the Mississippi State Survey

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

Department (the state agency) completed on September 24, 2004, October 22, 2004, and October 28, 2004.

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advised Petitioner that its authority to conduct a nurse aide training and competency evaluation program (NATCEP) was withdrawn.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

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

On October 28, 2004, the state agency completed an annual survey of Petitioner's facility. CMS notified Petitioner by letter dated December 14, 2004,[2] that deficiencies from the prior complaint surveys had been corrected but that new deficiencies were found. CMS advised Petitioner that the CMP continued but that it was reduced to $150 per day beginning October 28, 2004, and the other remedies previously imposed were unchanged. CMS notified Petitioner by letter dated January 18, 2005, that the state agency completed a revisit survey of Petitioner's facility on December 22, 2004, and found that Petitioner had returned to substantial compliance at that time. The accruing CMP and the DPNA ceased on December 21, 2004, and the termination remedy was rescinded. CMS Ex. 67.

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

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

A hearing was convened on July 12 and 13, 2005 in Jackson, Mississippi. CMS offered exhibits 1 through 67, which were admitted as evidence. Hearing Transcript (Tr.) 38. Petitioner offered exhibits (P. Ex.) 1 through 47, 49 through 60, and 64 through 72. Petitioner exhibits 48, 61, 62, and 63 were withdrawn. Tr. 15-16. Petitioner exhibits 9 through 24, 28 through 47, 49 through 60, 64 through 68, and 70 through 72 were admitted. Tr. 21-25. CMS objected to the admission of Petitioner exhibits 1 through 8, 25 through 27, and 69 on grounds that they had not been authenticated. Petitioner proffered that witnesses would be called to authenticate the exhibits. I deferred ruling upon the admissibility of Petitioner exhibits 1 through 8, 25 through 27, and 69 pending testimony to establish authenticity and relevance. Tr. 18-25. Petitioner did not produce the proffered testimony or reoffer the exhibits for admission and Petitioner exhibits 1 through 8, 25 through 27, and 69 are not admitted. CMS called two witnesses, Surveyors Linda Ward and Karen Baker. Petitioner elicited testimony from one witness, Gale McDill, Petitioner's dietary manager/kitchen supervisor. The parties submitted post-hearing briefs and reply briefs.

On April 21, 2008, I issued a decision concluding that:

> Petitioner, The Windsor Place, was in violation of 42 C.F.R. §§ 483.20(b)(2)(ii), 483.25(a)(3), and 483.25(c) from September 24, 2004 through October 27, 2004. Petitioner was in violation of 42 C.F.R. §§ 483.10(n) and 483.13(a) from October 25, 2004 through December 21, 2004. Petitioner returned to substantial compliance with all program participation requirements effective December 22, 2004.

> There is a basis for the imposition of a civil money penalty (CMP), and a denial of payment for new admissions (DPNA). A CMP of $350 per day for the 34 days from September 24, 2004 through October 27, 2004, and $150 per day for the 55 days from October 28, 2004 through December 21, 2004, for a total CMP of $20,150 is reasonable. A DPNA for the period October 27, 2004 through December 21, 2004, is also reasonable. Withdrawal of Petitioner's authority to conduct a Nurse Aide Training and Competency Evaluation Program (NATCEP) was required during the period October 12, 2004 through October 11, 2006. 42 C.F.R. §§ 483.151 and 483.152.

The Windsor Place, DAB CR1775, at 1 (2008) (footnote omitted).

On November 26, 2008, an appellate panel of the Departmental Appeals Board (the Board) issued a "Final Decision and Partial Remand on Review of Administrative Law Judge Decision," *The Windsor Place*, DAB No. 2209 (2008). The Board sustained my conclusions, and the findings upon which they were based, that Petitioner was in violation of 42 C.F.R. § 483.20(b)(2)(ii) (Tag F274) from September 24, 2004 through October 27, 2004 (*The Windsor Place*, DAB No. 2209, at 4-12); Petitioner was in violation of 42 C.F.R. § 483.25(c) (Tag F314) from September 24, 2004 through October 27, 2004 (*The Windsor Place*, DAB No. 2209, at 13-16); Petitioner was in violation of 42 C.F.R. § 483.25(a)(3) (Tag F312) from September 24, 2004 through October 27, 2004 (*The Windsor Place*, DAB No. 2209, at 16-19); and Petitioner was in violation of 42 C.F.R. § 483.10(n) (Tag F176) from October 25, 2004 through December 21, 2004 (*The Windsor Place*, DAB No. 2209, at 19-21). The Board also affirmed my conclusion that the following remedies were reasonable: a CMP of $350 per day for the 34 days from September 24, 2004 through October 27, 2004; the DPNA from October 27, 2004 through December 21, 2004; and the withdrawal of Petitioner's authority to conduct a NATCEP. *The Windsor Place*, DAB No. 2209, at 26-27. The Board remanded the case to me to consider "new evidence and to take whatever actions [I] deem necessary to develop the record" related to my findings and conclusion that Petitioner was in violation of 42 C.F.R. § 483.13(a) (Tag F221) from October 25, 2004 through December 21, 2004. *The Windsor Place*, DAB No. 2209, at 25. The "new evidence" to which the Board referred, is the evidence admitted to the record by the Board – the affidavits of two of Petitioner's employees. The Board also directed further consideration of the reasonableness of the CMP imposed based upon the alleged violation of 42 C.F.R. § 483.13(a) and any revised findings and conclusions based upon new evidence. *The Windsor Place*, DAB No. 2209, at 25.

The case was received at the Civil Remedies Division from the Board on December 2, 2008 and assigned docket number C-09-115. On December 19, 2009, I convened a

telephonic prehearing conference the substance of which is recorded in my Prehearing Conference Order and Notice of Hearing of the same date. A supplemental hearing was convened in Jackson, Mississippi on February 19, 2009, and a 180-page transcript of the supplemental hearing was prepared (Supp. Tr.).[3] Petitioner called two witnesses, Suzanne Talbert, Petitioner's current Director of Nursing and the Assistant Director of Nursing during the survey in issue (Supp. Tr. 17-18), and Charlotte A. Howard, Petitioner's Social Service Worker currently and at the time of the survey in issue (Supp. Tr. 142-43). The parties submitted supplemental post-hearing briefs and post-hearing reply briefs.

II. Discussion

A. Issues

The general issues in this case are:

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

On this remand, the specific issues remaining for adjudication are:

> Whether Petitioner was in violation of 42 C.F.R. § 483.13(a) (Tag F221) from October 25, 2004 through December 21, 2004; and
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> Whether a CMP of $150 per day is reasonable for the period October 28, 2004 through December 21, 2004.

The Windsor Place, DAB No. 2209, at 27.

B. 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.

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[3] No additional exhibits were offered or admitted at the supplemental hearing. References to the CMS and Petitioner's exhibits in this Decision on Remand are to the exhibits admitted at the first hearing and to the affidavits admitted before the Board that were marked by the Board as Board exhibits (Bd. Exs.) A and B.

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.[4] 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, 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's 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 regulations specify that a CMP that is imposed against a facility on a per day basis will fall into one of two ranges of penalties. 42 C.F.R. §§ 488.408, 488.438. The upper range of CMP, $3050 per day to $10,000 per day, is reserved for deficiencies that pose immediate jeopardy to a facility's residents and, in some circumstances, for repeated deficiencies. 42 C.F.R. §§ 488.438(a)(1)(i), (d)(2). Pursuant to 42 C.F.R. § 488.301, "*(i)mmediate jeopardy* means a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." (Emphasis in original.) The lower range of

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[4] 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.

CMP, $50 per day to $3000 per day, is reserved for deficiencies that do not constitute immediate jeopardy but either cause actual harm to residents, or cause no actual harm but have the potential for causing more than minimal harm. 42 C.F.R. § 488.438(a)(1)(ii).

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 § 1128A(c)(2); 1866(h); 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 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). The CMS determination as to the level of noncompliance "must be upheld unless it is clearly erroneous" (42 C.F.R. § 498.60(c)(2)), including the 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).

The standard of proof or quantum of evidence required is a preponderance of the evidence. CMS has the burden of making a *prima facie* showing of a basis for imposition of an enforcement remedy. Petitioner bears the burden of showing that it was in substantial compliance with participation requirements or any affirmative defense. *See Hillman Rehabilitation Center*, DAB No. 1611 (1997), *aff'd, Hillman Rehabilitation Ctr. v. United States Dep't of Health and Human Services, Health Care Fin. Admin.*, No. 98-3789 (GEB), slip op. at 25 (D.N.J. May 13, 1999); *Cross Creek Health Care Center*, DAB No. 1665 (1998); *Emerald Oaks*, DAB No. 1800; *Batavia Nursing and Convalescent Center*, DAB No. 1904 (2004), *aff'd, Batavia Nursing & Convalescent Ctr. v. Thompson*, 129 F. App'x. 181 (6th Cir. 2005); *Batavia Nursing and Convalescent Inn*, DAB No. 1911 (2004).

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

My conclusions of law on remand are set forth in bold followed by a statement of the pertinent facts and analysis.

The state agency conducted three surveys in this case. The first survey concluded on September 24, 2004, and the results are reported in a Statement of Deficiencies (SOD) of that date. CMS Ex. 2. The second survey was completed on October 22, 2004 and the results are reported in a SOD of that date. CMS Ex. 3. The results of the third survey are reported in a SOD dated October 28, 2004, the date the survey was completed. CMS Ex. 21. The third survey was both an annual recertification survey and a revisit survey to the prior complaint surveys that ended on September 24 and October 22, 2004. The revisit survey concluded that all deficiencies cited by the prior complaint surveys were corrected. CMS Ex. 57, at 2. In the October 28, 2004 SOD the surveyors allege the following new violations: 42 C.F.R. §§ 483.10(n) (Tag F176, S/S D); 483.13(a) (Tag F221, S/S E); 483.35(h)(2) (Tag F371, S/S F); and 483.75(l)(1) (Tag F514 S/S B). CMS Ex. 21. A revisit survey completed on December 22, 2004, determined that Petitioner had returned to substantial compliance with all program participation requirements effective December 22, 2004. CMS Ex. 67. In my prior decision, I concluded that Petitioner violated 42 C.F.R. §§ 483.10(n) (Tag F176, S/S D); and 483.13(a) (Tag F221, S/S E) from the October 28, 2004 survey;[5] and that the violations were a basis for imposition of a $150 per day CMP from October 28 through December 21, 2004. The Board upheld the violation of 42 C.F.R. § 483.10(n) (Tag F176, S/S D) but remanded for my consideration of new evidence related to the alleged violation of 42 C.F.R. § 483.13(a) (Tag F221, S/S E) and for reassessment, if necessary, of the CMP based upon the two violations from the October 28 survey.

1. Petitioner did not violate 42 C.F.R. § 483.13(a) (Tag F221, S/S E) contrary to the conclusion of the October 28, 2004 survey.[6]

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[5] I concluded in my prior decision that Petitioner established by a preponderance of the evidence that it was in substantial compliance with 42 C.F.R. § 483.35(h)(2) (Tag F371, S/S F) and this conclusion was not disturbed by the Board. The alleged violation of 42 C.F.R. § 483.75(l)(1) (Tag F514) was cited at a scope and severity of B, which shows that the surveyors did not find that there was a potential for more than minimal harm; thus, the alleged deficiency does not amount to an allegation of substantial noncompliance; therefore the alleged violation may not be the basis for an enforcement remedy; and it is not subject to my review.

[6] Lest silence be considered acquiescence, I am compelled to express strong disagreement with the Board's decision to admit the two affidavits offered by Petitioner
(Continued next page.)

This regulation provides:

> (a) Restraints. The resident has the right to be free from any

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(Continued from preceding page.)

on appeal and to accept Petitioner's argument that it was surprised by the basis for my initial decision regarding this deficiency. *The Windsor Place*, DAB No. 2209, at 25. Petitioner argued before the Board that it was unaware until reviewing the CMS post-hearing brief and my decision that its evidence was not sufficient to show that Petitioner considered less restrictive alternatives and counseled the residents or their representatives regarding the use of restraints, including the right to refuse restraints. The CMS post-hearing brief was filed on September 28, 2005 and the CMS post-hearing reply brief was filed on October 31, 2005. I did not issue my decision until April 21, 2008. Thus, Petitioner had sufficient time to move to reopen the record based upon any surprise by a change in the CMS theory of the case. Petitioner also had the opportunity to request reopening and revision of my April 21, 2008 decision, pursuant to 42 C.F.R. §§ 498.100-103, but failed to do so. The fact that Petitioner offered the affidavits, which I note were executed on August 15, 2008 nearly four months after my decision and nearly four years after the survey, indicates that the evidence was available to Petitioner at the time of hearing and clearly shows that Petitioner simply made a tactical legal judgment not to offer the evidence at hearing based upon its understanding of the law. The Board's acceptance of Petitioner's argument to justify admission of the affidavits and ultimately the remand, could suggest to some practitioners that there is no potential cost associated with a tactical judgment to withhold evidence at the trial-level. Certainly every governmental or nongovernmental party can voice surprise when it does not prevail upon its arguments before an ALJ. The argument by a losing party that it was surprised that its theories were not accepted or that the evidence it chose to present was insufficient could be made in every appeal, but such arguments generally are not made because parties recognize that appellate authorities hold them responsible for the presentation of their case at the trial-level through application of the doctrine of waiver or a similar principle. I further note that CMS clearly suffers prejudice under these circumstances due to the time and expense associated with conducting a supplemental hearing and briefing followed by possible further review by the Board. It also cannot be denied that a remand, particularly when a supplemental hearing is required, negatively impacts judicial resources. Despite my disagreement with the Board's approach in this case, I nevertheless review the evidence and arguments of the parties with my impartiality intact. Petitioner's astute counsel, having been given a second opportunity to address the specific failings of its evidence identified by my first decision, prevails on remand.

> physical or chemical restraints imposed for purposes of discipline or convenience, and not required to treat the resident's medical symptoms.

42 C.F.R. § 483.13(a).

The plain language of this regulation prohibits any use of restraint for discipline of a resident or for the convenience of a facility or its staff. The plain language also prohibits the use of any restraint not required to treat a resident's medical symptoms. The regulation, by its plain language, imposes upon a facility a heavy burden to show that any use of chemical or physical restraint in contravention of the resident's right to be free of such restraint, is warranted by the resident's medical symptoms.

Congress has directed that a facility must promote the rights of each resident including the right to be free from restraints.

> (ii) Free From Restraints. – The right to be free from physical or mental abuse, corporal punishment, involuntary seclusion, and any physical or chemical restraints imposed for discipline or convenience and not required to treat the resident's medical symptoms. Restraints may only be imposed –
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> (I) to ensure the physical safety of the resident or other residents, and
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> (II) only upon the written order of a physician that specified the duration and circumstances under which the restraints are to be used (except in emergency circumstances specified by the Secretary until such an order could reasonably be obtained).

Act §§ 1819(c)(1)(A)(ii), 1919(c)(1)(A)(ii).

In *Cross Creek*, the Board interpreted the Act (§§ 1819(c)(1)(A)(ii) & 1919(c)(1)(A)(ii)) and the regulation (42 C.F.R. § 483.13(a)) to prevent restraints from being used if they are not medically necessary. *Cross Creek*, at 10-12. The CMS interpretation of the regulation is that each resident should be able to attain and maintain the highest practicable well-being in an environment where use of restraints for discipline or staff convenience is prohibited and where restraints are only used for treatment of symptoms that warrant restraints. P. Ex. 34 (State Operations Manual (SOM) App. PP, Tag 221). According to the Board, it is sufficient when restraints are used, for CMS to show that a facility lacks documentation of medical necessity or that there is credible evidence of improper purpose. *Cross Creek*, at 16. The Board stated that section 483.13(a) "imposes on nursing facilities, not doctors, an obligation to use restraints in a very prescribed manner -- not for discipline, not for convenience, and only if required by the resident's

medical symptoms." *Cross Creek*, at 11 (quoting 59 Fed. Reg. 56,116, 56,227 (Nov. 10, 1994) ("[I]t is the facility's responsibility to ensure that the services provided by physicians will satisfy the facility's obligations under the Act and regulations."). The Board also noted in *Cross Creek* that "nursing facilities are subject to other Medicare/Medicaid requirements which are also not applicable to doctors and which could impact on a decision under section 483.13(a) to use or not use restraints." *Id*. Examples cited by the Board include the following: a long-term care facility is required to consult with the resident or the resident's surrogate about all treatment decisions (42 C.F.R. § 483.10(d)(2)); a long-term care facility is required to help a resident achieve his/her highest practicable physical, mental and psychosocial well-being (section 1819(b)(2) of the Act); and a long-term care facility resident has a right to refuse medical treatment (42 C.F.R. § 483.10(b)(4)). The Board concluded that, because section 483.13(a) is directed at nursing facilities, "the regulation imposes on the long-term care facility an independent obligation to ensure that the use of restraints, even with a doctor's order, meets the criteria of the regulation" and "an independent obligation to continue to assess the impact of the use of a restraint and to consult with the doctor if the nursing facility finds that use of the restraint no longer meets the criteria of the regulation." *Id*. Thus, while a physician's order for a restraint is clearly some evidence of its medical necessity, such an order is not by itself sufficient to establish that use of the restraint met the criteria of the regulation. *See also Lakeridge Villa Heath Care Center*, DAB No. 1988 (2005); *Milpitas Care Center*, DAB No. 1864 (2003).

The evidence necessary to establish permissible use of restraint, absent evidence of improper use for discipline or staff convenience, must be determined on a case-by-case basis. Both CMS policy and Petitioner's policy provide some criteria or standards by which to judge whether use of restraint is permissible. Petitioner must know and must be able to show that it and its care planning team knew whether or not restraints were necessary for treatment of a resident's condition. Further, Petitioner must reasonably determine and must be able to show that restraints are being used in the most minimally restrictive manner necessary to treat the resident's medical condition. In order for Petitioner to make the required showing, it must have some evidence that appropriate assessments were done and that the care planning team engaged in the necessary decision-making. CMS specifies in the SOM that prior to using restraints a facility must determine the specific medical symptom that necessitates the use of restraints, how the restraints effectively treat the symptoms, how the resident's safety is protected, and how the resident will be assisted in attaining or maintaining the highest level of well-being. Medical symptoms, assessments, and care plans must all be documented and a physician order is required, but an order alone is insufficient evidence of the need for restraint. The resident or the responsible party must be fully informed to include the condition or conditions that trigger consideration of restraining the resident, risks and benefits, and alternatives. P. Ex. 34, at 2-3 (SOM App. PP, Tag 221). Petitioner's policy on use of restraints is not inconsistent with the CMS guidance in the SOM, although Petitioner's policy is not as detailed as the SOM guidance. Petitioner's policy provides that restraints

are not to be used for convenience or as discipline, an assessment is required, a physician's order is required, the reason for and type of restraint and doctor's order must be in the medical record, and the resident or the responsible party must be counseled or educated on the use of restraints. Petitioner lists as examples of devices that are restraints: a merry walker; a lap buddy; a lap or waist belt; side rails; and a roll belt. CMS Ex. 58. The SOM is not enforceable as a regulation or statute but rather the SOM is a policy statement of CMS to provide guidance to surveyors. *See Vencor Nursing Ctrs., L.P. v. Shalala*, 63 F. Supp. 2d. 1, 11-12 (D.D.C. 1999); *Beverly Health & Rehab. Services, Inc., et al. v. Thompson*, 223 F. Supp. 2d 73, 98-103 (D.D.C. 2002); *Cal Turner Extended Care Pavilion*, DAB No. 2030 (2006); *see also State of Indiana by the Indiana Dep't of Pub. Welfare v. Sullivan*, 934 F.2d 853 (7th Cir. 1991); *cf. Northwest Tissue Ctr. v. Shalala*, 1 F.3d 522 (7th Cir. 1993). However, both the SOM and Petitioner's policy are good evidence of the standard of care to be delivered to Petitioner's long-term care facility residents.

Contrary to the suggestion of CMS, this deficiency was not cited because Petitioner failed to follow its restraint policy. CMS Initial Post-Hearing Brief filed April 20, 2009 (CMS Supp. Brief) at 5-6; CMS Post-Hearing Reply Brief filed May 18, 2009 (CMS Supp. Reply) at 2. Rather, the deficiency citation is based upon Petitioner's failure to comply with the requirements of the Act and regulations and standards of care or practice to the extent such standards are appropriate for consideration under either the Act or regulation. The SOD alleges generally that the facility violated 42 C.F.R. § 483.13(a) because Petitioner failed to properly assess, care plan, and document the use of restraints for Residents 1, 5, 7, 14,[7] 17, and 19, and failed to inform the residents and/or responsible parties of their rights and options regarding the use of restraints.[8] CMS Ex. 21, at 4.

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[7] CMS did not provide information to support an allegation of noncompliance for Resident 14. Tr. 67. Therefore, I treated the allegations of noncompliance with Tag F221 regarding Resident 14 to be withdrawn. My conclusion in this regard was left undisturbed by the Board. *The Windsor Place*, DAB No. 2209, at 22, n.14.

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

CMS argues that "prior to restraint use, the facility must demonstrate that not only did it assess the resident, but also that the facility considered and attempted less restrictive means without success." CMS Supp. Brief at 8; CMS Supp. Reply at 4. CMS cites no authority for the proposition that a facility must "attempt" less restrictive means before using a restraint. I find no authority for the requirement that CMS proposes. Prior decisions, the SOM, and the regulations require for example that Petitioner assess, consider less restrictive means, and weigh the risk of restraints, but I find no requirement that Petitioner actually attempt a less restrictive means that has been assessed and reasonably found to be ineffective or more risky than the use of an appropriate restraint.

Petitioner does not dispute that restraints were being used on Residents 1, 5, 7, and 19 as alleged by the surveyors.[9] CMS does not argue that there is evidence that the restraints were imposed as discipline or as a convenience for the staff in the case of Residents 1, 5, 7, and 19. Tr. 199; CMS Brief at 17-22. However, CMS maintains that the evidence elicited by Petitioner during the supplemental hearing fails to demonstrate that Petitioner used physical restraints for Residents 1, 5, 7, and 19 according to the regulations. Specifically, CMS argues that evidence that a resident or a resident's family member attended a care plan meeting does not show that facility staff advised the resident or responsible party of the right to refuse restraints or that less restrictive methods were considered and rejected. CMS Supp. Brief at 8-9. To the extent that the CMS arguments suggest that a facility may only prove its compliance with the Act and regulations by producing documents, I do not agree. Credible testimony may be probative evidence of what a facility or its staff did or did not do to achieve or maintain compliance with program participation requirements.

In my prior decision I concluded that Petitioner failed to satisfy its burden as to four of the residents cited as examples by the survey. After considering the testimonial evidence of Petitioner's witnesses at the supplemental hearing on February 19, 2009, I am satisfied that Petitioner met the condition for participation established by 42 C.F.R. § 483.13(a)

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[9] Petitioner suggests that it may also rebut the deficiency or establish an affirmative defense to the deficiency by showing that restraints were not used as restraints, but rather for example as an aid to mobility. The example cited by Petitioner is use of bed side rails. Bed side rails are often documented as being for "safety" and/or "mobility." P. Supp. Brief at 11. Petitioner's observation that some forms of restraint may also be used as enablers, *e.g.*, side rails ordered as an assist for rolling over in bed or a lap buddy ordered to remind a resident not to lean forward too far, is accurate. However, to the extent that any intervention limits freedom of movement, it should also be treated and assessed as a restraint. As a practical matter, facilities should consider whether it is not easier to do a proper restraint assessment than to demonstrate that what is typically used as a restraint did not actually limit freedom of movement of a resident.

with respect to Resident's 1, 5, 7, and 19. The example of each resident is considered as follows.

(1) Resident 1

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

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

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

However, in my initial decision I concluded that Petitioner failed to carry its burden in the example of Resident 1 because Petitioner had not shown that the resident or the responsible party was counseled regarding the use of restraints, including the right to refuse restraints. I did not find the fact that a resident and/or family was present at a care plan conference and the inference that the care plan was discussed during the conference, sufficient evidence that Petitioner's staff advised the resident or responsible party of the right to refuse restraints or that other less restrictive methods were considered and rejected. I also concluded that there was also no evidence from the counseling of the resident or responsible party, in the care plan, or in the doctors order that showed Petitioner considered whether Petitioner's medical condition could have been accommodated by less restrictive means, for example the use of alarms or a low bed to minimize or eliminate the risk for falls. I concluded that in the absence of some evidence that Petitioner considered less restrictive means, it is not possible to conclude that

restraint was medically necessary and, therefore, Petitioner violated 42 C.F.R. § 483.13(a) in the case of Resident 1.

At the supplemental hearing Petitioner elicited the testimony of Suzanne Talbert, Petitioner's assistant director of nursing at the time of the surveys. Supp. Tr. 16-18. Nurse Talbert testified that upon Resident 1's admission in July of 2004 she received a complete assessment. Supp. Tr. 42. She testified that all residents admitted to the facility received a similar formalized assessment and admission packet which included a resident's rights book that explained the use of restraints and right to refuse restraints. Supp. Tr. 19-25. She testified that Resident 1's responsible party received the admissions packet and resident's rights and that their receipt was acknowledged in writing. Supp. Tr. 42-44. The assessment performed for Resident 1 included: (1) an evaluation of Resident 1's medical history and all current diagnosis; (2) a head-to-toe assessment of all her systems and vital signs; (3) input from other disciplines such as therapy; (4) a separate fall risk assessment; (4) and an interview with the responsible party. CMS Ex. 51, at 15-18; Supp. Tr. 44-50. In this instance the responsible party was Resident 1's daughter who was very involved with the care of her mother.[10] Supp. Tr. 43. Resident 1's daughter was advised regarding the use of restraints and the right to refuse restraints on behalf of her mother. Supp. Tr. 22-23, 63-64. Nurse Talbert testified from Petitioner's exhibits that during the admission interview, Resident 1's daughter indicated that Resident 1 had been climbing out of bed at the assisted living facility she resided at previously, and that her dementia had advanced to the point that a skilled nursing facility was necessary. Supp. Tr. 46. Based on this and Resident 1's high fall risk assessment, the care plan team, of which Resident 1's daughter was a member, determined that the use of side rails was necessary for safety and mobility. Supp. Tr. 47-48, 54; CMS Ex. 51, at 17. A doctor's order was in place for the use of two side rails. CMS Ex. 51, at 17; Supp. Tr. 62. Nurse Talbert testified specifically that the care plan team considered less restrictive alternatives such as a single rail, low bed, and a bed alarm. Supp. Tr. 47-49, 57-59, 63-64. Resident 1 indicated that she did not want a low bed because it would embarrass her. Supp. Tr. 48-49, 62. Similarly, the care plan team determined that a bed alarm and a single rail would not have worked because, "it would have embarrassed [Resident 1] and brought attention to her, and the one side rail would not have been efficient because of the frequent history of falls." Supp. Tr. 48.

I find Nurse Talbert's testimony credible, supported by the documentary evidence as she explained it, and her testimony is unrebutted. Based on the additional testimonial evidence, I conclude that Petitioner has satisfied the requirements of the Act and

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[10] Resident 1 could not make medical care decisions for herself due to dementia. However, she was able to make day-to-day personal decisions and communicate her needs and desires. Tr. 44.

regulations in that Resident 1's daughter was counseled regarding the use of restraints including the right to refuse restraints, and the care plan team adequately assessed whether Resident 1's medical condition and emotional well being could have been accommodated by less restrictive means. 42 C.F.R. § 483.13(a).

(2) Resident 5

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

On August 16, 2004, Resident 5's doctor ordered that her side rails on both sides of her bed be up for safety and mobility, due to her decreased mental status. P. Ex. 53, at 1. Contrary to the surveyor's allegation, the resident's care plan reflects that the resident was at risk for falls and, among other interventions, her side rails were to be up for safety and mobility.[11] Petitioner also produced the signature page for the care planning conference, which shows the resident did attend. P. Ex. 53, at 3. However, the doctor's order and the signature sheet for the care planning do not show that the resident was ever advised that she had the right to refuse restraint or that other less restrictive interventions has been considered and rejected by Petitioner and/or the resident's doctor as ineffective to address her medical condition. Accordingly, I concluded in my initial decision as in the case of Resident 1, that Petitioner had not shown it complied with the resident's right to be free of restraint except when medically necessary.

Nurse Talbert, testified that Resident 5's responsible party received a complete assessment and information packet upon admission to the facility in June of 2004, including a statement of resident's rights that advised of the right to refuse restraints. Supp. Tr. 64-66. Because of Resident 5's dementia, history of falls and high fall risk assessment, the care plan team recommended the use of bed side rails. Supp. Tr. 67-68; CMS Ex. 39, at 14. However, Resident 5's daughter (her responsible party) indicated that Resident 5 did not want bed side rails because she did not want to feel "caged-in." CMS Ex. 39, at 12, 14; Supp. Tr. 67-68. As a result, the care plan team recommended

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[11] The fact that the doctor or Petitioner states that side rails are to be up for "safety and mobility" does not negate the fact that the side rails are also restraints to the extent that they limit or restrict the residents freedom of movement, even though they may also have an additional function for some activities of daily living such as serving as a grab bar to permit turning over in bed or stability while standing next to the bed.

and implemented a less restrictive alternative - a concave mattress. Supp. Tr. 68. Nurse Talbert explained the use of the concave mattress:

> It's raised a little bit on the side, so when she [Resident 5] rolled over it would remind her not to, you know we hope, will remind her not to try to get up over the edge of it. It's just a little lift.

Supp. Tr. 68. She testified that Resident 5's daughter agreed with the use of the concave mattress. Supp. Tr. 69. Resident 5 later experienced a decline in her physical and mental condition as a result of a series of mini-strokes, and on July 25, 2004 suffered a fall as she attempted to get out of bed unassisted to go to the bathroom. Supp. Tr. 69; Ex. 39, at 17-18. Resident 5 was then reassessed for the use of side rails, and with the consent of Resident 5's daughter, side rails were implemented for safety and mobility. Supp. Tr. 69-70.

I find Nurse Talbert's testimony credible, supported by the documentary evidence as she explained it, and her testimony is unrebutted. Based on the additional testimonial evidence, less restrictive means were assessed and the responsible party was appropriately counseled regarding the restraints and the right to refuse. I conclude that Petitioner did not violate 42 C.F.R. § 483.13(a) in the example of Resident 5.

(3) Resident 7

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

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

Nurse Talbert testified regarding Resident 7, who like Resident's 1 and 5, received a full assessment and an information packet upon her admission to the facility in September of 2004. Supp. Tr. 70, 76-77. Her responsible party was her son and he signed all the admissions papers. Supp. Tr. 70. Resident 7 was a total care resident, which meant that she was totally dependent on others for her care and activities of daily living. Supp. Tr. 70. Resident 7 had a medical diagnosis of seizures, a history of psychiatric problems, was not ambulatory and required a feeding tube. Supp. Tr. 70-71. Because of Resident 7's severe seizures and medical condition she was assessed for and received bed side rails because:

> side rails were the leas[t] restrictive for her [Resident 7] because when she had a seizure it was a high chance that she could flail and go out of the bed if there were no side rails there.

Supp. Tr. 71. Nurse Talbert further testified that it would have been "difficult" to use a less restrictive low bed because Resident 7's feeding tube required the bed to be of a certain height and because she was incontinent of bowel and bladder, she had to be changed frequently.[12] Supp. Tr. 74-75; CMS Ex. 52, at 4. Resident 7's son was counseled about the use of restraints and the right to refuse restrains and did not object to the use of side-rails. Supp. Tr. 73-74, 77, 81-82. The evidence also shows that less restrictive modes were considered and rejected.

I find Nurse Talbert's testimony credible, supported by the documentary evidence as she explained it, and her testimony is unrebutted. Based on the additional testimonial evidence, less restrictive means were assessed and the responsible party was appropriately counseled regarding the restraints and the right to refuse. I conclude that Petitioner did not violate 42 C.F.R. § 483.13(a) in the example of Resident 7.

(4) Resident 19

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

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[12] Use of side rails rather than a low bed because the resident had to be frequently provided incontinent care, implies that the decision was for the convenience of staff. Use of restraint for the convenience of staff is impermissible. However, I do not conclude there was a violation here as there were other permissible reasons for using side rails rather than a low bed.

Resident 19 was assessed for the use of a roll belt in bed on September 28, 2004. The resident had problems with safety awareness and confusion and reportedly he would attempt to climb over the bed side rails. P. Ex. 57, at 1. He was also assessed for the use of a lap buddy when up in his wheelchair, but that was changed to a lap belt on October 5, 2004, because he could remove the lap buddy. P. Ex. 57, at 2-3, 7. The use of a lap belt and then a "waist belt" while the resident was up in his wheelchair and side rails while in bed are interventions in his care plan. P. Ex. 57 at 6-7. The pages of the care plan provided by Petitioner do not list the use of a roll belt while the resident was in bed. Petitioner presented evidence that the resident attended his care planning conference on October 11, 2004.

I concluded in my initial decision that Petitioner had not shown that the resident or the responsible party was counseled regarding the use of restraints as required by Petitioner's policy and the SOM, including the right to refuse restraints. I found no evidence that showed Petitioner considered whether Petitioner's medical condition could have been accommodated by less restrictive means, for example the use of alarms or a low bed to minimize or eliminate the risk for falls from bed or a personal alarm while the resident was up in his wheelchair. I further concluded that in the absence of some evidence that Petitioner considered less restrictive means, it was not possible to conclude that restraint was medically necessary.

Nurse Talbert testified that Resident 19 received a full assessment and an information packet upon his admission to the facility in September of 2004. Resident 19's daughters, one of whom was his responsible party, were counseled regarding the use of restraints including the right to refuse restraints. Resident 19 had a history of falls, was generally disoriented, and was not ambulatory due to weakness caused by osteoarthritis. Resident 19 received several different assessments for restraints. Ultimately, he was assessed for more restrictive restraints after demonstrating that less restrictive restraints such as a lap buddy and a lap tray did not work because he could easily remove the lap buddy and the lap tray. A roll belt and side rails were recommended and implemented because Resident 19 was at a high risk for falls because: (1) he would try to get out of bed without assistance; (2) he had unsteady gait; (3) he had weakness and decreased balance; (4) he had decreased safety awareness and confusion; (5) he was agitated and combative; and (6) he would attempt to climb over bed rails. Supp. Tr. 85-99.

Thus, based on the additional testimonial evidence, I conclude that Petitioner has satisfied the requirements of the Act and regulations in that Resident 19's daughters were counseled regarding the use of restraints including the right to refuse restraints, and the care plan team adequately assessed whether Resident 19's medical condition and emotional well being could have been accommodated by less restrictive means. Accordingly, I conclude that Petitioner did not violate 42 C.F.R. § 483.13(a) in the example of Resident 19.

On cross-examination and my examination, Nurse Talbert conceded that she did not do the counseling of the four residents discussed as examples. However, she testified that her testimony described the practice at Petitioner and that the practice would have been followed for each resident. Supp. Tr. 106-10, 133-34. I do not find that this concession negatively impacts the credibility of Nurse Talbert's testimony. As the assistant director of nursing for Petitioner at the time of the survey and at the time of the admission of the four residents, she was well positioned to know Petitioner's policy, procedures, and practices. There is also no evidence that is inconsistent with her testimony.

Accordingly, I conclude that Petitioner was not in violation of 42 C.F.R. § 483.13(a) from October 25, 2004 through December 21, 2004.

2. A CMP of $150 per day from October 28, 2004 through December 21, 2004, is not a reasonable enforcement remedy.

3. A CMP of $75 per day from October 28, 2004 through December 21, 2004, is a reasonable enforcement remedy.

I previously concluded that Petitioner was in violation of 42 C.F.R. § 483.10(n) (Tag F176) from October 25, 2004 through December 21, 2004; the violation posed more than minimal harm that was not immediate jeopardy and there was no actual harm; and those conclusions were sustained by the Board on appeal. I have now concluded that Petitioner was not in violation of 42 C.F.R. § 483.13(a) from October 25, 2004 through December 21, 2004. Petitioner returned to substantial compliance with all program participation requirements effective December 22, 2004. There is a basis for the imposition of a CMP and the Board authorized me to determine on remand the appropriate CMP for the period October 28, 2004 through December 21, 2004.

If a facility is not in substantial compliance with program requirements, CMS has the authority to impose one or more of the enforcement remedies listed in 42 C.F.R. § 488.406, including a CMP. CMS may impose a CMP for the number of days that the facility is not in compliance or for each instance that a facility is not in substantial compliance. 42 C.F.R. § 488.430(a). There are two ranges for per day CMPs. 42 C.F.R. §§ 488.408, 488.438. The upper range of CMP, of from $3050 per day to $10,000 per day, is reserved for deficiencies that constitute immediate jeopardy to a facility's residents, and, in some circumstances, for repeated deficiencies. 42 C.F.R. §§ 488.438(a)(1)(i), (d)(2). The lower range of CMP, from $50 per day to $3000 per day, is reserved for deficiencies that do not constitute immediate jeopardy, but either cause actual harm to residents, or cause no actual harm, but have the potential for causing more than minimal harm. 42 C.F.R. § 488.438(a)(1)(ii).

In determining whether the amount of the CMP is reasonable, the following factors specified at 42 C.F.R. § 488.438(f) must be considered: (1) the facility's history of non-compliance, including repeated deficiencies; (2) the facility's financial condition; (3) the seriousness of the deficiencies as set forth at 42 C.F.R. § 488.404; and (4) the facility's degree of culpability.

There is no evidence that Petitioner has a history of noncompliance. Petitioner has not provided any evidence to show that its financial condition precludes it from paying the CMP. I have considered the required factors and I conclude that a CMP of $75 per day for the 55 days from October 28, 2004 through December 21, 2004, is reasonable.

III. Conclusion

For the foregoing reasons, I conclude: that there is a basis for the imposition of a CMP based upon the previously affirmed violation of 42 C.F.R. § 483.10(n) (Tag F176) from October 25, 2004 through December 21, 2004; that Petitioner was not in violation of 42 C.F.R. § 483.13(a) from October 25, 2004 through December 21, 2004; and that a CMP of $75 per day for 55 days is reasonable.

/s/
Keith W. Sickendick
Administrative Law Judge