Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Winterhaven Healthcare Center,
(CCN: 67-5686),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-14-424

Decision No. CR3978

Date: June 22, 2015

DECISION

Petitioner, Winterhaven Healthcare Center, violated 42 C.F.R. § 483.10(b)(1) and (6) in this case.[1] However, the regulatory violation did not constitute noncompliance because it did not have the potential to cause more than minimal harm. Accordingly, there is no basis for the imposition of an enforcement remedy, and the discretionary denial of payment for new admissions (DPNA) imposed from October 19, 2013, through November 29, 2013, is not a reasonable enforcement remedy.

I. Background

Petitioner, a long-term care facility, is located in Houston, Texas and participates in Medicare as a skilled nursing facility (SNF) and the state Medicaid program as a nursing facility (NF). Petitioner was subject to a recertification and licensure survey by the Texas Department of Aging and Disability Services (state agency) from September 17 through

---

[1] References are to the 2012 revision of the Code of Federal Regulations (C.F.R.), unless otherwise indicated.

20, 2013. The state agency surveyors concluded that Petitioner was not in substantial compliance with program participation requirements due to eleven deficiencies. Petitioner was also subject to a life safety code survey that was completed on September 19, 2013. The life safety code survey cited Petitioner with five additional deficiencies. Centers for Medicare & Medicaid Services (CMS) Exhibit (Exs.) 1 at 2, 2, and 5.

CMS notified Petitioner by letter dated October 22, 2013, that it was imposing the following enforcement remedies: termination of Petitioner's provider agreement and participation in Medicare effective March 20, 2014, if Petitioner did not return to substantial compliance prior to that date; and a DPNA effective October 19, 2013. CMS Ex. 1 at 2-3. CMS notified Petitioner by letter dated January 7, 2014, that Petitioner returned to substantial compliance on November 30, 2013. The letter advised Petitioner that the DPNA was in effect from October 19 through November 29, 2013, and that the termination of Petitioner's provider agreement was rescinded. CMS Ex. 1 at 1.

Petitioner requested a hearing before an administrative law judge (ALJ) on December 3, 2013. The case was assigned to me for hearing and decision on December 19, 2013, and an Acknowledgement and Prehearing Order (Prehearing Order) was issued at my direction.

On May 8, 2014, the parties filed a "Joint Settlement Status Report and Motion to Proceed to Hearing on Written Submission" (Jt. Rpt.). This document contained the parties' joint stipulations. Jt. Rpt. at 2-3. The parties stipulated that all the deficiencies cited by the September 19, 2013 life safety code survey and the September 20, 2013 recertification survey, with the exception of the deficiency citation under 42 C.F.R. § 483.10(b)(1) and (b)(5)-(10) (Tag F156)[2], were corrected by September 30, 2013. Jt. Rpt. at 2-3; CMS Ex. 6. Both parties waived an oral hearing and requested a decision on the briefs. Jt. Rpt. at 3-4. On May 12, 2014, I accepted the waiver of oral hearing and set

---

[2] This is a "Tag" designation as used in CMS Publication 100-07, State Operations Manual (SOM), Appendix PP – Guidance to Surveyors for Long Term Care Facilities (http://www.cms.hhs.gov/Manuals/IOM/list.asp). The "Tag" refers to the specific regulatory provision allegedly violated and CMS's 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 of Health and Human Services (Secretary) may not seek to enforce the provisions of the SOM, she may seek to enforce the provisions of the Social Security Act (Act) or regulations as interpreted by the SOM.

a briefing schedule. Order Accepting the Waiver of Oral Hearing and Establishing Briefing Schedule.

The parties filed opening briefs (CMS Br. and P. Br.) and reply briefs (CMS Reply and P. Reply). CMS offered CMS Exs. 1 through 13, and Petitioner offered exhibits (P. Exs.) 1 through 4.[3] No objection has been made to my consideration of the exhibits, and they are admitted as evidence.

II. Discussion

A. Issues

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

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 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

---

[3] CMS listed only 10 proposed exhibits on its exhibit list filed March 19, 2014, but submitted 13 proposed exhibits.

[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 the participation requirements established by sections 1919(b), (c), and (d) of the Act.

been less than 180 days of noncompliance. The Act also grants the Secretary authority to impose other enforcement remedies, including a discretionary DPNA, civil money penalties, appointment of temporary management, and other remedies such as a directed plan of correction. Act § 1819(h)(2)(B).

The Secretary has delegated to CMS and the states the authority to impose remedies against a long-term care facility that is not complying substantially with federal participation requirements. "*Substantial compliance* means a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm." 42 C.F.R. § 488.301 (emphasis in original). A deficiency is a violation of a participation requirement established by sections 1819(b), (c), and (d) of the Act or the Secretary's regulations at 42 C.F.R. 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. 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); 42 C.F.R. §§ 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 nurse aide training and competency evaluation program (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).

The hearing before an ALJ is a de novo proceeding, i.e., "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 Residence at Salem Woods*, DAB No. 2052 (2006); *Cal Turner Extended Care*

Pavilion, DAB No. 2030 (2006); *Beechwood Sanitarium*, DAB No. 1906 (2004); *Emerald Oaks*, DAB No. 1800, at 11 (2001); *Anesthesiologists Affiliated*, DAB CR65 (1990), *aff'd*, 941 F.2d 678 (8th Cir. 1991). The Secretary's regulations do not address the allocation of the burden of proof or the standard of proof. However, the Board has addressed the allocation of the burden of proof in many decisions. The standard of proof is a preponderance of the evidence. CMS has the burden of coming forward with the evidence and making a prima facie showing of a basis for imposition of an enforcement remedy. Petitioner bears the burden of persuasion to show by a preponderance of the evidence that it was in substantial compliance with participation requirements or any affirmative defense. *Batavia Nursing & Convalescent Inn*, DAB No. 1911 (2004); *Batavia Nursing & Convalescent Ctr.*, DAB No. 1904 (2004), *aff'd*, 129 F. App'x 181 (6th Cir. 2005); *Emerald Oaks*, DAB No. 1800; *Cross Creek Health Care Ctr.*, DAB No. 1665 (1998); *Hillman Rehab. Ctr.*, DAB No. 1611 (1997), DAB CR500 (1997) (on remand), *rev'd,* DAB No. 1663 (1998), *aff'd*, *Hillman Rehab. Ctr. v. United States,* No. 98-3789 (GEB), 1999 WL 34813783 (D.N.J. May 13, 1999).

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

My conclusions of law are set forth in bold text followed by my findings of fact and analysis. I have carefully considered all the evidence and the arguments of both parties, although not all may be specifically discussed in this decision. I discuss 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).

The parties stipulated that the only deficiency citation at issue before me is the alleged violation of 42 C.F.R. § 483.10(b)(1), (b)(5)-(10) (Tag F156) at a scope and severity level E, which means that the violation had the potential for more than minimal harm without actual harm or immediate jeopardy. Jt. Rpt. at 2. I infer, based on the stipulation, that CMS and Petitioner agree that the alleged violation of 42 C.F.R. § 483.10(b)(1), (b)(5)-(10), is the only basis for the imposition of the DPNA for the period October 19 through

---

[5] "Credible evidence" is evidence that is worthy of belief. *Black's Law Dictionary* 596 (18th ed. 2004). The "weight of evidence" is the persuasiveness of some evidence compared to other evidence. *Id*. at 1625.

November 29, 2013, because they stipulated that all other alleged deficiencies were corrected by September 30, 2013. Jt. Rpt. at 2-3, CMS Ex. 6. Accordingly, my jurisdiction is limited to reviewing the issues of whether there was a violation of 42 C.F.R. § 483.10(b)(1), (b)(5)-(10); whether the violation is a basis for the imposition of an enforcement remedy; and whether the proposed DPNA is a reasonable enforcement remedy. As discussed in more detail hereafter, Petitioner effectively concedes the regulatory violation, but argues that that violation does not pose a risk for more than minimal harm. If Petitioner is correct, then the regulatory violation would not amount to noncompliance and would not be a basis to impose an enforcement remedy, including the DPNA proposed by CMS. P. Br. at 7-10, P. Reply.

1. Judgment on the written pleadings and documentary evidence is permissible in this case.

Pursuant to 42 C.F.R. § 498.66(a), Petitioner may waive its right to appear and present evidence at an oral hearing by filing a written waiver. When a written waiver is filed by a petitioner, an ALJ need not conduct an oral hearing except in two circumstances: the ALJ concludes witness testimony is necessary to clarify facts at issue; or CMS shows good cause for presenting oral testimony. 42 C.F.R. § 498.66(b). Petitioner waived its right to an oral hearing consistent with the requirements of 42 C.F.R. § 498.66(a). After review of the evidence and pleadings of the parties, I conclude that oral testimony is not necessary for clarification of the facts at issue. CMS has not argued that oral testimony is necessary or otherwise shown good cause to convene an oral hearing.

In accordance with 42 C.F.R. § 498.66, the record of the hearing in this case without oral testimony consists of the documentary evidence admitted and the parties' pleadings. The parties also had a reasonable opportunity for rebuttal as reflected by their various filings.

Accordingly, this decision is on the merits.

2. Petitioner violated 42 C.F.R. § 483.10(b)(1) and (6).

3. The violation of 42 C.F.R. § 483.10(b)(1) and (6) did not pose a risk for more than minimal harm.

4. Petitioner's violation of 42 C.F.R. § 483.10(b)(1) and (6) did not amount to noncompliance.

5. There is no basis for the imposition of any enforcement remedy, and the proposed DPNA is not a reasonable enforcement remedy.

The regulations provide that each long-term care resident has "a right to a dignified existence, self-determination, and communication with and access to persons and services

inside and outside the facility." 42 C.F.R. § 483.10. The regulations list specific rights that a long-term care facility, such as Petitioner, must protect and promote for each of its residents. Petitioner is required to inform each resident, orally and in writing in a language the resident can understand, of the resident's rights and all rules and regulations governing resident conduct and responsibilities. 42 C.F.R. § 483.10(b)(1). The rights of a resident not competent to exercise his or her own rights are exercised by the resident's court-ordered or the resident-designated legal representative. 42 C.F.R. § 483.10(a)(3)-(4).

The Statement of Deficiencies alleges that Petitioner failed to meet the following requirements of the regulation in addition to 42 C.F.R. § 483.10(b)(1):

> (5) The facility must—
>
> > (i) Inform each resident who is entitled to Medicaid benefits, in writing, at the time of admission to the nursing facility or, when the resident becomes eligible for Medicaid of—
> >
> > > (A) The items and services that are included in nursing facility services under the State plan and for which the resident may not be charged;
> > >
> > > (B) Those other items and services that the facility offers and for which the resident may be charged, and the amount of charges for those services; and
> >
> > (ii) Inform each resident when changes are made to the items and services specified in paragraphs (5)(i)(A) and (B) of this section.
>
> (6) The facility must inform each resident before, or at the time of admission, and periodically during the resident's stay, of services available in the facility and of charges for those services, including any charges for services not covered under Medicare or by the facility's per diem rate.
>
> (7) The facility must furnish a written description of legal rights which includes—
>
> > (i) A description of the manner of protecting personal funds, under paragraph (c) of this section;

(ii) A description of the requirements and procedures for establishing eligibility for Medicaid, including the right to request an assessment under section 1924(c) which determines the extent of a couple’s non-exempt resources at the time of institutionalization and attributes to the community spouse an equitable share of resources which cannot be considered available for payment toward the cost of the institutionalized spouse's medical care in his or her process of spending down to Medicaid eligibility levels;

(iii) A posting of names, addresses, and telephone numbers of all pertinent State client advocacy groups such as the State survey and certification agency, the State licensure office, the State ombudsman program, the protection and advocacy network, and the Medicaid fraud control unit; and

(iv) A statement that the resident may file a complaint with the State survey and certification agency concerning resident abuse, neglect, misappropriation of resident property in the facility, and non-compliance with the advance directives requirements.

(8) The facility must comply with the requirements specified in subpart I of part 489 of this chapter relating to maintaining written policies and procedures regarding advance directives. These requirements include provisions to inform and provide written information to all adult residents concerning the right to accept or refuse medical or surgical treatment and, at the individual’s option, formulate an advance directive. This includes a written description of the facility’s policies to implement advance directives and applicable State law. Facilities are permitted to contract with other entities to furnish this information but are still legally responsible for ensuring that the requirements of this section are met. If an adult individual is incapacitated at the time of admission and is unable to receive information (due to the incapacitating condition or a mental disorder) or articulate whether or not he or she has executed an advance directive, the facility may give advance directive information to the individual’s family or surrogate in the same manner that it issues other materials

> about policies and procedures to the family of the incapacitated individual or to a surrogate or other concerned persons in accordance with State law. The facility is not relieved of its obligation to provide this information to the individual once he or she is no longer incapacitated or unable to receive such information. Follow-up procedures must be in place to provide the information to the individual directly at the appropriate time.
>
> (9) The facility must inform each resident of the name, specialty, and way of contacting the physician responsible for his or her care.
>
> (10) The facility must prominently display in the facility written information, and provide to residents and applicants for admission oral and written information about how to apply for and use Medicare and Medicaid benefits, and how to receive refunds for previous payments covered by such benefits.

42 C.F.R. § 483.10(b)(5)-(10); CMS Ex. 5 at 2-4. However, the more specific allegations of the surveyors in the SOD is that Petitioner had three cognitively impaired residents, Residents 96, 97, and 98, sign a "Notice of Medicare Non-Coverage," and there was no evidence that the resident's responsible parties were given the "Notice of Medicare Non-Coverage." Therefore, the factual allegations of the surveyors relate specifically to a failure to effectively inform the three residents or their legal representatives of non-coverage by Medicare, a violation of 42 C.F.R. § 483.10(b)(1) and (6). The factual allegations in the SOD do not support violations of 42 C.F.R. § 483.10(b)(5) or (7)-(10), and CMS does not urge me to find violations of those regulatory provisions.

a. Facts

The parties stipulated that: "Residents No. 96, 97, and 98 each signed Notices of Medicare Non-Coverage. Each resident had some cognitive impairment and had a responsible party." Jt. Rpt. at 3; P. Br. at 4.

Petitioner admits by its proposed findings of fact and conclusions of law (FFCL) as follows:

> Resident 96 was assessed in March and August 2013 as severely cognitively impaired for daily decision-making. FFCL 17, 18. Resident 96 had a designated responsible party and a primary financial contact. FFCL 19. Resident 96 signed a Notice of Medicare Non-Coverage on August 28, 2013, with an effective date of

termination of August 31, 2013. FFCL 20, 21; CMS Ex. 8 at 39-41. Resident 96's responsible party was not notified of Medicare non-coverage. FFCL 23.

Resident 97 was assessed as being severely cognitively impaired with impaired ability for daily decision making in July 2013. FFCL 26, 27. Resident 97 had a responsible party who was also her primary contact for financial matters. FFCL 28. Resident 97 signed a Notice of Medicare Non-Coverage on July 23, 2013, with an effective date of termination of July 27, 2013. FFCL 29; CMS Ex. 9 at 46-48. Petitioner cannot show that Resident 97's responsible party was notified of Medicare non-coverage. FFCL 31.

Resident 98 was assessed as being severely cognitively impaired for daily decision making in September 2013. FFCL 34, 35. Resident 98 had a responsible party or individual who held a power of attorney for decision-making. FFCL 37. Resident 98 signed a Notice of Medicare Non-Coverage on July 25, 2013, with a termination effective date of August 2, 2013. FFCL 36, 38; CMS Ex. 10 at 3-5. Resident 98's responsible party was not notified of Medicare non-coverage. FFCL 40.

b. Analysis

Petitioner concedes that it violated 42 C.F.R. § 483.10(b)(6), which also amounts to a violation of 42 C.F.R. § 483.10(b)(1), by having the three cognitively impaired residents sign Notices of Medicare Non-Coverage rather than providing the notices to the residents' representatives. I conclude based on the evidence and Petitioner's concession that Petitioner violated 42 C.F.R. § 483.10(b)(1) and (6) based on the examples of Residents 96, 97, and 98.

However, the conclusion that Petitioner committed a regulatory violation, which is a deficiency, is not a sufficient basis for the imposition of an enforcement remedy. The regulatory violation or deficiency must also cause Petitioner not to be in substantial compliance with program participation requirements. 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. An enforcement remedy is authorized only when a long-term care facility is not in substantial compliance with program participation requirements due to a deficiency. 42 C.F.R. § 488.400. "*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). Noncompliance refers to any deficiency that causes a facility not to be in substantial compliance. 42 C.F.R. § 488.301. CMS or the state agency may only impose an enforcement remedy for noncompliance. 42 C.F.R. § 488.402(b). The regulations specify the enforcement remedies that CMS or the state may impose if a facility is not in

substantial compliance with Medicare requirements. 42 C.F.R. § 488.406. A DPNA, either the mandatory or discretionary DPNA, may be imposed for failure to maintain substantial compliance with program participation requirements. 42 C.F.R. § 488.417(a), (b). No enforcement remedy is authorized for a deficiency that causes no actual harm and has only the potential for minimal harm. 42 C.F.R. §§ 488.404, 488.408.

The surveyors cited the violation of 42 C.F.R. § 483.10(b) (Tag F156), at a scope and severity level of E, meaning that in the surveyors' opinion, the violation did not cause actual harm but constituted a pattern that posed a risk for more than minimal harm. CMS Ex. 5 at 2. The surveyors allege that the violation placed a total of seven residents at risk for having their rights violated by not being properly notified of Medicare non-coverage. CMS Ex. 5 at 5. However, the surveyors did not specifically describe what harm the residents would suffer if their right to notice of Medicare non-coverage was violated.

The term "harm" is not defined in the regulations. However, surveyors are instructed by CMS to determine the level of severity of deficiencies as follows:

> A. General Objective
>
> After the survey team determines that a deficiency (ies) exists, assess the effect on resident outcome (severity level) and determine the number of residents potentially or actually affected (scope level). Use the results of this assessment to determine whether or not the facility is in substantial compliance or is noncompliant. When a facility is noncompliant, consider how the deficient practice is classified according to severity and scope levels in selecting an appropriate remedy. (See §7400 for discussion of remedies.) Scope and severity determinations are also applicable to deficiencies at §483.70(a), Life Safety from Fire.
>
> B. Guidance on Severity Levels
>
> There are four severity levels. Level 1, no actual harm with potential for minimal harm; Level 2, no actual harm with potential for more than minimal harm that is not immediate jeopardy; Level 3, actual harm that is not immediate jeopardy; Level 4, immediate jeopardy to resident health or safety. These four levels are defined accordingly:

> 1. Level 1 is a deficiency that has the potential for causing no more than a minor negative impact on the resident(s).
>
> 2. Level 2 is noncompliance that results in no more than minimal physical, mental and/or psychosocial discomfort to the resident and/or has the potential (not yet realized) to compromise the resident's ability to maintain and/or reach his/her highest practicable physical, mental and/or psychosocial well-being as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services.
>
> 3. Level 3 is noncompliance that results in a negative outcome that has compromised the resident's ability to maintain and/or reach his/her highest practicable physical, mental and psychosocial well-being as defined by an accurate and comprehensive resident assessment, plan of care, and provision of services. This does not include a deficient practice that only could or has caused limited consequence to the resident.
>
> 4. Level 4 is immediate jeopardy, a situation in which immediate corrective action is necessary because the facility'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 receiving care in a facility. (See Appendix Q.)

SOM, app. P, ¶ IV (eff. Apr. 24, 2009). This CMS policy statement makes clear that whether or not there is harm is determined by whether or not a deficiency impacts a resident's mental, physical, or psychosocial well-being or a resident's ability to achieve the highest practicable mental, physical, or psychosocial well-being. The CMS policy is consistent with the Secretary's regulatory guidance that the survey process uses resident outcomes as the primary means for determining facility compliance with participation requirements with the focus upon whether or not the care provided meets the needs of individual residents. 42 C.F.R. §§ 488.26(c)(2), 488.110. Therefore, the surveyors' conclusion that seven residents may suffer a violation of their rights does not constitute harm in the sense of the regulations and CMS policy, absent some additional evidence that the rights violated have some mental, physical, or psychosocial impact upon the resident. Further, the guidance of CMS policy and regulations is that the harm must affect or potentially affect the mental, physical, or psychosocial well-being of the resident and not the resident's representative or family.

CMS argues before me that the harm that could befall residents due to the infringement of their right to proper notice of Medicare non-coverage was that "future health care decisions may be impacted by whether they [the residents] are covered by Medicare." CMS Br. at 9. CMS further asserts that Petitioner exposed its "residents to the potential for excessive financial exposure" which "had the potential to cause more than minimal harm to the affected residents' health and safety." CMS Br. at 9. CMS suggests in its reply brief that the violation of the residents' right to notice of Medicare non-coverage, by failure to deliver such notice to the impaired residents' representatives, had the potential to impact the cognitively impaired residents' psychosocial well-being; but CMS points to no specific evidence to support that assertion. CMS Reply.

In this case, there is no evidence cited by the surveyors in the SOD or CMS in its briefs, that the failure to provide a "Notice of Medicare Non-Coverage" to Residents 96, 97, and 98 in a form that they could understand or to provide such notice to the residents' representatives had any actual or potential adverse impact upon the residents' mental, physical, or psychosocial well-being or their ability to achieve the highest practicable level of mental, physical, or psychosocial well-being. Whether or not there may have been some impact upon a resident's representative is not relevant, but in this case there is no evidence of such impact or the potential for such impact.

The CMS argument regarding potential financial impact is also unsupported and inconsistent with CMS policy and the law. The SOM states that residents should be told in advance the charges for which they will be billed and that the provider is required to fully inform the resident of services and related charges. SOM, app. PP, Tag F156 (eff. Jun. 12, 2009). The regulations specifically prohibit a facility from charging a resident for: (1) any item or service covered by Medicare or Medicaid; (2) any item or service not covered by Medicare or Medicaid and not requested by the resident or the resident's representative, even if requested by a physician except as part of the resident plan of care; or (3) any item or service for which the facility has not advised the resident or the resident's representative that there will be a charge and the amount of the charge. 42 C.F.R. § 483.10(c)(8); SOM, app. PP, Tag F162 (eff. Jun. 12, 2009). Therefore, in the scenario where a facility fails to advise a resident that the service is not covered by Medicare, the facility is prohibited from charging the resident or the resident's representative for the non-covered item or service. In this case, Petitioner argues it could turn to Medicaid for reimbursement in such a circumstance. It is not necessary for me to determine whether or not Petitioner could seek reimbursement from Medicaid. The key is that Petitioner cannot seek reimbursement from a resident without a valid notice in terms the resident can understand that the care or service is not covered and that the resident or representative is liable to pay the related charge. Thus, the failure to give a valid notice of termination of Medicare coverage has no negative financial impact upon a resident, only upon the facility.

The Secretary's regulations provide further protection to residents from harm associated with non-covered long-term care costs. A long-term care facility such as Petitioner and other Medicare providers or health plans are required to give advance notice of no fewer than two days before terminating services. The CMS Form CMS-10123 titled "Notice of Medicare Non-Coverage (NOMNC)," the form at issue in this case, is the form that must be used to satisfy the notice requirement. The purpose of the notice is to advise the resident or representative that Medicare coverage will end in two days and that the beneficiary is liable for the cost of any continued services. The regulations provide that a notice is valid only when signed and dated by the resident or authorized representative and the signatory can comprehend the contents of the notice. The regulations dictate that a provider, such as Petitioner, is financially liable for any continued services after Medicare coverage lapses for at least two days after the beneficiary or the responsible party receives a valid notice of service termination. 42 C.F.R. §§ 405.1200, 422.624; CMS Ex. 12. In the case before me, there is no dispute that the notices of Medicare non-coverage delivered to Residents 96, 97, and 98 were not valid because the residents were assessed as suffering severe cognitive limitations and could not understand the notices. Therefore, under the regulations, Petitioner became liable for the costs of continued care and services after the residents' Medicare coverage lapsed. Whether or not Petitioner could seek reimbursement from Medicaid is not an issue on which I need opine. What is determinative is that the regulation ensures that Petitioner's residents and their representatives were subject to no harm due to Petitioner's failure to deliver a valid notice that the residents' Medicare coverage was about to end.

I conclude that, although Petitioner violated 42 C.F.R. § 483.10(b)(1) and (6), the violation posed no risk for more than minimal harm to Petitioner's residents. Accordingly, I conclude that the violation of 42 C.F.R. § 483.10(b)(1) and (6) did not amount to noncompliance, and there was no basis for the imposition of an enforcement remedy.

III. Conclusion

For the foregoing reasons, I conclude that Petitioner violated 42 C.F.R. § 483.10(b)(1) and (6). I conclude, however, that the regulatory violation did not pose a risk for more than minimal harm and did not amount to noncompliance. Because the regulatory violation did not amount to noncompliance, there was no basis to impose an enforcement remedy, including a discretionary DPNA, from October 19, 2013 through November 29, 2013.

/s/
Keith W. Sickendick
Administrative Law Judge