

Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Consulate Health Care of Lakeland
(CCN: 10-5482),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-12-1252

Decision No. CR3315

Date: August 1, 2014

DECISION

Petitioner, Consulate Health Care of Lakeland, was not in substantial compliance with program participation requirements from February 27, 2012 through June 10, 2012. There is a basis for the imposition of enforcement remedies. A mandatory denial of payments for new admissions (DPNA) was in effect from May 27, 2012 through June 10, 2012. A civil money penalty (CMP) of \$150 per day from March 30, 2012 through May 10, 2012 and \$250 per day from May 11, 2012 through June 10, 2012, a total CMP of \$14,050, is a reasonable enforcement remedy.

I. Background

Petitioner is located in Lakeland, Florida, and participates in Medicare as a skilled nursing facility (SNF) and the state Medicaid program as a nursing facility (NF). Petitioner was subject to three surveys by the Florida Agency for Health Care Administration (state agency) that ended on February 27, 2012, March 30, 2012, and May 11, 2012, respectively. Petitioner was found not in substantial compliance with program participation requirements by each survey. Centers for Medicare & Medicaid Services (CMS) Exhibits (Exs.) 1-3. The state agency completed a revisit survey on August 10, 2012, and determined that Petitioner was in substantial compliance effective that date. Petitioner's Exhibit (P. Ex.) 7.

CMS notified Petitioner by letter dated April 19, 2012, that it was imposing the following enforcement remedies: mandatory termination effective August 27, 2012, if Petitioner did not return to substantial compliance before that date; a mandatory DPNA effective May 27, 2012, if Petitioner did not return to substantial compliance before that date; and a CMP of \$150 per day effective beginning March 30, 2012 and continuing until Petitioner returned to substantial compliance. CMS also notified Petitioner that it was ineligible to conduct a nurse aide training and competency evaluation program (NATCEP) for two years. P. Ex. 6. CMS notified Petitioner by letter dated July 12, 2012, that: the DPNA was effective May 27, 2012; the \$150 per-day CMP was in effect March 30 through May 10, 2012; and the CMP was increased to \$250 per day effective May 11, 2012; and these remedies would continue until Petitioner returned to substantial compliance. Request for Hearing, Ex. 5. CMS notified Petitioner by letter dated August 21, 2012, that Petitioner returned to substantial compliance on August 10, 2012; that the DPNA was in effect from May 27 through August 9, 2012; and that Petitioner's provider agreement would not be terminated. P. Ex. 7.

Petitioner requested a hearing before an administrative law judge (ALJ) on September 7, 2012. The case was assigned to Judge Richard Smith on September 20, 2012, and an Acknowledgement and Initial Docketing Order was issued at his direction. On June 7, 2013, this case was reassigned to me for hearing and decision due to Judge Smith's retirement. On September 17, 2013, I convened a hearing by video teleconference from Kansas City, with Petitioner participating from Tampa, Florida and CMS participating from Atlanta, Georgia. A transcript (Tr.) of the proceedings was prepared. CMS offered CMS Exs. 1 through 6 and Petitioner offered P. Exs. 1 through 32, all of which I admit as evidence. Tr. 47-48, 53-54. CMS called Surveyor Barbara Doyle, RN, as a witness. Petitioner called the following witnesses: Laurie VanderMeer, RN, and Brian McCoy. The parties filed post-hearing briefs (CMS Br. and P. Br., respectively) and post-hearing reply briefs (CMS Reply and P. Reply, respectively).

II. Discussion

A. Issues

Whether there is a basis for the imposition of an enforcement remedy; and,

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. 483.¹ Section 1819(h)(2) of the Act authorizes the Secretary of Health and Human Services (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.² 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 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

¹ Citations are to the 2011 revision of the Code of Federal Regulations which was in effect at the time of the surveys, unless otherwise stated.

² 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.

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 CMPs, \$50 per day to \$3,000 per day, is reserved for deficiencies that do not pose 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).

Petitioner was notified that it was ineligible to conduct a NATCEP for two years. Pursuant to sections 1819(b)(5) and 1919(b)(5) of the Act, SNFs and NFs may only use nurse aides who have completed a training and competency evaluation program. Pursuant to sections 1819(f)(2) and 1919(f)(2) of the Act, the Secretary was tasked to develop requirements for approval of NATCEPs and the process for review of those programs. Sections 1819(e) and 1919(e) of the Act impose upon the states the requirement to specify what NATCEPs they will approve that meet the requirements that the Secretary established and a process for reviewing and re-approving those programs using criteria the Secretary set. The Secretary promulgated regulations at 42 C.F.R. pt. 483, subpt. D. Pursuant to 42 C.F.R. § 483.151(b)(2) and (f), a state may not approve and must withdraw any prior approval of a NATCEP offered by a SNF or facility NF that has been: (1) subject to an extended or partial extended survey under sections 1819(g)(2)(B)(i) or 1919(g)(2)(B)(i) of the Act; (2) assessed a CMP of not less than \$5,000; or (3) subject to termination of its participation agreement, a DPNA, or the appointment of temporary management. Extended and partial extended surveys are triggered by a finding of "substandard quality of care" during a standard or abbreviated standard survey and involve evaluating additional participation requirements. "Substandard quality of care" is identified by the situation where surveyors identify one or more deficiencies related to participation requirements established by 42 C.F.R. § 483.13 (Resident Behavior and Facility Practices), § 483.15 (Quality of Life), or § 483.25 (Quality of Care) that are found to constitute either immediate jeopardy, a pattern of or widespread actual harm that does not amount to immediate jeopardy, or a widespread potential for more than minimal harm that does not amount to immediate jeopardy and there is no actual harm. 42 C.F.R. § 488.301.

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 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 NATCEP. 42 C.F.R. § 498.3(b)(14), (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). ALJ review of a CMP is subject to 42 C.F.R. § 488.438(e).

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 32 (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, *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.

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 (2007); *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 *Hillman Rehab. Ctr.*, the Board described the elements of the CMS prima facie case in general terms as follows:

HCFA [now known as CMS] must identify the legal criteria to which it seeks to hold a provider. Moreover, to the extent that a provider challenges HCFA’s findings, HCFA must come forward with evidence of the basis for its determination, including the factual findings on which HCFA is relying and, if HCFA has determined that a condition of participation was not met, HCFA’s evaluation that the deficiencies found meet the regulatory standard for a condition-level deficiency.

DAB No. 1611 at 8. Thus, CMS has the initial burden of coming forward with sufficient evidence to show that its decision to impose an enforcement remedy is legally sufficient under the statute and regulations. To make a prima facie case that its decision was legally sufficient, CMS must: (1) identify the statute, regulation or other legal criteria to which it seeks to hold the provider; (2) come forward with evidence upon which it relies for its factual conclusions that are disputed by Petitioner; and (3) show how the deficiencies it found amount to noncompliance that warrants an enforcement remedy, that is, that there was a risk for more than minimal harm due to the regulatory violation. 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. CMS makes a prima facie showing of noncompliance if the credible evidence CMS relies on is sufficient to support a decision in its favor absent an effective rebuttal. The regulation gives Petitioner notice of the criteria or elements it must meet to comply with the program participation requirement established by the regulation. 5 U.S.C. §§ 551(4), 552(a)(1). Therefore, in order to make a prima facie showing of noncompliance, CMS must show that Petitioner violated the regulation by not complying with one or more of the criteria or elements of the regulation, which is a deficiency. CMS must also show that the deficiency amounted to “noncompliance,” that

is, that Petitioner was not in substantial compliance because the deficiency posed a risk for more than minimal harm. *See Jennifer Matthew Nursing & Rehab. Ctr.*, DAB No. 2192 at 20 n.12 (2008). A facility can overcome CMS’s prima facie case either by rebutting the evidence upon which that case rests, or by proving facts that affirmatively show substantial compliance. “An effective rebuttal of CMS’s prima facie case would mean that at the close of the evidence the provider had shown that the facts on which its case depended (that is, for which it had the burden of proof) were supported by a preponderance of the evidence.” *Id.* at 7-8 (citations omitted).

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.³ 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 three surveys at issue in this case.

- **February 27, 2012 Survey.** A complaint investigation was completed on February 27, 2012. The surveyors concluded that Petitioner was not in substantial compliance due to violations of 42 C.F.R. §§ 483.15(h)(1) (Tag F252⁴ at a scope

³ “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.

⁴ This is a “Tag” designation as used in CMS Publication 100-07, State Operations Manual (SOM), app. PP, titled 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 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. Depart. of Pub. Welfare v. Sullivan*, 934 F.2d 853 (7th Cir. 1991); *Northwest Tissue Ctr. v. Shalala*, 1 (Footnote continued next page.)

and severity (s/s) of D⁵), 483.15(h)(2) (Tag F253, s/s E), and 483.75(l)(1) (Tag F514, s/s D). CMS Ex. 1. CMS stipulated at hearing that the surveyors concluded on March 30, 2012, that all three deficiencies were corrected as of March 27, 2012. Tr. 18-19; P. Ex. 3.

- **March 30, 2012 Survey.** A second complaint investigation was completed on March 30, 2012. The surveyors concluded that Petitioner was not in substantial compliance due to violations of 42 C.F.R. §§ 483.10(b)(11) (Tag F157, s/s D) and 483.35(c) (Tag F363, s/s E). CMS Ex. 2. CMS stipulated at hearing that the surveyors concluded on May 11, 2012, that both deficiencies were corrected as of April 13, 2012. Tr. 19-20; P. Ex. 4.
- **May 11, 2012 Survey.** A combined annual, life safety, complaint, and revisit survey was conducted from May 8 through 11, 2012. The surveyors concluded that Petitioner was not in substantial compliance due to the following 13 regulatory violations: 42 C.F.R. §§ 483.10(b)(1) and (5)-(10) (Tag F156, s/s D), 483.10(c)(2)-(5) (Tag F159, s/s D), 483.15(e)(1) (Tag F246, s/s D), 483.15(h)(2) (Tag F253, s/s E), 483.15(h)(6) (Tag F257, s/s D), 483.20(k)(3)(ii) (Tag F282, s/s D), 483.25(h) (Tag F323, s/s D), 483.25(n) (Tag F334, s/s D), 483.35(i) (Tag

(Footnote continued.)

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.

⁵ Scope and severity levels are used by CMS and a state when selecting remedies. The scope and severity level is designated by an alpha character, A through L, selected by CMS or the state agency from the scope and severity matrix published in the SOM, Chap. 7, § 7400E. A scope and severity level of A, B, or C indicates a deficiency that presents no actual harm but has the potential for minimal harm, 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.

F371, s/s D), 483.60(a), (b) (Tag F425, s/s D), 483.60(b), (d), and (e) (Tag F431, s/s D), 483.65 (Tag F441, s/s D), and 483.70(g) (Tag F464, s/s D).

CMS alleges that the three surveys establish that Petitioner was continually not in substantial compliance with program participation requirements from February 27 through August 9, 2012; that the mandatory DPNA was triggered; and that there was a basis for the imposition of the CMP.

Petitioner argues that there were periods of substantial compliance between the surveys and that it returned to substantial compliance not later than June 10, 2012. Petitioner does not dispute many of the deficiency citations or that for brief periods it was not in substantial compliance. Petitioner disputes the onset dates of the noncompliance alleged under Tag F157 of the March survey and Tag F334 of the May survey. Tr. 21-22; P. Br. at 5. Petitioner also disputes that the mandatory DPNA was triggered and that the duration of the CMP was reasonable. Tr. 24-25.

The allegations for the surveys are discussed sequentially to facilitate the analysis.

- 1. Petitioner violated 42 C.F.R. § 483.15(h)(1)(Tag F252, s/s D) from February 27 to March 27, 2012.**
- 2. Petitioner violated 42 C.F.R. § 483.15(h)(2) (Tag F253, s/s E), from February 27 to March 27, 2012.**
- 3. Petitioner violated 42 C.F.R. § 483.75(l)(1) (Tag F514, s/s D) from February 27 to March 27, 2012.**
- 4. Petitioner was not in substantial compliance with program participation requirements during the period February 27, 2012 through March 26, 2012, due to violations of 42 C.F.R. §§ 483.15(h)(1)(Tag F252), 483.15(h)(2) (Tag F253), and 483.75(l)(1) (Tag F514) that posed a risk for more than minimal harm to Petitioner's residents.**

The Statement of Deficiencies (SOD) for the survey that concluded on February 27, 2012, alleges that Petitioner was not in substantial compliance with program participation requirements due to violations of 42 C.F.R. §§ 483.15(h)(1)(Tag F252, s/s D), 483.15(h)(2) (Tag F253, s/s E), and 483.75(l)(1) (Tag F514, s/s D). CMS Ex. 1; P. Ex. 1. It is not alleged in the SOD or by CMS that the period of noncompliance began prior to the end of the survey on February 27, 2012. Tag F252 was based on the surveyor's observation on February 27, 2012, that a resident needed a new mattress and a new mattress was provided that day. CMS Ex. 1 at 1-3; P. Ex. 1 at 1-3. Tag F253 was based on the surveyor's observation on February 27, 2012, that there was "black bio-growth" in

some resident bathrooms; chipped and missing paint in some rooms; a broken air conditioner in one room; a missing handle on a dresser; a detached base board; broken and replacement furniture sitting in a hallway. CMS Ex. 1 at 3-5; P. Ex. 1 at 3-5. Tag F514 was based on errors in medication administration records for two residents that the surveyor identified on February 27, 2012. CMS Ex. 1 at 5-7; P. Ex. 1 at 5-7.

Petitioner does not dispute the violations alleged or that it was not in substantial compliance beginning February 27, 2012. CMS stipulated at hearing that the surveyors concluded on March 30, 2012, that all three deficiencies cited by this survey were corrected as of March 27, 2012. Tr. 18-19; P. Ex. 3. CMS did not stipulate that Petitioner returned to substantial compliance as of March 27, 2012. Whether or not Petitioner returned to substantial compliance is discussed in the context of the March survey.

The scope and severity of the cited deficiencies are not subject to my review because a successful challenge would not affect the range of the CMP that may be imposed or impact the facility's authority to conduct a NATCEP. 42 C.F.R. § 498.3(b)(14), (d)(10)(i).

Accordingly, I conclude that Petitioner was not in substantial compliance with program participation requirements during the period February 27, 2012 through March 26, 2012, due to violations of 42 C.F.R. §§ 483.15(h)(1)(Tag F252), 483.15(h)(2) (Tag F253), and 483.75(l)(1) (Tag F514) that posed a risk for more than minimal harm to Petitioner's residents.

5. Petitioner violated 42 C.F.R. § 483.10(b)(11) (Tag F157, s/s D) from March 23, 2012 to April 13, 2012.

6. Petitioner violated 42 C.F.R. § 483.35(c) (Tag F363, s/s E) from March 30, 2012 to April 13, 2012.

7. Petitioner was not in substantial compliance with program participation requirements during the period March 23, 2012 through April 13, 2012, due to violations of 42 C.F.R. §§ 483.10(b)(11) (Tag F157, s/s D) and 483.35(c) (Tag F363, s/s E) that posed a risk for more than minimal harm to Petitioner's residents.

The SOD for the survey that concluded on March 30, 2012, alleges that Petitioner was not in substantial compliance with program participation requirements due to violations of 42 C.F.R. §§ 483.10(b)(11) (Tag F157) and 483.35(c) (Tag F363). CMS Ex. 2; P. Ex.2. Tag F363 is discussed first as there is no dispute regarding that deficiency.

The surveyors allege under Tag F363 that on March 29 and 30, 2012, surveyors received complaints about the facility food. During lunch on March 30, a surveyor observed that some portions served were smaller than the menu required. CMS Ex. 2 at 8-10; P. Ex. 2 at 8-10. Petitioner does not dispute the deficiency citation and CMS stipulated that the deficiency was corrected on April 13, 2012. The surveyors cited this deficiency at a scope and severity of D, which is not subject to my review because a successful challenge would not affect the range of the CMP that may be imposed or impact the facility's authority to conduct a NATCEP. 42 C.F.R. § 498.3(b)(14), (d)(10)(i). Accordingly, I conclude that the deficiency cited under Tag F363 posed a risk for more than minimal harm and amounted to noncompliance. The deficiency continued from March 30 to April 13, 2012, when the deficiency was corrected as stipulated by CMS.

Petitioner does dispute the deficiency cited under Tag F157, which alleges that Petitioner violated 42 C.F.R. § 483.10(b)(11) because staff failed to immediately consult with Resident 2's physician and notify her family when Resident 2 fell on March 23, 2012. CMS Ex. 2 at 1-7; P. Ex. 2 at 1-7. The surveyors also alleged a deficiency under Tag F157 based on Petitioner's failure to consult the physician and report to the family when Resident 4 fell on March 29, 2012. CMS Ex. 2 at 7-10; P. Ex. 2 at 7-10. If the allegation that the deficiency related to Resident 2 began on March 23, 2012 is meritorious, that determination would compel the conclusions that: Petitioner did not return to substantial compliance on March 27, 2012, the date on which CMS agrees the deficiencies from the February survey were corrected; and Petitioner continued not to be in substantial compliance with program participation requirements from February 27 through at least April 13, 2012, due to the deficiency under Tag F157 identified by the March 30, 2012 survey. It is not necessary to examine the example of Resident 4 as the allegations related to Resident 2 have merit.

a. Facts Related to Resident 2's Fall on March 23, 2012

The surveyors allege in the SOD that nurse's notes show that at about 1:20 a.m. on March 23, 2012, Resident 2 was on the floor lying on her left-side. The notes show that Resident 2 denied hitting her head; her right-side range of motion was good but she had contractures on her left-side due to a prior stroke; she denied any pain; and no injury was noted. Resident 2's bedside commode was on its side, there was urine on the floor, and the resident stated that she had used the commode and when she leaned forward to wipe she fell. CMS Ex. 2 at 3; P. Ex. 2 at 3. At about 1:50 a.m. on March 23, 2012, 30 minutes after her fall, Resident 2 complained of left-leg pain and was given Percocet® for which she had an order to be administered as needed prior to the fall. Resident 2 was given another dose of Percocet® at 6:00 a.m. on March 23, 2012, four hours and 30 minutes after the fall. At 6:20 a.m. on March 23, 2012, Resident 2's physician was paged. The family was notified at 6:30 a.m. on March 23. Physician telephone orders were received at 6:45 a.m. for x-rays of the left femur and pelvis due to the resident's complaints of pain. The x-rays revealed that Resident 2 had a fracture of the left femoral

neck, that is, a hip fracture. CMS Ex. 2 at 4. Petitioner introduced as evidence a copy of the nursing progress notes and the physician progress notes related to the March 23 fall. P. Ex. 17 at 4-5. The notes from Petitioner's records are consistent with the allegations of the SOD, except the notes do not reflect the administration of Percocet® or the x-ray results, but those facts are not specifically denied by Petitioner.

b. Analysis

The regulation at issue 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 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).

42 C.F.R. § 483.10(b)(11)(i) (emphasis added). Residents in long-term care facilities have the rights enumerated in 42 C.F.R. § 483.10. Among the rights listed are the right to notice of rights and services, including the right to have the facility give immediate notice of significant changes in the resident's condition to the resident, the resident's physician, and the resident's legal representative or interested family member. 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 representative or an interested family member” whenever any of the specified circumstances occur.

42 C.F.R. § 483.10(b)(11)(emphasis added). The regulation distinguishes between informing the resident and family and the requirement to consult the resident's physician. The regulatory language is clear that the requirement to consult is not discretionary and requires more than merely informing or notifying the physician. The regulatory history for the regulation shows that the drafters' intended 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). The plain language of the regulation and the regulatory history support the conclusion that regulatory requirement to consult with the physician requires more than simply notifying the physician. 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 notification and consultation “immediately” upon discernment of a significant change in condition of the resident or 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 regulation 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 regulatory history shows that an early draft of the rule granted the facility up to 24 hours to consult with the resident’s physician and to notify the legal representative or family. However, after the receipt of comments emphasizing that time is of the essence in such circumstances, the final rule eliminated the 24-hour period for notification and imposed the requirement 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 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 immediately consulted, any inconvenience certainly is inconsequential and outweighed by the potential for significant harm to the resident if the facility fails to immediately consult the physician. The regulation at 42 C.F.R. § 483.10 is titled “Resident rights” and the requirements of this specific regulation provide that every resident has the right, among other things, 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. 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 that the facility immediately inform the resident, consult the physician and notify the resident’s legal representative or interested family member. The regulation also requires that the facility 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.

In this case Resident 2 fell from the bed-side commode on March 23, 2012 at about 1:20 a.m. There is no question that her fall was an accident within the meaning of 42 C.F.R.

§ 483.10(b)(11)(i)(A). It was not apparent at 1:20 a.m., when Resident 2 was found, that she suffered an injury. However, at 1:50 a.m., only 30 minutes after the fall she began complaining of left-leg pain. Therefore, at 1:50 a.m., it was certainly evident that the accident potentially caused an injury that would require physician intervention. However, Petitioner's staff failed to immediately consult with Resident 2's physician at 1:50 a.m. as required by the regulation. The fact that it was very early in the morning and that a call might disturb the physician is not a defense to the regulatory requirement to consult. Accordingly, I conclude that there was a prima facie showing that Petitioner violated 42 C.F.R. § 483.10(b)(11) on March 23, 2012. Resident 2 suffered pain from the hip fracture, which is actual harm even though the severity cited by the surveyors was no actual harm but a risk for more than minimal harm but not immediate jeopardy. The scope and severity of the deficiency is not subject to review. 42 C.F.R. § 498.3(b)(14), (d)(10)(i).

I conclude that Petitioner failed to rebut the prima facie showing or establish an affirmative defense. Petitioner urges me to rule that CMS cannot allege that the noncompliance cited by the March 30, 2012 survey under Tag F157 began earlier than March 30, 2012. Petitioner cites no authority that imposes such a limitation. Petitioner also argues that CMS raised the theory that a deficiency occurred prior to the March 30, 2012 for the first time in its prehearing brief. Petitioner's Prehearing Brief (P. Ph. Br.) at 12-13. However, the SOD for the March 30, 2012 survey clearly alleges that the deficiency cited under Tag F157 related to Resident 2 arose on March 23, 2012, when the resident fell and complained of pain and staff failed to immediately consult the physician. CMS Ex. 2 at 2, 4; P. Ex. 2, 4.

Petitioner argues that the allegations under Tag F157 related to Resident 2 do not state a violation of 42 C.F.R. § 483.10(b)(11). P. Ph. Br. at 13-14. Petitioner does not dispute that Resident 2 fell and that there was no consultation with the physician until four and one-half hours after the accident. However, Petitioner asserts that the resident complained of "left sided pain, which she had regularly." P. Ph. Br. at 13-14. Petitioner mischaracterizes the facts in evidence. The SOD specifically states that the complaint was "pain in the left leg" not generalized left sided pain. CMS Ex. 2 at 4; P. Ex. 2 at 4. Petitioner implies, without specifically arguing, that staff may have been unable to determine that the resident's complaints of pain were due to an injury secondary to the fall. P. Reply at 3-4. Petitioner presented no evidence that Resident 2 had regular complaints of pain associated with her left leg. Although I am willing to infer that she had a standing order for pain medication for some reason, I cannot infer that it was for left-leg pain. Furthermore the fact that staff may have not been clear that the complaints of pain were associated with the fall is simply no defense in this case. Resident 2 fell and she complained of pain within 30 minutes of the fall. Therefore, consultation with the physician was required to permit the physician to diagnose and decide how to intervene considering the known facts. Consultation did occur several hours later. However, Petitioner does not argue or point to any authority to support a conclusion that the

consultation with the physician several hours after the accident and the first complaint of pain met the regulatory requirement that the consultation occur immediately. Petitioner also argues that there was no potential for more than minimal harm and CMS failed to make a prima facie showing for that reason. P. Pr. Br. at 14. Petitioner does not dispute or rebut the evidence that Resident 2 made two complaints of left-leg pain the morning of March 23, 2012, prior to the consultation with her physician. I conclude, without hesitation, that pain secondary to a hip fracture is actual harm and more than adequate to satisfy the requirement for CMS to show as part of its prima facie case that there was a risk for more than minimal harm.

Contrary to Petitioner's arguments, I conclude that Petitioner was not in substantial compliance between March 23 and 30, 2012. Accordingly, I conclude that Petitioner continued not to be in substantial compliance with program participation requirements from February 27, 2012 through at least April 13, 2012.

- 8. Petitioner violated 42 C.F.R. § 483.10(b)(1) and (5)-(10) (Tag F156, s/s D) from March 30, 2012 through June 10, 2012.**
- 9. Petitioner violated 42 C.F.R. § 483.10(c)(2)-(5) (Tag F159, s/s D) from May 3, 2012 through June 10, 2012.**
- 10. Petitioner violated 42 C.F.R. § 483.15(e)(1) (Tag F246, s/s D) from May 10, 2012 through June 10, 2012.**
- 11. Petitioner violated 42 C.F.R. § 483.15(h)(2) (Tag F253, s/s E) from May 10, 2012 through June 10, 2012.**
- 12. Petitioner violated 42 C.F.R. § 483.15(h)(6) (Tag F257, s/s D) from May 8, 2012 through June 10, 2012.**
- 13. Petitioner violated 42 C.F.R. § 483.20(k)(3)(ii) (Tag F282, s/s D) from May 6, 2012 through June 10, 2012.**
- 14. Petitioner violated 42 C.F.R. § 483.25(h) (Tag F323, s/s D) from May 9, 2012 through June 10, 2012.**
- 15. Petitioner violated 42 C.F.R. § 483.25(n)(2) (Tag F334, s/s D) from February 27, 2012 through June 10, 2012.**
- 16. Petitioner violated 42 C.F.R. § 483.35(i) (Tag F371, s/s D) from May 8, 2012 through June 10, 2012.**

17. Petitioner violated 42 C.F.R. § 483.60(a), (b) (Tag F425, s/s D) from May 2, 2012 through June 10, 2012.

18. Petitioner violated 42 C.F.R. § 483.60(b), (d), and (e) (Tag F431, s/s D) from May 8, 2012 through June 10, 2012.

19. Petitioner violated 42 C.F.R. § 483.65 (Tag F441, s/s D) from May 8, 2012 through June 10, 2012.

20. Petitioner violated 42 C.F.R. § 483.70(g) (Tag F464, s/s D) from May 8, 2012 through June 10, 2012.

21. Petitioner was not in substantial compliance from program participation requirements from February 27 through June 10, 2012 and there is a basis for the imposition of enforcement remedies.

The combined annual, life safety, complaint, and revisit surveys conducted from May 8 through 11, 2012, concluded that Petitioner was not in substantial compliance due to the following 13 regulatory violations: 42 C.F.R. §§ 483.10(b)(1) and (5)-(10) (Tag F156, s/s D), 483.10(c)(2)-(5) (Tag F159, s/s D), 483.15(e)(1) (Tag F246, s/s D), 483.15(h)(2) (Tag F253, s/s E), 483.15(h)(6) (Tag F257, s/s D), 483.20(k)(3)(ii) (Tag F282, s/s D), 483.25(h) (Tag F323, s/s D), 483.25(n) (Tag F334, s/s D), 483.35(i) (Tag F371, s/s D), 483.60(a), (b) (Tag F425, s/s D), 483.60(b), (d), and (e) (Tag F431, s/s D), 483.65 (Tag F441, s/s D), and 483.70(g) (Tag F464, s/s D). CMS Ex. 4; P. Ex. 4. Except for the deficiency cited under Tag F334, Petitioner does not dispute that these deficiencies were properly cited by the surveys that ended on May 11, 2012, and I so conclude. P. Br. at 17-18. The dates that noncompliance began for each deficiency listed in Conclusion of Law 8 through 14 and 16 through 20 are the dates listed in the SOD, as those dates have not been disputed by Petitioner. Petitioner does dispute the date of correction for all the cited deficiencies arguing that Petitioner corrected the deficiencies and returned to substantial compliance on June 10, 2012 rather than August 10, 2012, as alleged by CMS.

Two deficiency citations require specific discussion, Tag F156 and Tag F334.

a. 42 C.F.R. § 483.10(b)(1) and (5)-(10) (Tag F156, s/s D)

The deficiency under Tag F156 is an alleged violation of 42 C.F.R. § 483.10(b)(1) and (5)-(10), which establish certain resident rights. Pursuant to 42 C.F.R. § 483.10(b)(5) and (6), a facility must inform residents of services available from the facility and which services are the responsibility of the resident to pay and which are covered. The SOD cites three separate findings under this deficiency. Finding 1 which has not been contested by Petitioner states:

1. Record review for resident #121 revealed that a Notice of Medicare Provider Non-Coverage form CMS – 1023 was initiated on 3/30/12 for a last day of coverage identified as 3/30/12. The facility failed to include which skilled services would not be covered and the amount that the resident would be responsible for after the date of non-coverage.

CMS Ex. 3 at 4; P. Ex. 4.⁶ The uncontested finding in the SOD establishes the violation of 42 C.F.R. § 483.10(b)(1). The surveyors determined that the deficiency posed a risk for more than minimal harm which is not contested by Petitioner and is not subject to my review anyway. Finding 1 establishes noncompliance with this requirement of participation as of March 30, 2012. There is no evidence that this deficiency was corrected prior to the May 2012 survey. Petitioner states in its plan of correction that the deficiency was corrected on June 10, 2012. P. Ex. 5 at 1. Therefore, contrary to Petitioner's arguments, this deficiency shows that Petitioner did not return to substantial compliance between April 13, 2012 and the May 2012 survey.

b. 42 C.F.R. § 483.25(n)(2) (Tag F334, s/s D)

Petitioner focused on Tag F334 from the May 11, 2012 survey arguing that the survey did not establish noncompliance after April 13, 2012 (when CMS stipulated the deficiencies cited in the March 2012 survey were corrected) and before the May 2012 survey. Tag F334 alleges a violation of 42 C.F.R. § 483.25(n). The regulation requires:

(n) Influenza and pneumococcal immunizations—

* * * *

(2) Pneumococcal disease. The facility must develop policies and procedures that ensure that—

(i) Before offering the pneumococcal immunization, each resident or the resident's legal representative receives education regarding the benefits and potential side effects of the immunization;

⁶ The form number cited in the SOD is incorrect. The form referred to is likely a CMS 10123, Expedited Review Notice-Notice of Medicare Provider Non-coverage.

- (ii) Each resident is offered a pneumococcal immunization, unless the immunization is medically contraindicated or the resident has already been immunized;
- (iii) The resident or the resident's legal representative has the opportunity to refuse immunization; and
- (iv) The resident's medical record includes documentation that indicates, at a minimum, the following:
 - (A) That the resident or resident's legal representative was provided education regarding the benefits and potential side effects of pneumococcal immunization; and
 - (B) That the resident either received the pneumococcal immunization or did not receive the pneumococcal immunization due to medical contraindication or refusal.
- (v) Exception. As an alternative, based on an assessment and practitioner recommendation, a second pneumococcal immunization may be given after 5 years following the first pneumococcal immunization, unless medically contraindicated or the resident or the resident's legal representative refuses the second immunization.

42 C.F.R. § 483.25(n)(2).⁷ The regulation does not require that every resident receive the pneumococcal immunization. The regulation does require that Petitioner ensure, through the adoption of policies and procedures,⁸ that:

⁷ There is no alleged violation of 42 C.F.R. § 483.25(n)(1) which imposes requirements related to influenza immunizations.

⁸ The purpose of the regulation is broader than simply requiring Petitioner to create a document and implement a policy and procedure. The regulatory history shows that the drafters intended to require that a facility “**offer** (without a specified timeframe) lifetime immunization against pneumococcal disease” with a second immunization when necessary. 70 Fed. Reg. 58,834, 58,839-46 (Oct. 7, 2005). The drafters also intended to (*Footnote continued next page.*)

- Every resident or the resident's legal representative is educated about the risks and benefits of the immunization;
- Every resident is offered the pneumococcal immunization, unless medically contraindicated or the resident was previously immunized;
- Every resident or the resident's legal resident must be given the right to refuse the immunization; and
- The resident's medical record must contain documentation of the education and administration of the immunization, or that the immunization was not administered because it was medically contraindicated or the resident or legal representative refused.

The regulation suggests, but does not require, that the pneumococcal immunization may be offered again five years after the first pneumococcal immunization is given. 42 C.F.R. § 483.25(n)(2)(v); Tr. 100. The regulation does not state if or when education and the immunization should be reoffered after an initial refusal. Tr. 105-06.

It is alleged in the SOD that Petitioner violated the regulation in the case of Residents 9 and 81. The allegation regarding Resident 9 is that the surveyor found in Resident 9's clinical record a form dated in December 2009 showing that she declined a pneumococcal immunization but no subsequent documentation that she received or declined the immunization. CMS Ex. 3 at 18; P. Ex. 5 at 18. The SOD does not allege that the clinical record fails to show education as required by 42 C.F.R. § 483.25(n)(2)(iv). The regulation does not establish a requirement for when a resident must be reoffered the vaccine; re-educated; and given the opportunity to accept or decline the vaccine. Surveyor Doyle testified in response to my question that there was no requirement for Petitioner to educate and re-offer the immunization to Resident 9 between December 2009 and the May 2012 survey. Tr. 105-06. In the case of Resident 9, the form completed in December 2009 satisfies the requirement of the regulation and the SOD fails to state a regulatory violation based on the example of Resident 9.

In the example of Resident 81, it is alleged that Resident 81 was admitted to the facility on August 5, 2011 but the surveyor could find no documentation in the clinical record

(Footnote continued.)

require that compliance with the regulatory requirement be documented in each resident's medical record.

that the resident was offered and either received or declined the vaccine. CMS Ex. 3 at 19; P. Ex. 5 at 19. Petitioner argues that the regulation does not establish a time by which a new resident must be offered the pneumococcal vaccine. P. Br. at 19-20. Petitioner is correct that the regulation specifies no deadline by which a resident must be educated and offered the immunization or that the resident's records must contain the required documentation. However, 42 C.F.R. § 483.25(n)(2)(iv) clearly states that at a minimum a resident's medical record must include evidence of education regarding the benefits and possible side-effects of the vaccine and evidence that the vaccine was either received, rejected, or could not administered due to medical contraindication. The regulation requires that the documentation be present in the medical records for all residents, I see no other interpretation. Although Petitioner might defend the absence of the required documents on grounds that a resident was recently admitted, Resident 81 was not recently admitted to Petitioner. Petitioner offers no evidence to rebut the surveyor's observation recorded in the SOD that there was no documentation in the medical record of Resident 81. Petitioner offers no evidence to explain the absence of the required documentation that might be considered a defense.

Petitioner argues that the violation related to Resident 81 does not rise to the level of noncompliance as there is no risk for more than minimal harm. P. Br. at 20; P. Reply at 6, 8-9. The surveyors cited the deficiency under Tag F334 at a severity of D, meaning that there was no actual harm or immediate jeopardy but a risk for more than minimal harm. CMS Ex. 3 at 16. The SOD does not specifically articulate the basis for the severity determination. However, I accept that the severity citation by the surveyors is some evidence that there was a risk for more than minimal harm. Surveyor Doyle also opined that there was a risk for more than minimal harm related to failure to ensure all residents were offered the vaccine. Tr. 70-71. CMS has also issued policy found in the SOM, app. PP, Tag F334, which discusses the purposes for the regulation including the reduction of the risk of transmission of influenza and pneumonia among nursing home residents who live in a closed setting and are at higher risk for infection and adverse results than the general population.

I conclude that the evidence offered by CMS is sufficient to meet its burden of making a prima facie showing that there is a risk for more than minimal harm due to violation of the regulatory requirement. Thus, it was incumbent upon Petitioner to present some evidence to show that there was no risk for more than minimal harm. Petitioner failed to satisfy its burden. Petitioner argues that there was no risk for more than minimal harm because Residents 9 and 81 represent less than two percent of the facility population and it was likely they would have declined the vaccine earlier if offered. P. Br. at 20. Petitioner was not cited, however, because Residents 9 and 81 did not take the vaccine. Resident 9 and 81 could not be compelled to take the vaccine. Petitioner was cited and I sustain the deficiency as to Resident 81, because there was no documentation that Resident 81 or her legal representative was educated on the benefits and risks of the vaccine and given the choice whether or not to take the vaccination. Residents have the

right to decline the vaccine but they should do so after being educated. Further, increasing the number residents educated and vaccinated theoretically reduces the risk for infection among the facility population.

In this case, Petitioner's policy and procedure failed to ensure that Resident 81 received the required education and that she was given the choice to be vaccinated or not. Petitioner argues that the regulation requires that Petitioner have policies and procedures, but CMS did not allege that Petitioner's policies and procedures were inadequate. Petitioner correctly points out that Petitioner's policy is not in evidence. P. Reply at 5. Neither CMS nor Petitioner offered Petitioner's influenza and pneumonia immunization policy as evidence. However, the deficiency was not cited because Petitioner failed to have the required policy or that the policy was defective in some regard. Rather, the deficiency was cited because Resident 81 did not have the required paperwork in her record and there was no evidence that Resident 81 had been educated and offered the pneumococcal immunization.

Petitioner complains that the only evidence of noncompliance under Tag F334 is the allegations of the surveyor in the SOD, which Petitioner asserts are uncorroborated and not subject to cross-examination. P. Br. at 2, 8; P. Reply at 5. Petitioner did not object to the admission of CMS Ex. 3 (the SOD for the May 2012 survey) even though "CMS's Final List of Witnesses" filed September 3, 2013, did not list the surveyor who prepared the SOD for the May 2012 survey as a witness CMS intended to call. Petitioner did not request a subpoena or an order to compel the availability for cross-examination of the surveyor who drafted the SOD. Civil Remedies Division Procedure (CRDP) § 9. Petitioner's argument that the statements in the SOD are uncorroborated hearsay is correct, but that does not address the credibility of the statements. Petitioner does not specifically argue the statements under Tag F334 are not credible and Petitioner offered no evidence to rebut the statements. Thus, I have no reason not to accept the statements as credible even though they are uncorroborated hearsay.

Accordingly, I conclude that Petitioner was in violation of 42 C.F.R. § 483.25(n) (Tag F334) when the survey cycle began on February 27, 2012,⁹ because there was no

⁹ Resident 81 was admitted to the facility on August 5, 2011. Because there is no evidence of compliance with 42 C.F.R. § 483.25(n)(2)(iv) between the resident's admission and the beginning of the survey cycle on February 27, 2012, it could be concluded that noncompliance began on or shortly after August 5, 2011. For purposes of this decision, it is not necessary to look back beyond the beginning of the survey cycle or to resolve the issue of how many days may elapse after admission before the regulation is violated.

evidence in the medical record of Resident 81 that the resident or her legal representatives were educated on the risks and benefits of the pneumonia immunization, or that she had taken or declined the immunization, or that the immunization was medically contraindicated. The deficiency posed a risk for more than minimal harm to Petitioner's residents. Therefore, Petitioner was not in substantial compliance with 42 C.F.R. § 483.25(n) (Tag F334) beginning not later than February 27, 2012. The noncompliance continued until the deficiency was corrected on June 10, 2012.

c. Return to Substantial Compliance

CMS concluded, based on a revisit survey completed on August 10, 2012, that Petitioner returned to substantial compliance with program participation requirements on August 10, 2012. P. Ex. 7. Petitioner asserts that it corrected all deficiencies cited by the May 2012 survey and returned to substantial compliance not later than June 10, 2012. P. Br. at 16-17. Petitioner may challenge and an ALJ may review whether or not Petitioner returned to substantial compliance earlier than the date determined by CMS. *Foxwood Springs Living Ctr.*, DAB No. 2294 at 6-13 (2009).

Petitioner's plan of correction for the May 2012 survey was admitted as evidence as CMS Ex. 6 and P. Ex. 5. This plan of correction lists June 10, 2012, as the date Petitioner completed its plan to correct each of the 13 deficiencies cited. P. Ex. 5. CMS accepted Petitioner's plan of correction. Based on the August 10, 2012 revisit survey, CMS concluded that Petitioner had implemented its plan of correction. But, CMS concluded that Petitioner did not return to substantial compliance until August 10, 2012, rather than June 10, 2012. Tr. 144, 152, 78-80.

CMS elicited testimony from Surveyor Doyle, who did not participate in the May 2012 survey, but did participate in the August 10, 2012 revisit survey as the survey team leader. Tr. 74-78. Surveyor Doyle confirmed that she concluded during the August 2012 revisit that Petitioner had completed its corrective action related to Tag F334 and that Petitioner was in substantial compliance with Tag F334. Tr. 79-80; CMS Ex. 6 at 17. Surveyor Doyle testified in response to my questions that she could not recall if she considered whether Petitioner corrected the deficiencies cited by the May 2012 survey earlier than August 10, 2012. Tr. 100-04.

Laurie VanderMeer, Regional Director of Clinical Services for Consulate Health Care was called as a witness by Petitioner. Tr. 124-25. She testified that she assisted with developing the plan of correction for the May 2012 survey. She testified that she believed all deficiencies were corrected by June 10, 2012. Tr. 140-46. Brian McCoy, Regional Vice President of Operations for Consulate Health Care Company, was called as a witness by Petitioner. Tr. 149-50. Mr. McCoy was also involved in developing the plans of correction for the surveys, including the May 2012 survey. He testified that the plan of correction for the May 2012 survey was completed by June 10, 2012. Tr. 152-56.

The testimony of Ms. VanderMeer and Mr. McCoy is credible and worthy of weight. The testimony of Petitioner's witnesses and the allegations of the plan of correction for the May 2012 survey are unrebutted by any documentary or testimonial evidence. Surveyor Doyle testified credibly, but her testimony is limited as she had no recollection of considering whether Petitioner corrected deficiencies or returned to substantial compliance prior to August 10, 2012, the date of the revisit survey.

22. A mandatory DPNA was triggered May 27, 2012 as a matter of law pursuant to section 1819(h)(2)(D) of the Act and continued until Petitioner completed correction of deficiencies and returned to substantial compliance with program participation requirements on June 10, 2012.

23. A CMP of \$150 per day from March 30, 2012 through May 10, 2012 and \$250 per day from May 11, 2012 through June 10, 2012, is a reasonable enforcement remedy in this case.

I have concluded that Petitioner was not in substantial compliance with program participation requirements from February 27, 2012 through June 10, 2012. Pursuant to section 1819(h)(2) of the Act, the DPNA directed by Congress was triggered after three months of noncompliance which began the last date of the survey that identified that Petitioner was not in substantial compliance. Noncompliance was identified by the survey completed on February 27, 2012. Noncompliance continued through May 27, 2012. Therefore, the mandatory DPNA began on May 27, 2012. There is no issue for me to resolve regarding the reasonableness of the DPNA. I have also concluded that Petitioner corrected all deficiencies as of June 10, 2012. Therefore, June 10, 2012 is the last date of noncompliance and the end of the mandatory DPNA.

If a facility is not in substantial compliance with program requirements, CMS has the authority to impose one or more of the enforcement remedies listed in 42 C.F.R. § 488.406, including a CMP. CMS is authorized to impose a per-day CMP for the number of days that the facility is not in substantial compliance. 42 C.F.R. § 488.430(a).

If there is a basis for the imposition of an enforcement remedy and the remedy proposed is a CMP, my authority to review the reasonableness of the CMP is limited by 42 C.F.R. § 488.438(e). The limitations are: (1) I may not set the CMP at zero or reduce it to zero; (2) I may not review the exercise of discretion by CMS in selecting to impose a CMP; and (3) I may only consider the factors specified by 42 C.F.R. § 488.438(f) when determining the reasonableness of the CMP amount. In determining whether the amount of a CMP is reasonable, the following factors specified at 42 C.F.R. § 488.438(f) must be considered: (1) the facility's history of non-compliance, including repeated deficiencies; (2) the facility's financial condition; (3) the seriousness of the deficiencies as set forth at

42 C.F.R. § 488.404(b), the same factors CMS and/or the state were to consider when setting the CMP amount; and (4) the facility's degree of culpability, including but not limited to the facilities neglect, indifference, or disregard for resident care, comfort, and safety and the absence of culpability is not a mitigating factor. The factors that CMS and the state were required to consider when setting the CMP amount and that I am required to consider when assessing the reasonableness of the amount are set forth in 42 C.F.R. § 488.404(b): (1) whether the deficiencies caused no actual harm but had the potential for minimal harm, no actual harm with the potential for more than minimal harm, but not immediate jeopardy, actual harm that is not immediate jeopardy, or immediate jeopardy to resident health and safety; and (2) whether the deficiencies are isolated, constitute a pattern, or are widespread. My review of the reasonableness of the CMP is *de novo* and based upon the evidence in the record before me. I am not bound to defer to the CMS determination of the reasonable amount of the CMP to impose but my authority is limited by regulation as already explained. I am to determine whether the amount of any CMP proposed is within reasonable bounds considering the purpose of the Act and regulations. *Emerald Oaks*, DAB No. 1800 at 10 ; *CarePlex of Silver Spring*, DAB No. 1683 at 14–16 (1999); *Capitol Hill Cmty. Rehab. & Specialty Care Ctr.*, DAB No. 1629 (1997).

There are two ranges for a per-day CMP. 42 C.F.R. §§ 488.408, 488.438. The lower range of CMPs, \$50 per day to \$3,000 per day, is reserved for deficiencies that do not pose immediate jeopardy, but either cause actual harm to residents, or cause no actual harm but have the potential for causing more than minimal harm. 42 C.F.R. § 488.438(a)(1)(ii). There is no immediate jeopardy in this case and only the lower range of CMPs may be considered. CMS proposed a CMP of \$150 per day from March 30, 2012 through May 10, 2012 and \$250 per day from May 11, 2012 until Petitioner returned to substantial compliance. I have concluded that the last day of noncompliance was June 10, 2012, and the CMP ends on that date. Petitioner asserted generally in its request for hearing that the CMP proposed by CMS, particularly the duration of the CMP, was unreasonable. Petitioner does not specifically challenge the reasonableness of the amount of the proposed CMPs.

I have received no evidence of noncompliance by Petitioner except that reflected by the February 2012, March 2012, and May 2012 surveys. Mr. McCoy testified that the economic impact of the mandatory DPNA over the period May 27 to August 10, 2012 would be approximately \$200,000. Tr. 164. However, Petitioner has not argued that the proposed CMP would have any significant financial impact upon Petitioner. None of the alleged deficiencies are alleged to have posed immediate jeopardy or caused actual harm, though Resident 2 may have suffered additional pain due to the delayed consultation with her physician. No deficiency was wide-spread. Petitioner was culpable but not highly culpable. Neglect was reflected by failure to deliver necessary care and services. However, Petitioner did respond promptly to correct deficiencies. Based on my review of the regulatory factors, I conclude that a CMP of \$150 per day from March 30, 2012

