Department of Health and Human Services
DEPARTMENTAL APPEALS BOARD
Civil Remedies Division

Grace Living Center - Stillwater,
(CCN: 37-5178),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-14-1841

Decision No. CR4331

Date: October 16, 2015

DECISION

Petitioner, Grace Living Center - Stillwater, was not in substantial compliance with program participation requirements from June 25, 2014 through August 26, 2014, based on violations of 42 C.F.R. §§ 483.10(b)(11) and 483.25 from the survey completed on May 28, 2014 survey and a violation of 42 C.F.R. § 483.13(c)(2)-(4) [1] from the survey completed on August 13, 2014. There is a basis for the imposition of an enforcement remedy. The enforcement remedy of a denial of payment for new admissions (DPNA) for the period June 25 through August 26, 2014, is reasonable.

I. Background

Petitioner is located in Stillwater, Oklahoma and participates in Medicare as a skilled nursing facility (SNF) and the state Medicaid program as a nursing facility (NF). On May 28, 2014, a complaint investigation and survey was completed by the Oklahoma State Department of Health, Protective Health Services (state agency) and Petitioner was found not in substantial compliance with program participation requirements due to

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[1] Citations are to the 2013 revision of the Code of Federal Regulations (C.F.R.), unless otherwise stated.

violations at 42 C.F.R. §§ 483.10(b)(11) (Tag F157[2]) and 483.25 (Tag F309). Centers for Medicare & Medicaid Services (CMS) Exhibits (Exs.) 1, 5.

CMS notified Petitioner on July 1, 2014, that it was imposing the following enforcement remedies based on the May 28, 2014 survey findings: termination of Petitioner's provider agreement, unless the facility achieved substantial compliance before November 28, 2014; a civil money penalty (CMP) in the amount of $350 per day, effective May 28, 2014 and continuing until further notice; and a DPNA beginning June 25, 2014 and continuing until further notice. CMS Ex. 1; Petitioner's Exhibit (P. Ex.) 2. Petitioner requested Informal Dispute Resolution (IDR). CMS notified Petitioner on August 7, 2014, that the IDR related to the May 28, 2014 survey resulted in rescission of the CMP but the threat of termination and the DPNA effective June 25, 2014, were unchanged. CMS Ex. 2; P. Ex. 5.

Petitioner requested a hearing before an administrative law judge (ALJ) on August 28, 2014. Petitioner requested review of the CMS determinations announced in its notices to Petitioner dated July 1, 2014 and August 7, 2014, including the deficiencies cited by the survey that ended on May 28, 2014, specifically Tags F157 and F309 and the related DPNA.

On September 5, 2014, CMS notified Petitioner that a complaint survey conducted on August 13, 2014, found that Petitioner was not in substantial compliance due to five regulatory violations: 42 C.F.R. § 483.13(c)(1)(ii)-(iii), (c)(2)-(4) (Tag F225);[3] 483.20(d)(3) and 483.10(k)(2) (Tag F280); 483.25 (Tag F309); 483.25(a)(3) (Tag F312) and 483.65 (Tag F441). CMS imposed a directed plan of correction and advised

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[2] This "Tag" designation is used in CMS Publication 100-07, State Operations Manual (SOM), app. 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 related policy 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. *Ind. Dep't of Pub. Welfare v. Sullivan*, 934 F.2d 853 (7th Cir. 1991); *Northwest Tissue Ctr. v. Shalala*, 1 F.3d 522 (7th Cir. 1993). Thus, while the Secretary may not seek to enforce the provisions of the SOM, she may seek to enforce the provisions of the Act or regulations as interpreted by the SOM.

[3] The allegations in the Statement of Deficiencies (SOD) do not reflect an alleged violation of 42 C.F.R. § 483.13(c)(1)(ii)-(iii) and the citation to those provisions are in error. Rather the allegations are that only 42 C.F.R. § 483.13(c)(2)-(4) was violated.

Petitioner that the DPNA that was effective beginning June 25, 2014 continued, and that termination would occur November 28, 2014, unless Petitioner returned to substantial compliance prior to that date. CMS Exs. 3, 15. CMS advised Petitioner of its right to request a hearing before an ALJ no later than November 4, 2014. CMS Ex. 3 at 2. There is no dispute that Petitioner did not request ALJ review of the August 13, 2014 survey either by filing a new request for hearing or by amending its pending request for hearing filed on August 28, 2014.

On October 2, 2014, CMS notified Petitioner that Petitioner achieved substantial compliance on August 27, 2014. CMS rescinded the termination but the DPNA from June 25, 2014 through August 26, 2014 was not changed. CMS Ex. 4; P. Exs. 6, 7.

The case was assigned to me for hearing and decision on September 19, 2014, and an Acknowledgement and Prehearing Order (Prehearing Order) was issued at my direction. On February 23, 2015, I notified the parties that the case was scheduled for hearing on May 6 and 7, 2015 by video teleconference. On February 24, 2015, Petitioner waived oral hearing and agreed to a decision on the briefs and documentary evidence. Although CMS stated that it was not willing to waive an oral hearing in the parties' Joint Status Report filed February 20, 2015, CMS did not object to Petitioner's waiver or show cause why an oral hearing was necessary pursuant to 42 C.F.R. § 498.66(b)(2). On March 16, 2015, I accepted Petitioner's waiver of oral hearing and set a briefing schedule.

On April 30, 2015, the parties filed opening briefs (CMS Br. and P. Br.). On June 1, 2015, CMS filed its reply brief (CMS Reply). On June 4, 2015, Petitioner waived filing a reply brief. CMS filed CMS Exs. 1 through 15 and Petitioner filed P. Exs. 1 through 10. No objections have been made to my consideration of the exhibits submitted and CMS Exs. 1 through 15 and P. Exs. 1 through 10 are admitted as evidence.

II. Discussion

A. Issues

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

B. Applicable Law

The statutory and regulatory requirements for participation of a SNF in Medicare are found at section 1819 of the Social Security Act (Act) and at 42 C.F.R. pt. 483. Section 1819(h)(2) of the Act authorizes the Secretary to impose enforcement remedies against a SNF for failure to comply substantially with the federal participation requirements

established by sections 1819(b), (c), and (d) of the Act.[4] The Act requires that the Secretary terminate the Medicare participation of any SNF that does not return to substantial compliance with participation requirements within six months of being found not to be in substantial compliance. Act § 1819(h)(2)(C). The Act also requires that the Secretary deny payment of Medicare benefits for any beneficiary admitted to a SNF, if the SNF fails to return to substantial compliance with program participation requirements within three months of being found not to be in substantial compliance – commonly referred to as the mandatory or statutory DPNA. Act § 1819(h)(2)(D). The Act grants the Secretary discretionary authority to terminate a noncompliant SNF's participation in Medicare, even if there has been less than 180 days of noncompliance. The Act also 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 enforcement remedies against a long-term care facility that is not complying substantially with federal participation requirements. "*Substantial compliance* means a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm." 42 C.F.R. § 488.301 (emphasis in original). A deficiency is a violation of a participation requirement established by sections 1819(b), (c), and (d) of the Act or the Secretary's regulations at 42 C.F.R. pt. 483, subpt. B. Noncompliance refers to any deficiency that causes a facility not to be in substantial compliance. 42 C.F.R. § 488.301. State survey agencies survey facilities that participate in Medicare on behalf of CMS 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, including a discretionary DPNA. 42 C.F.R. § 488.406.

The Act and regulations make a hearing before an ALJ available to a long-term care facility against which CMS has determined to impose an enforcement remedy. Act §§ 1128A(c)(2), 1866(h); 42 C.F.R. §§ 488.408(g), 498.3(b)(13). A facility has a right to appeal a "certification of noncompliance leading to an enforcement remedy." 42 C.F.R. §§ 488.408(g)(1); 488.330(e), 498.3. However, the choice of remedies, or the factors

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[4] Participation of a NF in Medicaid is governed by section 1919 of the Act. Section 1919(h)(2) of the Act gives enforcement authority to the states to ensure that NFs comply with their participation requirements established by sections 1919(b), (c), and (d) of the Act.

CMS considered when choosing remedies, are not subject to review. 42 C.F.R. § 488.408(g)(2). A facility may only challenge the scope and severity level of noncompliance determined by CMS if a successful challenge would affect the range of the CMP that may be imposed or impact the facility's authority to conduct a nurse aide training and competency evaluation program. 42 C.F.R. § 498.3(b)(14), (16), (d)(10)(i). The CMS 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 (the Board) has long held that the net effect of the regulations is that a provider has no right to challenge the scope and severity level assigned to a noncompliance finding, except in the situation where that finding was the basis for an immediate jeopardy determination. *See, e.g*., *Ridge Terrace*, DAB No. 1834 (2002); *Koester Pavilion*, DAB No. 1750 (2000).

The hearing before an ALJ is a de novo proceeding, that is, "a fresh look by a neutral decision-maker at the legal and factual basis for the deficiency findings underlying the remedies." *Life Care Ctr. of Bardstown*, DAB No. 2479 at 33 (2012) (citation omitted). The Board has long held that the 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. *Batavia Nursing & Convalescent Inn*, DAB No. 1911 (2004); *Batavia Nursing & Convalescent Ctr.*, DAB No. 1904, *aff'd*, *Batavia Nursing & Convalescent Ctr. v. Thompson*, 129 F. App'x 181 (6th Cir. 2005); *Emerald Oaks*, DAB No. 1800 (2001); *Cross Creek Health Care Ctr.*, DAB No. 1665 (1998); *Hillman Rehab. Ctr.*, DAB No. 1611 (1997) (remand to ALJ), DAB No. 1663 (1998) (after remand), *aff'd*, *Hillman Rehab. Ctr. v. United States*, No. 98-3789 (GEB), 1999 WL 34813783 (D.N.J. May 13, 1999). However, only when CMS makes a prima facie showing of noncompliance, is the facility burdened to show, by a preponderance of the evidence on the record as a whole, that it was in substantial compliance or had an affirmative defense. *Evergreene Nursing Care Ctr.*, DAB No. 2069 at 4 (2007).
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 imposing an enforcement remedy. The Board has stated that CMS must come forward with "evidence related to disputed findings that is sufficient (together with any undisputed findings and relevant legal authority) to establish a prima facie case of noncompliance with a regulatory requirement." *Evergreene Nursing Care Ctr.*, DAB No. 2069 at 7; *Batavia Nursing & Convalescent Ctr.*, DAB No 1904. "Prima facie" means generally that the evidence is "[s]ufficient to establish a fact or raise a presumption unless disproved or rebutted." *Black's Law Dictionary* 1228 (8th ed. 2004). In *Evergreene Nursing Care Ctr.*, the Board explained its "well-established framework for allocating the burden of proof on the issue of whether a SNF is out of substantial compliance" as follows:

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

DAB No. 2069 at 7.

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. I have carefully considered all the evidence and the arguments of both parties, though not all may be specifically discussed in this decision. I discuss in this decision the credible evidence given the greatest weight in my decision-making.[5] I also discuss any evidence that I find is not credible or worthy of weight. The fact that evidence is not specifically discussed should not be considered sufficient to rebut the presumption that I considered all the evidence and assigned such weight or probative value to the credible evidence that I determined appropriate within my discretion as an ALJ. There is no requirement for me to discuss the weight given every piece of evidence considered in this case, nor would it be consistent with notions of judicial economy to do so. Charles H. Koch, Jr., *Admin. L. and Prac.* § 5:64 (3d ed. 2013).

There are two surveys involved in this case, the survey completed on May 28, 2014 and the survey completed on August 13, 2014. Petitioner was cited with the following deficiencies that amounted to noncompliance based on the complaint survey completed on May 28, 2014: 42 C.F.R. §§ 483.10(b)(11) (Tag F157, scope and severity level (s/s) D[6]); and 483.25 (Tag F309, s/s H). CMS Exs. 1, 5. Petitioner was cited by the survey

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[5] "Credible evidence" is evidence that is worthy of belief. *Black's Law Dictionary* 596 (8th ed. 2004). The "weight of evidence" is the persuasiveness of some evidence compared to other evidence. *Id*. at 1625.

[6] Scope and severity levels are used by CMS and a state when selecting remedies. The scope and severity level is designated by an alpha character, A through L, selected by CMS or the state agency from the scope and severity matrix published in the SOM, chap. 7, § 7400.5 (Sep. 10, 2010). 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

(Footnote continued next page.)

completed on August 13, 2014 with five deficiencies all at a scope and severity of D: 42 C.F.R. § 483.13(c)(2)-(4) (Tag F225); 483.20(d)(3) and 483.10(k)(2) (Tag F280); 483.25 (Tag F309); 483.25(a)(3) (Tag F312) and 483.65 (Tag F441). CMS Exs. 3, 15. CMS imposed a DPNA based on the noncompliance found by the May 8, 2014 survey. CMS Ex. 1. CMS determined to continue the DPNA previously imposed beginning June 25, 2014, based on the noncompliance found by the survey that ended on August 13. CMS Ex. 3.

Under Conclusions of Law 1 and 2 I discuss that Petitioner failed to request ALJ review of the determination of noncompliance by the August 13, 2014 survey. The noncompliance under Tag F225 from the August 13, 2014 survey is an adequate basis for the imposition of a DPNA from June 25, 2014 through August 26, 2014. Therefore it is not necessary for me to determine whether or not noncompliance under Tag F157 and Tag F309 is a basis for the imposition of a DPNA during part of the same period, specifically June 25, 2014 through June 28, 2014.[7]

1. The violation of 42 C.F.R. § 483.13(c)(2)-(4) (Tag F225), at scope and severity of D, cited by the survey that ended August 13, 2014, is administratively final and binding, and not subject to review by me.

2. The noncompliance under Tag F225 during the period May 26, 2014 through August 26, 2014 is a basis for the imposition of a DPNA for the period June 25 through August 26, 2014.

A determination by CMS is final and binding unless a timely request for a hearing is filed. 42 C.F.R. §§ 498.20(b); 498.25(b); 498.32(b). A request for hearing must be filed

(Footnote continued.)

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, or L indicate 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.

[7] Petitioner argues that the DPNA should end on June 28, 2014 because the revisit survey completed on September 16, 2014, determined that Petitioner corrected the noncompliance under Tags F157 and F309 effective June 29, 2014. P. Ex. 6 at 4.

within 60 days of receipt of the CMS notice that it is imposing enforcement remedies, unless that time is extended by the ALJ for good cause shown. 42 C.F.R. § 498.40. Petitioner does not deny that it received the September 5, 2014 CMS notice that the August 13, 2014 survey determined that Petitioner was not in substantial compliance and that the DPNA continued based on that noncompliance. CMS Ex. 3. Petitioner does not mention the August 13, 2014 survey and the September 5, 2014 notice in its request for hearing, in its prehearing brief, or in its brief on the merits. I conclude that Petitioner did not request a hearing, either by filing a new request for hearing or seeking to amend its previously filed hearing request, related to the alleged noncompliance cited by the survey completed on August 13, 2014, or the enforcement remedy related to the noncompliance, specifically the DPNA that was continued.

Of the five deficiency citations by the August 13, 2014 survey, only one alleged noncompliance beginning on May 26, 2014. The noncompliance cited as a violation of 42 C.F.R. § 483.13(c)(2)-(4) (Tag F225) at a scope and severity of D alleged that on May 26, 2014, a resident had bruising under the left breast. The surveyors alleged that the bruising was an injury of unknown origin and, therefore, investigation and reporting were required by the regulation. The surveyors alleged that the Director of Nursing (DON) and the Administrator could find no record of an investigation or report to the state and the Administrator agreed that a report should have been made. CMS Ex. 15 at 4-5. The surveyors determined that the regulatory violation posed a risk for more than minimal harm to all of Petitioner's residents. CMS Ex. 15 at 2. Because Petitioner did not contest the alleged noncompliance cited under Tag F225, the surveyors' findings as adopted by CMS on September 5, 2014 (CMS Ex. 3) are final and binding.

A revisit survey was conducted at Petitioner's facility on September 16, 2014. The surveyors determined that Petitioner completed correction of the noncompliance cited under Tag F225, and all the other Tags cited by the August 13, 2014 survey, on August 27, 2014. P. Ex. 6 at 2. Petitioner did not amend its pending request for hearing, file a new request for hearing, or argue in any of its briefs that I should conclude that it was in substantial compliance with Tag F225 during the period May 26, 2014 to August 27, 2014. CMS notified Petitioner on October 2, 2014, that it accepted the state agency finding that Petitioner returned to substantial compliance with Medicare participation requirements on August 27, 2014, and that the DPNA was imposed for the period June 25, 2014 through August 26, 2014. P. Ex. 7. Petitioner failed to raise any issue as to whether the noncompliance under Tag F225 was a basis for the imposition of a DPNA or whether a DPNA was reasonable if based only on noncompliance under Tag F225.

I conclude that the uncontested CMS determination of noncompliance under Tag F225, which began on May 26, 2014 and continued until corrected on August 27, 2014, was an independent basis for the DPNA imposed by CMS from June 25, 2014 through August 26, 2014. The reasonableness of the DPNA as an enforcement remedy is discussed hereafter. Because the noncompliance under Tag F225 cited by the August 13, 2014

survey is an adequate basis for the imposition of a DPNA, consideration of the alleged noncompliance under Tags F157 and F309 challenged by Petitioner is not necessary. However, I briefly discuss both deficiencies for completeness.

3. CMS has made a prima facie showing that Petitioner violated 42 C.F.R. § 483.10(b)(11) (Tag F157).

4. The violation of 42 C.F.R. § 483.10(b)(11) posed a risk for more than minimal harm and amounted to noncompliance.

5. Petitioner has failed to rebut the prima facie showing of noncompliance or establish an affirmative defense.

Petitioner timely requested a hearing and preserved its right to review of the noncompliance alleged by the May 28, 2014 survey, specifically the noncompliance cited under Tags F157 and F309. Both citations involve Resident 1 and the material facts are not disputed. It is also not disputed that a revisit survey completed on September 16, 2014, determined that Petitioner corrected the noncompliance under Tags F157 and F309 as of June 29, 2014. P. Ex. 6 at 4. The noncompliance under Tags F157 and F309 could not have been the basis for the imposition of any enforcement remedy, including the DPNA, after it was corrected on June 29, 2014. 42 C.F.R. §§ 488.402(b) (enforcement remedies applied on the basis of noncompliance), 488.417(a) and (b) (DPNA may be imposed when a facility is not in substantial compliance), 488.417(c) (payment resumes when a facility achieves substantial compliance and it can maintain substantial compliance).

a. Facts

Resident 1 was a 60 year old male at the time of incident that is the subject of the alleged noncompliance. Resident 1 suffered from diabetes, end-stage renal disease, acute renal failure, and he required regular dialysis. CMS Ex. 12 at 3, 35-52.

Resident 1 received dialysis three times each week on Tuesday, Thursday, and Saturday. He was scheduled to be picked up from the facility at 6:00 a.m., to arrive at the dialysis clinic at 6:45 a.m., and get his dialysis treatment from 7:00 a.m. until 10:30 a.m. and then be picked up from the dialysis clinic at 10:45 a.m. for return to the facility. CMS Ex. 12 at 55. On Saturday May 17, 2014, Resident 1 was scheduled to be transported to the dialysis clinic. The arrangements for transportation were made by the Veteran's Administration (VA) through Core Transit. Because Resident 1 had refused transportation to dialysis by the VA on a previous occasion, the VA cancelled Resident 1's transportation on May 17 and did not notify Petitioner of the cancellation. P. Br. at 3. At 9:05 a.m., the DON received a text message from Resident 1's nurse that Resident 1 did not have a ride to his dialysis appointment. The DON told the nurse to find a staff

member to take Resident 1 to his dialysis appointment. Resident 1's nurse indicated that the dialysis center would close shortly and that it was too late to take Resident 1. It is undisputed that Resident 1 failed to receive dialysis on May 17, 2014. The facility staff contacted the dialysis clinic, which is directed by a nephrologist, and received instructions to monitor Resident 1 for signs and symptoms of fluid overload and to send the resident to the hospital if such symptoms were identified. P. Ex. 8 at 78-79.

Petitioner points to no evidence that Petitioner made any effort on May 17, May 18, or May 19 to arrange for Resident 1 to receive dialysis. The next regularly scheduled dialysis appointment was not until Tuesday, May 20, 2014. When Resident 1 exhibited symptoms of fluid overload on May 18, Petitioner contacted Resident 1's physician and made multiple attempts to transfer Resident 1 to the emergency room, however Resident 1 refused. Petitioner's staff noted that Resident 1 refused to allow Petitioner to contact his wife. CMS Ex. 12 at 64; P. Ex. 8 at 3.

On May 19 Resident 1 was transported to the emergency room due to edema, confusion, and decreased level of consciousness. CMS Ex. 12 at 5, 66; P. Ex. 8 at 11. Shortly after arriving in the emergency room, Resident 1 experienced respiratory failure and was intubated. CMS Ex. 12 at 9. Resident 1 was assessed in the emergency room as suffering an acute exacerbation of chronic renal failure and acute volume overload with acute carbon dioxide narcosis. CMS Ex. 12 at 9. The surveyors attributed Resident 1's decline to his failure to receive dialysis on May 17, 2014. CMS Ex. 5. Petitioner has not presented evidence to show that Resident 1's decline in his condition was not due to the missed dialysis on May 17, 2014.

There is no evidence and Petitioner does not assert that Resident 1's family or physician were immediately notified or consulted on May 17, 2014, when the resident missed his dialysis appointment. CMS Ex. 12 at 1-96. The evidence shows that Resident 1's physician was not consulted until May 18, 2014, when Resident 1's physician ordered that the resident be sent to the emergency room. P. Ex. 8 at 3.

b. Analysis

I conclude that CMS made a prima facie showing that Petitioner violated 42 C.F.R. § 483.10(b)(11) in the case of Resident 1 and that the violation posed a risk for more than minimal harm. I further conclude that Petitioner failed to rebut the prima facie showing.

A long-term care facility is required to recognize certain resident rights specified by the Act and the Secretary's regulations. Section 483.10(b)(11)(i) of 42 C.F.R. entitled "Resident rights" requires:

> (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 respresentative (sic) or an interested family member when there is –
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> > (A) An accident involving the resident which results in injury and has the potential for requiring physician intervention;
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> > (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);
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> > (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 Sec. 483.12(a).

42 C.F.R. § 483.10(b)(11)(i). The language of the regulation is very specific that the facility "**must immediately inform** the resident; **consult** with the resident's physician; and . . . **notify** the resident's legal respresentative (sic) or an interested family member." 42 C.F.R. § 483.10(b)(11)(i) (emphasis added). The regulation creates a distinction between informing the resident and family and the requirement that Petitioner "**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. *Id.* (emphasis added). It is clear from the regulatory language that the requirement to consult is not discretionary and requires more than merely informing or notifying the physician. The preamble to the final rule reflects the drafters' specific intention that the facility should "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, 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 with the physician means more than to simply notify the physician. Consultation implies the requirement for 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 notification and consultation "immediately" upon perceiving a change in condition of the resident, the occurrence of an accident that may require physician intervention, or the occurrence of any of the other triggers 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 notification of the resident and his or her representative and consultation 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 consult with the resident's physician and to notify 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 be consulted and the legal representative or family be notified immediately. 56 Fed. Reg. 48,826, 48,833 (Sept. 26, 1991). The point of using the word "immediately" is to recognize that in such situations, a delay could result in a situation where a resident is beyond recovery or dies. The Board has been consistent in its interpretation of the regulation that consultation with a physician must occur immediately, that is, without delay, after a significant change is detected or observed. *Magnolia Estates Skilled Care*, DAB No. 2228 at 9 (2009).

Furthermore, if 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. The 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 the facility staff when compared to the protection and facilitation of the rights of the resident. *See* 56 Fed. Reg. 48,826, 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 being accomplished by the resident or a third party such as an emergency room.

The surveyors allege in the SOD for the survey completed on May 28, 2014, that Petitioner violated 42 C.F.R. § 483.10(b)(11) (Tag F157) because Petitioner's staff failed to notify the family and consult with Resident 1's physician when Resident 1 missed a scheduled dialysis treatment. CMS Ex. 5 at 2. It is undisputed that Resident 1 was ordered to have dialysis three times a week, Tuesday, Thursday, and Saturday, because of his renal failure and end-stage renal disease. It is also undisputed that Resident 1 missed his dialysis appointment on May 17, 2014. It is also undisputed that Petitioner failed to immediately consult with Resident 1's physician and failed to notify Resident 1's family of the missed dialysis appointment until shortly before Resident 1 was sent to the hospital approximately 48 hours after his missed appointment. The missed dialysis appointment on Saturday, May 17, triggered the need to alter Resident 1's treatment significantly

within the meaning of 42 C.F.R. § 483.10(b)(11)(i)(C). The Tuesday, Thursday, Saturday, schedule reflected the physician's determination that the resident could go without dialysis for up to three days, e.g., Saturday to Tuesday. Because of the missed dialysis appointment the resident would be without dialysis for at least five days until his next appointment, exceeding the maximum three days ordered by the physician. Therefore, Petitioner needed to have Resident 1's dialysis schedule altered significantly to permit dialysis or, at minimum, physician intervention to determine how best to address the situation.

Due to Resident 1's renal failure and end-stage renal disease, Resident 1 was at risk for more than minimal harm due to the missed dialysis appointment as determined by the surveyors. The action of Petitioner's staff reflects that there was a known risk to Resident 1 prompting the call to the dialysis center to receive instructions. The instructions received by staff further reflect the risk for more than minimal harm, as those instructions were for staff to monitor Resident 1 for signs and symptoms of fluid overload and to send the resident to the hospital if such symptoms were present. P. Ex. 8 at 78-79. The evidence shows that Petitioner's staff did not immediately consult with Resident 1's physician to determine what alterations in Resident's 1 treatment were needed as a result of the missed dialysis treatment. I conclude that the undisputed facts constitute a prima facie showing of noncompliance based on a violation of 42 C.F.R. § 483.10(b)(11) and there was more than minimal harm due to the violation. The surveyors alleged a scope and severity level of D for Tag F157, that is, there was a risk for more than minimal harm without actual harm or immediate jeopardy. The facts support a finding that Resident 1 suffered actual harm and possibly even immediate jeopardy because Resident was sent to the emergency room, experienced respiratory failure shortly after arrival in the emergency room, and had to be intubated. However, it is not necessary for me to conclude that there was either actual harm or immediate jeopardy to conclude that there was noncompliance. It is enough for me to conclude that there was a risk for more than minimal harm.

Petitioner failed to rebut CMS's prima facie case. Petitioner argues that missing Resident 1's dialysis appointment was not Petitioner's fault because the VA cancelled the Resident 1's transportation arrangements without notifying Petitioner that it would be doing so. By the time Petitioner realized that the VA would not be transporting Resident 1 to his dialysis appointment, Petitioner argues it was too late to provide alternate transportation because the dialysis center would be closing soon. For purposes of this deficiency, the reason Resident 1 missed his appointment is irrelevant. What is relevant is whether Petitioner immediately consulted with Resident's 1's physician. The evidence shows that Resident 1's physician was not immediately consulted on May 17 when Resident 1 missed his dialysis. In fact, the resident's physician was not notified until May 18, 2014, when staff consulted the physician and he ordered that the resident be sent to the hospital. CMS Ex. 12 at 64; P. Ex. 8 at 3. Resident 1 refused to go to the hospital on May 18, 2014, and there is no evidence that the physician was consulted at that time. On May 19,

2014, when the resident became less responsive, Petitioner's records show that staff then sent the resident to the emergency room based on the order given on May 18. CMS Ex. 12 at 66; P. Ex. 8 at 11.

Petitioner argues that the dialysis clinic had a nephrologist and that the nephrologist would have been aware that Resident 1 had missed his appointment. P. Br. at 7. Petitioner fails to show however, that the dialysis clinic nephrologist had any treating relationship with Resident 1. A dialysis facility must have a medical director trained in nephrology and the director must have at least 12 months of experience. 42 C.F.R. § 494.140(a). The medical director's responsibilities are administrating the dialysis clinic not being the treating physician for all of the dialysis patients. 42 C.F.R. § 494.150. Petitioner's argument fails because the regulation clearly states that Petitioner must consult with the "resident's physician," a physician who is intimately aware of the resident's complete medical history and condition, not the director of a dialysis center who has no treating relationship with Resident 1. There is no dispute that Petitioner's staff did not immediately consult on May 17, 2014, with Resident 1's treating physician about the resident's missed dialysis appointment. CMS Ex. 12 at 64, 76; CMS Ex. 5 at 3.

Petitioner also argues that Resident 1 refused to allow contact with his family. The evidence shows that the question of whether or not to contact family did not arise until May 18, after the physician was consulted and ordered that the resident be sent to the hospital. Therefore, the evidence does not support an argument that the resident prevented immediate family contact. More important is the fact that the resident did not prevent immediate consultation with his physician which is sufficient to support the conclusion that there was noncompliance under Tag F157.

6. CMS has made a prima facie showing that Petitioner violated 42 C.F.R. § 483.25 (Tag F309).

7. The violation of 42 C.F.R. § 483.25 posed a risk for more than minimal harm and amounted to noncompliance.

8. Petitioner has failed to rebut the prima facie showing of noncompliance under Tag F309 or establish an affirmative defense.

a. Facts

This deficiency is cited based on the facts already set forth related to Resident 1.

b. Analysis

The regulation requires 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.

The surveyors allege that Petitioner failed to ensure that Resident 1 received transportation to a scheduled dialysis appointment which resulted in actual harm to Resident 1. The surveyors allege that due to the missed dialysis appointment on May 17, 2014, the resident had to be sent to the emergency room on May 19, 2014 due to a decreased level of consciousness, increased confusion, and possible fluid overload. The resident had to be intubated at the hospital. CMS Ex. 5.

CMS alleges under Tag F309 that Petitioner violated the quality of care requirement by failing to immediately address Resident 1's need for dialysis when it was determined that he missed his scheduled dialysis on May 17, 2014. The evidence that a physician ordered certain care and services triggers a rebuttable presumption that the care and services ordered are necessary care and services within the meaning of 42 C.F.R. § 483.25. The absence of evidence, such as documentation or testimony of the care giver, that ordered care and services were actually delivered, triggers an inference that care or services were not provided as ordered. There is no dispute that the dialysis was a necessary care or service ordered by Resident 1's physician. There is no dispute that Resident 1 did not receive dialysis on May 17. There is no dispute that Petitioner's staff did not consult Resident 1's physician for orders on how the resident's care needed to be changed in light of the missed dialysis appointment. Ultimately, the missed dialysis required Resident 1's hospitalization on May 19, 2014, due to his decreased level of consciousness, confusion, and possible fluid overload, symptoms I conclude reflect actual harm. Accordingly, I conclude CMS has made a prima facie showing of a violation of 42 C.F.R. § 483.25 which amounted to noncompliance.

The burden is upon Petitioner to rebut the CMS prima facie showing or to establish an affirmative defense. The quantum of evidence required is a preponderance of the evidence. Petitioner's defense is that it was not its fault that the transport was cancelled. Petitioner argues that the transportation company cancelled Resident 1's transportation due to Resident 1's noncompliant behavior prior to May 17, 2014 and had not informed Petitioner of the cancellation. P. Br. at 3, 6. This argument does not excuse Petitioner's failure to deliver necessary care and services. Petitioner's obligation to provide care and services remained even if Resident 1's transportation arrangements fell apart through no fault of the facility. Further, Petitioner's staff was aware that the resident missed his appointment on May 17, 2014, but waited until May 18, 2014 ,, when the resident started

to display symptoms of possible fluid overload, to contact the resident's physician for orders.

Petitioner asserts that Resident 1 was noncompliant with regard to receiving care, including dialysis treatment and transport to dialysis, refused to be taken to the hospital for treatment, and refused to allow the facility to contact his wife to update her on his condition. A resident has the right to refuse treatment. 42 C.F.R. § 483.10(b)(4). However, this is not a case where the resident refused dialysis. In this case the resident's transportation was cancelled and Petitioner failed to ensure that the resident was provided alternative means to timely obtain dialysis or other treatment ordered by the resident's physician. "Whether a facility employs its own staff and equipment or contracts for services and equipment to provide care and services, the regulatory obligation . . . remains with the facility." *Ft. Madison Health Ctr.*, DAB No. 2403 at 9 (2011).

9. The duration of the DPNA from June 25, 2014 through August 26, 2014 is reasonable.

I have concluded that Petitioner was not in substantial compliance from May 26, 2014 through August 26, 2014. If a facility is not in substantial compliance with program participation requirements, CMS has the authority to impose one or more of the enforcement remedies listed in 42 C.F.R. § 488.406, including a discretionary DPNA. CMS had authority to impose a discretionary DPNA because Petitioner was not in substantial compliance, and I have no authority to review the choice of that remedy. 42 C.F.R. § 488.408(g)(2). A DPNA may be imposed for the period during which a SNF is not in substantial compliance. 42 C.F.R. §§ 488.402(b) (enforcement remedies applied on the basis of noncompliance), 488.417(a) and (b) (DPNA may be imposed when a facility is not in substantial compliance), 488.417(c) (payment resumes when a facility achieves substantial compliance and it can maintain substantial compliance). CMS was authorized to impose a DPNA and the duration of the DPNA from June 25, 2014 through August 26, 2014 is reasonable as a matter of law.

III. Conclusion

For the foregoing reasons, Petitioner was not in substantial compliance with program participation requirements from June 25, 2014 through August 26, 2014 and there is a basis for the imposition of the enforcement remedy, a DPNA, from June 25, 2014 through August 26, 2014.

/s/

Keith W. Sickendick
Administrative Law Judge