Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Hilltop Manor Health Care Center
(CCN: 23-5511),

Petitioner,

v.

Centers for Medicare & Medicaid Services.

Docket No. C-12-176

Decision No. CR3052

Date: December 26, 2013

DECISION

Petitioner, Hilltop Manor Health Care Center, was not in substantial compliance with program participation requirements from June 23 through July 31, 2011, due to a violation of 42 C.F.R. § 483.65.[1] There is a basis for the imposition of enforcement remedies. The following enforcement remedies are reasonable: a civil money penalty (CMP) of $10,000 per day for the period June 23 through July 13, 2011; and a CMP of $200 per day for the period July 14 through July 31, 2011, a total CMP of $213,600. Petitioner was ineligible to conduct a Nurse Aide Training and Competency Evaluation Program (NATCEP) for two years.

I. Background

Petitioner is located in Roscommon, Michigan, and participates in Medicare as a skilled nursing facility (SNF) and the state Medicaid program as a nursing facility (NF). On July

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

14, 2011, a complaint investigation was completed at Petitioner's facility by the Michigan Department of Licensing and Regulatory Affairs, Bureau of Health Systems (state agency). Joint Stipulation of Undisputed Facts. Petitioner was found not in substantial compliance with program participation requirements. The Centers for Medicare & Medicaid Services (CMS) notified Petitioner by letter dated October 7, 2011, that it was imposing the following enforcement remedy: a CMP of $10,000 per day for the period June 23 through July 13, 2011; and a CMP of $200 per day for the period July 14 through July 31, 2011. CMS also notified Petitioner that it was ineligible to conduct a NATCEP for two years. CMS Exhibit (Ex.) 8.

Petitioner requested a hearing before an administrative law judge (ALJ) on December 6, 2011. The case was assigned to me for hearing and decision on December 8, 2011, and an Acknowledgement and Prehearing Order was issued at my direction. On July 17 and 18, 2012, a hearing was convened in Traverse City, Michigan, and a transcript (Tr.) of the proceedings was prepared. CMS offered CMS exhibits (CMS Exs.) 1 through 19, 21 through 32, 36, and 38 that were admitted as evidence. CMS withdrew CMS Exs. 20, 33 through 35, and 37. Petitioner offered Petitioner exhibits (P. Exs.) 1 through 7 that were admitted as evidence. CMS called the following witness: Surveyor Laura Bauer, RN. Petitioner called the following witnesses: Brenda Franklin, RN; Benjamin Elliott, RN; Tammy Crawford, CNA; and Brenda LaVigne, Petitioner's Administrator. The parties filed post-hearing briefs and post-hearing reply briefs.

II. Discussion

A. Issues

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

Whether the remedy imposed is reasonable.

B. Applicable Law

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

Act.[2] The Act requires that the Secretary terminate the Medicare participation of any SNF that does not return to substantial compliance with participation requirements within six months of being found not to be in substantial compliance. Act § 1819(h)(2)(C). The Act also requires that the Secretary deny payment of Medicare benefits for any beneficiary admitted to a SNF, if the SNF fails to return to substantial compliance with program participation requirements within three months of being found not to be in substantial compliance – commonly referred to as the mandatory or statutory denial of payments for new admissions (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 situation in which the provider's noncompliance with one or more requirements of

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

participation has caused, or is likely to cause, serious injury, harm, impairment, or death to a resident." 42 C.F.R. § 488.301 (emphasis in original). The lower range of CMPs, $50 per day to $3,000 per day, is reserved for deficiencies that do not pose immediate jeopardy, but either cause actual harm to residents, or cause no actual harm but have the potential for causing more than minimal harm. 42 C.F.R. § 488.438(a)(1)(ii).

Petitioner was notified in this case that it was ineligible to conduct a NATCEP for two years. Pursuant to sections 1819(b)(5) and 1919(b)(5) of the Act, SNFs and NFs may only use nurse aides who have completed a training and competency evaluation program. Pursuant to sections 1819(f)(2) and 1919(f)(2) of the Act, the Secretary was tasked to develop requirements for approval of NATCEPs and the process for review of those programs. Sections 1819(e) and 1919(e) of the Act impose upon the states the requirement to specify what NATCEPs they will approve that meet the requirements that the Secretary established and a process for reviewing and re-approving those programs using criteria the Secretary set. The Secretary promulgated regulations at 42 C.F.R. pt. 483, subpt. D. Pursuant to 42 C.F.R. § 483.151(b)(2) and (e)(1), a state may not approve and must withdraw any prior approval of a NATCEP offered by a skilled nursing or nursing facility that has been: (1) subject to an extended or partial extended survey under sections 1819(g)(2)(B)(i) or 1919(g)(2)(B)(i) of the Act; (2) assessed a CMP of not less than $5,000; or (3) subject to termination of its participation agreement, a DPNA, or the appointment of temporary management. Extended and partial extended surveys are triggered by a finding of "substandard quality of care" during a standard or abbreviated standard survey and involve evaluating additional participation requirements. "Substandard quality of care" is identified by the situation where surveyors identify one or more deficiencies related to participation requirements established by 42 C.F.R. § 483.13 (Resident Behavior and Facility Practices), § 483.15 (Quality of Life), or § 483.25 (Quality of Care) that are found to constitute either immediate jeopardy, a pattern of 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). The hearing before an ALJ is a *de novo* proceeding. *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). A facility has a right to appeal a "certification of noncompliance leading to an enforcement remedy." 42 C.F.R. § 488.408(g)(1); 42 C.F.R. §§ 488.330(e), 498.3. However, the choice of remedies, or the factors CMS considered when choosing remedies, are not subject to review. 42 C.F.R. § 488.408(g)(2). A facility may only challenge the scope and severity level of noncompliance determined by CMS, if a successful challenge would affect the range of

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

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

My conclusions of law are set forth in bold text followed by my findings of fact and analysis. I have carefully considered all the evidence and the arguments of both parties, although not all may be specifically discussed in this decision. I discuss the credible evidence given the greatest weight in my decision-making.[3] I also discuss evidence that I determine is entitled to little or no 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.

1. The allocation of the burden of proof does not affect the decision in this case on any issue.

Petitioner urges me to consider the appropriate allocation of the burden of proof in this case as it relates to proof of the existence of noncompliance and the existence of immediate jeopardy. Petitioner also raises an issue as to the quantum of evidence necessary to establish a prima facie case, the burden imposed by prior Board decisions upon CMS. Petitioner's Prehearing Brief at 3, 5; Tr. 7; Petitioner's Post-Hearing Brief (P. Br.) at 5-10; Petitioner's Reply Brief (P. Reply) at 1-2.

Some basic definitions are important to understand the issues raised by Petitioner. The "burden of proof" generally refers to a party's duty to prove a disputed assertion or

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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.

charge. The "burden of proof" includes both the "burden of persuasion" and the "burden of production." The "burden of persuasion" refers to a party's duty to convince the fact-finder to view facts in favor of the party. In a civil case the burden is usually a preponderance of the evidence while in a criminal trial it is proof beyond a reasonable doubt. The "burden of production" is a party's duty to introduce sufficient evidence on an issue to have the issue decided by the fact-finder rather than decided against the party on summary judgment, judgment on partial findings (judge alone trials), or a directed verdict (jury trials). *Black's Law Dictionary* 209 (8th ed. 2004). The "quantum of evidence" refers to the amount of evidence required. *Id.* at 1276. The "standard of proof" means the degree or level of proof required in a specific case such as a preponderance of the evidence or beyond a reasonable doubt. *Id.* at 1441. The standard or proof is generally the preponderance of the evidence standard in administrative proceedings subject to the Administrative Procedures Act (APA), 5 U.S.C. §§ 551-59.

> As with most civil trials, the standard of proof in an administrative adjudication is usually preponderance of the evidence. The language of the APA is less than clear that the standard of proof should be preponderance. The drafters clearly intended to establish that standard. The House Committee Report states that the language in the first three sentences of APA subsection 556(d) were intended to establish the preponderance standard. Subsequent interpretation firmly establish preponderance as standard of proof in administrative proceedings. The preponderance standard requires that the prevailing factual conclusions must be based on the weight of the evidence. Preponderance simply requires the trier of fact to believe that the existence of a fact is more probable than its nonexistence before ruling in favor of the party with the burden of persuasion. If the test could be quantified, the test would say that a factual conclusion must be supported by 51% of the evidence. In applying the preponderance standard, the administrative decisionmaker cannot be expected to assign the weight of the evidence as "mathematical probability." Rather, the factfinder must assess whether, on the whole, he is convinced that greater weight of evidence supports the plaintiff's account. In application the preponderance test means that the factfinder, either the administrative judge or any administrative appeal authority, must be convinced that the factual conclusion it chooses is more likely than not.

Charles H. Koch, Jr., 2 Admin. L. and Prac. § 5:64 (3d ed. 2013) (footnotes and some quotation marks omitted). "Prima facie" means "sufficient to establish a fact or raise a

presumption unless disproved or rebutted." *Black's Law Dictionary* 1228. A prima facie case is defined as "[t]he establishment of a legally required rebuttable presumption;" or "[a] party's production of enough evidence to allow the fact-trier to infer the fact at issue and rule in the party's favor." *Id.*

The regulations that control adjudications in cases involving long-term care facilities at 42 C.F.R. pt. 498, do not specify the allocation of the burden of proof, including the burden of production or the burden of persuasion; the standard of proof; or the quantum of evidence necessary to establish a prima facie case. The Board has filled the rule-making void by various decisions rendered over the years.

According to decisions of the Board, 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 case 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*, *Batavia Nursing & Convalescent Ctr. v. Thompson*, 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), *aff'd*, *Hillman Rehab. Ctr. v. United States*, No. 98-3789 (GEB), 1999 WL 34813783 (D.N.J. May 13, 1999).

Petitioner urges me to ignore the prior decisions of the Board and impose upon CMS the burden of proof, including the burden of persuasion and production, thus, requiring CMS to establish by a preponderance of the evidence that Petitioner was not in substantial compliance with program participation requirements and that the noncompliance posed immediate jeopardy. I conclude after review of all the evidence, that the evidence in this case is not in equipoise, that is, the evidence is not in a state of equilibrium on either question of whether there is a basis for imposition of an enforcement remedy or whether the declaration of immediate jeopardy was clearly erroneous. Thus, it is not necessary for me decide which party prevails by application of technical rules related to the burden of proof. Because the allocation of the burden of proof does not impact the decision in this case it is not necessary for me to consider further Petitioner's legal challenge to the Board's previously adopted interpretative rules.

I conclude that it is also not necessary for me to specifically resolve the legal issue of what quantum of evidence is required to satisfy the CMS burden to make a prima facie case as to the basis for imposition of enforcement remedies. Legal authority that specifically addresses the issue is neither clear nor consistent. It makes sense that in order to survive a motion for summary judgment or a motion for judgment on partial findings (see as an example Fed. R. Civ. P. 52(c)) at the completion of the CMS case-in-chief, CMS must have presented some quantum of evidence on disputed facts which

would permit a finding in CMS's favor, absent the presentation of evidence or rebuttal by Petitioner. Because the standard of proof generally applicable under the APA is a preponderance of the evidence, it is logical that the quantum of evidence in support of the CMS prima facie case must also make the existence of the disputed facts more likely true than not in order to permit a decision in CMS's favor at the conclusion of the CMS case-in-chief. In this case, I conclude that the CMS evidence establishes a prima facie case. As discussed in more detail hereafter, the evidence presented by CMS on each disputed fact shows that the existence of the fact is more likely true than not.

2. Petitioner violated 42 C.F.R. § 483.65.

3. The violation of 42 C.F.R. § 483.65 posed a risk for more than minimal harm and Petitioner was, therefore, not in substantial compliance with program participation requirements.

4. Petitioner was not in substantial compliance from June 23, 2011 through July 31, 2012.

CMS alleges that Petitioner was not in substantial compliance with the program participation established by 42 C.F.R. § 483.65 (Tag F441) from June 23, 2011 through July 31, 2011. CMS alleges noncompliance because Petitioner failed to investigate, control, and prevent infections as required by the regulation and Petitioner's infection control manual. CMS further alleges that the violation amounted to noncompliance that posed wide-spread immediate jeopardy to Petitioner's residents. CMS Post Hearing Brief (CMS Br.) at 2; CMS Ex. 1 at 1.

The regulation in issue 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 hand washing is indicated by accepted professional practice.

42 C.F.R. § 483.65(a), (b). In short, the regulation requires that Petitioner establish and maintain an infection control program. CMS Ex. 31 (State Operations Manual (SOM), app. PP, Tag F441, eff. Sep. 30, 2009). There is no dispute that Petitioner had established an adequate infection control program by publishing a policy. CMS Ex. 27; P. Ex. 1. But, the citation of deficiency in this case is based on Petitioner's alleged failure to investigate and control infections as required by the regulation and Petitioner's infection control policy and, thus, Petitioner's failure to maintain or implement its policy. P. Br. at 12.

In the Statement of Deficiencies (SOD) for the survey completed on July 14, 2011, alleges a period of noncompliance from June 23, 2011 through July 31, 2011. June 23, 2011 is the date on which Petitioner's clinical records for Resident 9 show that she had her second loose stool in a 24-hour period. The SOD alleges that immediate jeopardy, which was identified on July 14, 2011, began on June 23, 2011, and was abated on July 14, 2011. July 31, 2011 is the date the surveyor concluded Petitioner returned to substantial compliance. CMS Ex. 1 at 3. Petitioner argues that there was no noncompliance and does not attempt to show that if there was noncompliance that it returned to substantial compliance earlier than July 31, 2011.

The surveyor cites examples in the SOD involving Residents 9, 8, 1, 2, 3, 4, 5, 6, 7, 10, 11, 12, 13, 14, to support the following conclusions:

> Petitioner failed to identify and investigate nine residents (2, 4, 8, 9, 10, 11, 12, 13, and 14) who had gastrointestinal symptoms that should have triggered infection control surveillance procedures established by Petitioner's infection control policy (CMS Ex. 1 at 2-3);

> Petitioner failed to maintain an infection control program to help prevent the development and transmission of infection (CMS Ex. 1 at 3);
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> Petitioner failed to ensure that there was an adequately oriented infection control nurse who executed on an ongoing basis the responsibilities of the position established by Petitioner's infection control policy (CMS Ex. 1 at 16-17);
>
> Petitioner failed to identify, investigate, document surveillance, and attempt to contain an outbreak of gastrointestinal illness among at risk residents who developed symptoms of a contagious and potentially fatal gastrointestinal infection (CMS Ex. 1 at 17); and
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> Petitioner failed to implement an infection control/surveillance program that included the identification and investigation of infections, ensures the appropriate use of antibiotics, and that helps prevent the development and transmission of infections (CMS Ex. 1 at 17).

The SOD reflects that the survey was triggered by a complaint regarding Resident 9. The complaint, as characterized by the SOD, was that Resident 9 began experiencing diarrhea on June 25, 2011; family advised staff who advised Resident 9's physician; the physician started Resident 9 on anti-diarrhea medication; Resident 9 was discharged home; and Resident 9 was subsequently admitted to the hospital where she died on July 11, 2011 due severe sepsis secondary to clostridium difficile (C-diff) colitis. CMS Ex. 1 at 4-5. The SOD alleges that Resident 9 had two episodes of loose stools within 24 hours on June 22 and 23, 2011, June 25 and June 26, 2011, on June 26, and on June 27, 2011 but she was not treated as having symptoms of an infection in accordance with Petitioner's infection control policy and her physician was not advised of the symptoms. CMS Ex. 1 at 11-12.

The SOD alleges that Resident 8 was suspected to have gastrointestinal infection and a physician order to test for C-diff was given on June 16, 2011 but no sample was collected until June 21, 2011. The laboratory report on June 22, 2011 was negative. Resident 8 continued to have loose stools according to clinical records dated June 25, 2011. The SOD alleges Petitioner's staff failed to document the situation with Resident 8's continuing loose stools as required by Petitioner's infection control policy. The SOD also alleges that the Infection Control Nurse (ICN) was unable to explain what infection control surveillance actions were taken when Resident 8 was placed in isolation prior to the negative test result for C-diff. CMS Ex. 1 at 12-13.

The SOD alleges that Residents 1, 2, 3, and 4 were diagnosed with pneumonia on July 10, 2011. The four lived on three of Petitioner's four hallways.[4] Resident 1 was not listed on a report required by Petitioner's infection control policy. The SOD also alleges that the DON could not demonstrate what surveillance was done to ensure safe infection control practices were implemented based on four residents developing pneumonia at the same time. CMS Ex. 1 at 13-14.

The SOD also alleges that the July 2011 Monthly Line Listing Reports listed 14 residents but only 10 surveillance worksheets were provided to the surveyor. CMS Ex. 1 at 13.

The SOD alleges that the July 2011 Monthly Line Listing Report listed Resident 5 as receiving an antibiotic for cellulitis of her right lower extremity, an infection she developed while a resident. But the symptoms described on the form did not meet the requirements of Petitioner's infection control policy for the administration of antibiotics. CMS Ex. 1 at 14-15.

The SOD alleges that Residents 6 and 7 were listed on the July 2011 Monthly Line Listing Report as having an infection they acquired in the facility. However, no infection surveillance worksheets were provided to the surveyor that descripted the symptoms or the location of the infections. The SOD alleges that the ICN stated that the residents had skin infections; they developed the infections at the same time; and lived in adjacent rooms. The SOD alleges that the ICN reported to the surveyor that no actions were undertaken to ensure safe infection control practices were implemented related to the two residents. CMS Ex. 1 at 15-16. .

The SOD alleges that during a surveyor interview on July 14, 2011, the DON and ICN reported to the surveyor that seven residents had loose stools in the last two days, Residents 2, 4, 10, 11, 12, 13 and 14. The parties stipulated at hearing that the examples of Resident 2 and 12 were not at issue before me. Tr. 53-54. The SOD does not specifically allege how Petitioner's actions in the case of Resident 4, 10, 11, 13, and 14 violated Petitioner's infection control policy. CMS Ex. 16. The gist of the CMS allegations is that Petitioner failed to implement its regulatory-required infection control policy. Because the SOD does not give Petitioner notice or inform me how the examples of Resident 4, 10, 11, 13, and 14 constitute a violation of Petitioner's infection control policy or reflect a failure to implement the policy,[5] I give those examples no further consideration.

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[4] RN Benjamin Elliot testified that the facility has four wings and four units. Tr. 295.

[5] The testimony of Surveyor Bauer clarifies that she was concerned that the number of loose stools these residents had may have triggered the c-diff criteria of Petitioner's
(Footnote continued next page.)

It is not necessary to analyze all the examples cited in the SOD to show a violation of 42 C.F.R. § 483.65. The violation is established in the case by the example of Resident 9, evidence that staff was unfamiliar with the requirements of Petitioner's Infection Control Manual, and Petitioner's failure to maintain and possess the infection control documents required by its Infection Control Manual. The evidence also shows that the violation posed a risk for more than minimal harm and, thus, the violation amounted to noncompliance with program participation requirements.

There is no dispute that Petitioner issued an infection control policy. CMS and Petitioner each placed a copy in evidence. CMS Ex. 27; P. Ex. 1. I note with interest that the two documents are different. CMS Ex. 27 is a 72- page document apparently received by the surveyor during the survey with the representation or implication that it was Petitioner's infection control policy. Page 1 of CMS Ex. 27 is titled "Infection Control Manual" and states that the manual was reviewed and approved by the Administrator/Executive Director on July 1, 2008, the Director of Nursing on an unspecified date, and the Medical Director on the first day of an indecipherable month in 2008. The individual sections or parts of the manual reflect revisions dated in 2006, except the section titled "Infection Surveillance" which bears a revised date of February 2009, seven months after the Administrator reviewed and approved the manual. CMS Ex. 27 at 31-34. P. Ex. 1 is a 185-page document with the title page "Infection Control Manual." Each section of the document marked P. Ex. 1 bears a revision date in 2009 or 2010. Because the survey occurred in 2011, the 2009 and 2010 revisions of Petitioner's Infection Control Manual are given greater weight in my *de novo* review than the older revisions of the manual contained in CMS Ex. 27. I also infer that because the surveyor was given the older revisions of Petitioner's Infection Control Manual, the DON and ICN were either unable to locate the current version or were unaware of its existence.

The section of Petitioner's Infection Control Manual titled Infection Surveillance, Infection Criteria, revised February 2009, establishes the criteria to be used for surveillance reporting purposes. The manual provides that the Infection Control

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(Footnote continued.)

infection control policy. The SOD needs to speak for itself and I am not willing to read the SOD as providing adequate notice of the basis for the alleged deficiency unless such basis is expressly stated. Because other examples show that Petitioner was not following its Infection Control Manual, there is no need to consider these residents and their loose stools at any rate.

Coordinator or designee[6] was to use the criteria to determine if collected data met the criteria for a particular type of infection for surveillance purposes only. The section lists criteria for many different types of infections. For a gastrointestinal tract infection one of the following criteria must be met: two or more loose or watery stools above what is normal for the resident within a 24 hour period; two or more episodes of vomiting within a 24-hour period; or both a positive stool culture test for C-diff and nausea, vomiting, abdominal pain, tenderness or diarrhea. The manual directs that for gastrointestinal infections noninfectious causes for vomiting and diarrhea should be ruled-out such as medications and gallbladder disease. P. Ex. 1 at 62, 65.

The section of Petitioner's Infection Control Manual titled Infection Surveillance, Infection Prevention, revised February 2009, provides "[i]nfection prevention provides for a practical system of reporting, evaluating, and maintaining records of infections among residents/patients and personnel. . . . As a result of this collection and review of data, a follow-up plan of action is prepared and implemented." P. Ex. 1 at 66. The section requires that staff be trained upon hiring and on an ongoing basis. Staff members are instructed to report infections or potential infections to the Infection Control Coordinator. The section provides that the surveillance program is to be followed and current infection prevention standards are to be followed. Staff education and training is to be conducted following the collection and analysis of data to improve infection prevention and control outcomes. P. Ex. 1 at 66-67.

The section of Petitioner's Infection Control Manual titled Infection Surveillance, revised February 2009, requires that Petitioner use a "systematic method of collecting, consolidating, and analyzing data concerning the distribution and determining factors of a given disease or event." P. Ex. 1 at 68. An outbreak is defined as an increase in the incidence of a disease, complication or event above the background rate. The manual requires Petitioner to have "baseline surveillance data on the incidence of nosocomial infections [those acquired while a resident] in order to identify outbreaks." P. Ex. 1 at 68. Collected and analyzed data is to be provided to staff for educational purposes to improve infection prevention and control. The procedure established requires that an Infection Surveillance Worksheet be prepared for a resident if an infection appears likely using the infection criteria. The information on the Infection Surveillance Worksheet is to be summarized on the Monthly Line Listing Report if they meet the infection criteria specified in the Infection Control Manual. Infection data is tabulated on the Annual

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[6] Petitioner's Infection Control Manual does not refer to an "Infection Control Nurse." Based on the evidence before me, I infer that Petitioner's Infection Control Nurse (ICN) was either the Infection Control Coordinator or the designee referred to in the Infection Control Manual. Accordingly, I read all references in the Infection Control Manual to the "Infection Control Coordinator or designee" as referring to the ICN.

Infection Rate summary; incidence rates are calculated and compared to previous rates; information is presented to the Infection Prevention/Control Team at their regular meeting, unless unusual or unexpected occurrences necessitate an immediate meeting; conclusions and recommendations are formulated and presented to the Risk Management/Quality Improvement Committee; an action plan is implemented if needed; staff is trained as needed; and any action plan is reviewed and revised as needed. P. Ex. 1 at 68- 69.

Instructions for completing the Infection Surveillance Worksheet specify that a worksheet is to be completed anytime there are signs and symptoms of an infection; a culture is ordered or obtained; or antibiotic therapy is ordered. The Infection Control Coordinator or designee is responsible for initiating the worksheet which is part of the quality improvement process. P. Ex. 1 at 142. The Infection Control Coordinator is also responsible for completing the Monthly Line Listing Report, which is also a quality improvement document. Information for confirmed infections is to be entered on the Monthly Line Listing Report. P. Ex. 1 at 145.

Surveyor Laura Bauer testified that she conducted the complaint investigation that ended on July 14, 2011, and that her findings and conclusion are accurately set forth in the SOD with the corrections noted at hearing. Tr. 40-43. She testified that she concluded that immediate jeopardy began on June 23, 2011. Surveyor Bauer explained that was the date on which Resident 9 had a second loose stool within 24 hours which, under Petitioner's infection control policy, should have triggered investigation of whether Resident 9 suffered a gastrointestinal infection, such as C-diff. Tr. 45. Surveyor Bauer testified that she reviewed the records of two residents and was told about seven other residents by the Director of Nursing (DON) with recent histories of 2 loose stools in 24 hours, who she determined were subject to immediate jeopardy due to possibility that they suffered a gastrointestinal infection, specifically C-diff, that Petitioner failed to identify and treat due to Petitioner's noncompliance with its infection control policy. Tr. 45-47, 50-52. The parties stipulated at hearing that two of the seven residents mentioned to Surveyor Baurer by the DON, Residents 2 and 12, did not meet the two loose stools in 24 hours criteria of Petitioner's infection control policy. Tr. 53-54. Surveyor Bauer testified that she determined that immediate jeopardy for the seven remaining residents was removed on July 14, 2011, the day she completed the survey. According to the SOD, Petitioner continued not to be in substantial compliance even though immediate jeopardy was abated. Tr. 48; CMS Ex. 1 at 3-4.

Surveyor Bauer testified that she interviewed both the DON and the ICN, who had been the ICN since March 2011. Tr. 58-59. The ICN advised Surveyor Bauer that she had been absent from the facility from July 3 through 13, 2011, just prior to the survey, and she was not aware of who served as ICN in her absence. Tr. 60-61; CMS Ex. 1 at 9. Neither party called the DON or the ICN to testify and Surveyor Bauer's recollections of the statements of the DON and ICN as set forth here, are unrebutted. Surveyor Bauer's

recollection of the statements of the ICN and DON are credible and worthy of some weight despite the fact that the statements are hearsay to the extent that they are offered by CMS for the truth of the matter asserted. My conclusion that Petitioner failed to maintain its infection control policy is not based solely upon their statements. Rather their statements as recounted by Surveyor Bauer, like the fact that they gave the surveyor an outdated version of Petitioner's Infection Control Manual, as additional evidence that the ICN and DON were not very familiar with Petitioner's Infection Control Manual or the policies and procedures set forth in that manual.

Surveyor Bauer testified that the ICN stated that generally she first learned that a resident had an infection when she saw the resident listed on a Monthly Line Listing Report, which was kept at the nurses' station. According to the ICN, Nurses were to list on the Monthly Line Listing Report any resident who received an antibiotic. The ICN told Surveyor Bauer that she used the Monthly Line Listing Report information to report to the facility Infection Control Committee. Surveyor Bauer testified that the procedures described by the ICN differed from Surveyor Bauer's understanding of Petitioner's infection control policy. Surveyor Bauer's understanding of Petitioner's infection control program was that the appearance of symptoms of infection should cause Petitioner staff to initiate an Infection Surveillance Worksheet, which the ICN would use as a tool to collect her data. If it was determined that residents listed on the Infection Surveillance Worksheet had an infection, then they would be listed on the Monthly Line Listing Report. Tr. 59-62; CMS Ex. 27 at 37-38. Surveyor Bauer's understanding of Petitioner's Infection Control Manual is consistent with my understanding of the provisions of the manual as summarized above. The manual required that an Infection Surveillance Worksheet be completed for any resident who displayed signs or symptoms that met the criteria for the various types of infections set forth in Petitioner's Infection Control Manual. Confirmed infections were then listed on the Monthly Line Listing Report. P. Ex. 1 at 68-69, 142-45.

Surveyor Bauer testified that she reviewed Petitioner's Monthly Line Listing Reports and Infection Surveillance Worksheets for June 2011 (CMS Ex. 24) and July 2011 (CMS Ex. 23). Tr. 63. Surveyor Bauer testified to a number of perceived irregularities in Petitioner's infection control records. The irregularities she identified that are supported by the documentary evidence and that are pertinent to my decision are the following:

a. Resident 9 was listed on the June 2011 Monthly Line Listing Report for Hall D as receiving an antibiotic at the time of her admission on June 1, 2011, but the form also shows she began receiving Levaquin a day after admission on June 2, 2011. Tr. 42; CMS Ex. 24 at 4. But no June 2011 Infection Surveillance Worksheet was provided to Surveyor Bauer for Resident 9. Tr. 65; CMS Ex. 24. Petitioner has failed to present a June 2011 Monthly Line Listing Reporting listing Resident 9 for my consideration.

b. The July 2011 Monthly Line Listing Reports for Halls A, B, C, and D list 15 residents but Surveyor Bauer was only given 10 Infection Surveillance Worksheets. Surveyor Bauer's understanding of Petitioner's infection control program was that an Infection Surveillance Worksheet was to be initiated whenever a resident developed signs of an infection, therefore there should have been a minimum of 15 such worksheets. Tr. 65-66; CMS Ex. 23. Surveyor Bauer's understanding of Petitioner's Infection Control Manual, the version provided to her at the time of the survey and admitted as evidence marked CMS Ex. 27, is consistent with my reading of the requirements of the manual. I discern no difference in these procedures between the version given to the surveyor during the survey and the version in effect at the time of the survey which was admitted as P. Ex. 1.

c. Infection Surveillance Worksheets for Residents 1, 2, 3, and 4 were all reported to have pneumonia with an onset of symptoms on July 10, 2011.[7] Tr. 66-68; CMS Ex. 23 at 7, 11-13. Surveyor Bauer testified that because three the four residents resided on three different hallways in the facility, the development of symptoms of pneumonia on the same day should have caused investigation of whether someone was spreading the infection and examination of infection control practices. Tr. 73-74. Surveyor Bauer did not specify in the SOD or her testimony how the failure to investigate the circumstances amounted to a violation of Petitioner's Infection Control Manual or a failure to implement that manual. CMS Ex. 1 at 14; Tr. 66-77. She testified that Resident 1 was also not listed on the Monthly Line Listing Report (CMS Ex. 23 at 4) but an Infection Surveillance Worksheet was initiated for the resident (CMS Ex. 23 at 7). Tr. 75, 81-82. Surveyor Bauer testified that the DON could not tell her what was done to address the infection control issues raised by the examples of Residents 1, 2, 3, and 4.

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[7] Petitioner objected to the Surveyor's testimony regarding the four residents with the diagnosis of pneumonia. Petitioner argued that the testimony was not relevant because the deficiency alleged in the SOD and the determination that there was immediate jeopardy was based on the Surveyor's findings that the resident had loose stools. The Surveyor testified that the alleged deficiency was based, in part, on Petitioner's records that showed that the four residents had pneumonia and that evidence impacted her conclusion that Petitioner failed to implement its infection control policy. Tr. 68-72. The SOD reflects that Surveyor Bauer did consider the four residents and the facts related to them in determining Petitioner was noncompliant. CMS Ex. 1 at 13-14. Accordingly, the Surveyor's testimony regarding those residents is relevant.

Tr. 76; CMS Ex. 1 at 14. Surveyor Bauer testified that according to Petitioner's infection control policy there should have been examination of infection control procedures, airborne precautions, and isolation precautions either in separate rooms or in rooms where the infected were kept together. Tr. 76-77. Surveyor Bauer's testimony is consistent with and supported by Petitioner's Infection Control Manual. P. Ex. 1 at 52-60. The inability of the DON to describe what was done in response to the multiple pneumonias is further evidence of a lack of familiarity with the policies and procedures established by Petitioner's Infection Control Manual and supports an inference that the manual was not maintained or implemented.

d. Residents 6 and 7 are listed on the July 2011 Monthly Line Listing Report. CMS Ex. 23 at 4. However, Surveyor Bauer was not given Infection Surveillance Worksheets for the two residents. The residents lived on the same hall; one was on an antibiotic; and one was listed as having a nosocomial infection. The ICN could not recall specific facts about the two residents when questioned by Surveyor Bauer. Tr. 82-83. Petitioner has not presented Infection Surveillance Worksheets for the two residents for my consideration.

Surveyor Bauer also testified that she reviewed Petitioner's clinical records for Resident 9, specifically at CMS 21 at 12-50, which she considered in preparing the SOD. Tr. 90.

Resident 9 was 71 years old[8] when admitted to Petitioner on June 1, 2011. She was admitted to Petitioner for rehabilitation following hospitalization for surgical repair of a fractured ankle. Resident 9 was admitted to Petitioner with diagnoses of sepsis and a urinary tract infection, among other ailments. CMS 21 at 12, 25, 28. She was treated with antibiotics in the hospital prior to admission to Petitioner but, her physician orders dated June 1, 2011, do not include a prescription for an antibiotic. CMS Ex. 21 at 16, 25.

Resident 9 was discharged home on July 1, 2011. However, she had to be admitted to the hospital on July 8, 2011, where she died on July 11, 2011, due to sepsis and renal failure secondary to C-diff. CMS Ex. 21 at 7, 12, 29, 39; Tr. 134-35.

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[8] Surveyor Bauer testified that she believed that Resident 9 was 72 at the time of admission. Resident 9 was born March 13, 1939 and was admitted to Petitioner on June 1, 2011. Thus, Resident 9 was 71 years and 9 months old at admission. CMS Ex. 21at 12.

Resident 9's bowel and bladder care plan developed by Petitioner's staff required monitoring of bowel and bladder status. CMS Ex. 21 at 28. Petitioner's staff documented the monitoring of Resident 9's bowel movements. Surveyor Bauer testified that the documentation shows that Resident 9 had loose stools on June 22 and 23, June 25, two loose stools on June 26 and again on June 27, 2011. She testified that there was no documentation that the episodes of loose stools were reported to the resident's physician, a nurse denied calling the physician; and the physician denied being notified. Tr. 92-95; CMS Ex. 21 at 13, 45; P. Ex. 3 at 55. Her testimony is unrebutted. My findings based on examination of the evidence are the same. Surveyor Bauer concluded that pursuant to Petitioner's policy an Infection Surveillance Worksheet should have been initiated for Resident 9 when she had two loose stools within 24 hours and her physician should have been contacted. Tr. 97-100. I also find based upon the provisions of Petitioner's Infection Control Manual set forth above that and Infection Surveillance Worksheet should have be initiated for Resident 1 when she had the second loose stool within 24 hours on June 23, 2011. Petitioner has not presented for my consideration the required Infection Surveillance Worksheet.

Surveyor Bauer opined that failure to identify an infection that would go untreated posed a risk for serious harm or the death of a resident, which is more than minimal harm.[9] Tr. 100, 134-35. As an RN and trained surveyor, Surveyor Bauer is qualified to render such an opinion. Surveyor Bauer's opinion is unrebutted.

Surveyor Bauer's testimony regarding her observations and interviews is credible and entitled to weight. Surveyor Bauer concluded that Petitioner's infection control policy was not being maintained or implemented based on her interviews with the ICN and the DON, their lack of knowledge of the infection control policy, the absence of evidence specified by the policy for the surveillance of infections; and the absence of evidence showing that appropriate actions were taken to prevent the spread of infections. Tr. 100-01, 140.

Brenda Franklin, RN was Regional Clinical Consultant for La Vie Health Care Management, Petitioner's management company, at the time of the survey, was called by Petitioner and qualified to render opinions as an expert in long-term nursing care. Tr. 157-59, 168, 195. She testified that she reviewed Resident 9's records. Tr. 172-73. RN Franklin testified that Resident 9's bowel pattern was loose, soft, or formed stools frequently throughout the entire month she was a resident of Petitioner. RN Franklin testified that if Resident 9 had frequent watery diarrhea testing should have been done.

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[9] It is not necessary for me to attempt to determine whether Resident 9 developed a C-diff infection while a resident of Petitioner. Resident 9's cause of death is also not a fact that I need to determine or consider in this case. I make no findings regarding either.

Tr. 183-84. She testified on cross-examination that staff would have known that Resident 9 had diarrhea because she was dependent for care. Tr. 217. She agreed that Resident 9 had complained to therapy staff about diarrhea according to the records but she rejected that evidence stating that staff would have known because Resident 9 was dependent for care and, she suggested, Resident 9 probably wanted to avoid therapy. Tr. 217-18. RN Franklin did not specifically state whether or not in her opinion Resident 9 should have been evaluated and tested for C-diff. Tr. 183-84, 217-18. She testified that the infection control program at Petitioner was not perfect but opined that the situation was not such as to pose a likelihood for serious injury, harm, or death to a resident, i.e., immediate jeopardy. Tr. 189. RN Franklin's testimony was credible, but she did not deny that Petitioner's staff failed to comply with Petitioner's Infection Control Manual. She also did not explain why failure to comply with the infection control policies and procedures adopted by Petitioner would not likely result in serious injury, harm, or death to residents due to unidentified and untreated infections or failure to control their spread to the indisputably at risk elder population of Petitioner's facility.

Petitioner presented the testimony of Tammy Crawford, a CNA who cared for Resident 9 on the day shift, five days each week. Tr. 266-67. She testified that when a resident has watery diarrhea staff was to report to the nurse. She testified that she reported Resident 9's bowel movements to the nurse but she was told that there was consistency to the stool. Tr. 269-70. She explained that the document recording bowel movements was completed by nursing staff based on reports from CNAs. Tr. 274-75; CMS Ex. 21 at 45. CNA Crawford's testimony is additional evidence that Petitioner's nursing staff was not familiar with the provisions of Petitioner's Infection Control Manual, which provided that surveillance for a gastrointestinal tract infection would be triggered by two or more loose or watery stools above what is normal for the resident within a 24 hour period. P. Ex. 1 at 62, 65.

Benjamin Elliott RN, Petitioner's Director of Clinical Services, testified that he was not at the facility during the survey. Tr. 278-80. He was a unit manager at the time and knew Resident 9 as she resided on one of his units. He testified that there is not necessarily a difference between loose stools and diarrhea as both are watery. He testified that one with a C-diff infection would have several watery stools in a day with a distinct odor. He was never informed or aware that Resident 9 had excessive watery stools, loose stools, or diarrhea. Tr. 280-82, 296-97. He testified on cross-examination that he did not recall seeing the 24-Hour Report dated June 26, 2011 that reported the Resident 9 experience two episodes of loose stools. Tr. 302-03; CMS Ex. 21 at 13. RN Elliott explained that the Infection Surveillance Worksheet is to be completed by the nurse on the unit when symptoms are first discovered. The worksheets are kept on the unit until the symptoms resolve or the physician orders an antibiotic. Infections are listed by the floor nurse on the Monthly Line Listing Report. Tr. 283-84. He testified that he spoke with Resident 9 on the day of discharge and she told him she was not feeling well but she wanted to go home. Tr. 287. He testified that it was not uncommon for her to

complain that she did not feel well. Tr. 294. He agreed on cross-examination that Petitioner's Infection Control Manual requires that an Infection Surveillance Worksheet be completed if a resident two or more loose stools above what is normal for that resident within 24 hours. Tr. 308. RN Elliott's testimony reflects that he is knowledgeable of Petitioner's Infection Control Manual, but does not explain the lack of knowledge of the ICN, DON, and nursing staff evidenced by Surveyor Bauer's interviews during the survey or the testimony of CNA Crawford.[10] During my examination at hearing, RN Benjamin Elliott examined page 45 of CMS Ex. 21 and confirmed that Resident 9 had two loose stools within 24 hours, one during the morning shift on June 22 and another on the morning shift on June 23, 2011. He also agreed that the document shows she had two loose stools during 24-hour periods on June 25 and 26 (evening shift on June 25 and morning shift on June 26), June 26 (morning and evening shift), and again on June 27, 2011 (morning and evening shift). He testified that he could not recall why she was not identified for evaluation for possible infection. Tr. 323-24.

I infer based on the foregoing facts that Petitioner failed to maintain and implement its Infection Control Manual as required by 42 C.F.R. § 423.65 and that the failure posed a risk for more than minimal harm to Petitioner's residents. CMS made a prima facie case based on the testimony of Surveyor Bauer and the documentary evidence presented by CMS. The CMS evidence, without consideration of any evidence offered by Petitioner, establishes that it was more likely than not that Petitioner's staff failed to implement or maintain Petitioner's Infection Control Manual and that the failure posed a risk for more than minimal harm. Some of Petitioner's evidence further supports my findings and conclusions. I conclude based on review of all the evidence that Petitioner has failed to effectively rebut the CMS prima facie case or to establish and affirmative defense to excuse its regulatory violation.

5. Petitioner bears the burden to show that the determination that its noncompliance posed immediate jeopardy was clearly erroneous.

6. The determination that Petitioner's noncompliance posed immediate jeopardy was not clearly erroneous.

The SOD alleges that Petitioner's noncompliance based on the violation of 42 C.F.R. § 483.65 posed immediate jeopardy for Petitioner's residents from June 23, 2011 through

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[10] RN Elliott's testimony that the resident's complaints on the day of discharge were simply ignored or dismissed is troubling but I do not treat it as evidence that supports the deficiency citation in this case.

July 13, 2011.[11] CMS argues before me that there was immediate jeopardy and that Petitioner bears the burden to show that that determination is clearly erroneous. Petitioner argues that there was no immediate jeopardy and that it should not be burdened to show that the declaration of immediate jeopardy was clearly erroneous. Petitioner's arguments are not persuasive.

The Act requires that if the state survey agency finds that a facility's deficiencies "immediately jeopardize the health or safety" of the facility's residents, the state is to recommend that the Secretary take action to remove jeopardy and correct the deficiencies through the appointment of temporary management, or terminate the facility's participation. Act § 1819(h)(1)(A). Congress granted the Secretary authority and required that, if a facility was found to no longer meet the conditions for participation and the facility's deficiencies "immediately jeopardized the health or safety of its residents" the Secretary is to remove the jeopardy and correct the deficiencies through the appointment of temporary management or terminate the facility's participation. Act §1819(h)(2)(A)(i), (h)(4); *see also* Act § 1919(h)(3)(B)(i), (h)(5) (providing enforcement procedures for NFs that are similar to those for SNFs). The phrase "immediately jeopardize" is not defined in the statutes. However, the context suggests that Congress intended that the phrase be given its plain meaning and that it applies if there was any potential of instantaneous or proximate, hazard or risk for harm to the health or safety of a long-term care facility resident.

The phrase "immediate jeopardy," which seems to have derived from the statutory "immediately jeopardize," is given a specific and different effect or meaning by the Secretary through regulation. "*Immediate jeopardy*" under the regulations refers to "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, 489.3 (emphasis in original). Thus, "immediate jeopardy" under the regulation refers only to serious injury, serious harm, serious impairment, or death; whereas the statutory "immediately jeopardize" refers to any imminent risk to a resident no matter how severe. In the context of survey, certification, and enforcement related to SNFs and NFs under the regulations, a conclusion by the state agency and CMS that noncompliance with program participation requirements poses immediate jeopardy to the facility resident's, triggers specific regulatory provisions that

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[11] Petitioner argues that the immediate jeopardy determination was limited to the residents with alleged gastrointestinal problems, citing language of the SOD (CMS Ex. 1 at 2-4). P. Br. at 21-22. I do not read the allegations of the SOD to be that immediate jeopardy was based solely upon the examples of the residents who were alleged to have gastrointestinal issues.

require enhanced enforcement remedies, including authority for CMS to impose a larger CMP than may be imposed when there is no declaration of immediate jeopardy. 42 C.F.R. §§ 488.408(e), 488.438(a)(1)(i), (c), and (d). The regulations also require termination of the facility's provider agreement on an expedited basis or the removal of the immediate jeopardy through appointment of temporary management. 42 C.F.R. §§ 488.410, 488.440(g), 488.456, 489.53(d)(2)(B)(ii).

The regulations do not specifically state that Petitioner bears the burden to prove that the declaration of immediate jeopardy but that is a logical interpretation and one consistently applied by the Board. Pursuant to 42 C.F.R. § 498.3(d)(10) a finding by CMS that deficiencies pose immediate jeopardy to the health or safety of a facility's residents is not an initial determination that triggers a right to request a hearing by an ALJ or that is subject to review. A finding of noncompliance that results in the imposition of an enforcement remedy, except the remedy of monitoring by the state, does trigger a right to request a hearing and is subject to review. 42 C.F.R. §§ 488.408(g); 498.3(b)(8), (13). Furthermore, the level of noncompliance, i.e. scope and severity, is subject to review only if a successful challenge would: (1) affect the amount of CMP that may be imposed, i.e. the higher range of CMP authorized for immediate jeopardy; or (2) affect a finding of substandard quality of care that rendered the facility ineligible to conduct a NATCEP. 42 C.F.R. § 498.3(b)(14) and (15). Pursuant to 42 C.F.R. § 498.60(c)(2), in reviewing a CMP, the ALJ must uphold the CMS determination of the level of noncompliance (i.e. scope and severity), unless it is clearly erroneous. The phrase "clearly erroneous" is not defined by the Secretary.

Many appellate panels of the Board have addressed "immediate jeopardy."[12] In *Mississippi Care Ctr. of Greenville*, DAB No. 2450, at 14 (2012), the Board commented:

> CMS's determination that a deficiency constitutes immediate jeopardy must be upheld unless the facility is able to prove that the determination is clearly erroneous. 42 C.F.R. § 498.60(c)(2); *Woodstock Care Center*. The "clearly erroneous" standard means that CMS's immediate jeopardy determination is presumed to be correct, and the burden of

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[12] Some of the often cited: *Lakeport Skilled Nursing Ctr.*, DAB No. 2435 at 6 (2012); *Liberty Health & Rehab. of Indianola, LLC*, DAB No. 2434, at 12, 19 (2011); *Yakima Valley School*, DAB No. 2422, at 7 (2011); *Lutheran Home at Trinity Oaks*, DAB No. 2111 (2007); *Daughters of Miriam Ctr.*, DAB No. 2067 (2007); *Britthaven of Havelock*, DAB No. 2078 (2007); *Koester Paviliaon*, DAB No. 1750 (2000); *Woodstock Care Ctr.*, DAB No. 1726 (2000).

> proving the determination clearly erroneous is a heavy one. *See, e.g., Maysville Nursing & Rehabilitation Facility*, DAB No. 2317, at 11 (2010); *Liberty Commons Nursing and Rehab Center — Johnston*, DAB No. 2031, at 18 (2006), *aff'd*, *Liberty Commons Nursing and Rehab Ctr. — Johnston v. Leavitt*, 241 F. App'x 76 (4th Cir. 2007). When CMS issued the nursing facility survey, certification, and enforcement regulations, it acknowledged that "distinctions between different levels of noncompliance . . . do not represent mathematical judgments for which there are clear or objectively measured boundaries." 59 Fed. Reg. 56,116, 56,179 (Nov. 10, 1994). "This inherent imprecision is precisely why CMS's immediate jeopardy determination, a matter of professional judgment and expertise, is entitled to deference." *Daughters of Miriam Center*, DAB No. 2067, at 15(2007).

The Board's statements that the provider bears the burden to show that the immediate jeopardy determination was clearly erroneous and that the CMS immediate jeopardy determination is entitled to deference is consistent with the intent of the drafters of the regulations. But the Board's statements, standing alone, are also subject to being misunderstood to limit ALJ and Board review of immediate jeopardy beyond what was intended by the drafters of the regulations. In the notice of final rulemaking on November 10, 1994, the drafters of 42 C.F.R. § 498.60(c)(2), discussing the merits of the reviewability of deficiency citations, selection of remedy, and scope and severity, commented:

> We believe that a provider's burden of upsetting survey findings relating to the level of noncompliance should be high, however. As we indicated in the proposed rule, distinctions between different levels of noncompliance, whether measured in terms of their frequency or seriousness, do not represent mathematical judgments for which there are clear or objectively measured boundaries. Identifying failures in a facility's obligation to provide the kind of high quality care required by the Act and the implementing regulations most often reflect judgments that will reflect a range of noncompliant behavior. Thus, in civil money penalty cases, whether deficiencies pose immediate jeopardy, or are widespread and cause actual harm that is not immediate jeopardy, or are widespread and have a potential for more than minimal harm that is not immediate jeopardy does not reflect that a precise point of noncompliance has occurred,

> but rather that a range of noncompliance has occurred which may vary from facility to facility. While we understand the desire of those who seek the greatest possible consistency in survey findings, an objective that we share, the answer does not lie in designing yardsticks of compliance that can be reduced to rigid and objectively calculated numbers. Survey team members and their supervisors ought to have some degree of flexibility, and deference, in applying their expertise in working with these less than perfectly precise concepts. **For these reasons, we have revised the regulations to require an administrative law judge or appellate administrative review authority to uphold State or HCFA findings on the seriousness of facility deficiencies in civil money penalty cases unless they are clearly erroneous.**

59 Fed. Reg. 56,116, 56,179 (Nov. 10, 1994) (emphasis added). It is clear from this regulatory history, that the drafters of 42 C.F.R. § 498.60(c)(2) intended to place the burden on the provider and further to ensure that the state agency or CMS determination that there was immediate jeopardy would receive deferential consideration, by adopting the clearly erroneous standard of review. However, caution must be exercised to ensure that the Board's decision in *Mississippi Care Ctr. of Greenville, Daughters of Miriam Ctr.*, and other decisions that have mentioned deference relative to immediate jeopardy not be read to require deference for the determination that there was immediate jeopardy beyond that imposed by adoption of the clearly erroneous standard. Giving or requiring that the immediate jeopardy determination be given deference in addition to applying the "clearly erroneous standard" would be contrary to the intent of the drafters of the regulation; would significantly limit the review of the determination by an ALJ and the Board; and would impermissibly deny an affected party the due process right to review intended by the drafters of the regulation.

In the foregoing quotation from *Mississippi Care Ctr. of Greenville,* that panel of the Board states that the clearly erroneous standard means that "the immediate jeopardy determination is presumed to be correct, and the burden of proving the determination clearly erroneous is a heavy one." *Mississippi Care Ctr.*, DAB No. 2450, at 14 . Similar formulations have been used in other Board decisions when referring to the "clearly erroneous standard." However, the Board's characterization of the "clearly erroneous standard" in *Mississippi Care Ctr.* and other cases does not define the standard. The "clearly-erroneous standard" is described in Black's Law Dictionary as a standard of appellate review applied in judging the trial court's treatment of factual issues, under which a factual determination is upheld unless the appellate court has the firm conviction that an error was committed. *Black's Law Dictionary* 269 (18th ed. 2004). The Supreme Court has addressed the "clearly erroneous standard" in the context of the Administrative

Procedures Act (APA). The Court described the preponderance of the evidence standard, the most common standard, as requiring that the trier of fact believe that the existence of a fact is more probable than not before finding in favor of the party that had the burden to persuade the judge of the fact's existence. *In re Winship*, 397 U.S. 358, 371-72 (1970); *Concrete Pipe & Prods. of California, Inc. v. Constr. Laborers*, 508 U.S. 602, 622 (1993). The "substantial evidence" standard, a standard generally applied only on appellate review, considers whether a reasonable mind might accept a particular evidentiary record as adequate to support a conclusion. *Consolidated Edison*, 305 U.S. 197, 229 (1938); *Dickinson v. Zurko*, 527 U.S. 150, 162 (1999). Under the "clearly erroneous" standard a finding is clearly erroneous even though there may be some evidence to support it if, based on all the evidence, the reviewing judge or authority has a definite and firm conviction that an error has been committed. *United States v. United States Gypsum Co.*, 333 U.S. 364, 395 (1948); *Dickinson*, 527 U.S. at 162; *Concrete Pipe*, 508 U.S. at 622. The clearly erroneous standard has been characterized by the Court as being stricter than the substantial evidence test and significantly deferential.[13] The Court stressed in discussing the clearly erroneous standard the importance of not simply rubber–stamping agency fact-finding. The Court also commented that the APA requires meaningful review. *Dickinson*, 527 U.S. at 162 (citations omitted); *Concrete Pipe*, 508 U.S. at 622-23.

Various panels of the Board have recognized other principles applicable to the review of the immediate jeopardy issue. A finding of immediate jeopardy does not require a finding of actual harm, only a likelihood of serious harm. *Dumas Nursing & Rehab., L.P.*, DAB No. 2347 at 19 (2010), (citing *Life Care Ctr. of Tullahoma*, DAB No. 2304, at 58 (2010)), *aff'd*, *Life Care Ctr. of Tullahoma v. Sebelius*, No. 10-3465 (6th Cir., Dec. 16, 2011). The definition of immediate jeopardy at 42 C.F.R. § 488.301, does not define "likelihood" or establish any temporal parameters for potential harm. *Agape Rehab. of Rock Hill*, DAB No. 2411, at 18-19 (2011). The duration of the period of immediate jeopardy is also subject to the clearly erroneous standard. *Brian Ctr. Health & Rehab./Goldsboro*, DAB No. 2336, at 7-8 (2010). There is a difference between "likelihood" as required by the definition of immediate jeopardy and a mere potential. The synonym for likely is probable, which suggests a greater degree of probability that an

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[13] The Board's characterization of the clearly erroneous standard as being highly deferential to the fact finding by the state agency surveyor and CMS and even triggering a rebuttal presumption is entirely consistent with the Supreme Court's characterization of the standard. However, the Court's cautions about ensuring meaningful review rather than rubber-stamping agency decisions shows it is important for the ALJ and the Board not to be tempted to simply defer to the surveyor, the state agency, or CMS on the immediate jeopardy issue.

event will occur than suggested by such terms as possible or potential. *Daughters of Miriam Ctr.*, DAB No. 2067, at 10. Jeopardy generally means danger, hazard, or peril. The focus of the immediate jeopardy determination is how imminent the danger appears and how serious the potential consequences. *Woodstock Care Ctr.*, DAB No. 1726 (2000).

What is the meaning of serious injury, harm, or impairment as used in the definition of immediate jeopardy found in 42 C.F.R. §488.301? How does serious injury, harm, impairment compare with "actual harm?" On the first question the Board recognized in *Yakima Valley School*, DAB No. 2422, at 7 (2011), that the regulations do not define or explain the meaning of the term "serious" as used in the definition of immediate jeopardy.[14] The Board suggested that the definitions may be unimportant as the Board has held that under the clearly erroneous standard that once the state agency or CMS declares immediate jeopardy, there is a presumption that the actual or threatened harm was serious and the facility can only rebut the presumption of immediate jeopardy by showing that the harm or threatened harm meets no reasonable definition of the term "serious." *Id.* (citing *Daughters of Miriam Ctr.*, DAB No. 2067 at 9). In *Daughters of Miriam Ctr.*, the Board discussed that the ALJ attempted to define "serious," finding meanings such as dangerous, grave, grievous, or life-threatening. The Board notes that the ALJ stated that serious harm is outside the ordinary, requiring extraordinary care, or having lasting consequences. The Board further noted that the ALJ stated that a serious injury may require hospitalization, or result in long-term impairment, or cause severe pain as opposed to harm, injury, or impairment that is temporary, easily reversible with ordinary care, does not cause a period of incapacitation, heal without special medical intervention, or does not cause severe pain. The Board did not endorse or adopt the ALJ's definitional exercise, but concluded that it was simply unnecessary in the context of that case. The Board reasoned, as already noted, that the facility bore the burden to

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[14] Appendix Q of the State Operations Manual (SOM) also fails to provide surveyors a working definition of the term "serious" that they can use to determine whether harm, injury, or impairment is serious when deciding whether or not to declare immediate jeopardy. The Act does not define the phrase immediately jeopardize as previously discussed in this decision and does not introduce the concept of serious harm, injury, or impairment as the basis for finding immediate jeopardy. Thus, one is not in error concluding that absent a definition of the term "serious" in the Act, the regulations, the SOM, or decisions of the Board, it is essentially up to individual surveyors and whatever unpublished guidance they receive from their superiors or CMS officials, to exercise their individual discretion and judgment to decide that there was immediate jeopardy, which subjects a facility to the maximum imposable CMPs.

rebut the presumption by showing that the actual or threatened harm met no reasonable definition of serious. *Daughters of Miriam Ctr.*, DAB 2067 at 9.

Based on my review of all the evidence, I do not have a definite and firm conviction that the declaration of immediate jeopardy was erroneous. There is no real dispute here that infections pose a risk for serious harm or death to elderly nursing home residents. CMS Ex. 31 at 4; P. Reply at 4-5. Petitioner has presented no evidence to the contrary. Petitioner's Infection Control Manual was clearly adopted to comply with 42 C.F.R. § 483.65 to permit Petitioner to track infections, to identify infections and outbreaks of infections, and to train and guide Petitioner's staff in identifying, tracking, and mitigating the risk for infections and their spread among other things. Petitioner has failed to rebut by credible evidence the presumption of immediate jeopardy by showing that the harm or threatened harm was not serious under any reasonable definition of serious. *Barbourville Nursing Home*, DAB No. 1962 (2005). *Hermina Traeye Memorial Nursing Home*, DAB No. 1810 (2002).

7. The CMP proposed by CMS is not unreasonable.

8 Petitioner was ineligible to conduct a NATCEP for two years by operation of law.

Petitioner argues that the CMP proposed by CMS imposed is not reasonable for two reasons: (1) its prior history of compliance does not warrant the amount of the CMP; and (2) it is unable to pay the CMP imposed due to the facility's financial health.[15] P. Br. at 26-27.

My authority to review the reasonableness of the CMP is limited by 42 C.F.R. § 488.438(e). The limitations are: (1) I may not set the CMP at zero or reduce it to zero; (2) I may not review the exercise of discretion by CMS in selecting to impose a CMP; and (3) I may only consider the factors specified by 42 C.F.R. § 488.438(f) when determining the reasonableness of the CMP amount. In determining whether the amount of a CMP is reasonable, the following factors specified at 42 C.F.R. § 488.438(f) must be considered: (1) the facility's history of non-compliance, including repeated deficiencies; (2) the facility's financial condition; (3) the seriousness of the deficiencies as set forth at 42 C.F.R. § 488.404(b), the same factors CMS and/or the state were to consider when setting the CMP amount; and (4) the facility's degree of culpability, including but not limited to the facility's neglect, indifference, or disregard for resident care, comfort, and

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[15] Petitioner alleges that CMS failed to consider required regulatory factors. As explained hereafter, my review of the factors is *de novo* and I do not review the CMS action related to the proposed enforcement remedy.

safety and the absence of culpability is not a mitigating factor. The factors that CMS and the state were required to consider when setting the CMP amount and that I am required to consider when assessing the reasonableness of the amount are set forth in 42 C.F.R. § 488.404(b): (1) whether the deficiencies caused no actual harm but had the potential for minimal harm, no actual harm with the potential for more than minimal harm, but not immediate jeopardy, actual harm that is not immediate jeopardy, or immediate jeopardy to resident health and safety; and (2) whether the deficiencies are isolated, constitute a pattern, or are widespread. My review of the reasonableness of the CMP is *de novo* and based upon the evidence in the record before me. I am not bound to defer to the CMS determination of the reasonable amount of the CMP to impose but my authority is limited by regulation as already explained. I am to determine whether the amount of any CMP proposed is within reasonable bounds considering the purpose of the Act and regulations. *Emerald Oaks*, DAB No. 1800, at 10 (2001); *CarePlex of Silver Spring*, DAB No. 1683, at 14–16 (1999); *Capitol Hill Cmty. Rehab. & Specialty Care Ctr.*, DAB No. 1629 (1997). There are no formulas provided by the regulation or the Act for weighing the factors. Rather, the weighing of the factors is a matter left to the discretion of the ALJ, who is bound to follow the Act and regulations and ensure the law is applied consistent with the intent of Congress.

CMS submitted undisputed evidence that shows Petitioner was previously cited by a survey in November 2010, for noncompliance with 42 C.F.R. § 423.65 (Tag F441) that posed a risk for more than minimal harm without actual harm or immediate jeopardy. CMS Ex. 30 at 2; Tr. 202. No details regarding the previous deficiency are in evidence. CMS Ex. 30 also shows deficiencies cited during the November 2010 survey and a survey completed in December 2009, some of which were alleged to pose a risk for more than minimal harm but with no actual harm or immediate jeopardy. The evidence before me does not show whether enforcement remedies were imposed based on the deficiencies cited by the two surveys or whether Petitioner requested review by an ALJ.

Petitioner presented evidence regarding its ability to pay the proposed CMP. Brenda LaVigne, Petitioner's Administrator, was called and testified that Petitioner did not operate in the black in 2011, and had a loss of $800,000 with expenses exceeding revenue; there are improvements she would like to make to the facility; Petitioner is unable to pay a CMP of $213,000; Petitioner is privately owned but she could not identify the owner; she has no access to Petitioner's tax returns; and as of the hearing Petitioner was operating at a $300,000 loss. Tr. 338-44. Ms. LaVigne did not assert that if required to pay the total CMP of $213,000, that Petitioner would have to declare bankruptcy; terminate operations; or be unable to serve its residents as required to participate in Medicare or Medicaid. Ms. LaVigne's testimony that Petitioner was owned by another entity indicates more evidence regarding the ownership arrangement and financial resources available to Petitioner is needed before much weight can be given to the fact that Petitioner reported operating at a loss for tax or other purpose. CMS presented evidence which shows that for 2010 Petitioner reported total liabilities of

$2,412,627 exceeded total assets of $1,591,282. CMS Ex. 29 at 1. The information contained in CMS Ex. 29 appears to be somewhat inconsistent and it is not given significant weight except to the extent that it confirms that Petitioner was not financially sound.

Petitioner's failure to implement or maintain its Infection Control Manual is a serious deficiency. Although one can argue the deficiency was largely a failure to do the paperwork, the paperwork was one of the tools that Petitioner chose to prevent and control infections that could seriously harm or kill residents or staff. The evidence shows a failure to implement Petitioner's infection control procedures at all staff levels including the DON.

I also conclude that Petitioner was culpable for failure to maintain its infection control program. Only Petitioner was responsible to ensure that its staff full implemented its infection control program to protect its residents. Petitioner therefore, must bear the burden of the enforcement remedy.

The proposed CMP of $10,000 per day for the period of immediate jeopardy, June 23 through July 13, 2011, is the highest amount authorized by 42 C.F.R. § 488.438(a)(1)(i). The CMP of $200 per day for the period July 14 through July 31, 2011, is in the lower half of the range authorized by 42 C.F.R. § 488.438(a)(1)(ii). The total proposed CMP is $213,600. I conclude based upon my consideration of all the factors that the CMP proposed is not unreasonable.

Petitioner was ineligible to conduct a NATCEP for two years by operation of law based upon the amount of the CMP. 42 C.F.R. § 483.151(b)(2) and (e)(1).

III. Conclusion

For the foregoing reasons, I conclude that Petitioner was not in substantial compliance with program participation requirements from June 23, 2011 to July 31, 2011, due to a violation of 42 C.F.R. § 483.65. I further conclude that there is a basis for the imposition of enforcement remedies and that the remedies imposed are reasonable.

/s/
Keith W. Sickendick
Administrative Law Judge