Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Woodbine Healthcare and Rehabilitation Center
(CCN: 26-5137),

Petitioner

v.

Centers for Medicare and Medicaid Services.

Docket No. C-09-611

Decision No.CR2140

Date: May 28, 2010

DECISION

Petitioner, Woodbine Healthcare and Rehabilitation Center, was not in substantial compliance with program participation requirements from March 22, 2009 through May 26, 2009, and June 24, 2009 through August 19, 2009. Termination of Petitioner's participation in Medicare was not required by section 1819(h)(2)(C) of the Social Security Act (Act), because Petitioner returned to substantial compliance with program participation requirements in less than six months. There is a basis for the imposition of enforcement remedies. The following enforcement remedies are reasonable: a $150 per day civil money penalty (CMP) from April 13, 2009 through May 26, 2009, and June 24, 2009 through August 19, 2009; and a denial of payment for new admissions (DPNA) from March 22, 2009 through May 26, 2009, and June 24, 2009 through August 19, 2009.

I. Background

Petitioner is located in Gladstone, Missouri and, prior to its termination, participated in Medicare as a skilled nursing facility (SNF) and in the Missouri Medicaid program as a nursing facility (NF). On February 20, 2009, the Missouri Division of Health and Senior Services (the state agency) completed a survey of Petitioner and found Petitioner not in substantial compliance with program participation requirements. The state agency

completed another complaint survey at Petitioner's facility on March 18, 2009 and found that Petitioner was not in substantial compliance and that there was immediate jeopardy. Based on the February and March surveys, the Centers for Medicare and Medicaid Services (CMS) imposed a DPNA effective March 22, 2009 and a per instance CMP of $10,000. Petitioner did not request a hearing as to the February or March 2009 surveys and related enforcement remedies. A revisit survey on April 3, 2009 determined that immediate jeopardy had been removed, but Petitioner continued not to be in substantial compliance with program participation requirements. On April 30, 2009, a revisit survey found that Petitioner had not returned to substantial compliance. Joint Stipulation (Jt. Stip.) ¶¶ 1-9.

CMS notified Petitioner by letter dated May 26, 2009 that it was imposing a CMP of $150 per day effective April 13, 2009, based upon the findings of noncompliance of the April 30, 2009 revisit survey. A complaint survey completed on July 8, 2009 found that Petitioner was not in substantial compliance. CMS notified Petitioner by letter dated July 22, 2009 that it intended to terminate Petitioner's participation in Medicare effective August 20, 2009, if it did not return to substantial compliance before that date. On July 28, 2009, a complaint survey concluded that Petitioner was not in substantial compliance. A complaint and revisit survey from August 18 through 20, 2009 found that Petitioner had not returned to substantial compliance. Termination of Petitioner's participation in Medicare on August 20, 2009 was prevented by a temporary restraining order (TRO) issued by the United States District Court for the Western District of Missouri. On September 16, 2009, after the TRO action was dismissed, Petitioner's participation in Medicare was terminated. Jt. Stip. ¶¶ 10-16; CMS Exhibit (CMS Ex.) 300.

Petitioner requested a hearing before an administrative law judge (ALJ) on July 24, 2009. On August 4, 2009, the case was assigned to me for hearing and decision, and an Acknowledgement and Prehearing Order was issued at my direction. Petitioner filed an amended request for hearing on August 5, 2009. CMS filed a motion for an expedited hearing on August 20, 2009. CMS also filed a motion: to dismiss Petitioner's hearing request; or for a more definite and certain statement of Petitioner's basis for requesting a hearing. A prehearing conference was convened on August 28, 2009, the substance of which is memorialized in my Ruling Granting Expedited Hearing, Order Amending Prehearing Order, and Notice of Hearing dated August 28, 2009. On August 31, 2009, Petitioner filed a motion for leave to file its second amended hearing request and its response to the CMS motion to dismiss. On September 9, 2009, I denied the CMS motion to dismiss and accepted Petitioner's second amended hearing request.

On October 6 and 7, 2009, a hearing was convened in Kansas City, Missouri, and a 521-page transcript (Tr.) of the proceedings was prepared. CMS offered CMS Exhibits 101, 201, 300, 401 through 412, 501 through 508, 601 through 604, 701 through 712, 800, 901, and 902. CMS Exhibits 300, 401, 501 through 508, 601 through 604, 701 through 712, 800, 901, and 902 were admitted as evidence. Petitioner offered Petitioner's Exhibits (P. Ex.) 1 through 27, all of which were admitted as evidence. CMS called the

following witnesses: Surveyor Denise McConkey, RN; Surveyor, Judy Baker, RN; Jack Fincham, PhD; Daniel Swagerty, MD; Surveyor Susan Holzfaster, RN; Surveyor Linda Van Horn, RN; and Jane Weiler, CMS Quality Review Specialist. Petitioner called the following witnesses: Dennis Drews, MD, Petitioner's Medical Director; Sheila Heintzelman, RN; Karetha Rone, LPN; Yolanda Payan, LPN; Delilah Payan, GN; Andre Williams, CNA; Dawn M. Hand, RN; Latrece Holloway, LPN; Denise Phipps, LPN; Susan Ludy, Petitioner's Administrator; and Karen Robbins, Vice President of Clinical Services for Shoreline Healthcare Management, Petitioner's management company. CMS filed its post-hearing brief on November 30, 2009 (CMS Brief). Petitioner filed its post-hearing brief on November 30, 2009 (P. Brief), with an unopposed motion for leave to exceed the page-limit for the brief by three pages. Petitioner's post-hearing brief is accepted. The parties filed post-hearing reply briefs on December 21, 2009 (CMS Reply and P. Reply, respectively).

II. Discussion

A. Issues

The issues in this case are:

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

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. Section 1819(h)(2) of the Act vests the Secretary of Health and Human Services (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.[1] Pursuant to section 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 section 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

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

participation in Medicare, the Act grants the Secretary authority to impose other enforcement remedies, including a discretionary DPNA, CMPs, 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).[2] 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 to determine whether the facilities are complying with federal participation requirements. 42 C.F.R. §§ 488.10-.28, 488.300-.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 a CMP, $3,050 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). "*Immediate 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." 42 C.F.R. § 488.301 (emphasis in original). The lower range of a CMP, $50 per day to $3,000 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. *Residence at Salem Woods*, DAB No. 2052 (2006); *Cal Turner Extended Care*, DAB No. 2030 (2006)*; Beechwood Sanitarium*, DAB No. 1906 (2004); *Emerald Oaks*, DAB No. 1800 at 11 (2001); *Anesthesiologists Affiliated,* DAB CR65 (1990), *aff'd*, 941 F.2d 678 (8th Cir. 1991). A facility has a right to appeal a "certification of noncompliance leading to an enforcement remedy." 42 C.F.R.

[2] References are to the 2008 version of the Code of Federal Regulations (C.F.R.), unless otherwise indicated.

§§ 488.408(g)(1), 488.330(e), 498.3. However, CMS's choice of remedies, or the factors CMS considered when choosing remedies, is not subject to review. 42 C.F.R. § 488.408(g)(2). A facility may only challenge the scope and severity level of noncompliance that CMS finds if a successful challenge would affect the range of the CMP that CMS could impose, or impact the facility's authority to conduct a NATCEP. 42 C.F.R. §§ 498.3(b)(14), (d)(10)(i). CMS's determination as to the level of noncompliance, including the finding of immediate jeopardy, "must be upheld unless it is clearly erroneous." 42 C.F.R. § 498.60(c)(2); *Woodstock Care Ctr.*, DAB No. 1726 at 9, 38 (2000), *aff'd,* 363 F.3d 583 (6th Cir. 2003). The Departmental Appeals Board (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 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). ALJ review of a CMP 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 coming forward with the evidence and making a prima facie showing of a basis for imposition of an enforcement remedy. Petitioner bears the burden of persuasion to show by a preponderance of the evidence that it was in substantial compliance with participation requirements or any affirmative defense. *See Batavia Nursing & Convalescent Inn*, DAB No. 1911 (2004); *Batavia Nursing & Convalescent Ctr.*, DAB No. 1904 (2004), *aff'd, Batavia Nursing & Convalescent Ctr. v. Thompson*, 129 F. App'x. 181 (6th Cir. 2005); *Emerald Oaks*, DAB No. 1800; *Cross Creek Health Care Ctr.*, DAB No. 1665 (1998); *Hillman Rehab. Ctr.*, DAB No. 1611 (1997), *aff'd Hillman Rehab. Ctr. v. U.S. Dep't of Health and Human Servs.*, No. 98-3789, 1999 WL 34813783 (D.N.J. May 13, 1999).

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

My conclusions of law are set forth in bold text followed by my findings of fact and analysis.

Petitioner agrees that it did not request a hearing as to deficiency findings and related enforcement remedies from the February 2009 and March 2009 surveys, and those surveys and remedies are not before me. Petitioner also elected not to contest the deficiency findings of the survey completed on April 30, 2009, and related enforcement remedies, except that Petitioner did not waive its right to hearing as to the alleged duration of the deficiencies and the duration of the enforcement remedies. Petitioner disputes the alleged deficiencies from the July 8, July 28, and August 20, 2009 surveys and argues that it returned to substantial compliance on a date after April 30, 2009 but before August 20, 2009. Jt. Stip.¶ 18; Tr. 17-22. The enforcement remedies at issue are: the duration of the $150 per day CMP that commenced on April 13, 2009, and ended with termination on September 16, 2009; the DPNA that commenced on March 22, 2009, and

ended with termination on September 16, 2009; and the termination of Petitioner's provider agreement and participation in Medicare on September 16, 2009. Tr. 45. CMS alleges, based upon the survey that ended April 30, 2009, that Petitioner was not in substantial compliance with program participation requirements, based upon violations of 42 C.F.R. §§ 483.10(c)(2)-(5) (Tag F159,[3] scope and severity (s/s) D[4]), 483.20(k)(3)(i) (Tag F281, s/s E); 483.25(d) (Tag F315, s/s D), and 483.25(h) (Tag F323, s/s G). CMS Ex. 401. The parties agree that the survey, which concluded on April 30, 2009, found that Petitioner had corrected all deficiencies cited from the February and March surveys. CMS Brief at 17; P. Brief at 9; Tr. 33-36, 271-72; CMS Ex. 902. Petitioner argues that it corrected all the deficiencies cited by the April survey by not later than May 27, 2009. Petitioner reasons that it was, therefore, not out of substantial compliance between May 27, 2009 and the next survey on July 8, 2009. If Petitioner's theory is correct, then the

[3] This is a "Tag" designation as used in CMS Publication 100-07, State Operations Manual (SOM), Appendix PP – Guidance to Surveyors for Long Term Care Facilities (http://www.cms.hhs.gov/Manuals/IOM/list.asp). 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. *Northwest Tissue Ctr. v. Shalala*, 1 F.3d 522 (7th Cir. 1993); *Ind. Dep't of Pub. Welfare v. Sullivan*, 934 F.2d 853 (7th Cir. 1991). Thus, while the Secretary may not seek to enforce the provisions of the SOM, she may seek to enforce the provisions of the Act or regulations as the SOM interprets.

[4] CMS and a state use scope and severity levels 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, ch. 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, which is an insufficient basis for imposing an enforcement remedy. 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.

running of the six-month period that caused mandatory termination[5] of Petitioner's participation was interrupted and would have restarted on July 8, 2009. Petitioner's Post Hearing Reply Brief (P. Reply) at 8-10.

CMS alleges, based on the survey completed on July 8, 2009, that Petitioner was not in substantial compliance due to violations of 42 C.F.R. §§ 483.10(b)(11) (Tag F157, s/s D), 483.15(h)(2) (Tag F253, s/s E), 483.25 (Tag F309, s/s G), and 483.25(a)(3) (Tag F312, s/s D). CMS Ex. 501. CMS alleges, based on the survey completed on July 28, 2009, that Petitioner was not in substantial compliance due to violations of 42 C.F.R. §§ 483.15(a) (Tag F241, s/s G) and 483.15(b) (Tag F242, s/s E). CMS Ex. 601. As discussed hereafter, I conclude that: Petitioner did violate 42 C.F.R. §§ 483.10(b)(11) and 483.25 as the July 8 survey alleged; the violations posed more than minimal and actual harm; Petitioner was not in substantial compliance for the period from June 24 through August 19, 2009; and the violations provided a basis for the enforcement remedies that CMS proposed. Thus, I conclude, in the interest of judicial economy, that it is not necessary to review the alleged violations of 42 C.F.R. § 483.15(h)(2) (Tag F253, s/s E) and 42 C.F.R. § 483.25(a)(3) (Tag F312, s/s D) from the July 8 survey. I also conclude, in the interest of judicial economy, that it is not necessary to review the alleged violations of 42 C.F.R. § 483.15(a) (Tag F241, s/s G) and 42 C.F.R. § 483.15(b) (Tag F242, s/s E) from the July 28, 2009 survey.

A revisit survey was concluded on August 20, 2009. The surveyors determined that Petitioner had corrected the following violations as of August 20, 2009: 42 C.F.R. §§ 483.20(k)(3)(i) (Tag F281); 483.25(d) (Tag F315); 483.10(b)(11) (Tag F157); 483.15(h)(2) (Tag F253); 483.25 (Tag F309); 483.25(a)(3) (Tag F312); 483.15(a) (Tag F241); and 483.15(b) (Tag F242). CMS Ex. 902; P. Ex. 1, at 2; Tr. 144, 272. However, the revisit survey completed on August 20, 2009 also found that Petitioner continued not to be in substantial compliance with program participation requirements based on a violation of 42 C.F.R. § 483.25(m)(1) (Tag F332, s/s E) that surveyors allegedly observed on August 18, 2009. If, in fact, Petitioner was in violation of 42 C.F.R. § 483.25(m)(1) on August 18, 2009 and that violation posed more than minimal harm to one or more of Petitioner's residents, then the termination by operation of the Act was triggered, unless Petitioner can show it returned to substantial compliance before August 20, 2009.

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[5] The Secretary and CMS have limited discretion to terminate a facility's participation in Medicare prior to the running of the six-month statutory period. Act § 1819(h)(2), (4). However, there is no allegation here that CMS exercised its authority to terminate. Rather, the termination, which was to occur on August 20, 2009, was by operation of section 1819(h)(2)(C) of the Act. There is also no dispute that August 20, 2009 was the end of the six-month period and the date on which the statute required termination of Petitioner's participation. The surveyors began the revisit survey on August 18, 2009 and understood that they needed to complete the complaint and revisit survey not later than August 20. Tr. 269, 272.

Furthermore, if Petitioner was not in substantial compliance on August 20, the $150 per day CMP and DPNA had a basis and must be sustained, unless Petitioner can establish it returned to substantial compliance at an earlier date. Thus, it is appropriate to first consider the violation of 42 C.F.R. § 483.25(m)(1) that the survey completed on August 20, 2009 alleged.

> **1. Petitioner did not violate 42 C.F.R. § 483.25(m)(1) as alleged by the survey completed on August 20, 2009.**
>
> **2. Even if Petitioner violated 42 C.F.R. § 483.25(m)(1), the credible evidence shows that Petitioner was in substantial compliance, because the violation did not pose more than minimal harm to any resident.**
>
> **3. Petitioner was in substantial compliance with program participation requirements on August 20, 2009.**
>
> **4. Termination was not required pursuant to section 1819(h)(2)(C) of the Act, as Petitioner returned to substantial compliance within six months.**

The statement of deficiencies (SOD) for the survey that concluded on August 20, 2009 alleges that Petitioner violated 42 C.F.R. § 483.25(m)(1), because Petitioner failed to follow its policy and ensure a medication error rate of less than five percent. On August 18, 2009, the surveyors allegedly observed 21 errors in 48 opportunities for error, an error rate of 43 percent. Petitioner's population at the time was 139 residents, and Residents 17, 47, 54, 67, 68, 69, and 70 were allegedly affected. The surveyors cited the deficiency at a scope and severity of E, which represents more than minimal harm with no actual harm or immediate jeopardy. CMS Ex. 701, at 1.

The Secretary has established quality of care requirements at 42 C.F.R. § 483.25, with which each participating long-term care facility must comply. The regulation requires generally that:

> Each resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care.

42 C.F.R. § 483.25. Regarding medication errors the regulation requires:

> (m) *Medication Errors*. The facility must ensure that—
> (1) It is free of medication error rates of five percent or greater; and

(2) Residents are free of any significant medication errors.

42 C.F.R. § 483.25(m) (emphasis in original). The surveyors and CMS allege that Petitioner violated 42 C.F.R. § 483.25(m)(1), not 42 C.F.R. § 483.25(m)(2).

The SOM defines a medication error as follows:

> A medication error is the preparation or administration of medications or biologicals that is not in accordance with any of the following:
>
> - The prescriber's order (whether given incorrectly or omitting an ordered dosage);
>
> - Manufacturer's specifications (not recommendations) regarding the preparation and administration of the medication or biological; and
>
> - Accepted professional standards and principles that apply to professionals providing services . . . .[6]

The Guidance to Surveyors for Long Term Care Facilities (Guidance to Surveyors), SOM, app. PP, Tags F332 and F333,[7] defines a medication error as follows:

> Medication Error -- The observed preparation or administration of drugs or biologicals which is not in accordance with:
>
> 1. Physician's orders;
>
> 2. Manufacturer's specifications (not recommendations) regarding the preparation and administration of the drug or biological;
>
> 3. Accepted professional standards and principles which apply to professionals providing services. Accepted professional standards and principles include the various practice regulations in each State, and

[6] SOM, app. P. Sub-Task 5E – Medication Pass and Pharmacy Services (Rev. 22, Issued: 12-15-06, Effective/Implementation: 12-18-06), C.1. Medication Pass.

[7] Petitioner offered a copy of this section of the SOM as P. Ex. 13.

> current commonly accepted health standards established by national organizations, boards, and councils.

No preparation error is alleged in the SOD. The surveyors cite only administration errors.

The SOM explains that the medication error rate to determine whether a violation of 42 C.F.R. § 483.25(m)(1) exists is calculated by dividing the number of observed errors by the number of opportunities for error and multiplying the quotient by 100, i.e.,

$$\text{Medication Error Rate} = \frac{\text{Number of Observed Errors}}{\text{Number of Opportunities}} \text{ X } 100$$

Surveyors are instructed that the error rate must actually be five percent or greater for a citation under 42 C.F.R. § 483.25(m)(1) and that rounding of a lower rate to five percent is not permitted. Both significant and insignificant errors are considered when determining the medication error rate under 42 C.F.R. § 483.25(m)(1). Surveyors are instructed:

> "**Medication error rate**" -- A medication error rate of 5% or greater includes both significant and nonsignificant medication errors. It indicates that the facility may have systemic problems with its drug distribution system and a deficiency should be written.

SOM, app. PP, Tags F332 and F333 (emphasis in original). Thus, a citation under 42 C.F.R. § 483.25(m)(1) is based upon an error rate of five percent or more, including both significant and non-significant errors.

The SOM in a subsection entitled "Determining Medication Errors" provides the following guidance to surveyors to determine whether or not there was a medication error related to the time of administration of a medication:

> **Timing Errors** -- If a drug is ordered before meals (AC) and administered after meals (PC), always count this as a medication error. Likewise, if a drug is ordered PC and is given AC, count as a medication error. Count a wrong time error if the drug is administered 60 minutes earlier or later than its scheduled time of administration, BUT ONLY IF THAT WRONG TIME ERROR CAN CAUSE THE RESIDENT DISCOMFORT OR JEOPARDIZE THE RESIDENT'S HEALTH AND SAFETY. Counting a drug

> with a long half-life (e.g., digoxin) as a wrong time error when it is 15 minutes late is improper because this drug has a long half-life (beyond 24 hours) and 15 minutes has no significant impact on the resident. The same is true for many other wrong time errors (except AC AND PC errors).
>
> To determine the scheduled time, examine the facility's policy relative to dosing schedules. The facility's policy should dictate when it administers a.m. doses, or when it administers the first dose in a 4-times-a-day dosing schedule.

SOM, app. PP, Tags F332 and F333 (emphasis in original). Based on this language from the SOM, Petitioner argues that a wrong time error does not count as a medication error, significant or insignificant, unless it has the potential to cause the resident discomfort or to jeopardize the resident's health and safety. P. Brief at 23. In other words, Petitioner's interpretation is that administering a medication at the wrong time is only counted as a "medication error" if one of two conditions is met: the medication was "ordered" for before meals, and it was delivered after or vice versa; or the administration at some other wrong time can cause a resident discomfort or jeopardize the resident's health or safety. Petitioner presented evidence, as discussed hereafter, that none of the residents who received their medication late were subject to even the potential for minimal harm in this case.

CMS argues that a medication error counts for determining the medication error rate so long as there is a potential for more than minimal harm to a resident due to the error. In the context of this case, the gist of the CMS argument is that administering a medication more than one hour late is a medication error, and the only requirement for potential harm is the requirement that the regulatory violation must pose more than minimal harm to be substantial noncompliance and the basis for an enforcement remedy. 42 C.F.R. § 488.301 (substantial compliance is a level of compliance so that no identified deficiency poses a risk for more than minimal harm). CMS relies upon the decision of the Board in *Park Manor Nursing Home*, DAB No. 2005 (2005), which was based on that appellate panel's interpretation of the legislative history of 42 C.F.R. § 483.25(m). CMS Brief at 3-4. It is important to note initially that in the *Park Manor* case that CMS cites, an appellate panel of the Board had previously found in favor of Park Manor and rescinded all enforcement remedies. The issue before the Board in *Park Manor*, DAB No. 2005, was whether or not Petitioner was entitled to an award of attorneys fees pursuant to the Equal Access to Justice Act. In conducting its review of Park Manor's entitlement to attorney fees, the appellate panel determined that it was necessary to determine whether the CMS action against Petitioner was substantially justified. CMS had charged Petitioner with a violation of 42 C.F.R. § 483.25(m)(1) (Tag F332), among other violations. The panel in *Park Manor* determined that CMS had a reasonable basis for the charge. *Park Manor,* DAB No. 2005, at 51-52. In deciding whether there was a reasonable basis for the charge, the panel considered the language from the rule-making

for the regulation, which is found at 56 Fed. Reg. 48,826, 48,833 (Sept. 26, 1991). The piece of the legislative history cited by the Board confirms that the drafters intended to adopt two different criteria for determining medication errors: a medication error rate of five percent or more, including both significant and insignificant medication errors; and any significant medication error. The legislative history is consistent with the language of 42 C.F.R. § 483.25(m) and clarifies that 42 C.F.R. § 483.25(m)(1) is intended to include both significant and insignificant medication errors. *Park Manor,* DAB No. 2005, at 48. The appellate panel in *Park Manor* also considered the Guidance to Surveyors from the SOM. However, the panel did not discuss the CMS instructions to surveyors in the SOM regarding timing errors, which is set forth above and relied upon by Petitioner, most likely because the panel's discussion of the medication errors in *Park Manor* included three alleged timing errors related to the administration of insulin; however, they were errors that the panel declined to address. *Park Manor,* DAB No. 2005, at 49-52. Therefore, I do not find the decision in *Park Manor* helpful in deciding whether or not an error in the timing of administration of a medication is excluded from the definition of "medication error" by the SOM as Petitioner argues. CMS also cites to the decision of an ALJ in *Palm Garden of Gainsville*, CR1088 (2003) and the decision of an appellate panel of the Board affirming the ALJ decision, *Palm Garden of Gainsville*, DAB No. 1922 (2004). However, neither decision addresses the issue raised in this case.

The requirements of 42 C.F.R. § 483.25(m) are clear that Petitioner must not have a medication error rate of five percent or more, and Petitioner must not have any significant medication errors. Although the regulation does not provide a definition for "significant medication error," both significant and non-significant or insignificant medication errors are described in detail in the SOM, app. PP, Tags F332 and F333. A significant medication error is "one which causes the resident discomfort or jeopardizes his or her health and safety" and other medication errors are "nonsignificant." SOM, app. PP, Tags F332 and F333. The SOM instructs surveyors that "significance" is a matter of professional judgment based on consideration of the specific resident's condition, the drug category, and the frequency of the error. SOM, app. PP, Tags F332 and F333.

Although not specified by the regulation, both the SOM and the decision of the Board in *Park Manor* indicate that significant and insignificant medication errors should be counted when determining whether a facility has a medication error rate of five percent or more. The issue not addressed by the regulation, the SOM, or prior decisions is whether or not the SOM excludes from the definition of "medication error" an error arising from the timing of administration of a medication that did not involve failure to provide a medication before a meal, when that was required, and giving it after the meal or vice versa; or that did not have the potential to cause a resident discomfort or jeopardize the resident's health and safety.

My review of the language of the SOM, Tags F332 and 333, and its organization leads me to conclude that Petitioner advances the correct interpretation of CMS policy for how to determine whether a timing error amounted to a medication error that should be

counted for purposes of application of 42 C.F.R. § 483.25(m)(1). The discussion of timing errors upon which Petitioner relies is set forth in a subsection of the discussion for Tags F332 and 333 entitled "Timing Errors" that is also the first subsection of a subsection entitled "Determining Medication Errors." The discussion of timing errors is not included within the sections that discuss significant and insignificant errors or that provide examples of such errors. The titles of the two subsections – "Determining Medication Errors" and "Timing Errors" – and their organization cause me to conclude that the purpose of the discussion was to instruct surveyors to determine whether a timing error was to be counted as a "medication error" or not. The purpose of the subsection was not to instruct surveyors on how to determine whether a medication error was significant or insignificant. The first line of the subsection entitled "Timing Errors" states "[i]f a drug is ordered before meals (AC) and administered after meals (PC), always count this as a medication error." The sentence does not label such an error a "significant medication error," rather, it states that such an error is a "medication error." Similarly, the second sentence states "[l]ikewise, if a drug is ordered PC and is given AC, count as a medication error." Again, the second sentence does not state that such an error is a significant medication error. The third sentence creates confusion because the drafters refer to a "wrong time error," rather than a "medication error," and the drafters use the definition of a "significant medication error." CMS instructs in the third sentence that surveyors should "[c]ount a wrong time error if the drug is administered 60 minutes earlier or later than its scheduled time of administration, BUT ONLY IF THAT WRONG TIME ERROR CAN CAUSE THE RESIDENT DISCOMFORT OR JEOPARDIZE THE RESIDENT'S HEALTH AND SAFETY." The use of capital letters appears in the original text, and I surmise it was used for emphasis. Despite the emphasis, the sentence is confusing, because the text in capitol letters is the same as the definition for a significant medication error. There are a number of possible constructions that could be given to this confusing sentence. However, giving the drafters full credit for having been knowledgeable of the remaining text of the SOM under Tags F332 and F33, the logical construction for the sentence is that it instructs surveyors to count as a "medication error" only those errors in the timing of administration, i.e., those that are more than 60 minutes early or late that amount to a significant medication error. This construction makes sense for determination of whether or a violation of 42 C.F.R. § 483.25(m)(1) exists, because the counting of errors is necessary for determining whether or not the rate of error is five percent or more. There is no need to count the number of medication errors to determine whether a violation of 42 C.F.R. § 483.25(m)(2) exists, as the existence of even a single significant medication error constitutes a violation of the regulation. Furthermore, if a single significant medication error has the potential for more than minimal harm, then it is considered substantial noncompliance that will support an enforcement remedy. I conclude that the language of the SOM provides CMS policy guidance to surveyors that the following timing errors are counted as medication errors:

> 1. Failure to administer a medication before a meal or after a meal as ordered; and

> 2. Administration of a medication more than 60 minutes earlier or later than scheduled but only if such timing error amounts to a significant medication error, i.e., it can cause the specific resident discomfort or jeopardizes the resident's health and safety.

Under the second prong, if a timing error amounts to a medication error, it is also a significant medication error and should, arguably, be cited as a violation of 42 C.F.R. § 483.25(m)(2) (Tag F333). I neither accept nor reject the CMS argument that a timing error amounts to a medication error if it poses a risk for more than minimal harm as that is not the formulation that CMS chose for its policy. I note that if CMS intended for its policy to provide that a timing error is a medication error if it poses a risk for more than minimal harm, the drafters could have more simply stated that than the standard actually stated in the SOM. Of course, the issue of whether or not an alleged deficiency, i.e., regulatory violation, posed the risk for more than minimal harm is important for determining whether Petitioner was in substantial compliance. I also do not construe the surveyors' failure to cite any of the alleged timing errors as significant medication errors under 42 C.F.R. §483.25(m)(2) a concession that the timing errors did not amount to medication errors.

The issue for determination is whether or not Petitioner had a medication error rate of five percent or more on August 18, 2009, when the surveyors did their medication pass review. To decide the issue, it is necessary to analyze the facts in this case and determine which, if any, of the alleged timing errors may be correctly counted a medication error under the CMS policy. Any timing error that meets the requirement of the policy to be counted as a medication error would also be evidence of a violation of 42 C.F.R. § 483.25(m)(2), and one such violation would cause Petitioner not to be in substantial compliance with program participation requirements if the violation posed the risk for more than minimal harm. All of the 21 alleged medication errors in this case were alleged timing errors. One alleged error involved administering insulin after a meal, and that medication should have been administered prior to the meal per physician order. The administration after a meal of a medication ordered to be administered before a meal is presumptively a medication error under the CMS policy. The CMS policy does not require that the delivery of a medication after a meal when it is ordered for before cause the specific resident discomfort or jeopardize the resident's health and safety, for such a timing error to be counted a medication error. Thus, there is no inference triggered or presumption that the delivery of a medication after a meal when it is ordered for before is a "significant medication error" that would support a citation under 42 C.F.R. § 483.25(m)(2). The remaining 20 errors were due to failure of Petitioner's staff to administer medication within 60 minutes after the scheduled time for administration. Pursuant to the regulation and CMS policy stated in the SOM, it is necessary to determine whether there was a "medication error" or just a "timing error" and then apply the formula provided in the SOM to determine whether there were five percent or more medication errors and a violation of 42 C.F.R. § 483.25(m)(1).

The pertinent facts summarized in the SOD for the survey that concluded on August 20, 2009 are mostly undisputed. The surveyors observed the administration of 48 medications or supplements (48 opportunities) to 7 residents, and the surveyors allege that there were 21 errors for a medication error rate of 43 percent. There is no dispute that Petitioner had a policy, dated December 1, 2007, that required that authorized facility personnel administer medications at times directed by Petitioner's pharmacy committee, or as ordered by the physician or prescriber. The policy provided that administration of medication should commence within 60 minutes before the designated times for administration and 60 minutes after the designated times of administration. The policy also provided that medication to be administered before meals should be given approximately 30 minutes prior to meals and medication to be given after meals should be given no more than 30 minutes after the meal. CMS Ex. 708, at 7; CMS Ex. 701, at 8-9. CMS does not question that Petitioner's policy is consistent with the standard of care and also the SOM. The facts alleged in the SOD, as set forth hereafter for each individual resident, are also not disputed.[8] The statement of facts from the SOD for each resident is followed by a summary of the expert testimony related to each resident and the observed timing errors.

a. Resident 47

Resident 47 had orders for Novolog insulin, 23 units subcutaneous before breakfast and lunch. The resident's Medication Administration Record (MAR) showed scheduled administration of the insulin was to be at 7:00 a.m.[9] and 11:30 a.m. The resident was to receive Omega 3 (a supplement), 1000 milligrams (mg), three times per day, and the MAR showed scheduled administration at 8:00 a.m., Noon, and 4:00 p.m. Resident 47 was to receive Baclofen, half a 10 mg tablet, three times per day for muscle spasms, and the MAR showed scheduled administration at 8:00 a.m., Noon, and 4:00 p.m. The resident was to receive Fursoemide, 40 mg, one tablet two times a day for swelling, and the MAR showed scheduled administration at 8:00 a.m. and Noon. The resident was to receive Gabapentin, 300 mg (Neurontin), one capsule three times per day for pain, and the MAR showed scheduled administration at 8:00 a.m., Noon, and 4:00 p.m. The surveyor observed the nurse administer all these medications at 1:25 p.m. on August 18,

[8] Although not pertinent to my decision, CMS also does not dispute that the late administration of medication on August 18, 2009 was caused by a nurse failing to show-up for work that morning. CMS Brief at 16-17.

[9] The SOD states the time for administration on the MAR was 7:30 a.m. (CMS Ex. 701, at 1), but the surveyor testified that was an error in the SOD and that the time on the MAR was actually 7:00 a.m. Tr. 157.

2009.[10] CMS Ex. 701, at 1-2; CMS Ex. 702; Tr. 150-57. The order for the insulin specified that it was to be administered before lunch, and there is no dispute that it was administered after lunch. The other medications were scheduled for Noon and could have been administered between 11:00 a.m. and 1:00 p.m. under both Petitioner's policy and the guidance in the SOM. Whether or not the administration 25 minutes late amounts to a medication error is determined by whether or not the late administration can cause the resident discomfort or may jeopardize the resident's health or safety. Extensive expert testimony was provided by both parties on this fact issue.

CMS called as an expert witness, Jack E. Fincham, Ph.D. in Social and Administrative Pharmacy, and a professor in the School of Pharmacy, The University of Missouri at Kansas City. Tr. 162-63; CMS Ex. 711. Dr. Fincham opined that the administration of Baclofen 25 minutes late had the potential for more than minimal harm due to a possible increase in the resident's pain. Tr. 165-66. He testified that the late administration of Furosemide, a loop diuretic, did not pose even minimal harm. Tr. 166-67. Dr. Fincham testified that the late administration of Gabapentin posed the potential for more than minimal harm, as it could result in increased pain for the resident. Tr. 167. However, he admitted on cross-examination that he did not know whether the resident was taking the Neurontin (Gabapentin) for pain or a seizure disorder. Tr. 192-93. He testified that there was no potential harm due to the late administration of Omega 3. Tr. 168-69.

CMS also called as an expert witness, Daniel Swagerty, MD, a professor of family and internal medicine at the University of Kansas School of Medicine. Tr. 204; CMS Ex. 709. He testified that the standard of care for a long-term care facility is to administer medication within an hour before or an hour after the scheduled time for administration. Tr. 207. He testified that the late administration of Baclofen for Resident 47 had the potential for causing more than minimal harm. Tr. 206-07. He also testified that administering the Furosemide late did not pose more than minimal harm. Tr. 208. Dr. Swagerty testified that administering Gabapentin late posed a risk for more than minimal harm. Tr. 208. He testified that administering Omega 3 late did not risk any harm. Tr. 208.

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[10] The surveyors testified that although the medication was given late for each resident, the nurse who administered the medication did not make an entry on the MAR to reflect that the medication was administered late. The SOD also includes a statement for most of the examples that the nurse simply entered his or her initials on the MAR in the time slot for when the medication was to be administered. *See, e.g.,* Tr. 152; CMS Ex. 701, at 4. There is no deficiency cited related to the adequacy of Petitioner's documentation, and CMS does not advance an argument in that regard in its post-hearing briefing. CMS argues that the documentation of late administration of a medication should have been addressed by Petitioner in a plan of correction. CMS Brief at 15. However, I find that there is no deficiency and no plan of correction at issue.

Petitioner called Dennis Ray Drews, MD, Petitioner's Medical Director. Tr. 279-80. Dr. Drews testified that Resident 47 was his patient. He testified that for most medication that he orders he does not specify the time when the medication is to be administered. He testified that Resident 47 was prescribed Baclofen for spasticity. In the one or two years he had cared for her, there was no complaint of spasms. He concluded that a one-time delay in administering Baclofen would cause no harm to Resident 47. He testified that the delay in administering her Gabapentin would also cause no harm as it was not prescribed for acute pain but rather as a maintenance drug. He testified that Resident 47 would suffer no harm due to the late administration of the Novolog (insulin), because she is less compliant with her diet and often brings food to her room to eat, friends bring her food, and she is highly resistant to insulin. Tr. 281-85, 303-08; P. Ex. 12, at 2 ¶ 11.

b. Resident 54

Resident 54 had an order for Doxycycline, an antibiotic, 100 mg, twice a day for ten days, and the MAR showed scheduled administration at 8:00 a.m. and 8:00 p.m. The resident had an order for Propanolol for hypertension, 20 mg, twice a day, and the MAR showed scheduled administration at 8:00 a.m. and 8:00 p.m. The resident had an order for a potassium supplement, Klor-Con, 20 millequivalents, four times a day, and the MAR showed scheduled administration at 7:00 a.m., Noon, 5:00 p.m., and 9:00 p.m. The resident was to receive oyster shell calcium with vitamin D (500 mg), a supplement, twice a day, and the MAR showed scheduled administration at 8:00 a.m. and 8:00 p.m. The resident was to receive Neurontin, 300 mg, three times per day, and the MAR showed scheduled administration at 7:00 a.m., 2:00 p.m., and 10:00 p.m. Resident 54 had an order for one puff of Advair twice daily, and the MAR showed scheduled administration at 8:00 a.m. and 8:00 p.m. The surveyor observed a nurse give the resident his Doxycycline, Propanolol, calcium supplement, a puff of Advair, potassium supplement, and Neurontin at 9:45 a.m. on August 18, 2009. The MAR listed the Doxycycline, Propanolol, calcium supplement, and a puff of Advair, to be administered at 8:00 a.m., and they could have been administered between 7:00 a.m. and 9:00 a.m. without violating either the CMS or Petitioner's policies. These medications and supplement were thus delivered 45 minutes outside the policy parameters. The potassium supplement and the Neurontin were scheduled for administration at 7:00 a.m. and, pursuant to the CMS and Petitioner's policy, could have delivered between 6:00 a.m. and 8:00 a.m. Therefore, administration was 1 hour and 45 minutes late for these items. The surveyor also observed a nurse give the resident his Noon dose of potassium supplement at 1:23 p.m. on August 18, 2009, 23 minutes late. CMS Ex. 701, at 3-4; CMS Ex. 703; Tr. 51-64. To determine whether the late administration of these medications and supplements were medication errors, it is necessary to determine whether or not the late administration can cause the resident discomfort or may jeopardize the resident's health or safety.

Dr. Fincham opined that the administration of Doxycycline, an antibiotic, did not have the potential to cause more than minimal harm. Tr. 170-71. He testified that the delay in administering Propranolol had the potential for causing more than minimal harm. Tr. 171. He testified that there was no potential for harm due to the late administration of Klor-Con or the oyster shell calcium. Tr. 171. He opined that the late administration of the Neurontin (Gabapentin) could cause more than minimal harm due to increased pain. Tr. 171-72. Dr. Fincham testified that there was no potential for minimal harm due to the late administration of Advair. Tr. 172.

Dr. Swagerty testified that the late administration of Doxycycline did not pose a risk for more than minimal harm. Tr. 209. He testified that the late administration of Propranolol posed the risk for more than minimal harm. Tr. 209-11. He testified that there was no risk for more than minimal harm due to the late administration of Klor-Con, a potassium supplement, and the oyster shell calcium supplement. Tr. 212. He testified that there was a risk for more than minimal harm associated with the late administration of Neurontin due to the potential for increased pain or sedation or imbalance and an increased risk for falls due to giving another dose too close in time to the delayed dose. Tr. 212-13. He testified that the late administration of Advair posed the risk for more than minimal harm. Tr. 213.

Dr. Drews testified that Resident 54 was also his patient. He opined that the delayed administration of Propranolol would have no impact upon the resident, as it was prescribed for an essential tremor. He also opined that the delayed administration of the Neurontin would cause no harm to the resident, because it was prescribed as a maintenance drug for neuropathy and reflex sympathetic dystrophy. The resident was under better pain control with the Neurontin and had not complained of pain in the past month. Tr. 285-86.

c. Resident 68

Resident 68 had an order for Clonidine for hypertension, 0.2 mg, three times a day, and the MAR showed a schedule of 7:00 a.m., 2:00 p.m., and 10:00 p.m. The resident had an order for Labetalol for hypertension, 300 mg, and the MAR showed a schedule of 8:00 a.m. and 8:00 p.m.[11] The resident was to receive oyster shell calcium with vitamin D, 500 mg, twice a day at 8:00 a.m. and 8:00 p.m. according to the MAR. Resident 68 also had an order for Zoloft, 100 mg, twice a day, with scheduled administration at 8:00 a.m. and 8:00 p.m., according to the resident's MAR. The surveyor observed a nurse administer Resident 68's medications and supplement at 10:06 a.m. on August 18, 2009.

[11] The SOD alleges that the MAR had the Labetalol scheduled for administration at 7:00 a.m., 2:00 p.m., and 10:00 p.m. CMS Ex. 701, at 4. The surveyor testified, however, that the SOD was in error, and the correct times for administration were 8:00 a.m. and 8:00 p.m. Tr. 65-66.

CMS Ex. 701, at 4-5; CMS Ex. 704; Tr. 63-66. Thus, the resident's Clonidine was two hours and six minutes late, and the medications and supplement scheduled for 8:00 a.m. were one hour and six minutes late. However, according to the SOM, late administration alone is not enough to constitute a medication error. To determine whether the late administration of these medications and supplement were medication errors, it is necessary to determine whether or not the late administration can cause the resident discomfort or may jeopardize the resident's health or safety.

The CMS expert, Dr. Fincham, testified that the delay in administration of Clonidine had the potential to cause more than minimal harm. Tr. 173. He testified that the late administration of Labetalol had the potential for causing more than minimal harm. Tr. 173-74. Dr. Fincham testified that there was no potential for harm due to the late administration of the calcium supplement. Tr. 174. He also testified that there was no more than minimal harm possible due to the late administration of Zoloft. Tr. 174-75.

The CMS expert, Dr. Swagerty, testified that the late administration of Clonidine and Labetalol had the potential to cause more than minimal harm. Tr. 214-17. He testified that the late administration of the calcium supplement and the Zoloft did not pose the potential for more than minimal harm. Tr. 217-18.

Dr. Drews testified that Resident 68 was Dr. McGovney's patient but that he also saw her and was familiar with her case. He testified that the delay in administering Clonidine and Labetalol had no impact on the resident. She was prescribed Clonidine and Labetalol for hypertension, and it was stable. He testified that the delayed administration of Zoloft also had no harmful effect for Resident 68. Tr. 287-88.

d. Resident 69

Resident 69 had an order for Morphine Sulfate, a narcotic pain medication, 30 mg, twice a day, and the MAR scheduled administration for 8:00 a.m. and 8:00 p.m. The resident also had an order for Metoprolol for hypertension, 25 mg, twice a day, scheduled on the MAR for administration at 8:00 a.m. and 8:00 p.m. The surveyor observed a nurse give the resident his morphine at 9:40 a.m. on August 18, 2009, 40 minutes late under the SOM and Petitioner's policy, but the resident refused the Metoprolol. The surveyor subsequently observed the nurse give the resident the Metoprolol at 10:15 a.m., 1 hour and 15 minutes late per the SOM and Petitioner's policy. CMS Ex. 701, at 5-6; CMS Ex. 705; Tr. 66-68. However, according to the SOM, late administration alone is not enough to constitute a medication error. To determine whether the late administration of these medications and supplement were medication errors, it is necessary to determine whether or not the late administration can cause the resident discomfort or may jeopardize the resident's health or safety. The surveyor testified that the resident claimed to be in pain, but she could not tell if her pain level was higher at the time than usual. Tr. 114-15.

Dr. Fincham testified that the late administration of Morphine Sulfate had the potential for more than minimal harm due to increased pain. Tr. 175. He also opined that the late administration of Metoprolol posed the risk for more than minimal harm. Tr. 176. Dr. Swagerty testified that the late administration of Morphine posed the risk for more than minimal harm in the form of increased pain or increased sedation. Tr. 218. He testified that the late administration of Metoprolol also posed the potential for more than minimal harm. Tr. 218-19.

Dr. Drews testified that Resident 69 was his patient. He testified that there would be no harm to the resident due to the delayed administration of her Morphine, because it is slow release and a maintenance drug. He testified that she suffered no harm due to the late administration of Metoprolol because she receives the medication twice each day, and delayed administration would not change her blood pressure very much. Tr. 288-90.

e. Resident 70

Resident 70 had an order for Carvedilol for irregular heartbeat, 12.5 mg, twice a day, scheduled for administration on the MAR for 8:00 a.m. and 8:00 p.m. The surveyor observed Resident 70 receive his Carvedilol at 10:23 a.m. on August 18, 2009, 1 hour and 23 minutes late under the SOM and Petitioner's policy. CMS Ex. 701, at 6; CMS Ex. 706; Tr. 68-69. However, according to the SOM, late administration alone is not enough to constitute a medication error. To determine whether the late administration of these medications and supplement were medication errors, it is necessary to determine whether or not the late administration can cause the resident discomfort or may jeopardize the resident's health or safety.

Dr. Fincham opined that the late administration of Carvedilol had the potential to cause more than minimal harm for Resident 70. Tr. 177-82. Dr. Swagerty testified that the late administration of Carvedilol posed the risk for more than minimal harm to the resident. Tr. 219-20.

Dr. Drews testified that Resident 70 was his patient. He testified that the delayed administration of Carvedilol would cause no harm. He testified that the resident was given Carvedilol for coronary artery disease and atrial fibrillation, both of which were stable. Tr. 290-91.

f. Resident 17

Resident 17 had an order for Depakote DR (Divalproex Sodium, Delayed Release). 250 mg was scheduled for administration at 8:00 a.m. and 500 mg at 8:00 p.m. The resident had an order for Buspirone, 10 mg, two tablets three times a day, and on the MAR scheduled for administration at 8:00 a.m., 2:00 p.m., and 8:00 p.m. The surveyor observed the nurse administer these medications at 10:35 a.m. on August 18, 2009, 1 hour and 35 minutes late. CMS Ex. 701, at 6-7; CMS Ex. 707; Tr. 69-70. However,

according to the SOM, late administration alone is not enough to constitute a medication error. To determine whether the late administration of these medications and supplement were medication errors, it is necessary to determine whether or not the late administration can cause the resident discomfort or may jeopardize the resident's health or safety.

Dr. Fincham testified that the late administration of Divalproex (Depakote) posed the risk for minimal harm to Resident 17 due to a possible increase in seizure activity. Tr. 183. He testified that the late administration of Buspirone had the potential to cause more than minimal harm. Tr. 183. Dr. Swagerty opined that the delayed administration of Depakote and Buspirone posed a risk for more than minimal harm to Resident 17. Tr. 220-21.

Dr. Drews testified that the delayed administration of Depakote and Buspirone would cause no harm, as Resident 17 took the medications as a mood stabilizer for a behavior problem. Tr. 291-93.

g. Resident 67

Resident 67 had an order for Depakote for a mood disorder, 125 mg, two times a day, and the MAR showed the administration was scheduled for 8:00 a.m. and 8:00 p.m. The surveyor observed the medication administered through the resident's feeding tube at 10:46 a.m. on August 18, 2009, 1 hour and 46 minutes late. CMS Ex. 701, at 7; CMS Ex. 708; Tr. 71. However, according to the SOM, late administration alone is not enough to constitute a medication error. To determine whether the late administration of these medications and supplement were medication errors, it is necessary to determine whether or not the late administration can cause the resident discomfort or may jeopardize the resident's health or safety.

The CMS expert, Dr. Fincham, testified that the late administration of Depakote for this resident had the potential for causing more than minimal harm due to the possibility for increased seizure activity. Tr. 184. Dr. Swagerty testified that there was a risk for more than minimal harm due to the late administration of Depakote. Tr. 221-22.

Dr. Drews testified that Resident 67 is his patient, and she was prescribed Depakote for behavioral issues. He opined that she suffered no harm due to late administration of her Depakote. Tr. 293.

Dr. Drews testified that for all the residents cited by the surveyors, if he had been called he would have directed that all be given their medication even though it was late. Tr. 294.

Dr. Fincham testified on cross-examination that he did not review the medical records of the residents and that he was not personally familiar with them. He did review the medication administration records for the residents and the physician orders for the medications involved. Tr. 189-90.

Dr. Swagerty testified that he did not identify actual harm to any of the residents due to late administration of the medications. Tr. 211. He also testified on cross-examination that he did not review the clinical records for any of the residents. Tr. 227. He also agreed that he was aware of no evidence of any other instance when there was delayed administration of medication. Tr. 230.

On cross-examination Dr. Drews testified that he became Medical Director for Petitioner in 2001 but that he had seen patients at the facility since 1998 or 1999. He testified that he was at the facility four hours on Wednesday, and eight to ten hours on Friday. Dr. Drews testified that he was paid $3,000 per month as Medical Director pursuant to the terms of his contract. He testified that on average Petitioner has 180 to 200 residents, and that 80 to 90 percent are his patients. Tr. 294-302.

The surveyors observed 21 timing errors in 48 observed administrations of medications or supplements. Before me, CMS takes the position that for a timing error to be counted as a medication error, except when the error was failure to provide a medication before or after a meal, the timing error must pose a risk for at least minimal harm. The testimony of the CMS expert, Dr. Fincham, is that 13 of the observed timing errors posed the risk for more than minimal harm. Dr. Fincham's testimony could be construed to support a conclusion that there was a medication error rate of 27 percent. The testimony of Dr. Swagerty, the other CMS expert, was that 14 of the timing errors posed a risk for more than minimal harm. Dr. Swagerty's testimony could be construed to support a conclusion that there was a medication error rate of 29 percent. The CMS expert testimony is that the medication error rate was significantly lower than that alleged by the surveyors,[12] but still greater than 5 percent. However, as discussed in detail above, the SOM supports the position of the Petitioner that it is not the risk for more than minimal harm that elevates a timing error to a medication error. Rather, the administration of a medication 60 minutes or more before or after its scheduled time is not considered a "medication error" for purposes of 42 C.F.R. § 483.25(m)(1), unless the timing error can cause the resident discomfort or might jeopardize the resident's health or safety. The CMS experts did not testify to whether any of the timing errors alleged could cause any of the residents involved discomfort or whether the timing errors jeopardized the residents' health or safety. Therefore, the testimony of the CMS experts does not support any conclusions regarding the medication error rate. I do not question the credentials of the CMS experts

[12] The testimony of Surveyor McConkey shows that the surveyors cited timing errors as medication errors without any careful analysis, understanding, or knowledge of whether or not the timing error posed more than minimal harm or not. Tr. 112-19.

or their knowledge of the particular medication and supplements about which they testified. Indeed, although not specifically offered by CMS as experts at the hearing, Petitioner did not object to or challenge their credentials, and I find them well-qualified to provide the testimony they did. However, the CMS experts did not examine or interview any of the residents involved, and they only reviewed a limited part of the clinical record related to medication administration for each resident. Thus, their opinion that late administration of any of the medications posed more than minimal harm for the individual residents involved had a limited basis in fact. Had the CMS experts attempted to testify about whether or not any of the individual residents were subjected to discomfort or that their health or safety was jeopardized by the late administration of any of the medications, the credibility of their opinions would clearly have been subject to doubt.

Dr. Drews, on the other hand, was a treating physician for the residents involved. His testimony established his familiarity with and knowledge of the individuals, their clinical records, their individual diagnoses and prescribed treatment, the reasons for their prescription medication, and the likely effect of delayed administration. The fact that treating source evidence is potentially more probative than the opinion of medical experts with no treatment relationship to an individual is recognized by the Social Security Administration in the process for determination of entitlement to benefits under Title II of the Act, specifically at 20 C.F.R. § 404.1527. The regulation has no direct application to this case. Nevertheless, the rationale for weighing treating source evidence set forth in the regulation is instructive and is supportive of my finding Dr. Drews' testimony more probative than that of the CMS experts who had no treatment relationship with any of the residents, had never examined the residents, and had only limited knowledge of their clinical records. Dr. Drews opined that the late administration of medications in this case did not pose a risk for more than minimal harm to any of the residents involved. I find that testimony credible and persuasive. CMS attempts to impeach Dr. Drews by pointing to an allegedly inconsistent prior statement and his financial ties to Petitioner. CMS Brief at 11-13. Dr. Drews executed an affidavit on August 21, 2009, in which he states that Resident 47 received her insulin late but before she ate. P. Ex. 12, at 2 ¶ 11. Dr. Drews testified at hearing that he learned that the insulin was actually given after Resident 47 ate her lunch. Tr. 303. He explained at trial that he was not present at the facility when the error occurred. Rather, his affidavit and testimony were based on what was reported to him. He testified that whether Resident 47 received her insulin before or after lunch did not affect his opinion that, on the facts in this case, there was no risk for more than minimal harm to Resident 47. Tr. 303-04. Although the affidavit and testimony are inconsistent, Dr. Drews adequately explained the inconsistency and why it does not affect his opinion. Accordingly, I conclude that the inconsistency does not adversely affect his credibility or the probative value of his testimony. CMS also argues that Dr. Drews' compensation as medical director and attending physician for many residents detracts from his credibility. However, Dr. Drews forthrightly testified about his $3,000 per month compensation and the fact he is the treating physician for many residents. His monthly compensation does not seem excessive or an adequate motivation

to lie under oath or shade the truth in favor of Petitioner. The fact he has a treatment relationship with many residents also does not appear to be an adequate basis to determine that Dr. Drews was not honest in his opinions. If compensation as a Medical Director or a treatment relationship with facility residents was a sufficient basis for finding a medical director not credible, no medical director could ever be found credible, and there would be no value to having them testify in these proceedings.

Dr. Drews opined that none of the medication errors posed a risk for more than minimal harm to any of the residents involved. I find no source in law or CMS policy that compares the "no more than minimal harm" standard with the test for significant medication error, i.e. "whether or not an individual resident was subject to discomfort or that his or her health or safety was jeopardized." However, based upon the language of the two tests, I conclude that they are not the same and that the test for significance implies more than minimal harm. My conclusion is consistent with the provisions of the Secretary's regulations that a facility remains in substantial compliance so long as no deficiency poses a risk for causing more than minimal harm. 42 C.F.R. § 488.301. I conclude that the timing errors identified by the surveyors did not amount to medication errors, because they did not pose the risk of causing more than minimal harm to the residents involved or subject them to discomfort or jeopardize their health and safety. The administration of insulin after the meal to Resident 47, rather than before as prescribed, was a medication error under CMS policy, even though it did not pose the risk for more than minimal harm to Resident 47. Therefore, I conclude that there was only one "medication error" within the meaning of 42 C.F.R. § 483.25(m)(1) and CMS policy, out of 48 opportunities, an error rate of 2 percent. An error rate of 2 percent does not amount to a violation of 42 C.F.R. § 483.25(m)(1).

Furthermore, the credible evidence does not show that any of the timing errors or the single medication error involving Resident 47 posed the risk for more than minimal harm to any resident. The evidence does not show that there was another instance with numerous timing errors reflecting a systemic failure of Petitioner's drug distribution system – the primary focus of 42 C.F.R. § 483.25(m)(1), according to the SOM. SOM app. PP, Tags F332 and F333. The evidence does not show that there was a bunching effect, a concern of the CMS experts. As a matter of law, if a deficiency did not pose the risk for causing more than minimal harm to any resident, the deficiency did not cause Petitioner not to be in substantial compliance with program participation requirements. 42 C.F.R. § 488.301.

Accordingly, I conclude that there was no violation of 42 C.F.R. § 483.25(m)(1), but even if there was, it did not cause Petitioner not to be in substantial compliance on August 20, 2009. Because CMS had determined Petitioner had corrected all deficiencies from all prior surveys before August 20, 2009, Petitioner was in substantial compliance on August 20, 2009. Tr. 144, 272. Petitioner was first found not in substantial compliance by a survey that ended on February 20, 2009. Pursuant to section 1819(h)(2)(C) of the Act, the Secretary may not continue to pay a facility participating in

Medicare more than six months after the date on which the facility was first found not in substantial compliance with program participation requirements. Thus, termination from participation is required if a facility does not return to substantial compliance within six months. Petitioner had to return to substantial compliance before August 20, 2009, to avoid statutory termination pursuant to section 1819(h)(2)(C). Petitioner did return to substantial compliance, and termination was not required by the statute. Furthermore, while the Secretary and her delegate, CMS, have authority to exercise discretion to terminate a facility's participation under other circumstances specified by section 1819(h)(2) and (4), the evidence shows that such discretion was not exercised at any time when there was a basis for imposing the remedy of termination.

Petitioner advances other arguments in its defense that the survey procedure was defective in this case. Generally, inadequate survey performance does not relieve a facility of its obligation to meet all requirements for program participation or invalidate adequately documented deficiencies. 42 C.F.R. § 488.318(b). Petitioner argues that in conducting the medication review, the surveyors did not follow the procedure that the SOM "contemplated," and the surveyors did not do an objective review. Petitioner complains that no single complete medication pass was observed, only two nurses were observed passing medication, only seven residents were observed, the surveyors' observations did not begin until after the medication pass was already late, and the only medication errors cited were based on medication being administered 60 minutes or more after the scheduled time. P. Brief at 21. Petitioner also complains that the surveyors should have observed a more representative sampling of the medications being administered. Petitioner cites the Medication Pass Worksheet that the surveyors used as indicating that 20 to 25 medications should be observed and then 20 to 25 more. P. Brief at 21-22. I find these arguments to be of no merit.

The Guidance to Surveyors instructs surveyors to:

> Make every effort to observe residents during several different drug "passes," if possible, so the survey team will have an assessment of the entire facility rather than one staff member on one drug pass.

Surveyors are also instructed to:

> Strive to observe as many individuals administering medications as possible. This provides a better picture of accuracy of the facility's entire drug distribution system.

SOM, app. PP, Tags F332 and 333. In *Pacific Regency Arvin*, DAB No. 1823, at 11-12 (2002), the Board discussed the calculation of medication error rate and commented that the method that CMS required in its Medication Pass Worksheet and the SOM "assures that at least 40-50 observations are made in order to substantiate an alleged violation of

this regulation, so that, for example, a surveyor may not observe just a few instances of medication administration to support a violation." The Board also concluded that CMS makes a prima facie showing of a violation of 42 C.F.R. § 483.25(m)(1), when it shows a medication error rate of five percent or more. *Pacific Regency Arvin,* DAB No. 1823, at 12-13.

Petitioner does not dispute that the two surveyors observed at least 41 medications being passed by more than one staff member. P. Brief at 21, 23. The number observed satisfies the minimum that the SOM suggests. The SOM does not require observation of a complete medication pass or the observation of all staff that pass medication. The SOM also does not require observation beyond the point when surveyors have witnessed an error rate of five percent or more. The SOM suggests observation of more than one medication pass but does not specifically address whether more than one medication pass should be observed when the surveyors have already identified a five percent error rate. Finally, the approach of the surveyors in this case was very objective: they watched medications being passed; determined that the medications were not timely administered; and then applied the formula specified by the SOM for determining the rate of error. The problem for the surveyors was not a lack of objectivity. The problem was their failure to properly understand and apply the CMS policy for determining whether a timing error should be counted as a medication error.

CMS also suggests, by its Proposed Conclusion of Law 172, an argument that Petitioner did not preserve for hearing the issue of whether or not it was in substantial compliance before August 20, 2009. CMS raised a similar argument regarding the findings and conclusions of the April and July surveys. I do not find the CMS arguments persuasive for the reasons discussed under my Conclusions of Law 4 through 9.

> **5. Petitioner violated 42 C.F.R. § 483.10(c)(2)-(5) (Tag F159, s/s D), as determined by the survey completed on April 30, 2009.**
>
> **6. Petitioner violated 42 C.F.R. § 483.20(k)(3)(i) (Tag F281, s/s E), as determined by the survey completed on April 30, 2009.**
>
> **7. Petitioner violated 42 C.F.R. § 483.25(d) (Tag F315, s/s D), as determined by the survey completed on April 30, 2009.**
>
> **8. Petitioner violated 42 C.F.R. § 483.25(h) (F323, s/s G), as determined by the survey completed on April 30, 2009.**
>
> **9. Petitioner returned to substantial compliance on May 27, 2009.**

The first survey in the cycle of surveys that led to Petitioner's termination ended on February 20, 2009, triggering the running of the six-month period leading to mandatory termination from program participation. Surveys were also conducted in March 2009,

April 2009, July 2009, and, as already discussed, August 2009. Petitioner agrees that it did not request a hearing as to deficiency findings and related enforcement remedies from the February 2009 and March 2009 surveys, and they are not at issue before me. CMS agrees that the survey concluded on April 30, 2009 found that all deficiencies cited by the prior surveys were corrected. The parties agree that the April 30 survey found new examples of violations of regulations cited as violated by the February and March surveys. CMS Brief at 17; P. Brief at 9; Tr. 33-36, 271-72; CMS Ex. 902. Petitioner also elected not to contest the deficiency findings of the survey completed on April 30, 2009, and related enforcement remedies, except counsel for Petitioner specifically stated at hearing that Petitioner did not waive its right to hearing as to the alleged duration of the deficiencies and the duration of the enforcement remedies. Petitioner disputes the alleged deficiencies from the July 8, July 28, and August 20, 2009 surveys and argues that it returned to substantial compliance on a date after April 30, 2009, but before August 20, 2009. Counsel for CMS agreed at hearing that Petitioner had preserved for hearing its argument that it returned to substantial compliance after April 30, 2009, but before August 20, 2009. Jt. Stip.¶ 18; Tr. 17-22. Petitioner argues that it corrected all the deficiencies cited by the April survey by not later than May 27, 2009. Petitioner reasons that it was, therefore, not out of substantial compliance between May 27, 2009 and the next survey on July 8, 2009. If Petitioner's theory is correct, then the running of the six-month period that caused Petitioner's mandatory termination[13] on August 20, 2009 was interrupted and would have restarted on July 8, 2009. P. Reply at 8-10.

In its Post-Hearing Brief, CMS argues that I should discard all evidence that the facility corrected the deficiencies, cited by the April 30, 2009 survey, prior to August 2009. CMS argues that Petitioner withdrew its appeal as to the April 30, 2009 survey and that it cannot challenge the duration of the noncompliance and remedies imposed based on that survey. CMS Brief at 21-22; CMS Proposed Conclusions of Law 163; CMS Reply at 1-2. CMS's understanding of the stipulation that I accepted at hearing is faulty. The stipulation states that Petitioner withdrew its appeal with respect to the sanctions imposed and deficiencies cited by the April 30, 2009 survey. Jt. Stip. ¶ 18. However, I specifically inquired as to the parties' intent of this unclear provision of the stipulation, and counsel for Petitioner stated that it intended to challenge the duration of the noncompliance and enforcement remedies based on the April 30 survey. Counsel for CMS agreed that preservation of those issues by Petitioner did not violate the parties' stipulation. Tr. 19-21. Therefore, the written stipulation as orally modified at hearing did not amount to a waiver or withdrawal of Petitioner's request for hearing related to the April 30, 2009 survey. Rather, the stipulation reflects that Petitioner simply agreed not to

[13] The Secretary and CMS have limited discretion to terminate a facility's participation in Medicare prior to the running of the six-month statutory period. Act § 1819(h)(2), (4). However, there is no allegation here that CMS exercised its authority to terminate; rather, the termination that was to occur on August 20, 2009 was by operation of section 1819(h)(2)(C) of the Act.

dispute that it was in violation of the regulations as alleged by the surveyors in the SOD for the April 30, 2009 survey or that the violations provided a basis for imposition of enforcement remedies. Petitioner specifically preserved the issues of when it corrected the alleged deficiencies and the duration of the remedies imposed. Tr. 21. The issues Petitioner preserved are appropriately before me for resolution. *Foxwood Springs Living Ctr.*, DAB No. 2294, at 10-12 (2009) (CMS's determination of whether evidence shows facility returned to substantial compliance is subject to de novo review by ALJ and on appeal to Board.).

CMS also argues that Petitioner's request for hearing, as twice amended, did not preserve the issue of whether or not it returned to substantial compliance prior to August 20, 2009. CMS Brief at 19-22; CMS Reply at 1-3. I find the CMS argument to be without merit. In my Ruling Granting Petitioner's Motion to File Its Second Amended Request for Hearing and Denying the CMS Motion to Dismiss, dated September 9, 2009, I found that Petitioner's request for hearing, as amended, was sufficient to satisfy the requirements of 42 C.F.R. § 498.40(b) for a request for hearing. I specifically concluded that Petitioner's request for hearing, as amended, gave CMS notice of the specific issues, findings, and conclusions with which Petitioner disagreed and the basis for its disagreement. My conclusion is unchanged. CMS in its post-hearing briefs confuses the elements for a sufficient request for hearing with the legal theories a party might advance in its defense or to rebut a theory of the government. The regulations impose no requirement that Petitioner give notice of its legal theories in its request for a hearing. The document for disclosing and advancing a party's legal theory is the party's prehearing brief, as required by the Prehearing Order in this case. Contrary to the CMS argument, Petitioner did raise the theory that it returned to substantial compliance before August 20, 2009, in its prehearing brief by stating as follows:

> [Petitioner] contests the findings and conclusions of the July 8, 2009, July 28, 2009, and August 20, 2009 surveys; that the allegations constitute violations of the cited regulations, that there were any deficiencies; that the civil money penalty imposed, if any, is reasonable or in compliance with the statutory and regulatory factors, **and that if there were any deficiencies that they continued until August 20, 2009.**

Petitioner's Prehearing Brief at 4-5 (emphasis added). Petitioner made clear by its amended request for hearing and prehearing brief that it contested the termination and disputed the results of the July and August surveys. Petitioner's theory that it returned to substantial compliance sometime between April 30 and July 8, 2009, follows from its statement of that which is disputed. Petitioner's amended request for hearing and its prehearing brief sufficiently preserved the issues and gave CMS notice of Petitioner's defense. Furthermore, Petitioner specifically alleged in its plan of correction, as set forth on the SOD for the April 30, 2009 survey, that it completed the plan of correction not

later than May 27, 2009. P. Ex. 1, at 36. Therefore, CMS cannot plead ignorance of the fact that Petitioner alleged it returned to substantial compliance as early as May 27, 2009. CMS alleges based upon the survey that ended April 30, 2009, that Petitioner was not in substantial compliance with program participation requirements based upon violations of 42 C.F.R. §§ 483.10(c)(2)-(5) (Tag F159, s/s D), 483.20(k)(3)(i) (Tag F281, s/s E), 483.25(d) (Tag F315, s/s D), 483.25(h) (Tag F323, s/s G). CMS Ex. 401. As already discussed, Petitioner does not now dispute that it was in violation of the regulations as alleged by the SOD for the survey that ended on April 30, 2009. Petitioner also does not dispute that those violations were a basis for continuing the DPNA and for the subsequent imposition of the $150 per day CMP that CMS imposed effective April 13, 2009. Petitioner asserts, however, that it corrected the deficiencies not later than May 27, 2009.

a. 42 C.F.R. § 483.10(c)(2)-(5) (Tag F159, s/s D)

The regulation requires that Petitioner "hold, safeguard, manage, and account for the personal funds of the resident deposited with the facility" if authorized in writing by the resident. 42 C.F.R. § 483.10(c)(2)-(5). The surveyors allege that this deficiency was uncorrected from the February 2009 survey and that the violation was continuing, because Petitioner failed to "ensure proper reconciliation of the resident trust fund accounts, by failing to maintain documentation to support reconciliation for the time period of April 2008 through March 2009." CMS Ex. 401, at 2. Petitioner concedes that it was in violation on April 30, 2009, as alleged by the surveyors, and as already noted. Petitioner argues, however, that it corrected the deficiency not later than May 27, 2009. CMS argues that Petitioner did not correct the deficiency until the survey that concluded on August 20, 2009.

b. 42 C.F.R. § 483.20(k)(3)(i) (Tag F281, s/s E)

Petitioner is required by the regulation to ensure that services provided or arranged by the facility meet professional standards of quality. The surveyors allege that this deficiency was not corrected from the survey that ended on March 18, 2009. The surveyors allege that the regulation was violated, because Petitioner failed to ensure staff administered medication as ordered for Residents 28, 53, and 55 and failed to give all doses of insulin, as required by physician order for Residents 35 and 58. CMS Ex. 401, at 3-4. Petitioner has conceded that it was in violation on April 30, 2009. Petitioner argues, however, that it corrected the deficiency not later than May 27, 2009. CMS argues that Petitioner did not correct the deficiency until the survey that concluded on August 20, 2009.

c. 42 C.F.R. § 483.25(d) (Tag F315, s/s D)

The regulation establishes standards related to urinary incontinence with which a facility must comply. The regulation requires that:

> [T]he facility must ensure that [a] resident who enters the facility without an indwelling catheter is not catheterized unless the resident's clinical condition demonstrates that catheterization was necessary; and [a] resident who is incontinent of bladder receives appropriate treatment and services to prevent urinary tract infections and to restore as much normal bladder function as possible.

42 C.F.R. § 483.25(d). The surveyors alleged that this regulation was violated, because facility staff failed to obtain a physician's order and develop a care plan for an indwelling catheter for Resident 50. The surveyors alleged that Petitioner also violated the regulation, because staff failed to follow a physician's order to change Resident 49's indwelling urinary catheter every month. CMS Ex. 401, at 15-16. Petitioner has conceded that it was in violation on April 30, 2009. Petitioner argues, however, that it corrected the deficiency not later than May 27, 2009. CMS argues that Petitioner did not correct the deficiency until the survey that concluded on August 20, 2009.

d. 42 C.F.R. § 483.25(h) (F323, s/s G)

The regulation requires that a facility ensure that the resident environment is as free of accident hazards as possible and that each resident receive adequate supervision and assistance devices to prevent accidents. The surveyors allege the regulation was violated, because Petitioner failed to ensure staff transferred Residents 54 and 52 safely, resulting in actual harm to Resident 54 who fell while being lifted and injured her leg. CMS Ex. 401, at 20-21. Petitioner has conceded that it was in violation on April 30, 2009. Petitioner argues, however, that it corrected the deficiency not later than May 27, 2009. CMS argues that Petitioner did not correct the deficiency until the survey that concluded on August 20, 2009.

e. Return to substantial compliance on May 27, 2009.

Petitioner urges me to find that it corrected the four violations cited by the April 30 survey and to conclude that it returned to substantial compliance not later than May 27, 2009, based on: (1) the testimony of Karen Robbins; (2) the fact that surveyors were in the facility on July 8 and July 28, 2009 for complaint surveys. Petitioner urges me to infer that if the deficiencies from the April 30, 2009 survey were not corrected, the surveyors would have again cited the deficiencies, or otherwise mentioned their observation; and (3) the fact that it was unreasonable for the state agency to delay a revisit related to the April 30, 2009 survey for four months and until the termination date. P. Brief at 10. The evidence does not show that the surveyors involved in either the July 8 or July 28, 2009 complaint survey considered whether any of the deficiencies from the April 30, 2009 continued at the time of those complaint surveys. I will not infer from the fact that the surveyors were in the facility on July 8 and 28 that they would have observed whether the violations cited by the April 30, 2009 survey were corrected or not.

Petitioner's argument that it was unreasonable for a revisit not to have occurred until August 18 through 20, 2009, is nothing more than argument. Petitioner points to no statutory or regulatory authority that requires a revisit survey at any particular time. 42 C.F.R. § 488.308(c)(2) (survey agency may conduct "as frequently as necessary . . . ."). More significantly, Petitioner points to no authority for me to fashion a remedy in Petitioner's favor or to punish the government, even if I concluded that there was an unreasonable delay in conducting a revisit. However, after weighing the evidence of record, I conclude that Petitioner has rebutted the presumption upon which CMS relies (CMS Reply at 4-6), that the deficiencies cited by the April 30 survey continued until the revisit survey that commenced on August 18, 2009.

The evidence shows that the state agency first received Petitioner's plan of correction for the April 30, 2009 survey on May 27, 2009. However, the state agency advised Petitioner by letter dated June 1, 2009 that the plan was not acceptable and that an amended plan was required. The state agency provided specific direction for how the plan of correction was to be amended. P. Ex. 1, at 7-8. By letter dated June 10, 2009, the state agency acknowledged receipt of Petitioner's amended plan of correction on June 4, 2009 and advised Petitioner that the plan was acceptable as amended. P. Ex. 1, at 6.

Karen Robbins, RN, Vice President of Clinical Services for Shoreline Healthcare Management, Petitioner's management company, testified that she reviewed and advised on Petitioner's plan of correction for the April 30, 2009 survey. She testified that she monitored compliance or completion of the plan of correction. She testified that the plan of correction was completed by May 27, 2009. Tr. 435-42; P. Ex. 1, at 14-49.

The evidence thus shows that the state agency found Petitioner's plan of correction acceptable as of June 4, 2009. The state agency's acceptance of the plan of correction is not tantamount to a conclusion – which may only be based on acceptable evidence or a revisit survey – that a facility has returned to substantial compliance with program participation requirements. 42 C.F.R. §§ 488.417(c)(1), (d); 488.454(a)(1), (e). However, where as here the state agency has acknowledged that the plan of correction is acceptable, the question that remains for determination is whether Petitioner has carried-out or executed the acceptable plan and thereby corrected the cited deficiencies. The evidence in this case shows that the elements of the plan of correction set forth in the SOD were completed at latest on May 27, 2009. P. Ex. 1, at 14-49. Karen Robbins, who was responsible to the management company to ensure correction of the deficiencies, testified to her personal knowledge that the elements of the plan of correction were fully implemented or completed not later than May 27, 2009. I have no reason to find that Ms. Robbins' testimony was not fully credible. CMS presented no evidence to rebut the testimony of Ms. Robbins that each of the elements of the plan of correction accepted by the state agency were fully implemented by May 27, 2009. There is no testimony from the surveyors or other evidence that the surveyors made any findings that are inconsistent with the evidence that the elements of the plan of correction for the deficiencies cited by

the April 30, 2009 survey were fully implemented or completed on May 27, 2009.[14] The evidence does not show that the revisit survey completed on August 20, 2009 found any element of the plan of correction not completed as of May 27, 2009, as specifically alleged in the plan of correction set forth on the SOD. P. Ex. 1, at 36.

CMS argues that the surveyors properly applied SOM § 7317B to certify that Petitioner returned to substantial compliance as of the date of the third revisit survey on August 20, 2009. The Board has specifically rejected CMS's argument, based on SOM § 7317B, that the date of return to substantial compliance is no earlier than the date of the third revisit survey. *Foxwood Springs Living Ctr.*, DAB No. 2294 (2009). CMS also argues that the determination of when Petitioner returned to substantial compliance is not an initial determination subject to ALJ review, which is an argument that the Board also rejected in *Foxwood*.

Accordingly, while I concluded that Petitioner was not in substantial compliance with program participation requirements as alleged by the survey completed on April 30, 2009, I also conclude that Petitioner returned to substantial compliance on May 27, 2009. The running of the six-month statutory period leading to termination triggered by the survey that ended on February 20, 2009, therefore ended on May 27, 2009, with Petitioner's return to substantial compliance. Accordingly, the Act did not mandate termination of Petitioner's participation on August 20, 2009, as CMS alleged. Petitioner's return to substantial compliance also ended the running of the DPNA and the per day CMP on May 26, 2009. 42 C.F.R. §§ 488.417(d), 488.440(b).

[14] CMS argues that it was error for me to exclude the SODs for the surveys completed in February and March 2009 (CMS Exs. 101 and 201), on the theory that those documents show the "facility's self-declaration of compliance is not reliable." CMS Reply at 8, n.6. The SODs for the February and March 2009 surveys were not admitted, as evidence as they were not appealed and not relevant to any issue before me. Tr. 31-36. After considering the additional CMS argument in its reply brief, I will not change my prior ruling that the SODs are not relevant and they are not admitted as evidence. CMS Exs. 101 and 201 do not include the plan of correction for those surveys to compare with the plan of correction for the April 30, 2009 survey set forth at P. Ex. 1, at 14-49. Further, the fact that Petitioner did not request review of the February and March 2009 surveys, and the fact that Petitioner did not contest the deficiencies cited by the April 30, 2009 survey, does not reflect positively or negatively upon the credibility of Petitioner's evidence that it corrected the deficiencies and returned to substantial compliance by May 27, 2009.

10. Petitioner violated 42 C.F.R. § 483.10(b)(11) (Tag F157, s/s D), as determined by the survey completed on July 8, 2009.

11. Petitioner violated 42 C.F.R. § 483.25 (Tag F309, s/s G), as determined by the survey completed on July 8, 2009.

Petitioner argues that it was not in violation of any regulation at the time of the survey that ended on July 8, 2009. CMS does not dispute that these deficiencies were corrected as of August 20, 2009. CMS Ex. 902, at 2.

The alleged violations of 42 C.F.R. §§ 483.10(b)(11) (Tag F157) and 493.25 (Tag F309) involve Resident 60. On June 24, 2009, Resident 60 was discharged from North Kansas City Hospital to Petitioner. Resident 60 had been in the hospital since June 3, 2009 for reduction and repair of an incarcerated umbilical hernia. According to the discharge summary, he had an extreme and complicated hospital course, as he suffered a tear of the mucous membrane at the junction of the esophagus and stomach with significant blood loss that required a transfusion. He then developed a postoperative ileus (a paralysis of part of the intestine), which required parenteral nutrition (IV feeding). He then developed aspiration pneumonia from vomiting and adult respiratory distress and had to be put on a ventilator. On the day prior to discharge, his speech was incoherent, but it was listed as more coherent on the date of discharge to Petitioner. There were 23 medications included in his list of discharge medications, and he had instructions for tube feeding and a puree with thick liquid diet. P. Ex. 7, at 11-12.

Petitioner's clinical records indicate that Resident 60 was received at Petitioner about 3:40 p.m. on June 24, 2009 and no distress was noted. No vital signs or other evidence of an assessment are noted on Petitioner's progress notes for Resident 60 at the time of his return. P. Ex. 7, at 54. A progress note on June 24, 2009, noted as 9:00 p.m., indicates that the resident was found unresponsive in his wheelchair, with a blank stare, eyes open, breathing, and with nose bleeding. He was noted to be having a hard time catching his breath, and his fingers were noted to be turning blue. The progress note states he was given oxygen, and an ambulance was requested to carry him back to the hospital. The note indicates that the ambulance arrived to transport Resident 60 at 9:15 p.m. P. Ex. 7, at 54.

Resident 60 was readmitted to North Kansas City Hospital on June 24, 2009 at 9:54 p.m., and the admission assessment indicates that he had acute shortness of breath, his gastrostomy tube was displaced into the soft tissues, and he continued to have pneumonia. P. Ex. 7, at 38.

a. 42 C.F.R. § 483.10(b)(11) (Tag F157, s/s D)

The regulation requires that the facility immediately inform the resident, consult with the resident's physician, and notify the resident's legal representative and/or family, if any, under specified circumstances. The surveyors allege that the regulation was violated because staff failed to notify Resident 60's physician and family when he was found unresponsive and having respiratory difficulty, and staff sent the resident back to the hospital by ambulance. CMS Ex. 501, at 1-2.

Surveyor McConkey testified that the deficiency was cited, because Petitioner's staff failed to notify the family and the doctor when Resident 60 was sent back to the hospital. Tr. 90-98; CMS Ex. 502, at 1, 6, 8-12, 19.

Section 483.10(b)(11)(i) provides:

> (11) *Notification of changes*. (i) A facility must immediately inform the resident; consult with the resident's physician; and if known, notify the resident's legal representative [sic] or an interested family member when there is ─
>
> (A) An accident involving the resident which results in injury and has the potential for requiring physician intervention;
>
> (B) A significant change in the resident's physical, mental, or psychosocial status (i.e., a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications);
>
> (C) A need to alter treatment significantly (i.e., a need to discontinue an existing form of treatment due to adverse consequences, or to commence a new form of treatment); or
>
> (D) A decision to transfer or discharge the resident from the facility as specified in § 483.12(a).

The regulatory requirements are abundantly clear, yet they are often misquoted and misconstrued. Patients in long-term care facilities have certain rights. Among these are that the facility "**must immediately . . . consult with the resident's physician** . . . when there is[:] a significant change in the resident's physical, mental, or psychosocial status" (meaning a deterioration in the resident's condition); an accident that may require physician intervention; a need to alter treatment; or a decision to transfer or discharge the resident to another facility or institution. 42 C.F.R. § 483.10(b)(11) (emphasis added). The requirement is not discretionary, and it requires more than merely informing or notifying the physician, which is evident from the plain language of the regulation. The drafters chose the language carefully. The regulation is specific that the facility is required to **immediately:** "**inform** the resident; **consult** the physician; and . . . **notify** the

legal representative or an interested family member." *Id.* (emphasis added). The preamble to the final rule indicates the drafters' specific intention that the facility should not just "inform" the resident of the changes that have occurred but should "consult with the physician about actions that are needed." 56 Fed. Reg. 48,826, at 48,833 (Sept. 26, 1991). Thus, it is clear from the language of the regulation and its history that the requirement of the regulation to consult means more than to simply notify. Consultation requires a dialogue with, and a responsive directive from, the resident's physician as to what actions are needed. It is not enough to merely notify the physician. Nor is it enough to leave a message for the physician. The regulation also requires consultation "immediately" upon discernment of a change in condition of the resident or any of the other triggers noted in the regulation. The use of the term immediately in the regulatory requirement indicates that consultation is expected to be done as soon as the change is detected, without any intervening interval of time. It does not mean that the facility can wait hours or days before consulting with the physician. The preamble to the final rule indicates that originally the proposed rule granted the facility up to 24 hours in which to notify the resident's physician and the legal representative or family. However, after the receipt of comments that time is of the essence in such circumstances, the final rule amended that provision to require that the physician and legal representative or family be consulted/notified immediately. 56 Fed. Reg. at 48,833. The point of using the word "immediately" was the recognition that in such situations a delay could result in a situation where a resident is beyond recovery or dies. Furthermore, when we balance the relative inconvenience to a physician and the facility staff to consult with the possibility for dire consequences to the resident if the physician is not consulted, it seems that any inconvenience certainly is inconsequential and outweighed by the potential for significant harm if the facility fails to consult the physician. This regulation is entitled "Resident Rights," and the requirements of this specific regulation provide that every resident has the right to a dignified existence and access to and communication with persons and services inside and outside the facility. Therefore, the regulatory requirements make inconsequential any inconvenience under the regulation to the resident's physician or to the facility staff when compared to the protection and facilitation of the rights of the resident. *See* 56 Fed. Reg. at 48,834. Finally, the regulation does not allow the facility to pick and choose whom to notify and whom to consult. Rather, it requires the facility to immediately inform the resident, consult the physician, **and** notify the resident's legal representative or interested family member. The regulation also directly burdens the facility to consult and notify and does not permit a facility to rely upon a notification or consultation handled by a third-party, such as the emergency room.

Petitioner erroneously argues that it had no duty to contact the family or the physician. P. Brief at 13. Petitioner is wrong as a matter of law. The regulation clearly obliges Petitioner to notify the family if a resident is transferred, and the fact that Petitioner's records may not have been updated to show a correct family contact was Petitioner's oversight. The regulation also clearly required Petitioner's staff to consult with Resident 60's physician when his was transferred. Petitioner argues that there was no risk for harm due to its failure to consult with Resident 60's physician, but Petitioner presents no

evidence or argument in support of that assertion. Rather, the undisputed fact that Resident 60's physician was not consulted by Petitioner's staff when Resident 60 was sent back to the hospital in distress supports an inference that Resident 60 was at risk for more than minimal harm due to delayed treatment, particularly in light of his complicated hospital course just prior to his return to Petitioner.

Petitioner states in its plan of correction for this deficiency that it was completed on August 12, 2009. However, Petitioner presented no testimony or documentary evidence to corroborate that the elements of its plan of correction were implemented and sustainable.

Accordingly, I conclude that Petitioner was in violation of 42 C.F.R. § 483.10(b)(11) (Tag F157) beginning June 24, 2009. I further conclude that the violation continued through August 19, 2009, as Petitioner did not establish that it corrected the deficiency prior to August 20, 2009, as alleged by the survey completed on that date. Finally, I conclude that Resident 60 was at risk for more than minimal harm due to the failure of Petitioner's staff to consult with Resident 60's physician when he was sent back to the hospital on June 24, 2009.

b. 42 C.F.R. § 483.25 (Tag F309, s/s G)

The general quality of care regulation requires that each resident receive care and services necessary to attain and maintain the highest practicable physical, mental, and psychosocial well-being of the resident. The care and services are to be based upon the resident's comprehensive assessment and plan of care. The surveyors allege that Petitioner violated the regulation, because staff failed to assess and provide care for Resident 60 within four hours after his return from the hospital, including failure to implement physician orders and feed the resident. Resident 60 was subsequently returned to the hospital when found unresponsive and having difficulty breathing. CMS Ex. 501, at 10-11.

Surveyor McConkey testified that this deficiency was cited, because Petitioner: failed to assess Resident 60 for several hours after his return from the hospital; did not initiate physician's orders; and did not start tube feeding the resident. Tr. 98-102; CMS Ex. 506. On cross-examination, she agreed that there is no required time for doing a full nursing assessment upon readmission from the hospital. Tr. 133. She also agreed that it would not be abnormal for it to take a few hours for delivery of medication from the pharmacy for a resident readmitted from the hospital. Tr. 134. She also clarified on my examination that while staff had assessed the resident's blood pressure, pulse, respirations, and oxygen saturation when he returned from the hospital, she expected a more comprehensive assessment of his care needs. Tr. 140.

LPN Rone testified that after Resident 60 returned from the hospital on June 24, 2009, she was told by a CNA that Resident 60 was asking for his medication. However, she had to record his medication orders on his MAR before the medication could be administered. She completed working on his MAR and took his medication to his room where she found him sitting in his wheelchair in no apparent distress. She later went back to his room to do a nursing assessment and found him nonresponsive, with a small amount of blood at his nose and with a blank stare. She called for the crash cart and oxygen and went to call for the ambulance. She testified that when she saw Resident 60 earlier he was moving around in his wheelchair, and he was capable of taking off and putting on his oxygen. Tr. 344-48. On cross-examination, she testified that Resident 60 was not using oxygen when she saw him, and, even when she found him nonresponsive, he was breathing regularly. Tr. 349. LPN Rone's nurse's notes indicate that she saw Resident 60 first at 3:40 p.m. and later found him nonresponsive just before 9:00 p.m. P. Ex. 7, at 54; Tr. 351-54. She testified on cross-examination that she also saw him several times between 3:40 p.m. and 9:00 p.m. Tr. 354. She testified that a resident should be assessed soon after being readmitted to the facility to ensure the resident is not in distress. She testified that within 24 hours of return everything must be completed, but she did not clarify what "everything" includes. She could not give a specific time within which a complete nursing assessment should be done. Tr. 355-57. She testified in response to my questioning that she had not done a nursing assessment earlier, because she was very busy with medication administration and another resident who had been readmitted. Tr. 363-64. She also testified that at some point after she found Resident 60 unresponsive, he was having difficulty catching his breath as indicated in her nurse's notes and that is why she called for oxygen. Tr. 366; P. Ex. 7, at 54. LPN Rone testified that Resident 60 was more responsive at the time the ambulance arrived on June 24, 2009. Tr. 366.

CNA Andre Williams testified that when Resident 60 came back from the hospital on June 24, 2009, the resident told CNA Williams that he was fine. CNA Williams took his vital signs. He noted his oxygen tank was low, so he got a new tank and hooked him up. He then told the nurse that Resident 60 wanted his medication. He went back at dinner time and offered Resident 60 food, but he refused to eat and asked for his medication again. He testified that Resident 60 appeared very weak and could not transfer himself from his wheelchair to his bed, but he could roll his wheelchair. He saw the resident about every 15 minutes after his return from the hospital, and he seemed fine. Later, however, the nurse asked CNA Williams to help move the resident to the bed and to do vital signs, because the resident was going to be sent back to the hospital. CNA Williams testified that he was present until the paramedics took Resident 60 to the hospital. Resident 60 seemed to be hyperventilating rather than gasping for air, but he was not normal. Tr. 404-12; P. Ex. 8, at 5.

Petitioner argues that the evidence shows that: Resident 60 was properly attended when he returned to Petitioner from the hospital; no requirement exists that he be evaluated any sooner than he was; he received necessary care and services; no actual harm occurred to Resident 60; and no potential for harm existed to any other resident. P. Brief at 15; P. Reply at 9.

Petitioner is correct that Karen Robbins testified that no standard requires that a nursing assessment be done within a specific time after a resident's admission. She opined that Resident 60 was evaluated and observed by the nurse and that he was appropriately observed and evaluated. Tr. 445-46, 474-75. She testified that, at the time, a corporate policy required a detailed assessment within 24 hours of admission. Tr. 477. Ms. Robbins did not dispute my characterization of the assessment that Resident 60 received upon return from the hospital as being the minimum necessary to determine his vital signs. She also opined that a physical assessment of Resident 60 would have been better. Tr. 479-80.

The copy of the discharge summary for Resident 60's discharge on June 24, 2009, provided by Petitioner, shows that it was dictated on June 24, 2009 at 12:24:12 and printed at 13:55 (1:55 p.m.). P. Ex. 7, at 11. The evidence does not reveal whether a copy of the discharge summary was delivered to Petitioner with Resident 60 when he was returned to Petitioner at about 3:40 p.m. on June 24, 2009. I do not infer that the discharge summary was sent to Petitioner with Resident 60 and, even if it was, there is no evidence anyone read it. The progress note created at about the time of his return to Petitioner only notes the assessment that no distress was noted and no vital signs are noted. A recording of Resident 60's vital signs appears with an entry at 9:00 p.m. The evidence does not show that Petitioner's staff was aware of Resident 60's difficult hospital course, though the evidence indicates that staff was aware that Resident 60 had medication and other orders.

The documents and testimony of Petitioner's witnesses support my conclusion that Petitioner's staff did a minimal assessment of Resident 60, upon his return to Petitioner about 3:40 p.m. on June 24, 2009. The assessment that was done involved little more than determining that the resident was alive and not in apparent distress. I conclude that this assessment was inadequate and that Petitioner violated the requirements of 42 C.F.R. § 483.25. The regulation obligates Petitioner to ensure that each of its residents receive care and services necessary to attain and maintain their highest practicable physical, mental, and psychosocial well-being. The regulation requires that necessary care and services be delivered in accordance with the resident's comprehensive assessment and plan of care. Petitioner is correct that the regulation allows Petitioner time to complete the comprehensive assessment and plan of care. However, the regulation does not relieve Petitioner of the obligation to ensure a resident receives necessary care and services as soon as the resident is accepted, and Petitioner takes custody of the resident. In this case, Resident 60 had a particularly difficult hospital course, with significant surgery during the three weeks he was out of the facility. Whether staff who received Petitioner at the

facility was aware of Resident 60's difficult hospital course is not clear from the record. What is clear is that, upon his arrival, staff did little to assess his needs other than to determine that he was not in distress, and then staff left him to sit in his wheelchair for an extended period during which he asked for his medication at least twice. I conclude that for as many as six hours, Petitioner failed to determine what care and services were necessary for Resident 60. I infer that Petitioner failed to deliver necessary care and services, because Petitioner failed to determine what care and services were actually necessary. Because Petitioner did not do a more thorough assessment of Resident 60 upon his readmission, Petitioner is unable to show that necessary care and services were delivered. I conclude that Petitioner failed to ensure that necessary care and services were delivered and that Petitioner violated 42 C.F.R. § 483.25 on June 24, 2009.

Furthermore, I conclude that Resident 60 suffered actual harm. When Resident 60 was readmitted to North Kansas City Hospital on June 24, 2009 at 9:54 p.m., the admission assessment shows that he had acute shortness of breath, and his gastrostomy tube was displaced into the soft tissues. P. Ex. 7, at 38. I am satisfied that either problem is sufficient to support an inference that Resident 60 suffered actual harm in the form of discomfort or pain, either of which amounts to actual harm. Petitioner alleges in its plan of correction that it corrected the deficiency by August 12, 2009. P. Ex. 2, at 15. But I do not accept the mere allegation that the correction occurred on August 12, 2009 sufficient to rebut the presumption of continuing noncompliance absent more significant corroborating evidence. Therefore, I conclude that Petitioner was not in substantial compliance from June 24 through August 19, 2009, due to the violation of 42 C.F.R. § 483.25 (Tag F309).

12. The ultimate burden of persuasion was not at issue and Petitioner suffered no prejudice.

Petitioner argues that the allocation of the burden of persuasion in this case according to the rationale of the Board in the prior decisions cited above, violates the Administrative Procedures Act, 5 U.S.C. § 551 *et. seq.*, specifically 5 U.S.C. § 556(d). Petitioner argues that CMS should bear the burden of persuasion and should establish its case by a preponderance of the evidence. Petitioner's Prehearing Brief at 3; P. Brief at 5-9. In this case, I required, consistent with the rationale of the Board in its prior cases on point, that CMS come forward with the evidence and make a prima facie showing of the alleged violations. Only if CMS made a prima facie showing was Petitioner obliged to show by a preponderance of the evidence that it was in compliance, or that it had an affirmative defense that would excuse its noncompliance. Because the evidence is not in equipoise in this case on any alleged deficiency or element of a deficiency, the allocation of the ultimate burden of persuasion did not affect my decision, and Petitioner suffered no prejudice. *Jennifer Matthew Nursing & Rehab. Ctr.*, DAB 2192, at 19 (2008).

13. Reasonable enforcement remedies are: a $150 per day CMP from April 13, 2009 through May 26, 2009, and June 24, 2009 through August 19, 2009; and a DPNA from March 22, 2009 through May 26, 2009, and June 24, 2009 through August 19, 2009.

I have concluded that Petitioner was not in substantial compliance with program participation requirements from March 22, 2009 through May 26, 2009, and June 24, 2009 through August 19, 2009. 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 from $3,050 per day to $10,000 per day is 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). There was no finding of immediate jeopardy for the deficiencies before me, and the upper range is not applicable to this case. The lower range of CMPs from $50 per day to $3,000 per day is 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 $150 per day CMP that CMS proposed in this case is at the low end of the lower range of authorized CMPs.

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 noncompliance, 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. I do not have evidence of a history of noncompliance other than the evidence from the surveys at issue before me. Petitioner offered no evidence or argument that it is unable to pay the proposed CMPs. I conclude that the $150 per day CMP and the DPNA are consistent with Petitioner's culpability and the seriousness of the deficiencies. Therefore, the following enforcement remedies are reasonable: a $150 per day CMP from April 13, 2009 through May 26, 2009, and June 24, 2009 through August 19, 2009; and a DPNA from March 22, 2009 through May 26, 2009, and June 24, 2009 through August 19, 2009.

III. Conclusion

For the foregoing reasons, I conclude that Petitioner was not in substantial compliance with program participation requirements from March 22, 2009 through May 26, 2009, and June 24, 2009 through August 19, 2009. Petitioner was not out of substantial compliance for a period of six months and termination of Petitioner's participation in Medicare was not required by the Act. I further conclude that the following enforcement remedies are reasonable: a $150 per day CMP from April 13, 2009 through May 26, 2009, and June 24, 2009 through August 19, 2009; and a DPNA from March 22, 2009 through May 26, 2009, and June 24, 2009 through August 19, 2009.

/s/
Keith W. Sickendick
Administrative Law Judge