Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Autumn Healthcare of Zanesville,
(CCN: 36-5464),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-12-407

Decision No. CR3384

Date: September 24, 2014

DECISION

Petitioner, Autumn Healthcare of Zanesville, violated 42 C.F.R. § 483.65(a)(1) on February 16, 2012; the violation posed more than a minimal risk for more than minimal harm; Petitioner was not in substantial compliance with program participation requirements from October 30, 2011 through March 22, 2012; and a denial of payments for new admissions (DPNA) for the period December 30, 2011 through March 22, 2012, was authorized and reasonable.

I. Background

Petitioner is located in Zanesville, Ohio, and participates in the Medicare program as a skilled nursing facility (SNF) and in the state Medicaid program as a nursing facility (NF). On October 30, 2011, December 28, 2011, January 18, 2012, February 16, 2012, and March 23, 2012, the Ohio Department of Health (state agency) completed recertification, revisit, complaint, and life safety code surveys of Petitioner. The state agency determined during each of the first four surveys that Petitioner was not in substantial compliance with program participation requirements, based on surveyor findings of various deficiencies that amounted to noncompliance. Based on the March 23, 2012 revisit survey, the state agency concluded that Petitioner returned to substantial

compliance with program participation requirements on that date. Joint Stipulations of Undisputed Facts (Jt. Stip.) ¶¶ 1-5.

CMS notified Petitioner on February 16, 2012, that it was imposing a per-instance civil money penalty (PICMP) of $3,500 for noncompliance cited by the October 30, 2011 survey under Tag F314. CMS also notified Petitioner that a discretionary DPNA was imposed effective December 30, 2011, that would continue until Petitioner returned to substantial compliance. CMS Exhibit (Ex.) 4 at 2. CMS sent Petitioner a second notice on March 7, 2012, advising Petitioner that the survey completed on February 16, 2012, found Petitioner not in substantial compliance with Tag F441 (42 C.F.R. § 483.65). CMS advised Petitioner that its provider agreements would be terminated March 30, 2012, and that the other enforcement remedies, including the DPNA, continued. CMS Ex. 6. CMS notified Petitioner on May 11, 2012, that the revisit survey on March 23, 2012, found that Petitioner was in substantial compliance on that date. Based on the conclusion that Petitioner returned to substantial compliance on March 23, 2012, CMS rescinded the termination and the DPNA was discontinued effective March 23, 2012. CMS also stated in its notice that, because Petitioner waived its right to challenge the PICMP based on the October 2011 survey, the PICMP was reduced by 35 percent from $3,500 to $2,275, pursuant to 42 C.F.R. § 488.436. CMS Ex. 8.

Petitioner requested a hearing before an administrative law judge (ALJ) on February 21, 2012. On March 5, 2012, the case was assigned to me for hearing and decision and an Acknowledgement and Prehearing Order (Prehearing Order) was issued at my direction. On March 27, 2012, I convened a hearing by video teleconference and a transcript (Tr.) of the proceedings was prepared. CMS offered CMS Exs. 1 through 18 that were admitted as evidence. Tr. 33. Petitioner offered Petitioner exhibits (P. Exs.) 1 through 3. I admitted P. Ex. 1, pages 1, 2, and 10 through 15, and P. Exs. 2 and 3 as evidence. Tr. 38. CMS called Surveyor Patricia McElroy, RN, as a witness. Petitioner called the following witnesses: Randall Alan Woodings of Kontogiannis and Associates, Architects Planners, (the architect who designed Petitioner's facility); and Heidi Harper, RN, Petitioner's Director of Nursing (DON). The parties filed post-hearing briefs (CMS Br. and P. Br.) and post-hearing reply briefs (CMS Reply and P. Reply).

II. Discussion

A. Applicable Law

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

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

The Secretary has delegated to CMS and the states the authority to impose remedies against a long-term care facility that is not complying substantially with federal participation requirements. "*Substantial compliance* means a level of compliance with the requirements of participation such that any identified deficiencies pose no greater risk to resident health or safety than the potential for causing minimal harm." 42 C.F.R. § 488.301 (emphasis in original). A deficiency is a violation of a participation requirement established by sections 1819(b), (c), and (d) of the Act or the Secretary's regulations at 42 C.F.R. pt. 483, subpt. B. Noncompliance refers to any deficiency that causes a facility not to be in substantial compliance. 42 C.F.R. § 488.301. State survey agencies survey facilities that participate in Medicare on behalf of CMS to determine 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

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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.

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).

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 Nurse Aide Training and Competency Evaluation Program. 42 C.F.R. § 498.3(b)(14), (16), (d)(10)(i). The CMS determination as to the level of noncompliance, including the finding of immediate jeopardy, "must be upheld unless it is clearly erroneous." 42 C.F.R. § 498.60(c)(2); *Woodstock Care Ctr.*, DAB No. 1726 at 9, 38 (2000), *aff'd*, 363 F.3d 583 (6th Cir. 2003). The Departmental Appeals Board (the Board) has long held that the net effect of the regulations is that a provider has no right to challenge the scope and severity level assigned to a noncompliance finding, except in the situation where that finding was the basis for an immediate jeopardy determination. *See, e.g.*, *Ridge Terrace*, DAB No. 1834 (2002); *Koester Pavilion*, DAB No. 1750 (2000). ALJ review of a CMP is subject to 42 C.F.R. § 488.438(e).

The hearing before an ALJ is a de novo proceeding, that is, "a fresh look by a neutral decision-maker at the legal and factual basis for the deficiency findings underlying the remedies." *Life Care Ctr. of Bardstown*, DAB No. 2479 at 32 (2012) (citation omitted). The Board has long held that the petitioner bears the burden of persuasion to show by a preponderance of the evidence that it was in substantial compliance with participation requirements or any affirmative defense. *Batavia Nursing & Convalescent Inn*, DAB No. 1911 (2004); *Batavia Nursing & Convalescent Ctr.*, DAB No. 1904, *aff'd*, *Batavia Nursing & Convalescent Ctr. v. Thompson*, 129 F. App'x 181 (6th Cir. 2005); *Emerald Oaks*, DAB No. 1800 (2001); *Cross Creek Health Care Ctr.*, DAB No. 1665 (1998); *Hillman Rehab. Ctr.*, DAB No. 1611, *aff'd*, *Hillman Rehab. Ctr. v. United States*, No. 98-3789 (GEB), 1999 WL 34813783 (D.N.J. May 13, 1999). However, only when CMS makes a prima facie showing of noncompliance, is the facility burdened to show, by a

preponderance of the evidence on the record as a whole, that it was in substantial compliance or had an affirmative defense. *Evergreene Nursing Care Ctr.*, DAB No. 2069 at 4.

The standard of proof, or quantum of evidence required, is a preponderance of the evidence. CMS has the burden of coming forward with the evidence and making a prima facie showing of a basis for imposing an enforcement remedy. The Board has stated that CMS must come forward with "evidence related to disputed findings that is sufficient (together with any undisputed findings and relevant legal authority) to establish a prima facie case of noncompliance with a regulatory requirement." *Evergreene Nursing Care Ctr.*, DAB No. 2069 at 7 (2007); *Batavia Nursing & Convalescent Ctr.*, DAB No 1904. "Prima facie" means generally that the evidence is "[s]ufficient to establish a fact or raise a presumption unless disproved or rebutted." *Black's Law Dictionary* 1228 (8th ed. 2004). In *Hillman Rehab. Ctr.*, the Board described the elements of the CMS prima facie case in general terms as follows:

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

DAB No. 1611 at 8. Thus, CMS has the initial burden of coming forward with sufficient evidence to show that its decision to impose an enforcement remedy is legally sufficient under the statute and regulations. To make a prima facie case that its decision was legally sufficient, CMS must: (1) identify the statute, regulation or other legal criteria to which it seeks to hold the provider; (2) come forward with evidence upon which it relies for its factual conclusions that are disputed by Petitioner; and (3) show how the deficiencies it found amount to noncompliance that warrants an enforcement remedy, that is, that there was a risk for more than minimal harm due to the regulatory violation. In *Evergreene Nursing Care Ctr.*, the Board explained its "well-established framework for allocating the burden of proof on the issue of whether a SNF is out of substantial compliance" as follows:

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

> showing, by a preponderance of the evidence, on the record as a whole, that it was in substantial compliance during the relevant period.

DAB No. 2069 at 7. CMS makes a prima facie showing of noncompliance if the credible evidence CMS relies on is sufficient to support a decision in its favor absent an effective rebuttal. The regulation gives Petitioner notice of the criteria or elements it must meet to comply with the program participation requirement established by the regulation. 5 U.S.C. §§ 551(4), 552(a)(1). Therefore, in order to make a prima facie showing of noncompliance, CMS must show that Petitioner violated the regulation by not complying with one or more of the criteria or elements of the regulation, which is a deficiency. CMS must also show that the deficiency amounted to "noncompliance," that is, that Petitioner was not in substantial compliance because the deficiency posed a risk for more than minimal harm. *See Jennifer Matthew Nursing & Rehab. Ctr.*, DAB No. 2192 at 20 n.12 (2008). A facility can overcome CMS's prima facie case either by rebutting the evidence upon which that case rests, or by proving facts that affirmatively show substantial compliance. "An effective rebuttal of CMS's prima facie case would mean that at the close of the evidence the provider had shown that the facts on which its case depended (that is, for which it had the burden of proof) were supported by a preponderance of the evidence." *Id.* at 7-8 (citations omitted).

B. Issues

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

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.[2] 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

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[2] "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.

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. & Prac.* § 5:64 (3d ed. 2013).

The survey cycle in this case included a total of five surveys, October 20, 2011, December 28, 2011, January 18, 2012, February 16, 2012, and March 23, 2013. The final survey on March 23 determined that Petitioner was back in substantial compliance on that date. The parties stipulated that only the February 16, 2012 survey is at issue in this case, however that is inaccurate. Jt. Stip. ¶ 7; Tr. 16-17. The February 2012 survey cited Petitioner for noncompliance with 42 C.F.R. § 483.65 (Tag F441) at a scope and severity of E, indicating a pattern of incidents posing a risk for more than minimal harm. CMS Ex. 15. The parties have also stipulated that the only enforcement remedy at issue is the DPNA, which began on December 30, 2012. The duration of the DPNA is in dispute. Petitioner argues that it returned to substantial compliance on January 19, 2012 and that the last day of the DPNA should have been January 18, 2012. Jt. Stip. ¶¶ 7, 8; Tr. 16-17. Petitioner was cited by the December 28, 2011 survey for noncompliance with 42 C.F.R. § 483.65 (Tag F441) also at a scope and severity of E. CMS Ex. 13. Petitioner was cited by the January 18, 2012 survey with noncompliance with 42 C.F.R. § 483.13(c)(1)(ii)-(iii), (c)(2)-(4) (Tag F225); 483.13(c) (Tag F226); and 483.75(i)(1) (Tag F514), each at a scope and severity of D indicating an isolated incident that posed a risk for more than minimal harm. CMS Ex. 14. Therefore, in order to determine when Petitioner returned to substantial compliance and the date on which the DPNA should end, it is necessary to determine when Petitioner corrected the deficiencies for the December, January, and February surveys. Tr. 20-21. CMS argues that Petitioner did not return to substantial compliance until March 23, 2012, as determined by the survey completed on that date. CMS argues, in the alternative, that if the noncompliance under Tag F441 cited by the February 2012 survey is unfounded, Petitioner did not return to substantial compliance prior to February 16, 2012 and the DPNA should run to that date. Tr. 17; CMS Br. at 13-16; CMS Reply at 8-9. The parties stipulated that Surveyor McElroy found that the noncompliance with Tags F225, F226, and F514 had been corrected as of the February 16, 2012 survey. Jt. Stip. ¶ 15.

I first examine whether or not Petitioner was in violation of 42 C.F.R. § 483.65 on February 16, 2012 and, if there was a violation, whether or not there was a risk for more than minimal harm. I then consider when Petitioner returned to substantial compliance with program participation requirements.

1. Petitioner violated 42 C.F.R. § 483.65 (Tag 441) on February 16, 2012 and the violation posed more than a minimal risk for more than minimal harm.

a. Facts

Surveyor McElroy conducted the survey of Petitioner on February 16, 2012. The survey was a revisit survey for the biannual healthcare survey in December 2011 and the complaint investigation in January 2012. Her revisit was to determine whether Petitioner had corrected noncompliance with Tags F225, F226, and F514 as cited by the January 2012 complaint investigation and Tag F441 as cited by the October and December 2011 surveys. Tr. 46-47; CMS Exs. 12-15. Surveyor McElroy recorded her findings and conclusions for the February 16, 2012 survey in the Statement of Deficiencies (SOD) admitted as CMS Ex. 15. Tr. 47.

Surveyor McElroy stated in the SOD that on February 16, 2012, at about 8:30 a.m., she observed three "isolation carts" sitting in the hall of Unit One and three carts in the corridor for Unit Two. At about 8:45 a.m. on February 16, 2012, she observed a housekeeper mopping the floor of Resident 17's room. Resident 17 was in isolation for Methicillin Resistant Staphylococcus Aureus (MRSA) in her sputum. CMS Ex. 15 at 3; Tr. 52, 72-73. The parties stipulated that the room number was 111 and that the housekeeper was Marie Jungling. Jt. Stip. ¶¶ 10, 11. Surveyor McElroy recorded in the SOD that Ms. Jungling's cart was in front of the room door. Ms. Jungling was wearing a disposable gown, gloves, and mask while mopping. CMS Ex. 15 at 3; Jt. Stip. ¶ 13. Surveyor McElroy recorded that she observed Ms. Jungling remove the mop head and put it in a plastic bag when she finished mopping the floor in room 111. CMS Ex. 15 at 3; Jt. Stip. ¶ 14. Surveyor McElroy then saw Ms. Jungling remove her gown, gloves, and mask and place them in a box in the room that was lined with a yellow trash bag. Surveyor McElroy recorded in the SOD that Ms. Jungling left room 111 without washing her hands and took the bagged mop head to the laundry room. Ms. Jungling then washed her hands. Surveyor McElroy recorded that she asked Ms. Jungling about why she did not wash her hands before leaving room 111 and Ms. Jungling responded that she did not want to touch the sink handles but then stated that she did wash but really quick. CMS Ex. 15 at 3. The parties stipulated that Petitioner's isolation procedures require hand washing before leaving the room of a patient who is in isolation, which is consistent with what the DON told Surveyor McElroy and Petitioner's policy regarding cleaning isolation rooms. Jt. Stip. ¶ 12; CMS Ex. 15 at 4. Surveyor McElroy testified consistently at hearing regarding her observations. Tr. 51-58. She testified that MRSA is very contagious and difficult to treat. Tr. 52. She testified that she made her observations while sitting across from room 111; there was nothing between her and the door to room 111 except the cart and that did not block her view of Ms. Jungling; and she was certain Ms. Jungling did not wash her hands as she was never out of Surveyor McElroy's sight as she would have been if she washed her hands in the bathroom of room 111. Tr. 53-54.

Surveyor McElroy opined that there is risk for harm if staff does not wash hands when leaving an isolation room due to the potential for spreading infection. Tr. 58-59. She

testified that Centers Disease Control (CDC) guidelines require washing hands after removing gloves. Tr. 74, 103.

Surveyor McElroy opined that Petitioner had not implemented is policy and procedure for cleaning isolation rooms (CMS Ex. 16 at 1-3) based on her observation that Ms. Jungling failed to wash her hands when leaving room 111. She concluded that Petitioner had not implemented its plan of correction for the citation of Tag F441 from the December 2011 survey. Tr. 60. On cross-examination she agreed that Petitioner had the infection control program with the elements required by 42 C.F.R. § 483.65. Tr. 75-76. She admitted that she did not know if Ms. Jungling had direct contact with Resident 17 while cleaning room 111. She agreed that she did not cite Petitioner during the February 2012 survey for a deficiency related to handling linen. Tr. 77. She agreed that the appropriate response to forgetting to wash ones hands is to promptly wash the hands and she agreed that Ms. Jungling did, in fact, wash her hands after dropping off the mop head in the laundry. She agreed that Ms. Jungling did not enter any other resident rooms, she did not touch any staff, no residents were in the hall, and she did not see Ms. Jungling touch any resident door handles, or furniture in the common area. Tr. 81-82. Surveyor McElroy agreed that P. Ex. 1 shows that it was not possible to see into the bathroom of room 111 from where she was sitting when she made her observations on February 16, 2012. Tr. 94.

In response to my questioning, Surveyor McElroy opined that Ms. Jungling was properly attired for cleaning room 111. Surveyor McElroy admitted that she did not record any observations about how or the order in which Ms. Jungling removed her protective attire. She admitted that she had no specialized training in the area of infectious disease control. Surveyor McElroy agreed during my examination that by being properly attired, properly cleaning room 111, properly removing and disposing her protective attire, Ms. Jungling reduced the risk for spread of MRSA. Surveyor McElroy had great difficulty rendering an opinion regarding the risk for spreading MRSA posed by Ms. Jungling's failure to wash her hands before leaving room 111. She testified that the remedy for failure to wash hands was to wash the hands as soon as the oversight was discovered and maybe wipe down any areas touched prior to the hand washing. She ultimately opined that Ms. Jungling's failure to wash her hands posed some risk, but it was not a great risk. Tr. 61-72.

DON Harper testified that housekeeper carts in the facility are approximately 38 inches tall and 28 inches wide. Tr. 137. She testified that after Surveyor McElroy told her that she observed that Ms. Jungling failed to wash her hands before leaving room 111, she interviewed Ms. Jungling and concluded that Ms. Jungling had washed her hands. Tr. 140-41. She testified that she requested that Ms. Jungling prepare a statement that was used for informal dispute resolution. Ms. Jungling's unsworn statement, which is not in the form of a declaration, was admitted as P. Ex. 2 at 5 without objection by CMS. The Secretary requires that witnesses in this proceeding testify under oath or affirmation.

42 C.F.R. § 498.62. Therefore, I may not consider witness testimony, in any form, that is not sworn or affirmed. The Prehearing Order, ¶ II.L.8 provided in pertinent part:

> A written witness' statement may be submitted in lieu of live direct testimony at hearings, or in support of a motion for summary judgment, or when a hearing is waived. Written witness statements must be submitted in the form of an affidavit made under oath or as a written unsworn declaration executed in accordance with 28 U.S.C. § 1746.

The Prehearing Order clearly notified the parties that an unsworn statement must be executed in accordance with 28 U.S.C. § 1746, by which Congress provided an exception to the requirement that testimony be under oath or affirmation. Ms. Jungling's written statement is not sworn or affirmed and does not substantially comply with 28 U.S.C. § 1746, therefore it cannot be considered as substantive evidence, despite the absence of an objection by CMS. Ms. Jungling resigned from her employment with Petitioner on September 9, 2012. Tr. 144.

Whether or not Ms. Jungling washed her hands prior to leaving room 111 is an issue of fact. Ms. Jungling's statements regarding whether or not she washed her hands as reported by Surveyor McElroy are inconsistent. Surveyor McElroy recorded at the time of the survey that Ms. Jungling first said she did not want to touch the sink but then she said she washed her hands quickly. CMS Ex. 15 at 3; CMS Ex. 17 at 5. DON Harper testified that she concluded based on her interview with Ms. Jungling that Ms. Jungling did wash her hands, but DON Harper did not specify at what point she concluded Ms. Jungling washed her hands, before leaving room 111 or after putting the mop head in the laundry. Tr. 140-41. Surveyor McElroy admitted that the housekeeping cart was between her and the door to room 111 when she was making her observations, but she asserted the cart did not prevent her from seeing Ms. Jungling. She also admitted that she was making notes while watching Ms. Jungling. Tr. 53-54, 56. Based on my review of Surveyor McElroy's notes, they do not appear so detailed as to suggest that note taking may have prevented the surveyor from attending to her observations most of the time. CMS Ex. 17 at 4-5. I also consider that Surveyor McElroy was a trained and experienced observer based on her survey and nursing experience. There is a possibility given the position of the cart and the fact that Surveyor McElroy was writing notes, that Ms. Jungling entered the bathroom of room 111 without being observed. However, given her initial inconsistent statement and the fact she was not present to testify under oath, I find it more likely than not that Ms. Jungling simply failed to wash her hands when leaving room 111 and did not do so until after she delivered the bagged mop head to the laundry room.

Regarding the risk for harm associated with the transmission of MRSA, I find that the failure of Ms. Jungling to wash her hands when leaving the room posed a risk for the

transmission of MRSA to other staff and residents. There is no conflict in the evidence that MRSA is very contagious and difficult to treat. But, the degree or amount of risk associated with the spread of MRSA by a staff member who was otherwise properly attired because the staff member failed to wash his or her hands after removing protective attire is significantly more difficult to determine in this case in the absence of qualified expert testimony. Resident 17 was on isolation for MRSA as there was a risk for spreading MRSA due to its presence in her sputum or other fluids, according to the parties. Sputum, phlegm, or other bodily floods with MRSA could be present on bedding, the bed frame, the furniture, the floor. Surveyor McElroy could not recall whether or not Ms. Jungling was wearing booties or protective covers over her shoes. Surveyor McElroy did not cite Petitioner because Ms. Jungling was not wearing shoe covers. However, if Ms. Jungling walked through sputum, phlegm, or other infectious fluids on the floor there was certainly a risk that she would track the material into the hall where it could be stepped in by residents or staff who would subsequently touch their shoes. Additionally, residents that self-propel in wheelchairs often do so by gripping the wheels of the wheelchair to propel. According to DON Harper the cleaning policy requires the cleaning staff to enter the room and start cleaning in the farthest corner of the room from the door and then work their way back through the room to the door. Tr. 152. Thus, there are two chances for housekeepers to step in contaminated fluid on the floor before working back to the hallway. DON Harper also testified that there is no requirement for mop handles, brooms and other cleaning devices to be left in the room when isolation is due to MRSA, but there is no procedure for those items to be cleaned before being placed back on the cleaning cart in the hall where they may be touched by staff or even residents. Tr. 158. However, Surveyor McElroy did not cite Petitioner with any deficiency for failure to sanitize potentially contaminated equipment before returning it to the cleaning cart or for failure to include such a requirement in the Petitioner's infection control policy. DON Harper explained that there is a different procedure when the infectious agent is Clostridium difficile (C. diff.). If the infection is C. diff. the policy is that the broom must remain in the room and then be destroyed when the need for isolation is removed. Tr. 159-60; CMS Ex. 16 at 1. There is no evidence that suggests that the risk for spreading MRSA due to a staff member's failure to wash her hands after removing protective attire and gloves is any greater than the risk associated with wearing shoes that are potentially contaminated or removing items such as brooms and mop handles that have not been sanitized from the room. In fact, common sense dictates that because a staff member's hands would have been protected by gloves during the cleaning process, the risk of transmission because hands were not washed, is likely less than the risk of moving potentially contaminated cleaning equipment from room-to-room. Thus, the evidence regarding the risk for spreading MRSA due to contamination of hands that were gloved versus shoes and equipment that were not covered or sanitized appears to be in conflict. I do not have competent evidence that permits me to resolve the apparent inconsistency.

b. Analysis

The legal issue that must be resolved is whether the housekeeper's violation of Petitioner's infection control policy and procedures because she failed to wash her hands before leaving room 111 amounts to a violation of 42 C.F.R. § 483.65.

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.
>
> (a) *Infection control program*. The facility must establish an infection control program under which it—
>
> (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.
>
> (c) *Linens*. Personnel must handle, store, process, and transport linens so as to prevent the spread of infection.

42 C.F.R. § 483.65.

There is no allegation in the SOD for the February 16, 2012 survey of a violation of 42 C.F.R. § 483.65(c), which pertains to handling potentially contaminated linens. There is no evidence that Ms. Jungling had direct contact with Resident 17 when she was cleaning room 111 or that she had any communicable disease or open skin lesions. Therefore, 42 C.F.R. § 483.65(b)(2) and (3) were not violated on February 16, 2012. There is no dispute that Resident 17 required isolation and was isolated. Therefore, 42 C.F.R. § 483.65(b)(1) was not violated.

The evidence shows that Petitioner had an infection control program as required by 42 C.F.R. § 483.65(a). Surveyor McElroy agreed on cross-examination that Petitioner had created the required program. Tr. 75-76. However, Surveyor McElroy testified that she cited Petitioner for failure to implement its policy and procedure for cleaning isolation rooms, which is part of Petitioner's infection control policy. Petitioner's infection control policy was violated because Ms. Jungling failed to wash her hands before leaving room 111. Tr. 59-60; CMS Ex. 16 at 1-2. Surveyor McElroy stated in the SOD that Petitioner "failed to ensure infection control practices were maintained related to hand washing after providing room cleaning for one resident." CMS Ex. 15 at 2. The requirement that housekeeping staff wash their hands after removing gloves and before exiting an isolation area is well established and not challenged in this case. Petitioner's infection control policy instructs cleaning staff that "[w]hen all surfaces and the floor are cleaned and disinfected, remove Personal Protective Equipment and wash hands before leaving the room." CMS Ex. 16 at 1. Surveyor McElroy's testimony that CDC guidelines recommend washing hands after removing gloves is unrebutted. Tr. 74, 103; CMS Ex. 18. CMS Publication 100-07, State Operations Manual (SOM),[3] app. PP – Guidance to Surveyors for Long Term Care Facilities, Tag F441 (Sep. 30, 2009),

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[3] The SOM is available at 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. Dept. 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. Policy statements of the Secretary and CMS 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).

provides that hand hygiene[4] is required in many circumstances, including before and after entering isolation precaution settings and after removing gloves or aprons. The SOM states that consistent use of proper hygiene is critical to preventing the spread of infections. The SOM cites numerous published sources as support for the findings regarding infections and infection controls. Surveyors are instructed by the SOM that one of the objectives of a survey of infection control practices is to determine if staff practices, including hand hygiene, are consistent with current infection control principles. Surveyors are instructed to observe hand hygiene practices and the use of gloves. Surveyors are instructed that actual or potential harm may result from failure of staff to properly perform hand hygiene when entering and exiting the room of a resident on special precautions.

I conclude that although Petitioner had established the infection control policy required by 42 C.F.R. § 483.65(a), the failure of Ms. Jungling to wash her hands prior to leaving room 111, is an instance when Petitioner failed to ensure its infection control program was adequately implemented to control and prevent infections in the facility in violation of 42 C.F.R. § 483.65(a)(1).

In addition to the regulatory violation or deficiency, CMS must show that the deficiency posed a risk for more than minimal harm in order for there to be noncompliance that will support the imposition of an enforcement remedy, the continuation of the DPNA in this case. 42 C.F.R. §§ 488.301 (substantial compliance means that no deficiency poses a "greater risk to resident health and safety than the potential for causing minimal harm" and noncompliance "means any deficiency that causes a facility not to be in substantial compliance"), 488.330(a)(2) (certification of noncompliance requires enforcement action), 488.400 (section 1819(h) of the Act specifies remedies that may be used when a SNF is not in substantial compliance with participation requirements), 488.402(b) (enforcement remedies are imposed based on noncompliance), 488.404-.408 (no enforcement remedy authorized if a deficiency poses minimal harm with no actual harm). Therefore, CMS has the initial burden, as part of its prima facie case, to show that the violation of 42 C.F.R. § 483.65(a)(1) poses a greater risk to resident health and safety than the potential for causing minimal harm. 42 C.F.R. § 483.301 (definition of substantial compliance); *see Jennifer Matthew Nursing & Rehab. Ctr.*, DAB No. 2192 at 20 n.12 (the Board recognized that CMS has initial burden of making a prima facie showing but declined to define what is required for the showing). In this case, however, CMS need not present some quantum of evidence to show that there is a risk for more

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[4] In the SOM, hand hygiene refers to both washing with soap and water and the use of alcohol-based hand rubs. Hand washing refers to washing hands with plain soap and water. SOM, app. PP, Tag F441.

than minimal harm.[5] For a deficiency cited under Tag F441 (42 C.F.R. § 483.65), the SOM provides that "[t]he failure of the facility to provide appropriate care and services for infection control practices places the resident at risk for more than minimal harm."[6] Therefore, as a matter of policy the Secretary, or her delegate CMS, has declared that a deficiency under Tag F441 poses a risk for more than minimal harm. It is within the Secretary's discretion to make the determination that violation of infection control practices places residents at risk for more than minimal harm. Act § 1819(f) ("duty and responsibility of the Secretary to assure that requirements which govern the provision of care in skilled nursing facilities . . . and the enforcement of such requirements, are adequate to protect the health, safety, welfare, and rights of residents and to promote the effective and efficient use of public moneys."). Whether the SOM language should be interpreted to mean that any failure to follow infection control practices is per se noncompliance, and not subject to rebuttal; or whether it should be treated as establishing a rebuttable presumption of noncompliance, need not be resolved in this case. If failure to follow infection control practices is noncompliance per se, Petitioner cannot prevail in this case as the facts show that Ms. Jungling failed to follow the infection control practice of washing her hands prior to leaving room 111. If failure to follow an infection control practice triggers a rebuttable presumption, Petitioner has not rebutted the presumption in this case.

The evidence shows that hand hygiene before leaving an isolation area is a standard for infection control found in Petitioner's policy (CMS Ex. 16 at 1); CDC guidance (CMS Ex. 18), and the SOM app. PP, Tag F441. The evidence shows that Ms. Jungling failed to wash her hands before leaving room 111. The SOM establishes that any failure to follow an infection control practice poses a risk for more than minimal harm to Petitioner's residents. To the extent the SOM creates a rebuttable presumption of more than minimal harm, Petitioner bears the burden to rebut that presumption. Petitioner has not presented persuasive testimonial or documentary evidence that rebuts the

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[5] CMS argues that the requirement is for CMS to show that there is a "risk for more than minimal harm" rather than "more than a minimal risk for harm." CMS argues that it is the nature of the harm rather than the risk for harm that is determinative. CMS argues that the risk for harm from MRSA is always more than minimal and, therefore, the CMS burden is satisfied any time the risk for harm is related to MRSA or a similar infectious agent. CMS Br. at 12-13; CMS Reply at 5-7. I need not address this argument to resolve this case.

[6] Citations to the SOM are difficult, particularly in the case of Tag F441. The pages of the SOM are not numbered and the various sections and parts are not numbered consistently. This quote however, is found at the end of Tag F441 in a section titled "V. Deficiency Categorization (Part IV, Appendix P)."

presumption. I find credible the testimony of DON Harper that there was no increase of nosocomial infections at the facility after Ms. Jungling left room 111 without washing her hands on February 16, 2012. Tr. 148. But, the fact that there was no increase in nosocomial infections does not show that it was more likely than not that Ms. Jungling's failure to wash her hands did not pose more than a minimal risk for such infections or pose a risk for infections that could cause more than minimal harm to residents. Accordingly, I conclude that Petitioner violated 42 C.F.R. § 483.65(a)(1) on February 16, 2012; the violation posed a risk for more than minimal harm; and there is a basis for imposition of an enforcement remedy.

2. Petitioner returned to substantial compliance with program participation requirements on March 23, 2012.

3. The DPNA from December 30, 2011 through March 22, 2012, was a reasonable enforcement remedy.

Petitioner bears the burden of showing by a preponderance of the evidence that it returned to substantial compliance on a date earlier than that determined by CMS. *Sunshine Haven Lordsburg*, DAB No. 2456 at 2 (2012).

Petitioner was found not in substantial compliance by a survey completed on October 30, 2011, which included a conclusion that Petitioner was not in substantial compliance due to a violation of 42 C.F.R. § 483.65 (Tag F441). CMS Ex. 12. The state agency conducted a revisit survey on December 28, 2011, and concluded that Petitioner remained out of substantial compliance due to a continuing violation of 42 C.F.R. § 483.65 (Tag F441). CMS Ex. 13. On February 16, 2012, the state agency conducted a revisit survey and concluded that Petitioner continued to be noncompliant with 42 C.F.R. § 483.65 (Tag F441). CMS Ex. 16. I have concluded that Petitioner has failed to show by a preponderance of the evidence that it was in substantial compliance with 42 C.F.R. § 483.65 (Tag F441) on February 16, 2012. Therefore, the February 16, 2012 survey shows continuing noncompliance under Tag F441 as of February 16, 2012. On March 23, 2012, the state agency completed another revisit survey and determined that Petitioner returned to substantial compliance with program requirements as of that date. CMS Ex. 8. Petitioner has presented no evidence that it corrected the noncompliance found by the February 16, 2012 survey, prior to March 23, 2012.

The Act 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). CMS is authorized to impose a discretionary DPNA even if noncompliance has existed for less than three months. 42 C.F.R. §§ 488.406, 488.417(a). In this case, noncompliance was found on October 30, 2011. CMS imposed a

discretionary DPNA that was effective on December 30, 2011, and the imposition of a DPNA was authorized under the regulations. 42 C.F.R. §§ 488.406-.408. Pursuant to 42 C.F.R. §§ 488.417(d) and 488.454, payments for new admissions are resumed prospectively on the date that the facility achieves substantial compliance. I have concluded that Petitioner was not in substantial compliance with program participation requirements from October 30, 2011 through March 22, 2012. A DPNA is an authorized enforcement remedy. Accordingly, I conclude that a DPNA effective from December 30, 2011 through March 22, 2012, was a reasonable enforcement remedy.

III. Conclusion

For the foregoing reasons, I conclude that:

- Petitioner violated 42 C.F.R. § 483.65(a)(1) on February 16, 2012;
- The violation of 42 C.F.R. § 483.65(a)(1) on February 16, 2012 posed more than a minimal risk for more than minimal harm;
- Petitioner was not in substantial compliance with program participation requirements from October 30, 2011 through March 22, 2012; and
- A DPNA for the period December 30, 2011 through March 22, 2012, was an authorized and reasonable enforcement remedy.

/s/
Keith W. Sickendick
Administrative Law Judge