Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Libertywood Nursing Center,
(CCN: 34-5520),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-12-340

Decision No. CR3199

Date: April 11, 2014

DECISION

Petitioner, Libertywood Nursing Center, did not violate 42 C.F.R. § 483.65(a) from about November 3, 2011 to December 1, 2011, as alleged by the Centers for Medicare & Medicaid Services (CMS). There is no basis for the imposition of enforcement remedies.

I. Background

Petitioner is located in Thomasville, North Carolina, and participates in Medicare as a skilled nursing facility (SNF) and the state Medicaid program as a nursing facility (NF). On November 22, 2011, the North Carolina Department of Health and Human Services (state agency) completed a survey of Petitioner's facility and found Petitioner noncompliant with program participation requirements. CMS notified Petitioner by letter dated December 8, 2011, that CMS was imposing the following enforcement remedies: a per instance civil money penalty (PICMP) of $10,000 for an alleged violation of 42 C.F.R. § 483.65 (Tag F441); a denial of payment for new admissions (DPNA) effective December 22, 2011; and termination of Petitioner's provider agreement effective March 22, 2012, if Petitioner did not return to substantial compliance prior to that date. CMS also advised Petitioner that it was ineligible to be approved to conduct a nurse aide training and competency evaluation program (NATCEP) for two years. A revisit survey conducted on January 5, 2012, found that Petitioner returned to substantial compliance on

December 1, 2011. Thus, the DPNA and termination remedies were not effectuated. Joint Stipulations of Undisputed Facts (Jt. Stip.).

Petitioner requested a hearing before an administrative law judge (ALJ) on January 30, 2012. The case was assigned to me for hearing and decision on February 3, 2012, and an Acknowledgement and Prehearing Order was issued at my direction. On January 9, 2013, a hearing was convened by video teleconference and a transcript (Tr.) of the proceedings was prepared. CMS offered CMS exhibits (Exs.) 1 through 53, and all but CMS Ex. 52 were admitted as evidence. Tr. 34, 40-42. Petitioner offered Petitioner's exhibits (P. Ex.) 1 through 13 that were admitted as evidence. Tr. 43-44. CMS called the following witnesses: Surveyor Jean Farley, R.Ph. and Surveyor James Hartman, R.N. Petitioner called the following witnesses: Saad Amin, M.D., Petitioner's Medical Director; William Schultze, Petitioner's Administrator; Sallie Hepler, R.N., Petitioner's Staff Development Coordinator; and Margaret James, R.N., Petitioner's Assistant Director of Nursing (ADON). The parties filed post-hearing briefs (CMS Br. and P. Br., respectively) and post-hearing reply briefs (CMS Reply and P. Reply, respectively).

II. Discussion

A. Issues

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

Whether the remedy imposed is reasonable.

B. Applicable Law

The statutory and regulatory requirements for participation of a SNF in Medicare are at section 1819 of the Social Security Act (Act) and 42 C.F.R. pt. 483. Section 1819(h)(2) of the Act authorizes the Secretary of Health and Human Services (Secretary) to impose enforcement remedies against a SNF for failure to comply substantially with the federal participation requirements established by sections 1819(b), (c), and (d) of the Act.[1] 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

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

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 (CMP), 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, that is, a deficiency that poses a risk for more than minimal harm. 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.

CMS is authorized to impose a CMP for the number of days of noncompliance – a per day CMP – or for each instance of noncompliance – a PICMP. 42 C.F.R. § 488.430. 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 CMPs, $3,050 per day to $10,000 per day, is reserved for deficiencies that pose immediate jeopardy to a facility's residents, and, in some circumstances, for repeated deficiencies. 42 C.F.R. § 488.438(a)(1)(i), (d)(2). "*Immediate jeopardy* means a situation in which the provider's noncompliance with one or more requirements of participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301 (emphasis in original). The lower range of CMPs, $50 per day to $3,000 per day, is reserved for deficiencies that do not pose immediate jeopardy, but either cause actual harm to residents, or cause no actual harm but have the potential for causing more than minimal harm. 42 C.F.R. § 488.438(a)(1)(ii). The only range for a PICMP is $1,000 to $10,000. 42 C.F.R. §§ 488.408, 488(a)(2).

Petitioner was notified in this case that it was ineligible to conduct a NATCEP for two years.[2] 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 reapproving those programs using criteria the Secretary set. The Secretary promulgated regulations at 42 C.F.R. pt. 483, subpt. D. Pursuant to 42 C.F.R. § 483.151(b)(2) and (f), a state may not approve and must withdraw any prior approval of a NATCEP offered by a SNF or NF that has been: (1) subject to an extended or partial extended survey under sections 1819(g)(2)(B)(i) or 1919(g)(2)(B)(i) of the Act; (2) assessed a PICMP or CMP of not less than $5,000; or (3) subject to termination of its participation agreement, a DPNA, or the appointment of temporary management. Extended and partial extended surveys are triggered by a finding of "substandard quality of care" during a standard or abbreviated standard survey and involve evaluating additional participation requirements. "Substandard quality of care" is identified by the situation where surveyors identify one or more deficiencies related to participation requirements established by 42 C.F.R. § 483.13 (Resident Behavior and Facility Practices), § 483.15 (Quality of Life), or § 483.25 (Quality of Care) that are found to constitute either immediate jeopardy, a pattern of or widespread actual harm that does not amount to immediate jeopardy, or a widespread potential for more than minimal harm that does not amount to immediate jeopardy and there is no actual harm. 42 C.F.R. § 488.301.

The Act and regulations make a hearing before an ALJ available to a long-term care facility against which CMS has determined to impose an enforcement remedy. Act §§ 1128A(c)(2), 1866(h); 42 C.F.R. §§ 488.408(g), 498.3(b)(13). A facility has a right to seek review of 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 and the factors CMS considered when choosing remedies, are not subject to review. 42 C.F.R. § 488.408(g)(2). A facility may only challenge the scope and severity level of noncompliance determined by CMS if a successful challenge would affect the range of the CMP that may be imposed or impact the facility's authority to conduct a NATCEP. 42 C.F.R. § 498.3(b)(14), (d)(10)(i). The CMS determination as to the level of noncompliance, including the finding of immediate jeopardy, "must be upheld unless it is

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[2] Petitioner was not conducting a NATCEP at the time of the survey. Nevertheless, Petitioner was ineligible to be approved to conduct a NATCEP for two years based on the survey and proposed enforcement remedy.

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 long-term care facility 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, 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*, 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) (*remand)*, DAB No. 1663 (1998) (*aft. remand*), *aff'd*, *Hillman Rehab. Ctr. v. United States*, No. 98-3789 (GEB), 1999 WL 34813783 (D.N.J. May 13, 1999).

"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. In the final *Hillman* decision after remand, the Board explained:

> The ALJ should be able to determine the existence of a prima facie case at the close of HCFA's presentation. Hence, as we pointed out in our first decision, HCFA would lose even if the provider offered no evidence at all, if HCFA did not come forward with evidence sufficient to support a conclusion in its favor in presenting its prima facie case. Thus, we held that HCFA must make its case "at the outset."
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> Once HCFA has established a prima facie case, the provider may then offer evidence in rebuttal, both by attacking the factual underpinnings on which HCFA relied and by offering evidence in support of its own affirmative arguments. An effective rebuttal of HCFA'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.
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> The major purpose of requiring HCFA to establish a prima facie case is to assure that the action taken by HCFA has a legally sufficient foundation, if the facts are determined to be as alleged by HCFA (since it would be unfair and inefficient to require a provider to defend against a case that, even if proven, would not suffice to support the action taken). In addition, we concluded that fairness requires HCFA to set out evidence of the factual basis for its action in order that the provider not have to offer a shot-gun defense without adequate notice to respond to the case against it. These purposes are accomplished once HCFA has presented a case sufficient, if not effectively rebutted, to sustain its action. At that point, HCFA has established a prima facie case and, to prevail, the provider must proceed to prove its case by the preponderance of the evidence on the record as a whole.

Hillman, DAB No. 1663 (internal citations omitted). HCFA was the predecessor to CMS.

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. 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. 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 Petitioner; (2) come forward with evidence upon which it relies for its factual conclusions that are disputed by the Petitioner; and (3) show how the deficiencies it found amounted to noncompliance that warrants an enforcement remedy, that is, that there was a risk for more than minimal harm due to the regulatory violation. *Evergreene Nursing Care Ctr.*, DAB No. 2069 at 7 (2007).

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

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

On November 22, 2011, a complaint and revisit survey was completed at Petitioner's facility.[4] The surveyors concluded that Petitioner violated 42 C.F.R. § 482.20(k)(3)(i) (Tag F281, services must meet professional standards) and that the violation posed a risk for more than minimal harm. The surveyors also concluded that Petitioner was in violation of 42 C.F.R. § 483.65 (Tag F441, infection control) and that the violation posed immediate jeopardy for Petitioner's residents. Both deficiencies are based on the same facts. However, CMS imposed a $10,000 PICMP based only upon the deficiency under Tag F441. CMS Exs. 2; 5; P. Exs. 1, 2. Therefore, only the alleged violation of

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[3] "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.

[4] The evidence shows that a complaint and recertification survey was completed at Petitioner's facility on September 22, 2011. But, no deficiency findings from the September 2011 survey are before me. CMS Exs. 1, 4.

42 C.F.R. § 483.65 (Tag F441) is at issue before me, because it is the only deficiency that was cited by CMS as the basis for the imposition of an enforcement remedy. 42 C.F.R. § 488.408(g); 498.3(b)(13). A revisit survey on January 5, 2012, concluded that Petitioner returned to substantial compliance on December 1, 2011. The parties stipulated that only the deficiency cited under Tag F441 and the PICMP based on that deficiency citation are at issue before me. Jt. Stip.

1. Petitioner did not violate 42 C.F.R. § 483.65.

2. There is no basis for the imposition of the $10,000 PICMP or any enforcement remedy in this case.

a. Facts

This case involves a series of intentional or unintentional errors[5] made by one nurse, R. Selman, RN, on November 3, 2011, when she was administering influenza vaccine by injection to several of Petitioner's residents. Petitioner admits that RN Selman breached injection safety protocol standards and practices and Petitioner's own policies. P. Br. at 1-2, 11, 21; P. Reply at 1, 9, 15.

Petitioner employed RN Selman on an as needed basis. P. Ex. 3; Tr. 177. RN Selman was licensed as a RN in 1975, completed a medical/surgical nursing review sponsored by the University of North Carolina in July 2011, and Petitioner's staff validated her medication administration competency and knowledge and understanding of infection control in February 2011. RN Hepler, who was Petitioner's staff development coordinator at the time of the incident, testified that RN Selman would have been trained annually on Petitioner's infection prevention policies. RN Hepler testified that she did not personally conduct RN Selman's competency checks, as RN Hepler was not employed at Petitioner when RN Selman was hired. RN Selman signed an acknowledgment that she had received Petitioner's infection control and bloodborne pathogen policies. P. Exs. 3-6; Tr. 92-94; 175-82, 192-93.

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[5] The difference could be viewed as the difference between a criminal offense and neglect. I make no findings in this regard. I note that RN Selman was immediately suspended and then terminated by Petitioner based on this incident. Subsequently, she was reprimanded by the state board of nursing but she did not lose her nursing license as a result of this incident and there is no evidence that she was subject to criminal prosecution. CMS Exs. 20, 26; Tr. 90-91, 118, 213, 215-16.

On November 3, 2011, Petitioner assigned RN Selman to give flu shots to a number of residents. P. Exs. 7, 10. This was not the first time RN Selman had given flu shots to Petitioner's residents. RN James, Administrator Schultze, and RN Hepler, all testified to Petitioner's belief that RN Selman was competent to give flu shots, as Petitioner's policy is that a RN should be able to administer flu shots without direct supervision. Tr. 112, 178, 208, 212-13, 217-18. There is no dispute that a registered nurse is trained and authorized to give a flu shot by him or herself and without direct supervision. Tr. 112, 178, 207-08. The evidence shows that RN Selman went to the medication room to obtain the vaccine and syringes. Another nurse was present but I have no evidence as to any observations made by that nurse. The evidence shows that RN Selman asked the DON for alcohol sponges. The evidence also shows that RN Selman filled the syringes at the nurse's station. The evidence does not show that any other nurses observed RN Selman as she filled the syringes and placed them in her metal clipboard. P. Ex. 8 at 8, 10; CMS Ex. 14; CMS Ex. 16.

Petitioner admits that the syringes RN Selman used were the wrong size; she filled some but not all with vaccine; she placed the syringes inside a metal clipboard that was not sterile; she vaccinated four residents; and she failed to dispose of the used syringes in a sharps container, instead returning them to her clipboard. When she reached a younger male resident, Resident 2, she verified his identity and engaged in some conversation with him, but she did not check to see whether the syringe she was using to vaccinate him was filled and she injected him in his thigh rather than the preferred deltoid muscle of the upper arm, with an empty syringe. P. Br. at 9-10. After realizing that the syringe was empty, RN Selman reported the incident to her Unit Manager and DON. P. Br. at 9-10; P. Reply at 5-6. RN Selman also did not properly record on the medication administration records that she administered vaccine to the residents and she failed to check the temperature of at least one resident prior to giving the flu shot that day. Tr. 77; CMS Ex. 17 at 2.

Petitioner investigated the incident, but was unable to determine whether RN Selman had injected Resident 2 with a needle she had already used on another resident or whether RN Selman injected Resident 2 with an unused needle that she simply neglected to fill with vaccine. Tr. 109-10; P. Ex. 8 at 10. Because of the possibility that RN Selman had injected Resident 2 with a needle used on another resident, Petitioner's medical director, Dr. Amin, contacted the Centers for Disease Control and the County Health Department for advice within an hour of the incident. Although Petitioner was not aware of and did not believe that any of the residents vaccinated before Resident 2 had a communicable disease such as HIV or Hepatitis, Petitioner received permission to and then tested the blood of all the residents to whom RN Selman had given a flu shot that day in order to determine whether they were infected with HIV or Hepatitis B or C. Petitioner also tested their blood periodically for several months thereafter. No evidence of infection was ever found. Tr. 96, 112-13, 115-18, 184-89. Petitioner's Prehearing Brief (P. PH Br.) at 5-6; P. Exs. 7-10.

There is no dispute in this case that there is a correct practice or protocol for giving a flu shot. Petitioner acknowledges that proper injection technique is described in a variety of sources, including Centers for Disease Control (CDC) Guidelines, textbooks, and package inserts. Petitioner asserts that this correct practice and protocol is described in its own policies and procedures and that assertion is supported by the surveyors' testimony. P. Br. at 7; P. Reply at 4-5; P. Ex. 4 at 1-2, 8-12; Tr. 92, 153. Petitioner does not dispute that the documents submitted by CMS set forth proper practices and protocols for administering flu vaccine and does not dispute that safe injection techniques are "fundamental" to an infection control program, "elementary," and "critical for patient safety." Petitioner does not dispute the proper practice for an individual administering an injection is to use one needle, one syringe, one time, as the evidence offered by CMS reflects. P. Reply at 4-5; CMS Exs. 39-42. Surveyor Hartman testified, and Petitioner does not contest, that standard injection safety protocol requires that a registered nurse: (1) identify the patient and the medication to be given; (2) gather the appropriate syringe and needle type required to give the medication; (3) prepare the syringe in a clean environment (such as a medication room or bedside medication cart); (4) prepare only one syringe at a time for one patient at a time; (5) administer the medication to the designated patient via the proper route, taking vital signs beforehand, if necessary; (6) immediately dispose of the used needle and syringe in a sharps container; and (7) record the medication administration in a patient or resident chart. This protocol is intended to prevent needle contamination and eliminate the potential for confusion between needles used on or intended for different patients. Nurses should follow the protocol at all times, unless directed otherwise by a physician. Tr. 130-34.

Surveyor Farley testified that Petitioner's policies with regard to intramuscular injections were consistent with standards of practice and that there was no evidence of violation by other nurses or staff. Tr. 91- 92, 99. She testified that she saw evidence that RN Selman had attend a nursing refresher course at the University of North Carolina. Tr. 94. Surveyor Farley testified that the investigation undertaken by Petitioner after the incident and Petitioner's response to the incident was appropriate. Tr. 94-97. Surveyor Farley testified that her concern was not that the facility did not have infection control policies, because they had such policies in place; her concern was that they did not follow the policies and oversee this particular nurse. Tr. 98. Surveyor Farley testified she found no other instance where the facility infection control policy and procedures were not followed. But she testified that the standard for giving an injection is so strong, that a single error is enough to communicate a bloodborne pathogen to another resident. She opined that the single error of a nurse is enough to show a breakdown of the facility infection control program. Tr. 99-100, 103-04. Surveyor Farley based her conclusions on CDC guidelines concerning one needle, one stick, one time. Tr. 69, 104.

Surveyor Hartman testified that this incident posed an infection control issue due to the possibility of infection with a contaminated needle. RN Selman's breach in protocol

posed a risk for more than minimal harm because a contaminated needle, filled in what was not a clean area, transported in a clipboard, and possibly used on one resident and then used on a second resident, risks resident exposure to diseases such as HIV or Hepatitis B or C. Tr. 137-38. Surveyor Hartman opined that when RN Selman asked the DON for alcohol swabs, the DON should have corrected RN Selman then. However, Surveyor Harman did not cite the evidence that the DON had any opportunity to observe that RN Selman had the wrong syringes in her clipboard. Tr. 138-39, 146-49, 152, 160-61. He also opined that because RN Selman was not attempting to hide her activities, such activities may have been acceptable in the facility. However, he cited no evidence to support his belief that RN Selman was actually doing things in an open area without concealing her actions and his opinion is clearly unsupported by the evidence before me. Tr. 138-39, 146-49. Surveyor Hartman testified that the surveyors determined that Petitioner did have a policy and procedure for administering flu shots that incorporated the standard of care. Surveyor Hartman testified that Petitioner did train its nurses on that policy and procedure. He agreed that there was evidence that all nurses, including RN Selman, had received required education, were properly licensed, and references had been checked. Surveyor Hartman testified that the surveyors found no evidence that other nurses employed by Petitioner made any mistakes administering injections. Tr. 153-54. Surveyor Hartman testified that Petitioner's in-servicing its staff after the incident on how to correctly give injections was an appropriate response to the incident. He testified that some of the in-service training was done by telephone. Surveyor Hartman opined that training should not be done by telephone. He cited no regulatory provision or policy that prohibited telephone training but simply asserted that it is not standard to do training by telephone. He also agreed that Petitioner was not cited with a deficiency for training its staff by telephone. Tr. 154, 156, 158-60, 162-63.

b. Analysis

The parties agree that RN Selman committed several acts that violated infection control procedures, CDC guidelines, and nursing practice. Petitioner comments that RN Selman's actions were an "inexplicable breach of professional standards that would embarrass a first year nursing student" and admits that her actions would sustain a finding of deficiency under 42 C.F.R. § 483.20(k)(3)(i) (Tag F281), which requires that the services Petitioner provides residents must meet professional standards of quality. P. Br. at 2. Although Petitioner was cited for a violation of 42 C.F.R. § 483.20(k)(3)(i) based on the conduct of RN Selman, CMS imposed no enforcement remedy for that violation. The only deficiency for which CMS proposed an enforcement remedy is the alleged violation of 42 C.F.R. § 483.65(a) and that is the only deficiency at issue before me. The issue that must be resolved is whether RN Selman's admitted violation of Petitioner's infection control policy and procedures amounts to a violation of 42 C.F.R. § 483.65(a). Because I conclude that RN Selman's acts do not show that Petitioner failed to maintain its infection control program in violation of 42 C.F.R. § 483.65(a), no enforcement remedy is reasonable and no remedy may be imposed in this case.

(i.) The Regulatory Requirement for an Infection Control Program

The infection control regulation requires:

> The facility must establish and maintain an infection control program designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of disease and infection.
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> (a) *Infection control program.* The facility must establish an infection control program under which it—
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> (1) Investigates, controls, and prevents infections in the facility;
> (2) Decides what procedures, such as isolation, should be applied to an individual resident; and
> (3) Maintains a record of incidents and corrective actions related to infections.
>
> (b) *Preventing spread of infection.*
>
> (1) When the infection control program determines that a resident needs isolation to prevent the spread of infection, the facility must isolate the resident.
> (2) The facility must prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease.
> (3) The facility must require staff to wash their hands after each direct resident contact for which handwashing (sic) is indicated by accepted professional practice.
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> (c) *Linens.* Personnel must handle, store, process, and transport linens so as to prevent the spread of infection.

42 C.F.R. § 483.65. The surveyors allege in the Statement of Deficiencies (SOD) for the survey completed on November 22, 2011, that Petitioner violated the regulation because Petitioner "failed to maintain standards of infection control as designated by the Centers for Disease Control (CDC)." This allegation could be misconstrued to be that Petitioner violated a law established by the CDC regarding infection control. However, CMS does not pursue that argument before me arguing, rather, that the CDC guidance constitutes

the standard of practice. P. Br. at 3-4. The arguments of the parties reflect that they understand that guidance from the CDC involved in this case is policy rather than a law that may be enforced directly against Petitioner. CMS Ex. 39-42. Therefore, I interpret the allegation to be that Petitioner violated 42 C.F.R. § 483.65 because failure to comply with the standard of practice reflected by the CDC standards, constitutes a failure to establish and maintain an infection control policy that controls and prevents the spread of infections in the facility, the requirements of 42 C.F.R. § 483.65(a)(1).[6]

HCFA, the predecessor to CMS, issued a final rule with comment period on February 2, 1989, which included 42 C.F.R. § 483.65. In promulgating 42 C.F.R. § 483.65, HCFA stated in the preamble to the final rule that it eliminated from the proposed rule a prior requirement for an infection control committee because "the emphasis we wanted to place was on the actual performance of a facility in providing care rather than on its capacity to perform." 54 Fed. Reg. 5,316, 5,345 (Feb. 2, 1989). HCFA received 26 comments to the proposed rule that recommended that the infection control committee be retained as a regulatory requirement. In response to the comments, HCFA created the requirement for an infection control program, now reflected in 42 C.F.R. § 483.65. HCFA stated that "the facility is responsible for establishing policies and procedures for investigating infections in the facility" and that the newly required quality assurance committee would fulfill the function of the old infection control committee. 54 Fed. Reg. at 5,345. HCFA stated in the final rulemaking that it elected to focus on hand washing rather than the originally proposed requirement for all personnel to follow aseptic and isolation techniques. HCFA stated that it decided to give the facility responsibility to determine when and to what degree isolation is required. HCFA chose not to further define the terms "incidents" and "corrective actions" used in the regulation stating that it did not "wish to institute prescriptive regulatory requirements, but intended to elaborate further in interpretive guidelines." *Id.* In summarizing the differences between the proposed infection control regulation and 42 C.F.R. § 483.65 as promulgated, HCFA stated that "[w]e require a facility to establish an infection control program under which it investigates, controls and prevents infections, decides on isolation procedures, and maintains a record of incidents and corrective actions related to infections." *Id*. On September 26, 1991, HCFA promulgated a final rule revising the regulations issued on February 2, 1989, including 42 C.F.R. § 483.65 which was unchanged except for minor edits. HCFA acknowledged a comment received in response to the September 1991 rule-making, that it was unreasonable to require an infection control program that prevents infection as total prevention is not possible. HCFA stated that it did not accept the

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[6] The allegations and evidence show that 42 C.F.R. § 65(a)(2) (isolation) and (3) (records); (b) (isolation of residents and staff, and hand washing); and (c) (linens) have no application in this case.

comments, but noted that "the word 'prevents' does not absolutely mean that residents will never experience infections." 56 Fed. Reg. 48,826, 48,861 (Sep. 26, 1991). A non-substantive edit was made to the regulation by HCFA by a final rule issued on September 23, 1992. 57 Fed. Reg. 43,922, 43,925 (Sep. 23, 1992). The regulatory history for 42 C.F.R. § 483.65 indicates that HCFA did not intend to implement prescriptive regulatory requirements for infection control; to require facilities to eliminate every infection risk for infections; or to prevent the occurrence of all infections.

Current CMS policy set forth in the State Operations Manual (SOM) states that the intent of 42 C.F.R. § 483.65 is to ensure that a facility "develops, implements, and maintains" an infection prevention and control program to "prevent, recognize, and control, **to the extent possible**, the onset and spread of infection within the facility." SOM, CMS Pub. 100-07, app. PP, Tag F441 (emphasis added). The SOM (like the preamble to the rule-making that promulgated 42 C.F.R. § 483.65) is not enforceable as law, but rather, sets forth CMS policy guidance to the state survey agencies regarding the interpretation and application of the Act and regulations. The CMS policy statements are given effect to the extent they are consistent with the law. *E.g.*, *Cedar Lake Nursing Home*, DAB No. 2344 at 5 (2010); *Foxwood Springs Living Ctr.*, DAB No. 2294 at 9 (2009); *Columbus Nursing & Rehab. Ctr.*, DAB No. 2247 at 23 (2009); *Cal Turner Extended Care Pavilion*, DAB No. 2030 at 13 (2006). The SOM states that it is important that a facility's infection prevention and control practices reflect the current CDC guidelines. The SOM instructs surveyors as follows regarding whether or not a facility is in compliance with 42 C.F.R. § 483.65:

> The facility is in compliance with 42 C.F.R. § 483.65 Infection Control if:
>
> - The infection prevention and control program demonstrates ongoing surveillance, recognition, investigation and control of infections to prevent the onset and the spread of infection, **to the extent possible**;
>
> - The facility demonstrates practices to reduce the spread of infection and control outbreaks through transmission based precautions (e.g., isolation precautions);
>
> - The facility demonstrates practices and processes (e.g., intravenous catheter care, hand hygiene) consistent with infection prevention and prevention of cross-contamination;

- The facility demonstrates that it uses records of incidents to improve its infection control processes and outcomes by taking corrective action;

- The facility has processes and procedures to identify and prohibit employees with a communicable disease or infected skin lesions from direct contact with residents or their food, if direct contact will transmit the disease;

- The facility consistently demonstrates appropriate hand hygiene (e.g., hand washing) practices, after each direct resident contact as indicated by professional practice; and

- The facility demonstrates handling, storage, processing and transporting of linens so as to prevent the spread of infection.

If not, cite at Tag F441.

SOM, app. PP, Tag F441 (emphasis added). The SOM instructs surveyors that failure to do any of the following may be cited as noncompliance under Tag F441:

- Develop an infection prevention and control program;

- Utilize infection precautions **to minimize the transmission of infection**;

- Identify and prohibit employees with a communicable disease from direct contact with a resident;

- Demonstrate proper hand hygiene;

- Properly dispose of soiled linens;

- Demonstrate use of surveillance; or

- Adjust facility processes as needed to address a known infection risk.

SOM, app. PP, Tag F441 (emphasis added). The use of the phrases "to the extent possible" and "to minimize the transmission" in the foregoing passages from the SOM, show that CMS recognizes that no infection control program can eliminate all risks for infection or prevent all infections. Accordingly, a "zero tolerance" approach to enforcement of 42 C.F.R. § 483.65, is not consistent with current CMS policy.

(ii.) The Requirement for a Prima Facie Showing of a Violation of a Regulatory Requirement and That There Was a Risk for More Than Minimal Harm

The Board has been consistent in prior decisions that CMS has the burden of coming forward with evidence to make a prima facie showing of a regulatory violation and that the violation posed a risk for more than minimal harm to one or more residents. 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.

Evergreene Nursing Care Ctr., DAB No. 2069 at 7 (2007). CMS makes a prima facie showing of noncompliance, that is, a regulatory violation plus a risk for more than minimal harm, if the credible evidence CMS relies on is sufficient to support a decision in its favor. 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).

The regulation allegedly violated, in this case 42 C.F.R. § 483.65(a), gives Petitioner notice of the criteria or elements Petitioner 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 present sufficient evidence on any disputed facts to show that Petitioner violated a regulation by not complying with one or more of the criteria or elements of the regulation, which is

referred to by the regulations as a deficiency. CMS must also present sufficient evidence to show that the deficiency amounted to "noncompliance," that is, the regulatory violation posed a risk for more than minimal harm, if that is disputed. The Board's prior decisions are consistent with this construction. *See Jennifer Matthew Nursing & Rehab. Ctr.*, DAB No. 2192 at 20 n.12 (2008). The requirement for CMS to show that there was a risk for more than minimal harm is derived from the regulations and the Act.

> *Noncompliance* means any deficiency that causes a facility to not be in substantial compliance.
>
> *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.

> Sections 1819(h) and 1919(h) of the Act specify remedies that may be used by the Secretary or the State respectively when a SNF or a NF is not in substantial compliance with the requirements for participation in the Medicare and Medicaid programs. These sections also provide for ensuring prompt compliance and specify that these remedies are in addition to any others available under State or Federal law, and, except for civil money penalties imposed on NFs-only by the State, are imposed prior to the conduct of a hearing.

42 C.F.R. § 488.400.

> (b) *Basis for imposition and duration of remedies.* When CMS or the State chooses to apply one or more remedies specified in § 488.406, the remedies are applied on the basis of noncompliance found during surveys conducted by CMS or by the survey agency.

42 C.F.R. § 488.402(b). Therefore, an enforcement remedy may only be imposed for noncompliance, i.e. failure to maintain a level of compliance such that there is no greater risk to resident health or safety than the potential for causing minimal harm. Thus, an essential element of the CMS prima facie case is to show that any failure to maintain compliance poses a risk for more than minimal harm.

An issue that has not been specifically addressed by the Board is the issue of what quantum of evidence CMS must present to establish the elements of its prima facie case. In *Sunshine Haven Lordsburg*, DAB No. 2456 at 3 n.2 (2012), the Board stated:

> The ALJ incorrectly stated that "CMS bears the burden to come forward with the evidence and to establish a prima facie showing of the alleged regulatory violations in this case by a preponderance of the evidence." ALJ Decision at 52 (emphasis added). The preponderance of the evidence standard does not apply to CMS's prima facie case of noncompliance; rather, once CMS has made a prima facie case, the facility then must show by a preponderance of the evidence that it was in substantial compliance.

I agree that according to prior decisions of the Board, the standard of proof for judging whether Petitioner meets its burden of proof is the preponderance of the evidence. But that does not address what quantum of evidence, that is, how much evidence must be presented by CMS to establish a fact. One possible reading of the Board's language is that it is not necessary for CMS to present a particular quantum of evidence to establish the facts necessary to show the elements of its prima facie case. However, such a reading would mean that if at the conclusion of the CMS case, Petitioner moved for judgment because CMS failed to make a prima facie showing and Petitioner elected to present no evidence, there is no required quantum of evidence by which to judge whether the CMS evidence is sufficient to show a deficiency that will support an enforcement remedy. That, however, is likely not what the Board intended to say. Logically, there must be some quantum of evidence necessary to establish the facts necessary to establish the CMS prima facie case. Commonly recognized standards at the trial-level in the civil and criminal courts include, among others, a "mere scintilla," "probable cause," "preponderance of the evidence," "clearly convincing," "clearly erroneous," and "beyond a reasonable doubt." CJS Evidence §§ 1620-28; CJS Searches § 62. In administrative law the most commonly applied standard for the quantum of evidence is "preponderance of the evidence" which means more likely true than not or 51 percent. *In re Winship*, 397 U.S. 358, 371-72 (1970); *Concrete Pipe and Products of California, Inc. v. Construction Laborers*, 508 U.S. 602, 622 (1993). The Board's comment in *Sunshine Haven* suggests that no quantum of evidence applies to judging the CMS prima facie case, but that would create the situation where the mere allegation of a surveyor and CMS would be sufficient evidence to make a prima facie showing, which cannot be correct. Because the preponderance of the evidence test is most commonly applied, that is the test applied in this case to judge whether there is sufficient evidence presented by CMS to support a conclusion that CMS has made the required prima facie showing of a violation of the elements of the applicable regulation and the risk for more than minimal harm.

(iii.) The Evidence Does Not Establish a Prima Facie Showing of a Violation of 42 C.F.R. § 483.65(a)

The surveyors allege in the SOD that 42 C.F.R. § 483.65 was violated because RN Selman: (1) used the "same needle" on both Residents 2 and 11; (2) failed to discard the syringes in the designated container; and (3) contaminated syringes prior to injections. CMS Ex. 2 at 8. The surveyors declared that the violation posed immediate jeopardy from November 3 through 22, 2011, and that the deficiency continued after immediate jeopardy was removed as there remained the potential for more than minimal harm with no actual harm. CMS Ex. 2 at 8; P. Ex. 1 at 8. The testimony of surveyors Farley and Hartman shows that Petitioner had established an infection control program; Petitioner's policy regarding intramuscular injections was consistent with standards of practice and care; Petitioner's staff was trained on Petitioner's infection control policy and procedures; there was no evidence of any other violation by another nurse; Petitioner's investigation of the incident was appropriate; and in-service training of staff was an appropriate response to the incident. The surveyors' conclusion that there was a violation was based on Petitioner's failure to ensure RN Selman complied with Petitioner's infection control program with respect to giving injections and handling syringes.[7] Tr. 92, 94, 97-98, 153-54, 156, 158-59, 162.

There is really no dispute about what RN Selman did. There is some dispute as to whether the syringe used on Resident 2 had already been used on another resident. But, whether or not the syringe had previously been used or was simply never filled by RN Selman need not be resolved as her actions clearly violate nursing standards, CDC recommendations, and Petitioner's policy regarding safe injection practices. The issue that requires resolution is whether the undisputed acts of RN Selman establish a prima facie showing of a violation of 42 C.F.R. § 483.65.

The specific regulatory requirements or elements at issue here are those found in 42 C.F.R. § 483.65 and subparagraph (a)(1) of that section. Following are the elements:

(1) The facility must establish an infection control program; and

(2) The facility must maintain an infection control program; and

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[7] The fact that RN Selman used an incorrect type of syringe to administer flu vaccine was not a stated finding that supported the surveyors' conclusion that 42 C.F.R. § 483.65 was violated. There was also no citation of a deficiency related to a medication error or failure to document the administration of the flu vaccine.

> (3) The facility infection control program must be designed to provide a safe, sanitary, and comfortable environment and to help prevent the development and transmission of disease and infection; and
>
> (4) The infection control program established must provide for the investigation, control, and prevention of infections in the facility.

The regulation clearly notifies Petitioner of these requirements and Petitioner's failure to satisfy any of these elements is a violation of 42 C.F.R. § 483.65. The other requirements listed in the various subparagraphs of 42 C.F.R. § 483.65 are, by their plain language, not applicable in this case.

In this case, the only element of 42 C.F.R. § 483.65 at issue, based on the allegations of the SOD, is whether Petitioner failed to maintain its infection control policy. The positions of the parties may be briefly summarized. CMS argues that the undisputed evidence of RN Selman's actions is sufficient evidence to show that Petitioner failed to maintain its infection control policy. The specific acts cited by the surveyors are that RN Selman: (1) used the "same needle" on both Residents 2 and 11; (2) failed to discard the syringes in the designated container; and (3) contaminated syringes prior to injections. CMS Ex. 2 at 8. Petitioner argues that RN Selman's acts, while unfortunate and inexplicable, are insufficient to show that Petitioner failed to implement or maintain its infection control policy. I conclude that the evidence of RN Selman's acts does not show that it is more likely than not, that Petitioner failed to maintain its infection control policy. Even if one concluded that CMS met its burden of making a prima facie showing with some quantum of evidence less than a preponderance of the evidence, considering the whole record, one must conclude that the prima facie showing has been rebutted in this case because the evidence shows that, but for RN Selman's actions there is no evidence that Petitioner was not maintaining its infection control policy.

It is significant for this case that the acts are acts of a single staff member, RN Selman. It is also significant that the acts were not discrete acts over a period of days or even hours. Rather, the undisputed evidence shows a sequence of acts by RN Selman that occurred within a brief period of roughly one-half hour between 1:30 p.m. and 2 p.m. CMS Ex. 14, 16; P. Ex. 8 at 1, 5, 7-8. Tr. 182-84. On November 3, 2011, RN Selman went to the medication room; she obtained flu vaccine and syringes; she obtained alcohol sponges from the DON; she filled the syringes at the nurse's station; she placed the syringes in her clipboard; she injected four residents; she returned the used syringes to her clipboard; she stuck Resident 2 in the thigh but the syringe was empty; and she immediately reported to her unit manager and the DON. P. Br. at 9-10; P. Reply at 5-6. The evidence does not reflect why RN Selman engaged in these acts. There is no question that the acts violated Petitioner's infection control policy, standards of nursing care or practice, and CDC guidelines. However, there is no question that Petitioner had the required policy and there is no evidence other than the acts of RN Selman that CMS identifies as the basis for

its conclusion that Petitioner failed to maintain its infection control policy. On the facts of this case, RN Selman's actions are an isolated incident of brief duration. Petitioner may not successfully argue that it is not responsible for RN Selman's actions. However, the single incident which Petitioner promptly and correctly addressed consistent with its policies and procedures, is insufficient evidence to show that it is more likely than not that Petitioner failed to maintain its infection control policy.

Accordingly, I conclude that the evidence of RN Selman's acts is insufficient to establish a prima facie showing that Petitioner failed to implement and maintain its infection control policy in violation of 42 C.F.R. § 483.65(a). Because there was no violation of 42 C.F.R. § 483.65, there is no basis for the imposition of an enforcement remedy.

CMS advances several arguments post-hearing not already addressed by this decision that require some discussion. CMS argues for the first time post-hearing that Petitioner's policies and training materials were not sufficiently compliant with the regulations because they did not emphasize CDC's one needle, one patient, one time approach, or explain aseptic techniques for injection safety. CMS Br. at 14. CMS, also for the first time post-hearing, takes exception to the fact that Petitioner did not require staff to demonstrate that they understood the remedial in-service training they received following the incident until prompted by Surveyor Farley. CMS Reply at 8-9. However, the SOD and surveyors' testimony do not support the CMS arguments. The surveyors testified that they did not find a problem with Petitioner's policies and procedures; their issue was with Petitioner's implementation of those policies. Surveyor Hepler mentioned in testimony that she expected to see nurses demonstrate their mastery of in-service training topics. But the SOD does not allege failure to do return demonstrations as a deficiency. And, while Surveyor Hartman did not like that in-service training was done by telephone in some cases, he agreed that no deficiency was cited for that reason. Tr. 63-65, 92, 94, 97-98, 100-04, 139-40, 153-56, 158-59, 162. CMS points to no legal requirement that requires that CDC standards be described in any particular detail in Petitioner's policies. CMS also points to no law that specifies how training is to be conducted. There is no evidence that suggests that any other nurse at the facility did not know how to properly give injections following the CDC guidelines. There is also no evidence that suggests that Petitioner's registered nurses were not fully trained and licensed by the state and authorized to administer flu shots without direct supervision.

The Board has previously concluded that when a facility fails to effectively implement an infection control program, the facility is not in compliance with the regulations. *Barbourville Nursing Home,* DAB No. 1962 at 17-18 (2005) (multiple examples of violations of multiple provisions of 42 C.F.R. § 483.65); *Hermina Traeye Mem. Nursing Home,* DAB No. 1810 at 8-10 (2002), *aff'd* 79 Fed. App'x 563 (4th Cir. 2003) (infection tracking system not implemented). The Board has also decided that if a facility fails to follow its own infection control policies, it is not in substantial compliance with the regulations. *Grand Oaks Care Ctr.*, DAB No. 2372 at 9-13 (2011) (failure to implement

scabies policy resulting in multiple residents contracting scabies); *Western Care Mgmt. Corp., d/b/a Rehab Specialties Inn*, DAB No. 1921 at 78-79 (2004) (multiple residents not isolated when facility policy required isolation). The Board's prior decisions show that the determination that a facility failed to implement an infection control program or that it failed to follow its infection control program is highly fact specific. CMS cites several prior Board and ALJ decisions, none of which involved facts comparable to the case before me. In *Park Manor Nursing Home,* the Board found *Park Manor* failed to implement an infection control program pursuant to 42 C.F.R. § 483.65(b)(3) when several facility staff failed to wash their hands after direct resident contact in direct contravention of the regulation and facility policy. *Park Manor Nursing Home*, DAB No. 2005 at 57-62 (2005). In *Barbourville Nursing Home* the Board upheld a deficiency based on multiple individual staff lapses in infection control technique and failure to follow facility policy. *Barbourville Nursing Home,* DAB No. 1962 at 14-18. In *Woodbine Healthcare and Rehab. Center* an ALJ rejected *Woodbine's* argument that a series of lapses in infection control technique involving staff failures to wear protective gowns and do wound dressings in a sanitary manner could be described as isolated, and held that the lapses conclusively demonstrated that the facility was not adequately carrying out its infection control responsibilities. *Woodbine Healthcare and Rehab. Ctr.,* DAB CR1200 at 35-37 (2004). The obvious distinction between the cases cited by CMS and the present case is that all the cited cases involved more than one staff member or multiple failures, permitting the Board and the ALJ to infer that the lapses in infection control were systemic and not isolated.

CMS argues that I should consider prior Board decisions interpreting the neglect and abuse regulation at 42 C.F.R. § 483.13(c) in which the failure of an individual staff member to follow facility policies was found sufficient to show that a facility had not implemented policies prohibiting abuse, neglect, and misappropriation of resident property. CMS directs my attention to the decision of an appellate panel of the Board in *Life Care of Gwinnett* in which it is stated that the "Board has repeatedly held that multiple or sufficiently serious examples of neglect may support a reasonable inference that a facility has failed to implement an anti-neglect policy within the meaning of the regulation." *Life Care of Gwinnett,* DAB No 2240 at 5-6 (2009), *citing Liberty Commons Rehab. and Nursing Ctr. – Johnston,* DAB No. 2031; (failure by one CNA on one occasion to follow latex allergy precautions procedures); *Barn Hill Care Ctr.,* DAB No. 1848 (2002) (medication errors and untimely medication passes by one nurse on a single day).[8] The cited decisions show that the Board has been willing to infer that a facility has

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[8] CMS also cites the decision in *Florence Park Care Ctr.,* DAB No. 1931 at 17-19 (2004) for the proposition that CMS is not required to show "systemic" failings as part of its prima facie case. However, CMS overlooks that that case is inapposite as it involved the facilities duty to minimize the risk for harm due to accidents and to provide assistive

(Footnote continued next page.)

failed to implement its abuse and neglect prevention policy or other policies required by regulation based on a sufficiently serious example of a violation of the facility policy. However, the same Board decision may be cited for the proposition that the Board has recognized that not every individual failure or violation is sufficient to establish a failure to implement required policies. Applying the Board's reasoning in this case, I conclude that the acts of RN Selman simply do not trigger a reasonable inference that Petitioner failed to implement its infection control policy. Considering the totality of the evidence in this case, I cannot conclude that it is more likely than not that Petitioner failed to implement or maintain its infection control policy.

CMS also argues that facilities are responsible for the acts or omissions of their employees and Petitioner cannot disavow responsibility for staff noncompliance by arguing that a staff member failed to carry out instructions or act in conformity with their training. *Sunshine Haven Lordsburg*, DAB No. 2456 at 16; *Fort Madison Health Ctr.*, DAB No. 2403 at 5-6 (2011), *citing NHC Healthcare Athens*, DAB No. 2258 at 14 (2009); *Life Care of Gwinnett*, DAB No. 2240 at 12-13; *Florence Park Care Ctr.*, DAB No. 1931 at 16; *Georgian Court Nursing Ctr.*, DAB No. 1866 (2003); *Cherrywood Nursing and Living Ctr.*, DAB No. 1845 (2002). I do not disagree with the proposition that an employer may be responsible for the acts of an employee. But the case before me is not a civil law suit for money damages in which the question is whether Petitioner is liable for RN Selman's negligent or intentional acts. The issue before me is whether RN Selman's actions show that Petitioner failed to implement its infection control program. Therefore, the issue presented actually imputes RN Selman's conduct to Petitioner.

Analogizing to the quality of care regulation at 42 C.F.R. § 483.25, CMS argues that Petitioner did not take "all necessary steps" to prevent RN Selman's actions. CMS Reply at 7. There is no evidence that Petitioner failed to satisfy all requirements of the act and regulations when hiring, orienting, and training RN Selman. There is no evidence that Petitioner failed to ensure that RN Selman received the supervision required by state law when performing her duties as a registered nurse. CMS points to no necessary step Petitioner failed to take and I can draw no inference that there was a failure based simply on the occurrence of RN Selman's acts as CMS invites.

CMS argues that it is unlikely that RN Selman would have felt at liberty to do what she did in a facility that maintained appropriate adherence to injection safety protocols. CMS also argues that RN Selman felt at liberty to commit her acts in plain view despite the presence of other staff in the medication room and the nursing station and, including,

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(Continued from preceding page.)

devices and supervision under 42 C.F.R. § 483.25(h). The regulation in that case did not require that the facility implement and maintain policies as does 42 C.F.R. § 483.65.

asking the DON for alcohol sponges before going to vaccinate the residents. CMS Br. at 15; CMS Reply at 7-8. CMS argues that according to health care industry standards, good infection control relies, in part, on a culture of shared vigilance and on-the-spot correction, citing CMS Ex. 44 at 7-8, 41, 45, 46 and Surveyor Hartman's testimony (Tr. 151). CMS asserts that RN Selman's actions do not evince a culture of infection control vigilance at Petitioner's facility. CMS Br. at 15. In short, CMS invites the inference that because no other staff member or the DON noticed what RN Selman was doing, Petitioner failed to maintain its infection control policy. The inference is not supported in this case. There is no dispute that a registered nurse does not require direct supervision to administer injections. RN Selman was a registered nurse and qualified to give injections based on her training, experience, and licensure. RN Selman was directed to administer influenza vaccine to several residents on November 3, 2011, as part of her duties. CMS cites to no legal requirement or standard of practice that required other staff or the DON to oversee the steps that RN Selman took to perform her duty to vaccinate residents or to interrogate her about how she was performing the duties. Further, what RN Selman felt at the time is wholly speculative as that assertion by CMS is unsupported by any evidence as to what she was feeling and I will not draw any inference based on the fact she committed the acts.

CMS argues that RN Selman's action would not even have been identified or stopped if not for Resident 2's reaction. CMS Reply at 8. This argument is also based on speculation. The evidence shows that Resident 2 reacted and RN Selman reported to her Unit Manager and the DON. There is no evidence that suggests RN Selman was not going to report her error.

In analogizing to other cases outside the infection control area, CMS fails to mention that the Board has held that "the quality of care regulations under section 483.25 'hold facilities to meeting their commitments to provide care and services in accordance with the high standards to which they agreed but do not impose strict liability, i.e., they do not punish facilities for unavoidable negative outcomes or untoward events that could not reasonably have been foreseen and forestalled.'" *Cedar Lake Nursing Home*, DAB No. 2288 at 12 (2009), *citing Tri-County Extended Care Ctr.*, DAB No. 1936 at 7 (2004). Safe injection protocol is a fundamental nursing skill that nurses should follow at all times. CMS Reply at 4. Both parties clearly recognize this. However, Petitioner could not reasonably have foreseen in this case that a properly licensed, qualified, and trained registered nurse would commit such a series of fundamental errors in injection practice and protocol.

Applying principles from the various cases cited by CMS not related to infection control, does not change my conclusion that CMS has not made a prima facie showing that Petitioner violated 42 C.F.R. § 483.65(a) by failing to implement and maintain its infection control based on this single incident involving RN Selman. There is no question that RN Selman made gross errors in injection safety protocol, however, that

does not show that there was such a systemic failure of Petitioner's infection control program to support an inference that Petitioner failed to maintain the required program. Rather, the CMS evidence shows, and CMS's surveyors concede, that in every other respect Petitioner met the regulatory requirement. The actions of RN Selman constitute a single incident, caused solely by her, and were simply unforeseeable. I conclude that this single incident is not sufficient to show that Petitioner failed to implement its infection control policies.

3. Other issues raised by Petitioner are without merit in this case.

Petitioner argues at page 5 of its request for hearing and in its prehearing brief (P. PH Br. at 13) that the allocation of the burden of persuasion in this case, according to the rationale of the Board in prior decisions violates the Administrative Procedures Act, 5 U.S.C. § 551-59, specifically 5 U.S.C. § 556(d). Petitioner also argues the allocation of the burden to Petitioner deprives Petitioner of property without due process of law by permitting the Board to minimize or disregard Petitioner's evidence. Pursuant to the scheme for the allocation of burdens adopted by the Board in its prior cases, CMS bears the burden to come forward with the evidence and to establish a prima facie showing of the alleged regulatory violations in this case by a preponderance of the evidence. If CMS makes its prima facie showing, Petitioner has the burden of coming forward with any evidence in rebuttal and the burden of showing by a preponderance of the evidence that it was in substantial compliance with program participation requirements. Petitioner bears the burden to establish by a preponderance of the evidence any affirmative defense. The allocation of burdens suggested by the Board is not inconsistent with the requirements of 5 U.S.C. § 556(d), as CMS is required to come forward with the evidence that establishes its prima facie case. Furthermore, Petitioner prevails on the merits in this case and Petitioner suffered no prejudice by the allocation of burdens in this case.

III. Conclusion

For the foregoing reasons, there was no regulatory violation and there is no basis for the imposition of enforcement remedies in this case.

/s/
Keith W. Sickendick
Administrative Law Judge