Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

The Peaks Care Center,
(CCN: 065189),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-13-67

Decision No. CR3551

Date: January 6, 2015

DECISION

Petitioner, The Peaks Care Center, did not violate 42 C.F.R. § 483.75(m)(1) as alleged by a survey of Petitioner's facility completed on June 19, 2012. There is no basis for the imposition of an enforcement remedy in this case.

I. Background

Petitioner is located in Longmont, Colorado, and participates in Medicare as a skilled nursing facility (SNF). Petitioner was subject to a survey by the Colorado Department of Public Health and Environment, Health Facilities and Emergency Medical Services Division (state agency) that concluded on June 19, 2012. The surveyors found violations of 42 C.F.R. §§ 483.25(h) and 483.75(m)(1),[1] among others that are not at issue before me. The surveyors found that the violation of 42 C.F.R. § 483.25(h) posed immediate jeopardy to a resident and the violation of 42 C.F.R. § 483.75(m)(1) posed a risk for more

---

[1] Citations are to the 2011 revision of the Code of Federal Regulations (C.F.R.), unless otherwise stated.

than minimal harm without actual harm or immediate jeopardy. Joint Stipulation of Facts (Jt. Stip.) ¶¶ 1-2.

The Centers for Medicare & Medicaid Services (CMS) notified Petitioner by letter dated July 17, 2012, that it was imposing the following enforcement remedies: a per instance civil money penalty (PICMP) of $10,000 for the violation 42 C.F.R. § 483.25(h); a discretionary denial of payment for new admissions (DPNA) effective August 1, 2012, if Petitioner did not return to substantial compliance before that date; and termination of Petitioner's provider agreement and participation in Medicare effective December 19, 2012, if Petitioner did not return to substantial compliance before that date. Petitioner was also advised that it was ineligible to be approved to conduct a nurse aide training and competency evaluation program (NATCEP) for two years. Jt. Stip.¶ 3; CMS Exhibit (CMS Ex.) 3. On September 10, 2012, CMS notified Petitioner that a revisit survey on August 27, 2012, found that Petitioner had returned to substantial compliance effective July 23, 2012; CMS rescinded the DPNA; and the termination was not effectuated. CMS Ex. 6.

Petitioner requested independent informal dispute resolution (IIDR). The state agency notified Petitioner of the CMS action on IIDR by letter dated September 28, 2012. Based on the IIDR, CMS moved allegations related to Resident 102 from the deficiency citing a violation of 42 C.F.R. § 483.25(h) (Tag F323)[2] to the deficiency cited as a violation of 42 C.F.R. § 483.75(m) (Tag F517). CMS reduced the scope and severity of the F323 deficiency to "E," which means the deficiency posed a risk for more than minimal harm that is not immediate jeopardy. CMS changed the scope and severity of the F517 deficiency to "J," which means that there was an isolated deficiency that posed immediate jeopardy. CMS Exs. 7, 8; Jt. Stip. ¶¶ 4-5. CMS notified Petitioner on October 18, 2012, that it revised its July 17, 2012 initial determination and that CMS was imposing a PICMP of $6,500 for the violation of 42 C.F.R. § 483.75(m)(1). The $10,000 PICMP based on the alleged violation of 42 C.F.R. § 483.25(h) imposed by the July 17,

---

[2] This is a "Tag" designation as used in the State Operations Manual, CMS Pub.100-07 (SOM), app. PP – Guidance to Surveyors for Long Term Care Facilities (http://www.cms.hhs.gov/Manuals/IOM/list.asp). The "Tag" refers to the specific regulatory provision allegedly violated and CMS's policy guidance to surveyors. Although the SOM does not have the force and effect of law, the provisions of the Act and regulations interpreted clearly do have such force and effect. *Ind. Dep't. of Pub. Welfare v. Sullivan*, 934 F.2d 853 (7th Cir. 1991); *Northwest Tissue Ctr. v. Shalala*, 1 F.3d 522 (7th Cir. 1993). Thus, while the Secretary may not seek to enforce the provisions of the SOM, she may seek to enforce the provisions of the Act or regulations as interpreted by the SOM.

2012 CMS notice (CMS Ex. 3) is not specifically mentioned in the October 18 notice of the revised initial determination. However, based on the context, I conclude that CMS rescinded the $10,000 PICMP it proposed based on the violation of 42 C.F.R. § 483.25(h). CMS also notified Petitioner it was ineligible to conduct a NATCEP for two years. CMS Ex. 34; Jt. Stip. ¶ 6.

Petitioner requested a hearing before an administrative law judge (ALJ) on October 19, 2012. The case was assigned to me for hearing and decision on November 2, 2012, and an Acknowledgement and Prehearing Order was issued at my direction. On August 13 and 14, 2013, a hearing was convened by video teleconference and a transcript (Tr.) of the proceedings was prepared. CMS offered CMS Exs. 1 through 42 that were admitted as evidence. Tr. 49-50. Petitioner offered Petitioner exhibits (P. Exs.) 1 through 62 that were admitted as evidence. Tr. 50-52. CMS called the following witnesses: Surveyor April Batdorf and Surveyor Matt Williams. Petitioner called the following witnesses: David W. McCarty, M.D., Petitioner's Medical Director and Resident 102's physician; Heather Stratton, Registered Nurse (RN), Director of Clinical Operations for Frontline Management which operates Petitioner; Kama Deneau, Licensed Practical Nurse (LPN), Petitioner's Assistant Director of Nursing (ADON); Karen Baugh, LPN; and Nicole Remus, LPN. The parties filed post-hearing briefs (CMS Br. and P. Br.[3]) and post-hearing reply briefs (CMS Reply and P. Reply).

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. Section 1819(h)(2) of the Act authorizes the Secretary to impose enforcement remedies against a

---

[3] Petitioner timely filed its post-hearing brief on November 14, 2013. However, on December 3, 2013, Petition filed an unopposed motion for leave to file an amended post-hearing brief that contained corrected citations to the electronic transcript. The corrected post-hearing brief is accepted. "P. Br." in this decision refers to the corrected brief.

SNF for failure to comply substantially with the federal participation requirements established by sections 1819(b), (c), and (d) of the Act.[4] The Act requires that the Secretary terminate the Medicare participation of any SNF that does not return to substantial compliance with participation requirements within six months of being found not to be in substantial compliance. Act § 1819(h)(2)(C). The Act also requires that the Secretary deny payment of Medicare benefits for any beneficiary admitted to a SNF, if the SNF fails to return to substantial compliance with program participation requirements within three months of being found not to be in substantial compliance – commonly referred to as the mandatory or statutory DPNA. Act § 1819(h)(2)(D). The Act grants the Secretary discretionary authority to terminate a noncompliant SNF's participation in Medicare, even if there has been less than 180 days of noncompliance. The Act also grants the Secretary authority to impose other enforcement remedies, including a discretionary DPNA, 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 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

---

[4] Participation of a nursing facility 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.

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). CMS is also authorized to impose a PICMP for each instance that a facility is not in substantial compliance, whether or not the deficiency poses immediate jeopardy. 42 C.F.R. § 488.430(a). The authorized range for a PICMP is $1,000 to $10,000. 42 C.F.R. § 488.438(a)(2).

Petitioner was notified in this case that it was ineligible to conduct a NATCEP for two years. CMS Ex. 3 at 3. 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. Part 483, subpart 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 skilled nursing or nursing facility 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 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. In this case, approval of a PICMP of not less than $5,000 would cause Petitioner to be ineligible to be approved to conduct a NATCEP. Conclusions that there was no noncompliance and no basis for a civil money penalty restore Petitioner's eligibility.

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), (16), (d)(10)(i). The CMS determination as to the level of noncompliance, including the finding of immediate jeopardy, "must be upheld unless it is clearly erroneous." 42 C.F.R. § 498.60(c)(2); *Woodstock Care Ctr.*, DAB No. 1726 at 9, 38 (2000), *aff'd*, 363 F.3d 583 (6th Cir. 2003). The Departmental Appeals Board (the Board) has long held that the net effect of the regulations is that a provider has no right to challenge the scope and severity level assigned to a noncompliance finding, except in the situation where that finding was the basis for an immediate jeopardy determination. *See, e.g., Ridge Terrace*, DAB No. 1834 (2002); *Koester Pavilion*, DAB No. 1750 (2000). 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 & Conv. Inn*, DAB No. 1911 (2004); *Batavia Nursing & Conv. Ctr.*, DAB No. 1904, *aff'd*, *Batavia Nursing & Conv. Ctr. v. Thompson*, 129 F. App'x 181 (6th Cir. 2005); *Emerald Oaks*, DAB No. 1800 (2001); *Cross Creek Health Care Ctr.*, DAB No. 1665 (1998); *Hillman Rehab. Ctr.*, DAB No. 1611 (1997) (remand to ALJ), DAB No. 1663 (1998) (after remand), *aff'd*, *Hillman Rehab. Ctr. v. United States*, No. 98-3789 (GEB), 1999 WL 34813783 (D.N.J. May 13, 1999). However, only when CMS makes a prima facie showing of noncompliance, is the facility burdened to show, by a preponderance of the evidence on the record as a whole, that it was in substantial compliance or had an affirmative defense. *Evergreene Nursing Care Ctr.*, DAB No. 2069 at 4 (2007).

The standard of proof, or quantum of evidence required, is a preponderance of the evidence. CMS has the burden of coming forward with the evidence and making a prima facie showing of a basis for imposing an enforcement remedy. The Board has stated that CMS must come forward with "evidence related to disputed findings that is sufficient (together with any undisputed findings and relevant legal authority) to establish a prima facie case of noncompliance with a regulatory requirement." *Evergreene Nursing Care Ctr.*, DAB No. 2069 at 7; *Batavia Nursing & Conv. 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.[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).

Only the alleged violation of 42 C.F.R. § 483.75(m)(1) (Tag F517, scope and severity level J) is in issue before me, because that is the only alleged deficiency for which CMS proposed an enforcement remedy, that is, the $6,500 PICMP.[6] Tr. 18-19; CMS Ex. 34; CMS Reply at 1. Counsel for CMS agreed at hearing that the Statement of Deficiencies (SOD) issued following the IIDR, sets forth the deficiency citation under Tag F517 that is at issue before me. CMS Ex. 8 at 94-110; Tr. 67-68.

1. CMS did not make a prima facie showing of noncompliance under Tag F517 based on a violation of 42 C.F.R. § 483.75(m)(1) that posed a risk for more than minimal harm to any resident.

At the close of the government's case-in-chief, Petitioner made a motion in the nature of a motion for judgment on partial findings under Fed. R. Civ. Pro. 52(c). Tr. 308. The motion has merit. CMS failed to make a prima facie showing of noncompliance under

---

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

[6] Whether or not Petitioner was ineligible to conduct a NATCEP for two years depends upon whether a PICMP of not less than $5,000 is ultimately approved.

Tag F517 based on a violation of 42 C.F.R. § 483.75(m)(1). CMS failed to make a prima facie showing for two reasons. CMS filed to identify a statutory, regulatory, or policy provision that Petitioner violated. CMS also failed to present sufficient evidence to support a decision in its favor, even without consideration of contrary evidence presented by Petitioner.

a. The CMS Case-In-Chief.

The revision of the SOD following IIDR (CMS Ex. 8) alleges the deficiency at issue before me, specifically the alleged noncompliance under F517 based on an alleged violation 42 C.F.R. § 423.75(m)(1). CMS Ex. 8 at 94-110; Tr. 67-68. The SOD alleges that 42 C.F.R. § 423.75(m)(1) was violated because:

> [T]he facility failed to have detailed written plans and procedures to meet all resident emergencies . . . . Specifically, the facility failed to have a sufficient plan explaining if and where emergency power could be located in the building and how resident care equipment would be powered in the event of a power outage.

CMS Ex. 8 at 94-95. The surveyors made the following specific findings, among others:

> Petitioner had no emergency power source to power suction devices in the event of a power outage.
>
> Petitioner did not develop a plan to address how residents who required suctioning could be suctioned in the event of a power outage, such as occurred for six hours in October 2011 and two hours in December 2011.
>
> One resident required "chronic suctioning due to severe dysphagia."[7]

CMS Ex. 8 at 95. The surveyors specifically cite Petitioner's "Electrical Outage" plan dated December 27, 2012, as being insufficient.[8] The surveyors stated that the electrical outage plan was insufficient because it did not specify how to "locate details about residents with special needs or who depend on electrically powered care equipment" or what was to be powered by Petitioner's backup generator. CMS Ex. 8 at 99.

---

[7] Dysphagia is difficulty swallowing. Tr. 194; P. Ex. 29.

[8] The "Electrical Outage" plan at issue was admitted as P. Ex. 13. Tr. 93.

The SOD reflects that the surveyors conducted staff interviews on June 13 and 14, 2012. Staff stated during the interviews that there was a power outage on October 12, 2011 that lasted six hours and another on December 13, 2011 that lasted two hours. The SOD also reflects that a staff member provided surveyors an undated email from the administrator to Petitioner's staff. The email mentions an 11.5 inch snowfall on October 26, 2011 that caused a power outage of 8.5 hours. During the outage according to the email, a backup generator came on but after four hours it was apparent that the backup was insufficient to keep the facility at a proper temperature. Staff was asked to write an analysis of what they did during the outage, what they thought their job was and what it should have been, and what was done well and what could have been done better. The SOD reports that the email stated that the general consensus was staff did an excellent job; maintenance was advocating for a larger generator; and it was suggested that Petitioner have more defined description of staff jobs in the event of a disaster or drill, including during an electrical outage. The SOD reports that the email stated that the Administrator decided to prepare a roster of resident special needs early during a power outage or other emergency; to ensure that staff was aware of policy and procedures for a power outage; and to ensure that staff and managers have specific jobs assigned. CMS Ex. 8 at 100-01; CMS Ex. 27 at 3-4; Tr. 97.

The SOD reports that an electrically powered suction device was observed in the room of Resident 102, and three others were observed by the surveyors near dining rooms. CMS Ex. 8 at 104; Tr. 86-87.

The SOD reports that the environmental director (ED) was interviewed and toured the facility with a surveyor on June 13, 2012. The ED was asked whether there was an emergency power system. The ED stated that exit lights were powered by batteries; residents on oxygen concentrators were moved to portable tanks during a power outage; when asked how resident care equipment such as air mattresses or suction devices were powered he responded that there was a mini generator; he also stated that the mini generator powered some rooms in the assisted living area and some offices; he could not identify any outlets that were powered by an emergency generator and told the surveyors that none of the outlets in the long-term care area received power from a generator. CMS Ex. 8 at 104.

The SOD reports that on June 13, 2012, a LPN told surveyors that there were no emergency outlets on the wing where Resident 102 lived; and if suctioning was required during a power outage she stated that within minutes she could take the resident to the Frontier unit where there were emergency outlets though she was uncertain where the outlets were located in the other unit. CMS Ex. 8 at 105. A LPN interviewed on June 14, 2012 also told surveyors that she believed that there were emergency power outlets on the Frontier unit because she was able to make coffee there during a power outage. CMS Ex. 8 at 109. Interviews with a RN and a certified nurse assistant (CNA) on the Frontier unit

revealed that they were unaware of any emergency outlets on that unit. CMS Ex. 8 at 105, 108-09.

The SOD states that the clinical coordinator stated that there was a six-hour power outage on October 12, 2011, and a two-hour outage on December 13, 2011. CMS Ex. Ex. 8 at 105. The SOD reports that the Administrator told surveyors that in the event of a power outage a generator could be obtained from the store. She told surveyors that there was no plan to power suction devices in the event of a power outage. She also told surveyors that she had ordered three battery powered suction devices after the ED told her about the concern about lack of emergency power. CMS Ex. 8 at 105-06.

The surveyors list seven residents as being at risk for choking, Residents 102, 179, 68, 89, 119, 116, and 39. The surveyors allege in the SOD that six had potential trouble swallowing but do not allege that any had a history of or orders for suctioning. Resident 102 had a history of needing suctioning. CMS Ex. 8 at 106-08; Tr. 191, 194.

The SOD summarizes an interview of the Administrator on June 14, 2012. The Administrator told surveyors that an emergency generator supplied power to six hot water storage tanks and the radiant heating system only. The Administrator told surveyors that the "Electrical Outage" policy could be written more specifically. CMS Ex. 8 at 109-10.

CMS presented the testimony of two surveyors: Surveyor April Batdorf and Surveyor Matt Williams. Surveyor Batdorf, testified that she has a bachelor of science degree in gerontology, with prior work experience as a CNA, an activities coordinator, and a long-term care case manager. Tr. 82. She participated as part of a four-person team, in the survey of Petitioner that began on June 6, 2012. She did the environmental tour on June 13, 2012. Tr. 83. Surveyor Batdorf explained that she did the environmental tour with the ED. She testified that as part of the environmental tour surveyors ask about emergency power systems. She testified that the ED told her he believed that there was a mini generator in the building that he believed powered the front offices and the assisted living facility. The ED told her that there was no emergency power in the long-term care facility and he could not identify outlets in the front offices or the assisted living facility that could provide emergency power. Tr. 84-85. Surveyor Batdorf identified her notes from the survey that were admitted as CMS Ex. 29. When asked if she could recall exactly her discussion with the ED, she testified that she asked if there was an emergency power system in place in case of a power outage, the ED responded that there was a mini generator, and her impression was that the ED thought it provided electrical power for the building. Tr. 86. Surveyor Batdorf's testimony is not as detailed as her notes, which state:

> The environmental director (ED) was asked if there was an emergency power system in place in the event of a power outage. The ED stated that the exit lights were illuminated as

> they ran off of batteries. The ED stated residents on oxygen concentrators were moved to portable tanks. When asked how other resident care equipment, such as, air mattresses or suction devices were powered in the event of a power outage, the ED said the building had a "mini generator." When asked what the mini generator powered, the ED stated the generator powered some rooms in the assisted living section of the building and some of the front offices. The ED was unable to identify what outlets specifically received power from the emergency generator.

CMS Ex. 29 at 3. She testified that she noted a suction machine in Resident 102's room on June 13, 2012, with some substance in it, which caused her to believe that he needed suctioning. She became concerned because it occurred to her that there was no way to power the suction device in the event of a power outage. She testified that the ED told her that air mattresses and suction machines could not be powered during an electrical outage, which is incorrect as her notes show that the ED told her there was a mini generator that could be used for that purpose. She testified that the Administrator told her that Petitioner would need to purchase a generator. She testified that the Administrator told her that the ED mentioned the environmental tour and it was then that the Administrator realized they could not power the suction devices. The Administrator told her that Petitioner had a plan for power outages but it did not address suction machines. The Administrator told her that Petitioner was going to purchase four battery powered suction machines. Tr. 88-89. According to Surveyor Batdorf's notes, the Administrator also ordered three battery backups within minutes of learning of the surveyor's concern from the ED. CMS Ex. 29 at 4. Surveyor Batdorf testified that the ED did locate a battery pack in the Administrator's office but it was not charged and ready. Tr. 91. Surveyor Batdorf testified that, at about 10:00 p.m. on June 13, 2012, the day of the environmental tour (Tr. at 87), she was told that Petitioner would use its mini generator to power a suction machine. Actually, her notes show that the ED told her that the mini generator could be used during the environmental tour earlier in the day. CMS Ex. 29 at 3. She was shown the generator about 10:00 p.m. and shown that the gasoline-powered portable generator worked. The generator was started and demonstrated by powering an electric fan. Tr. 92, 149-50, 158. In response to my questions, Surveyor Batdorf agreed that she cited Petitioner because if the electricity was off the electrically operated suction machines she observed could not be used and she did not consider whether a bulb syringe could have been used as an alternative because there was no mention of a bulb syringe during the survey. Tr. 129-30. In response to my questions, Surveyor Batdorf testified that if the ED had told her when she first asked that there was a portable or "mini generator" that could be used when the electricity was off, she would not have cited the facility. She would also not have cited the facility if she had been told that in the event of a power outage suction bulbs would be used rather than suction machines. Tr. 152, 184. Surveyor Batdorf testified that Petitioner was not required to have emergency power

because it has no residents that require life support systems. Tr. 162. Surveyor Batdorf testified that Petitioner was cited because the only plan was to suction Resident 102 using an electrically powered suction device, not because Petitioner did not have emergency power. Tr. 162-63. Surveyor Batdorf agreed on cross-examination that she is not a licensed health professional and she never dealt with suctioning. Tr. 165-66. She testified that while doing her environmental tour she did not check to see if there were bulb syringes on the crash carts. Tr. 182. Surveyor Batdorf testified on cross-examination that she did not conclude that Resident 102 required suction machine as a life support system and she admitted that she found no physician order for suctioning of Resident 102. Tr. 203-04.

Surveyor Matt Williams testified that he has a bachelor of science degree in biology, a master's degree, and doctorate in chiropractic. He taught anatomy, physiology, and medical terminology at Front Range University. He was Division Chair of Clinical Sciences at Life University, and taught neuromusculoskeletal diagnosis. He participated in the survey of Petitioner that ended on June 19, 2012. Tr. 219. He testified that during the initial walk-through of the facility, the surveyors looked for red power outlets, which are outlets that are powered by a backup generator, but they observed none. He testified that Petitioner did not have a backup generator but there was a small "mini generator" in the courtyard. He testified that the mini generator was demonstrated and that it took four to six pulls of the starter rope to start, which he characterized as difficult to start. He opined that the Petitioner's electrical outage plan (P. Ex. 13) did not mention the use of a mini generator and that the backup generator referred to in the plan was not the mini generator that required manual starting. He opined that if the mini generator was intended to be used, there should have been starting instructions in the electrical outage plan. Surveyor Williams did not state the bases for his opinions. Surveyor Williams conceded that he did not simply ask the nurse he interviewed what she would do in the case of an electrical outage. He asked about the call-light system but not about the use of suction machines. When he interviewed a CNA he asked what she would do in the event of a power outage and she told him that she would put residents on oxygen on portable tanks and would conduct emergency checks. Just as the nurse interviewed earlier, the CNA was not aware that there were no emergency power outlets, according to Surveyor Williams. He conceded that he never asked the CNA or the RN if they knew whether there would be electrical power during an outage. Tr. 220-35. Referring to Petitioner's "Electrical Outage" plan, specifically paragraph 10 (P. Ex. 13) he opined that the reference to a backup generator could not be to the mini generator, but he admitted he never asked anyone about what the reference to a backup generator meant. Tr. 238. On-cross examination he stated that he had surveyed Petitioner many times and was probably aware that there were no red outlets in the facility. Tr. 239-41. He agreed that given the configuration of the facility, the mini generator in the central courtyard could be used to power electrical equipment in the facility. Tr. 241, 246. He agreed on cross-examination that he had no training related to suctioning as a surveyor and he has never observed suctioning. Tr. 251-53.

CMS also offered as evidence a copy of 6 Colo. Code Regs. § 1011-1 (2011) establishing standards for hospitals and health facilities. Chap. 5, pt. 18, para. 18.5 of 6 Colo. Code Regs. § 1011-1 establishes requirements for emergency equipment and supplies, stating:

> The following shall be readily available at all times:
> 1) Oxygen; 2) Suction; 3) Portable emergency equipment, supplies and medications; and in nursing care facilities
> 4) Compatible supplies and equipment for immediate intravenous therapy to be administered only in accordance with applicable Colorado laws.

The regulation does not specify whether suction needs to be by electric pump, vacuum pump, gas pump, or manual. The regulation also does not require backup generators, batteries, or other sources of electrical energy in the event of a power outage.

b. Analysis

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." *Evergreene Nursing Care Ctr.*, DAB No. 2069 at 7; *Batavia Nursing & Conv. 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). The elements of a CMS prima facie showing, as identified by the Board in *Hillman*, require CMS to: (1) identify the statute, regulation or other legal criteria to which CMS seeks to hold Petitioner; (2) come forward with evidence upon which it relies for its factual findings that are disputed by Petitioner; and (3) show how the deficiency it found amounts to noncompliance that warrants an enforcement remedy, that is, that there was a risk for more than minimal harm due to the regulatory violation. *Hillman Rehab. Ctr.*, DAB No. 1611 at 8. Only if CMS makes a prima facie showing is the burden upon Petitioner to meet 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 pertinent period. *Evergreene Nursing Care Ctr.*, DAB No. 2069 at 7.

Petitioner preserved its argument that CMS failed to make the required prima facie showing by moving for a judgment on partial findings at the conclusion of the CMS case-in-chief. *See Jennifer Matthew Nursing & Rehab. Ctr.*, DAB No. 2192 at 20 n.12; *Hillman Rehab. Ctr.*, DAB No. 1663 at 9-10. Pursuant to 5 U.S.C. § 557(c) a decision may not issue in these cases until the parties have been given a reasonable opportunity to submit proposed findings and conclusions with supporting reasons after the taking of the evidence. Therefore, a decision disposing of the case could not be made upon the motion until such time as the parties had completed their post-hearing briefing. Bifurcating the

proceeding by stopping the hearing to permit briefing and decision on the motion, with a subsequent proceeding to hear Petitioner's case-in-chief in the event of an unfavorable ruling on the motion, is inconsistent with notions of judicial economy and would cause substantial delay. CMS should not be relieved of its initial burden to come forward and make a prima facie showing of noncompliance when, as here, Petitioner elects to present its case-in-chief following preserving by a proper motion the issue of the sufficiency of the CMS prima facie showing. The requirement for CMS to make a prima facie showing is important to the integrity of the adjudication process. The district court stated when affirming the Board's *Hillman* decision following the remand:

> HCFA [now known as CMS] had the initial burden of production of demonstrating noncompliance with any applicable condition of participation. If such a showing can be made, then termination cannot be based on improper motives. It is only then that the provider must affirmatively demonstrate compliance. Therefore, it is not the shifting of the burden of proof during the ALJ hearing – after the termination has been effectuated – which could potentially allow the HCFA to terminate participation on the basis of "innuendo, suspicion and prejudice" due process concerns are not implicated.

Hillman, No. 98-3789 (GEB) at 20. Furthermore, Petitioner should not be required to waive its right to present its case-in-chief in order to preserve a challenge to the sufficiency of the CMS prima facie case.

The Secretary's regulations give Petitioner notice of the criteria Petitioner must meet to comply with the program participation requirement established by the Act and regulations. Each federal agency is required to make available to the public through publication in the Federal Register, substantive rules of general applicability and statements of general policy. Unless it can be shown that a person had actual and timely notice of the terms of the substantive rules and policies, the person may not be required to comply with or be adversely affected by a regulation or policy not properly published in the Federal Register or properly incorporated in the Federal Register by reference. 5 U.S.C. §§ 551(4), 552(a)(1). CMS is required as part of its prima facie case to identify a participation requirement established by the Act; the Secretary's regulations or published policy; or other requirement of which Petitioner had actual knowledge, which Petitioner violated. CMS has failed to make the required showing in this case.

The Secretary promulgated a specific regulation establishing requirements for the administration of long-term care facilities. The general rule is that:

> A facility must be administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.

42 C.F.R. § 483.75. Following the IIDR action in this case, CMS alleges that Petitioner was noncompliant with the participation requirement under Tag F517 based on a violation of 42 C.F.R. § 483.75(m)(1), which provides:

> (m) *Disaster and emergency preparedness.* (1) The facility must have detailed written plans and procedures to meet all potential emergencies and disasters, such as fire, severe weather, and missing residents.

CMS has failed to make a prima facie showing of noncompliance under Tag F517 based on a violation of 42 C.F.R. § 483.75(m)(1) that posed a risk for more than minimal harm to any resident because:

> CMS has identified no statute, regulation, or policy that required that Petitioner have a backup generator to power resident care equipment such as suction machines or air mattresses;
>
> Petitioner's electrical outage plan specified that a backup generator would be used and the CMS evidence shows that surveyors were shown a backup generator and the generator was demonstrated for the surveyors;
>
> The CMS evidence shows that when staff was asked about what would be done in the case of an electrical outage, staff responses were consistent with Petitioner's electrical outage policy; and
>
> CMS presented no competent evidence that there was a risk for more than minimal harm to any resident.

The SOD alleges that Petitioner violated 42 C.F.R. § 483.75(m)(1) because Petitioner did not have detailed written plans and procedures addressing all resident emergencies. The SOD specifies that Petitioner did not have a plan explaining the availability of emergency electrical power in a power outage or how resident care equipment that required electricity could be powered in the event of an outage. The SOD alleges even more specifically that Petitioner had no emergency power source to power suction devices in the event of a power outage; and no plan for how to suction residents who required suction in the case of a power outage. CMS Ex. 8 at 94-95. The SOD also alleges that Petitioner's "Electrical Outage" plan was insufficient because it did not provide for identification of residents who had care equipment that required backup power or specify

what equipment would be powered by Petitioner's backup generator. CMS Ex. 8 at 98-99.

Counsel for CMS argued in opening statement that Petitioner had four suction machines in the facility, but Petitioner's "Electrical Outage" plan did not provide for how electrically powered equipment could be operated during a power outage or how residents could be suctioned in the event of a power outage. Tr. 57-60.

The Secretary has established separate requirements related to the physical environment of long-term care facilities under 42 C.F.R. § 483.70, which provides:

> The facility must be designed, constructed, equipped, and maintained to protect the health and safety of residents, personnel and the public.

The only regulation of the Secretary that specifically requires emergency power is 42 C.F.R. § 483.70(b), which provides:

> (b) *Emergency power.* (1) An emergency electrical power system must supply power adequate at least for lighting all entrances and exits; equipment to maintain the fire detection, alarm, and extinguishing systems; and life support systems in the event the normal electrical supply is interrupted.
>
> (2) When life support systems are used, the facility must provide emergency electrical power with an emergency generator (as defined in NFPA 99, Health Care Facilities) that is located on the premises.

Counsel for CMS stated at hearing that there is no alleged violation of 42 C.F.R. § 483.70(b) or noncompliance under the related Tag F455 in this case. Tr. 64. There is no dispute that Petitioner met the requirements of 42 C.F.R. § 483.70(b)(1). There is no dispute that Petitioner did not admit residents who required life support systems and no resident required the use of suction as a life support measure. There is no dispute by CMS that Petitioner was not required to have an emergency generator to provide emergency power for suction machines or any other resident equipment in the event of a power outage. CMS Br. at 3. I explained to counsel for CMS my observation that 42 C.F.R. § 483.75(m)(1) includes no requirement for a facility to have backup power to operate electrical equipment. Counsel for CMS argued that 42 C.F.R. § 483.75(m)(1) requires detailed written plans to address all potential emergencies; Petitioner had identified electrical outages as a potential emergency; Petitioner adopted an "Electrical Outage" plan; the "Electrical Outage" plan specified that a backup generator would be used but Petitioner had no backup generator that provided powered electrical outlets in

the facility; and staff was unaware of the availability of backup power to operate suction and other electrical equipment. Counsel for CMS conceded that there is no requirement under 42 C.F.R. § 483.75(m)(1) that Petitioner have an emergency generator but asserted that Petitioner had to have some alternative for powering electrically powered equipment such as battery packs. Counsel for CMS also asserted that Petitioner's plan needed to be correct. Tr. 63-77.

Surveyor Batdorf admitted in response to my questions that she cited Petitioner for noncompliance with Tag F517 because she concluded that Resident 102 required suction and if the power was out the suction machines she observed could not be used. Tr. 129-30. She testified that Petitioner was not required to have emergency power because it had no residents who required life support systems. However, she cited Petitioner because she concluded that the only plan for suctioning Resident 102 was using an electrically powered suction machine and Petitioner's plan did not address how to power that machine during a power outage. Tr. 162-63, 203-04. In response to my questions, Surveyor Batdorf testified that if the ED had told her when she first asked that there was a portable or mini generator that could be used when the electricity was off, she would not have cited the facility. She would also not have cited the facility if she had been told that in the event of a power outage, suction bulbs would be used rather than suction machines. Tr. 152, 184. Surveyor Batdorf testified that Petitioner was not required to have emergency power because it has no residents that require life support systems. Tr. 162. Surveyor Batdorf testified that Petitioner was cited because the only plan was to suction Resident 102 using an electrically powered suction device, not because Petitioner did not have emergency power. Tr. 162-63.

In post-hearing briefing, CMS admits that Petitioner is not required to have an emergency generator to provide power for suction machines during a power outage. CMS argues that the issue of backup power only became an issue because Petitioner's electrical outage plan stated that Petitioner had a backup generator. CMS states that had Petitioner's electrical outage plan simply stated that during a power outage there would be no backup power, the absence of an emergency generator would not have been an issue. CMS asserts that Petitioner was required to have a backup generator solely because its written emergency plan said it had one and not because the regulation required a generator. CMS further asserts in post-hearing briefing that Petitioner's electrical outage plan and procedures did not provide sufficient detail to ensure residents would not be harmed during a power outage. CMS Br. at 3-4, 21. CMS states in post-hearing briefing that if the mini generator had been mentioned in Petitioner's electrical outage plan the regulatory requirements may have been met. CMS Reply at 14. In fact, Petitioner's electrical outage plan did mention the use of the backup generator and the surveyors simply assumed that was a different type of generator than the small generator located in the courtyard, that used gasoline, and had a rope starter that was demonstrated for the surveyors.

The CMS theory in this case has become sharply focused. Based on her testimony and the language she chose in drafting Tag F517 of the SOD, Surveyor Batdorf clearly cited Petitioner because she was concerned that Resident 102 required suction and there was no plan to power his suction machine during a power outage. Surveyor Batdorf originally cited Petitioner related to suction under both Tag F323 and Tag F517 (CMS Ex. 2 at 55, 59-69, 118-23) but the example was removed from Tag F323 by the IIDR. The CMS argument at this point in the proceedings is not that Petitioner was required by regulation to have a generator but, because the generator was part of Petitioner's electrical outage plan. CMS has conceded that there was no regulation applicable to Petitioner that required that Petitioner maintain a source of emergency electrical power, because Petitioner did not accept residents who required life support services. There is no dispute that the electrical suction pumps observed in Petitioner's facility were not required for life support. Therefore, the absence of a source of emergency electrical power was not noncompliance by Petitioner and CMS could not make a prima facie showing of noncompliance on that basis.

The parties have not questioned that an electrical outage qualifies as an emergency within the meaning of 42 C.F.R. § 483.75(m)(1). There is also no question that Petitioner had adopted an "Electrical Outage" plan which was modified following electrical outages in late 2011. CMS Ex. 27 at 5. The plan required that in the event of an electrical outage the supervisor in the building was to contact the maintenance director, the administrator and director of nursing, and the fire department, if necessary. The plan provided for the supervisor on site to make additional calls to the city and electric company at the request of the maintenance director. The plan required the administrator or his designee to contact the state agency. The plan provided that: emergency lights on an alternative power supply would activate in hallways; staff were to move residents on oxygen concentrators to portable oxygen tanks; flashlights were located at each nurse's station and the administrative office; staff was to be assigned to do 15-minute walking rounds if the power outage lasted more than 10 minutes; a backup generator would be used; if room temperatures fell to a certain temperature residents were to be moved to areas that still had heat and if the entire facility fell below a certain temperature all residents were to be evacuated. CMS Ex. 27 at 5. The CMS argument post-hearing is that Petitioner referred to the use of a backup generator in its plan, and for that reason Petitioner had to have a backup generator to satisfy the participation requirement of 42 C.F.R. § 483.75(m)(1) even though no regulation otherwise required that Petitioner have a generator.

The surveyors and CMS apparently assumed that the backup generator referred to in Petitioner's plan to be of the type that would provide power to red electrical outlets throughout Petitioner's facility, such as would be required in hospitals or facilities with life support systems. Surveyors Batdorf and Williams did not explain why they made that assumption. Surveyor Williams testified that during the initial walk-through of the facility on June 12, 2012, the surveyors were specifically looking for red power outlets

which might be powered by a generator in the event of an emergency, but they observed none. Tr. 221. The initial walk-through by the surveyors and their search for red outlets occurred the day before Surveyor Batdorf's environmental tour with the ED. Tr. 83. During the environmental tour that Surveyor Batdorf took with the ED, there is no dispute by CMS that the ED told her that there was a mini generator in response to her question about how air mattresses or suction devices could be powered in the event of a power outage. CMS Ex. 29 at 3. Surveyor Batdorf's notes show that she asked the ED questions about what the mini generator powered and which outlets specifically received power, based on her assumption that the generator to which he referred was a generator of the type that was wired into the facility electrical system. Surveyor Batdorf's notes record that the ED gave confusing responses, no doubt provoked by the surveyor's confusing questions that were based on a faulty assumption about the type of generator referred to in Petitioner's electrical outage plan. The fallacy of the assumption that the electrical outage plan referred to some large generator connected to the facility wiring, should have been revealed when later the same day, Surveyors Batdorf and Williams were shown the mini generator and given a demonstration that it worked. Tr. 92, 149-50, 158, 222-23. The surveyors did not testify to seeing any other generator nor, apparently, did they ask to look at any other generators that may or may not have been present.

I conclude that CMS has failed to make a prima facie showing that Petitioner violated 42 C.F.R. § 483.75(m)(1). The regulation does not require that Petitioner have a generator, battery, or any other source of electrical power to run suction pumps, air mattresses, or any other patient care and comfort items during an electrical outage. The CMS argument that because Petitioner's plan required a backup generator, Petitioner had to have a backup generator to satisfy 42 C.F.R. § 483.75(m)(1) is meritorious to the extent that a facility's emergency plans must be executable to be considered a plan that satisfies 42 C.F.R. § 483.75(m)(1). However, the argument is without merit to the extent that the CMS argument assumes that the reference to a backup generator in Petitioner's policy (CMS Ex. 27 at 5, ¶ 182) meant any generator other than that shown to the surveyors. In fact, Petitioner had a mini generator and it worked. Accordingly, CMS has failed to make a prima facie showing as it failed to establish any legal requirement for Petitioner to have a backup generator other than the one it had. CMS also failed to make a prima facie showing because the evidence CMS presented shows that Petitioner had a plan to address the emergency of an electrical outage, Petitioner had the backup generator required by its plan that could be used to power suction or air mattresses, or other electrical equipment, and the plan is not otherwise alleged by CMS to be defective.

I further conclude that CMS has failed to show as part of its prima facie case that there was any risk for more than minimal harm due the alleged violation of 42 C.F.R. § 483.75(m)(1). The evidence shows that there were two power outages that affected Petitioner in late 2011. The record reflects no negative outcomes from those outages. Following those outages, Petitioner's administrator solicited input from staff and Petitioner's electrical outage plan was modified and reissued and staff was trained in

January 2012. CMS Ex. 27. The testimony of the surveyors and Surveyor Batdorf's notes show that the ED and some of the health care professional staff seemed to be confused about the plan in the case of an electrical outage. However, given the ED's responses to Surveyor Batdorf as reflected in her notes and the responses of staff as reflected in the SOD, staff was not confused about what they were supposed to do, they were confused by the questions asked by the surveyors. According to Surveyor Batdorf's notes, when she asked the ED "if there was an emergency power system in place in the event of a power outage" he responded that the exit lights were powered by batteries, residents on oxygen concentrators were put on portable tanks, and electric resident care equipment such as air mattresses and suction equipment could be powered by a mini generator. The ED's responses were consistent with Petitioner's electrical outage plan. The ED's responses became confused when he was asked what the mini generator powered and which outlets. CMS Ex. 29 at 3. The health care professionals interviewed also gave detailed responses consistent with Petitioner's policy, except their response became confused or confusing when they were asked where outlets with emergency power were located. CMS Ex. 8 at 109. Of course, there was no emergency generator wired into Petitioner's electrical system and staff would have been aware of that based on the outages in the fall of 2011. The revised electrical outage plan from December 2011 mentioned nothing about the red outlets about which the surveyors were asking and because they did not exist in Petitioner's facility, no mention of red outlets would have been made in staff training in January 2012. However, staff was confronted with surveyors demanding to know where the red outlets were. I attribute staff's confused responses to the surveyors' questioning. Surveyor Williams admitted that he did not ask direct questions. Tr. 228-30. Surveyor Batdorf's notes also reflect that she was not asking direct questions. CMS Ex. 8. The surveyors were generally not asking simple and direct questions such as:

> What do you do when the power goes off?
>
> How do you suction a resident when the power goes off?
>
> What do you do when the call lights won't work?
>
> What do you do when the oxygen concentrators won't work?

As a result, the surveyors received confusing responses that do nothing to make the CMS prima facie showing. In fact, despite the confusing questions of the surveyors about red outlets, staff interviews show that the staff had knowledge of the electrical outage plan and how to respond to an electrical outage. The fact that staff knew how to react to an electrical outage is inconsistent with the conclusion of the surveyors that there was a risk for more than minimal harm based on a defective policy statement, which was not defective at all.

Furthermore, Surveyor Batdorf, who wrote Tag F517, was not a licensed medical professional and she had no experience with suctioning. Tr. 82, 133-34, 165-66. Surveyor Williams was a doctor of chiropractic but he had no training related to suctioning and had never observed suctioning. Tr. 219. There is no evidence that the RN who participated in the survey or other member of the surveyor team qualified to render medical opinions made the determination that there was a risk for more than minimal harm. Accordingly, CMS has failed to show that the alleged noncompliance under Tag F517 posed a risk for more than minimal harm to any resident.

I conclude CMS failed to make a prima facie showing of noncompliance under Tag F517 based on a violation of 42 C.F.R. § 483.75(m)(1).

2. Petitioner did not violate 42 C.F.R. § 483.75(m)(1) (Tag F517).

3. There is no basis for the imposition of an enforcement remedy.

If I concluded that CMS made a prima facie showing of noncompliance under Tag F517 based on a violation of 42 C.F.R. § 483.75(m)(1); I would conclude after consideration of Petitioner's evidence that there was no regulatory violation.

a. Facts

Resident 102 was the resident who received the most attention from the surveyors and is discussed in greatest detail in the SOD under Tag F517. CMS Ex. 8 at 101-04. Resident 102 was assessed upon readmission to Petitioner on February 14, 2012 and again during his assessment that ended on May 28, 2012, as having difficulty swallowing. P. Ex. 20 at 29; CMS Ex. 13 at 1. He was assessed on May 28, 2012, as being totally dependent on staff for eating and drinking and required the physical assistance of one staff member. P. Ex. 20 at 21-22. Resident 102 suffered from non-Alzheimer's dementia and Parkinson's disease. P. Ex. 20 at 28-29. He had a history of increased oral secretions for which he was treated with both scopolamine and atropine at various times from December 2011 through June 2012. P. Exs. 24, 46.

A physician assessment dated December 20, 2011, indicates that Resident 102 was at risk for aspiration and he was on a pureed and thickened diet. Speech and swallow therapy had recommended tube feeding but that was not accepted. The physician's assessment states that he would reevaluate tube feeding and he "[o]rdered suction for now." P. Ex. 46 at 1; Tr. 359. The physician ordered suction as needed on December 22, 2011, and he ordered a scopolamine patch for excess secretions on December 28, 2011. P. Ex. 22 at 1-2. The scopolamine patch was order again on February 27, 2012 and March 14, 2012; atropine sulfate for increased secretions was ordered on March 24, 2012; and the scopolamine patch was ordered again on March 31, 2012. P. Ex. 22 at 3-6.

A nurse practitioner's note for a visit on December 28, 2011, reflects that Resident 102 had a fracture of the cervical spine (neck) and he was wearing a neck brace. Orders on December 28, 2011, include evaluation and treatment by speech therapy, but no reference to suctioning. P. Ex. 46 at 2-4. Hospital discharge orders dated February 14, 2012 do not mention suctioning. A nurse practitioner's note for a visit on February 15, 2012, shows that Resident 102 had been readmitted to Petitioner; he continued to wear a neck brace due to the cervical fracture; evaluation and treatment by speech therapy was to continue; and there was no reference to the use of suction. P. Ex. 46 at 5-7. A nurse practitioner's note for a visit on February 20, 2012, shows Resident 102 had new complaint of arm pain. The note also indicates that the nurse practitioner discussed Resident 102's dysphagia with his speech therapist and that his dysphagia might improve by removing the neck brace during eating. The order for pudding thick foods and drinks with assistance was continued but there was no order regarding suction. P. Ex. 46 at 8-9. On February 27, 2012, Resident 102 was seen by the nurse practitioner for increased oral secretions, acute cough, and dysphagia. The history and assessment attribute his dysphagia to an old stroke. Orders were issued for a CT scan of Resident 102's neck to evaluate for stability and ability to eat without the neck brace to decrease problems with aspiration. No order for suctioning is mentioned. P. Ex. 46 at 10-11. A physician's note dated March 14, 2012, reflects that: Resident 102 had recently been hospitalized due to an acute decline in his condition; his insurer refused to cover his scopolamine ear patch and the physician elected to monitor; his medications were continued; and there was no mention of suctioning. P. Ex. 46 at 13. The nurse practitioner saw Resident 102 on May 30, 2012. The nurse practitioner notes indicate that Resident 102 was again on scopolamine and he was also prescribed atropine sulfate; his dysphasia was characterized as stable and would continue to be monitored; and he would continue to wear the hard neck brace. There was no mention of suctioning. P. Ex. 46 at 14-15. Nurse practitioner notes from June 6, 2012, reflect that Resident 102's wife and Petitioner's charge nurse requested that he be evaluated for continuing need for the neck brace. Medications ordered included scopolamine and atropine. The determination was to continue the neck brace with a possible follow-up with an orthopedist and family. There is no mention of any need for suction. P. Ex. 46 at 16-18.

Resident 102's care plan dated June 14, 2012, states that he was at "Respiratory Risk" related to suctioning and pulse oximetry. The care plans placed in evidence did not require suctioning as an intervention. P. Ex. 21; CMS Ex. 14. According to RN Stratton, the reference to suctioning was added based on surveyor comments. Tr. 456-60. She further testified that if there was a physician order for suctioning, there should have been a suctioning care plan. Tr. 477.

A nurse's note entry on March 14, 2012, at 10:05 a.m., states that Resident 102's scopolamine patch was discontinued because insurance refused to pay. P. Ex. 25 at 1; P. Ex. 48 at 15; CMS Ex. 16 at 6. A nurse's note entry on March 23, 2012, at 6:00 a.m., shows that Resident 102 was suctioned six times during the night shift for increased

secretions. The note shows that the physician was notified and an order for atropine was issued. A nurse's note at 5:00 p.m. on March 24, 2012, shows that the resident was suctioned five times due to increased secretions. P. Ex. 25 at 1; P. Ex. 48 at 15; CMS Ex. 16 at 6. The resident was suctioned again on March 27, 2012, after his wife gave him thin liquid which caused coughing. P. Ex. 25 at 2; P. Ex. 48 at 16. A nurse's note on March 31, 2012, at 10:30 a.m., shows that scopolamine was restarted. P. Ex. 25 at 2; P. Ex. 48 at 16; CMS Ex. 16 at 7. The evidence shows that Resident 102 had an order dated December 22, 2011 for suction as necessary to remove secretions. P. Ex. 22 at 1. There is no evidence before me that shows that Resident 102 required suctioning between December 22, 2011 and March 22, 2012, or after March 27, 2012 through the date of the survey. There is no evidence that a new physician order for suctioning was issued after Resident 102's readmission to Petitioner in February 2012. There is no care plan for suctioning of Resident 102 or management of his oral secretions in evidence. Petitioner was not cited for failure to care plan for Resident 102. CMS Ex. 8 at 15.

Dr. McCarty is Petitioner's Medical Director and Resident 102's treating physician with a specialty in geriatric medicine. Tr. 333-34. Dr. McCarty testified that the suction ordered in December 2011 would have been for oral suctioning. A resident that required nasopharyngeal suctioning would not have been an appropriate resident for Petitioner. Tr. 338-39. He testified that his recollection was that there was no order for suctioning after Resident 102 returned to Petitioner from the hospital on February 14, 2012. Tr. 341, 370-71. Dr. McCarty testified that oral and nasal secretions pool and cause coughing and that suctioning the pharyngeal area removes secretions and is part of normal nursing protocol and did not require a physician's order. Tr. 342. He testified that suctioning does not maintain an open airway and would do nothing for esophageal or tracheal obstruction and is not used to treat choking. Tr. 343-45. The standard of care requires the Heimlich maneuver to treat choking. Tr. 345. He testified that it is common to prescribe scopolamine or atropine to help dry a resident's mouth for patient comfort and as a dignity measure to limit drooling. Tr. 350. He testified that if there is food or saliva pooled at the back of the throat that had to be removed and it would take time to get the suction off the crash cart, the resident would be positioned head down and a finger swipe or cloth would be used to clear the mouth followed by suction when it arrived. But suctioning would not be used to clear the trachea or the esophagus. Tr. 364-65. Dr. McCarty described how a resident with excess secretions might be treated during a power outage using a finger swipe, washcloth, and a suction bulb. Tr. 393-95. Dr. McCarty testified that nasotracheal suctioning is performed through a resident's nose. He also explained that for a resident who was choking, nasotracheal suctioning might be used in the hospital or by an ambulance crew but not in a nursing home. Tr. 398-99.
Dr. McCarty testified that Resident 102 was able to cough to clear his airway and did not, in his opinion, require suctioning. Tr. 400. Dr. McCarty reviewed the notes from a nurse practitioner visit on June 6, 2012. He opined that there was no medical need for suctioning on June 6, 2012, because the nurse practitioner found Resident 102's oral pharynx, mucosa, tongue and lungs to be normal and nasal mucosa partly obscured by

clear drainage. He opined that it would be impossible to have yellow mucous in the canister of the suction machine in Resident 102's room that came from Resident 102, as noted by the surveyors on June 6, 2012, in light of the notes from the June 6 nurse practitioner visit. P. Ex. 46 at 17; Tr. 353[9]. The presence of some substance in the machine may trigger an inference that it was used for suctioning but given the portability of such units the further inference that the substance was suctioned from Resident 102 around the time of the survey is not supported. Tr. 470, 473-76.

The evidence does not show that between August 2011 and the survey in June 2012, Resident 102 suffered aspiration pneumonia or a restricted airway that required any emergency intervention. His brief hospitalization in February 2012 was due to an altered mental state and though he had some emesis (vomiting) it appears from the notes that it was cleared without the need of suction. P. Exs. 46, 47, 48.

RN Stratton, previously the administrator for Petitioner and at the time of hearing Director of Clinical Operations for Frontline Management, Petitioner's operator, described the generator the surveyors were shown during the survey. She testified that the backup generator was checked by the ED monthly and a log was maintained. Tr. 425. She testified that the generator was the same as was present when she was the administrator. Tr. 426. The generator was kept in the interior courtyard on a rolling cart. An extension cord was kept on top of the generator and a total of three extension cords could be connected to the generator. Tr. 429-30. During the survey, the ED and a nurse, ADON Kama Deneau, demonstrated starting the generator and a fan was used to demonstrate that the generator was producing electricity. Tr. 432. She testified that LPNs are not authorized to do endotracheal suctioning. Tr. 436. She explained that oral secretions can be cleared from a resident's mouth by using a suction pump, a bulb syringe, a toothette (an oral swab), or a gauze pad. She explained that no physician order is required for using a suction bulb, gauze, or toothettes because secretions are only being removed from the oral cavity. She also testified that using a suction bulb, gauze, a toothette, a washcloth, or a towel to remove secretions are basic nursing procedures. Tr. 437. RN Stratton explained that Petitioner's electrical outage plan did not specify how

---

[9] I have no doubt Surveyor Batdorf saw a yellow substance in the canister of the suction machine in Resident 102's room during the survey. Whether or not the substance was human secretions from Resident 102 or another resident or something else altogether such as vomit or liquefied food is not established by the evidence. I note that the alleged deficiency at issue does not allege failure to clean the canister. Tr. 469. It is surprising that Surveyor Batdorf did not point-out the canister to staff for prompt cleaning and cite Petitioner for a deficiency on that basis.

staff was to provide suction or deal with excess oral secretions in the event of a power outage because that is a basic nursing function for which nurses are trained. Tr. 438, 465. She testified that staff at Petitioner did not do nasopharyngeal (through the nose to the trachea) suctioning. Tr. 442. She testified that Petitioner does not accept residents who require endotracheal suctioning, which is suctioning deeper in the respiratory tract. If a need for such suctioning arose the resident would be transferred to a facility that could provide that service. Tr. 460-61. She opined that Resident 102 was not at risk for any harm if he needed suction during a power outage because there were other methods for removal of oral secretions including manual bulbs, toothettes, and gauze. Tr. 465. She testified that suction bulbs were maintained on the crash carts and nurse's stations. Toothettes and gauze were available at nurse's stations and the supply room. Tr. 466-67.

ADON Deneau testified that the surveyors first mentioned the suction machine in Resident 102's room on June 13, 2012, when they announced immediate jeopardy. The surveyors also stated at that time that they found some substance in the suction machine canister. ADON Deneau testified that when she removed the suction machine from Resident 102's room on June 13, the canister was empty. Tr. 513-14. She testified that she interviewed all the nurses after learning that the surveyors declared immediate jeopardy and none admitted to suctioning Resident 102 after April 1, 2012. Tr. 517. She testified that she demonstrated starting the generator for the surveyors. Tr. 515. ADON Deneau testified that she did not tell the surveyors about the generator sooner because they did not ask. She did not recall the surveyors asking about alternatives to the electric powered suction machines but she recalled that she told one of the surveyors that she could use a syringe bulb to suction if necessary. Tr. 534-35.

LPN Baugh testified that she worked the night shift on the north unit, three nights each week, and she knew Resident 102. She testified that she called in the prescription for scopolamine patch for Resident 102 on December 28, 2011, and the medication effectively controlled his excess secretions. She did not have to suction after Resident 102 received the patch until March 23, 2012, when the scopolamine patch was discontinued. She testified that the suction on March 23 was just for comfort. She testified that rather than the electric suction pump she could have used a bulb syringe or a cloth. She testified that use of the suction bulb, toothette, or cloth is common nursing knowledge. She testified that the secretions suctioned were clear. She testified that she never saw yellow mucus in the suction machine in Resident 102's room after April 1, 2012. Tr. 539, 541, 544-49. She explained that the suction she performed was only in the mouth. She would not use suction for choking but she would use the Heimlich maneuver. She testified that an attempt to suction in the case of choking could cause the object causing the obstruction to be pushed further into the throat. Tr. 552. She testified that there were always suction bulbs on the crash carts and the nurse's station. Tr. 553. She testified she needed no written plan for how to suction in the event the power was out as that was common nursing knowledge. She opined that the unavailability of an electric suction pump during a power outage posed no risk for harm. Tr. 555.

LPN Nicole Remus testified she worked the day shift at Petitioner on the north unit and she knew Resident 102 extremely well. In December 2011, Resident 102 had problems with excess oral secretions and the decision was made to treat him with the scopolamine patch which was very effective for controlling secretions. No suction was required until March 2012, when the scopolamine was discontinued due to an insurance problem. Atropine was ordered which was fairly effective. Resident 102 was often up in his wheelchair and, while up, he drooled rather than the oral secretions pooling in his mouth and there was no need for suction. Suction was a comfort measure. Suction was not required chronically. She never saw yellow mucus in the suction machine in Resident 102's room. She testified that if the electric suction machine is not available a bulb syringe, towels, or a washcloth can be used to remove excess secretions. She testified that LPNs are not allowed to deep suction beyond the back of the throat and into the trachea. She testified that the Heimlich maneuver is used in response to choking not suction. She testified that she told the surveyors that if the power was out she would take Resident 102 to the dining room of the Frontier unit where there was power. She testified that she understood the surveyors question to be whether she could power the electric suction machine in the event of a power outage. But she testified that there are always alternative methods to using an electric suction pump, such as the bulb syringe, a towel, or gauze and she did not need an emergency plan to tell her how or when to use those alternative methods for removing excess secretions, which were basic nursing procedures. She testified that the inability to use a suction machine in the event of a power outage posed no risk for injury to Resident 102. Tr. 570-84. She testified that a suction machine would only be used at Petitioner to remove oral secretions from the mouth. She testified that a bulb syringe would be used in a similar manner to remove excess secretions from the mouth, except that it is necessary to compress the bulb to create the suction. Use of the electric suction machine is faster but its use is generally a matter of preference not necessity. Tr. 589-97.

b. Analysis

CMS alleges that Petitioner violated 42 C.F.R. § 483.75(m)(1), which provides:

> (m) *Disaster and emergency preparedness.* (1) The facility must have detailed written plans and procedures to meet all potential emergencies and disasters, such as fire, severe weather, and missing residents.

The specific focus of the CMS allegation is Petitioner's "Electrical Outage" plan revised on or about December 27, 2011. P. Ex. 13. CMS argues that the plan is essentially unworkable because the plan does not specify how staff is to power electrical appliances such as suction machines during a power outage. CMS argues that the plan is unworkable and misleading because it refers to the use of a backup generator. CMS also

argues that surveyors received confused and confusing responses from staff. CMS Br. at 3, 18-25; CMS Reply at 2-4. CMS argues that Petitioner's electrical outage plan misinformed staff and thereby created a risk for more than minimal harm to residents. CMS Br. at 26-30. Considering the entire record as a whole, I conclude that Petitioner has shown by the preponderance of the evidence that its "Electrical Outage" plan is sufficient and does not violate the regulation.

The surveyors' findings and conclusion reflected in the SOD as amended by the IIDR (CMS Ex. 8) and the CMS arguments are based on two unfounded assumptions that:

1. Suction may only be done with an electric suction pump; and

2. The term "backup generator" used in Petitioner's "Electrical Outage" plan (P. Ex. 13) refers to some type of generator other than the portable, manual start generator that Petitioner maintained in its interior courtyard.

The pertinent facts are set forth above. Petitioner presented the testimony of a physician, a RN, and three LPNs, all licensed medical professionals whose credentials have not been challenged by CMS. One CMS surveyor was not a licensed medical professional and the other was a chiropractor and both admitted no experience with suctioning. I give greater weight to the medical opinions of the licensed medical professionals presented by Petitioner than I do to the medical opinions of the surveyors in this case. Although all Petitioner's witnesses are employed by Petitioner, I find no reason to discount the credibility of Petitioner's witnesses for that reason alone. I also find no other basis to discount the credibility of Petitioner's witnesses. There were few inconsistencies in the testimony of Petitioner's witnesses and no inconsistencies as to the material facts. Although there was some confusion on the part of all the witnesses, including the CMS witnesses, at various times in the proceedings, I attribute that to lack of clarity of my questions and those of counsel.

The credible medical opinions before me are that suction from an electric suction pump is not required to remove excess secretions from the mouths and from the back of the throats of Petitioner's residents. Other alternative means are available such as manual suction bulbs, gauze, washcloths or towels, toothettes, or a finger. The evidence shows that all the alternative resources or interventions were readily available for use in the event of an emergency at Petitioner's facility, including during an electrical outage. Use of suction other than in the mouth is beyond the level of care provided by Petitioner. The evidence shows that use of alternative means for the removal of excess secretions are standard nursing practice, and Petitioner's nurse witnesses were consistent that staff needed no written policy to know how to use the alternative means. The credible medical evidence also shows that suctioning is not used to address choking in Petitioner's facility. The Heimlich maneuver is the standard of care to address choking.

Petitioner's electrical outage policy states that if a power outage "will be above and beyond the alternate power source, backup generator will be used." P. Ex. 13, ¶ 10. The type of backup generator, its location, and operation are not specified in Petitioner's plan. The evidence shows that Petitioner's emergency lights were powered by battery not a generator. There is evidence that Petitioner had a generator that maintained a hot water heating system but that generator did not power lights. Petitioner's administrator stated in her email dated November 9, 2011, that during the power outage on October 26, 2011, the backup generator came on but after four hours that generator was not able to keep the facility at a proper temperature. The email also shows that following that outage, the ED recommended a larger generator. P. Ex. 15. There is no allegation by the surveyors or CMS in this case that the backup generator for heating was defective or caused a regulatory violation. During the survey, Petitioner's staff showed the surveyors the small portable, pull-start generator maintained in the interior courtyard. Staff demonstrated starting the generator, which admittedly required several pulls to start, and that it could be used to power a fan. The evidence shows that as many as three extension cords could be energized with the portable generator to power electric devices in the facility if necessary. Petitioner's electrical plan specified that a backup generator would be used. Petitioner had two backup generators, one for heat and the portable generator which could be used to power small electric devices. There is no basis to assume that Petitioner's electrical outage policy referred to any other backup generators than those Petitioner had during the outages in the fall 2011 and at the time of the survey.

During the survey, staff responses to surveyor questions reflected that they were knowledgeable of the provisions of Petitioner's electrical outage plan. CMS Ex. 8 at 100, 104-106. For reasons previously discussed, I attribute staff's apparent confusion in responding to surveyor questions to be due to confusing surveyor questions about the location of red power outlets; about how one powers an electric suction machine when the power is out; and the failure of the surveyors to ask simple and direct questions.

The credible medical opinions expressed by Petitioner's witnesses were that there was no risk for any harm to Resident 102 if he had excess secretions and no electric suction pump was available. The witness opinions were that if no electric suction was available Resident 102's excess secretions would be handled with the readily available alternatives. I conclude that those opinions apply equally to all the other residents cited in the SOD, based on the medical evidence offered as to each of those residents. P. Exs. 34-40; CMS Exs. 18-23.

I conclude that Petitioner's electrical outage policy was not defective for any of the reasons cited by CMS or the surveyors. CMS conceded that no law requires that Petitioner have any backup generator. Surveyor Batdorf admitted that if she had been aware of the portable generator sooner during the survey or if it had been explained to her that there were non-electrical alternatives to address excess secretions she would not have cited Petitioner for a deficiency under Tag F517. Tr. 151-52, 184; CMS Reply at 14.

The CMS argument that Petitioner's policy was defective because Petitioner did not have the backup generator referred to in the policy is based on the unfounded assumption that backup generator refers to some type of generator other than the portable generator maintained in the courtyard. The CMS argument that the policy was defective because it did not include detailed starting instructions is also without merit. The ED and ADON Deneau both started the generator in the presence of one or more surveyors, albeit not with one pull of the starter cord. The evidence shows that starting the generator was a simple three-step process similar to starting any small, gasoline motor powered equipment like a lawn mower – choke, pull the cord, and adjust the throttle or choke so that the motor makes the right noise – and there was simply no need for detailed instructions. Colorado regulations applicable to Petitioner require the availability of suction, but do not specify that suction be electrically powered. CMS Ex. 35. Finally, even if one concluded that the electrical outage policy was defective because it did not specifically instruct staff how to power an electric suction pump the defect did not pose a risk for more than minimal harm for Petitioner's residents.

4. Additional issues raised by Petitioner in its hearing request are beyond my jurisdiction to hear and decide.

Petitioner raised additional issues in its hearing request and seeks to preserve those issues for any subsequent appeal of my decision. The issues generally concern CMS's survey procedures, enforcement and Petitioner's due process rights. I agree with the parties that I do not have authority to decide the issues listed as issues 1 through 7 in the Joint Statement of Issues Presented filed April 1, 2013. Tr. 20.

III. Conclusion

For the foregoing reasons, I conclude that Petitioner did not violate 42 C.F.R. § 483.75(m)(1), and there is no basis for the imposition of a $6,500 PICMP.

/s/
Keith W. Sickendick
Administrative Law Judge