Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Tennessee State Veterans Home - Humboldt
(CCN: 44-5366),

Petitioner

v.

Centers for Medicare and Medicaid Services.

Docket No. C-10-80

Decision No. CR2474

Date: December 12, 2011

DECISION

Petitioner, Tennessee State Veterans Home - Humboldt, was not in substantial compliance with program participation requirements from July 29, 2009 through August 23, 2009. There is a basis for the imposition of enforcement remedies. A civil money penalty (CMP) of $3,050 per day from July 29, 2009 through August 11, 2009, and $150 per day from August 12 through August 23, 2009, is a reasonable enforcement remedy.

I. Background

Petitioner is located in Humboldt, Tennessee, and participates in Medicare as a skilled nursing facility (SNF) and the state Medicaid program as a nursing facility (NF). On August 12, 2009, the Tennessee Department of Health, West Tennessee Regional Office of Health Care Facilities (state agency), completed a recertification survey and compliant investigation of Petitioner's facility. The survey concluded that Petitioner was not in substantial compliance with program participation requirements and that the noncompliance posed immediate jeopardy to Petitioner's residents. The Centers for Medicare and Medicaid Services (CMS) notified Petitioner by letter dated August 24, 2009, that it was imposing the following enforcement remedies: a CMP $5,050 per day from July 29, 2009 through August 11, 2009; and a CMP of $150 per day beginning

August 12, 2009 and continuing until Petitioner returned to substantial compliance. CMS also advised Petitioner that: Petitioner was ineligible to conduct a Nurse Aide Training and Competency Evaluation Program (NATCEP) for a period of two years from the end of the survey; a mandatory denial of payments for new admissions (DPNA) would be effective November 12, 2009 and a discretionary DPNA would be effective September 8, 2009, if Petitioner did not return to substantial compliance before those dates; and Petitioner's participation would be terminated February 12, 2010, if it did not return to substantial compliance before that date. A revisit survey completed on September 10, 2009, found that Petitioner returned to substantial compliance on August 24, 2009. CMS advised Petitioner by letter dated September 30, 2009, that the DPNAs and termination would not be effectuated. Joint Stipulation of Facts; CMS Exhibit (Ex.) 2, at 13-17; CMS Ex. 5, at 4-11.

Petitioner requested a hearing before an administrative law judge (ALJ) by letter dated October 23, 2009. On October 28, 2009, the case was assigned to me for hearing and decision. An Acknowledgement and Prehearing Order was issued at my direction on November 2, 2009. On August 24 and 25, 2010, a hearing was convened in Nashville, Tennessee. A transcript (Tr.) of the proceedings was prepared. CMS offered CMS exhibits (CMS Ex.) 2 through 29 that were admitted as evidence.[1] Tr. at 20. Petitioner offered Petitioner exhibits (P. Exs.) 1 through 8; P. Exs. 7 and 8 were withdrawn, and P. Exs. 1through 6 were admitted as evidence. Tr. at 21-87. CMS called the following witnesses: Surveyor Penny Pope, RN; Surveyor Melissa Thomas, RN; and Surveyor Virginia King-Johnson, RN. Petitioner called the following witnesses: Sherry Wehner, RN, Petitioner's Director of Nursing (DON); and Sandra Edmonds, RN, Petitioner's Regional Compliance Nurse. The parties filed post-hearing briefs (CMS Br. and P. Br) and post-hearing reply briefs (CMS Reply and P. Rely).

In its post-hearing brief, CMS includes a discussion of hypoglycemia, hyperglycemia, diabetes and its complications, glucagon, low blood sugar, and insulin. CMS cites "Wikipedia" as the source for its information. CMS also cites to information from the website of the manufacturer of Novolin R, a brand of insulin, prescribed for some of the residents reviewed by the surveyors. CMS Br. at 7-9. Petitioner objects to my consideration of the information included in the CMS brief on grounds that it was not properly offered as evidence by CMS and that it was obtained from internet sources with no showing that they are reliable sources. P. Reply at 7. I cautioned counsel at hearing about reliance upon Wikipedia and other internet resources and the need to properly request administrative notice of extra-record sources. Tr. at 359-61, 460-62. Petitioner's

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[1] CMS Ex. 9, page 55 does not relate to the same resident as the other documents in the exhibit. I conclude that page 55 was erroneously offered and admitted as part of CMS Ex. 9, and that page is not considered for any purpose.

objection is sustained, and the internet materials cited by CMS are not considered for any purpose. CMS did not file a motion requesting administrative notice to which Petitioner could respond. Even if Petitioner failed to object, I would give little weight to the material extracted from Wikipedia as the reliability of the information is not established. The information from the manufacturer's website has not been shown to be authentic, and its relevance cannot be determined.

Petitioner also objects to my consideration of argument of CMS (CMS Br. at 15) related to actions of Petitioner's quality assurance committee in March 2009. Petitioner cites 42 C.F.R. § 483.75(o)(4) and argues that actions of the quality assurance committee cannot be cited as a basis for sanctions. P. Reply at 6. I find it unnecessary to comment upon the grounds cited by Petitioner, as I conclude that the CMS arguments regarding conduct of Petitioner in March 2009 are simply not relevant to the resolution of any issues before me. The three deficiencies before me are not alleged to be based upon events in March 2009. Further, CMS has not presented evidence of prior deficiency citations related to events in March 2009, which might affect my consideration of the reasonableness of the proposed enforcement remedy. Petitioner's objection is sustained.

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. Part 483.[2] 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),

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[2] Citations are to the version of the Code of Federal Regulations in effect at the time of the survey, unless otherwise stated.

(c), and (d) of the Act.[3] The Act requires that the Secretary terminate the Medicare participation of any SNF that does not return to substantial compliance with participation requirements within six months of being found not to be in substantial compliance. Act § 1819(h)(2)(C). The Act also requires that the Secretary deny payment of Medicare benefits for any beneficiary admitted to a SNF, if the SNF fails to return to substantial compliance with program participation requirements within three months of being found not to be in substantial compliance – commonly referred to as the mandatory or statutory DPNA. Act § 1819(h)(2)(D). The Act grants the Secretary discretionary authority to terminate a noncompliant SNF's participation in Medicare, even if there has been less than 180 days of noncompliance. The Act also grants the Secretary authority to impose other enforcement remedies, including a discretionary DPNA, civil money penalties (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. Part 483, subpart 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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[3] 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. Part 483, subpart 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).

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 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. U.S.*, No. 98-3789 (GEB), 1999 WL 34813783 (D.N.J. May 13, 1999).

C. 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, including the documents and the testimony at hearing, 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. 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 that the weight given every piece of evidence considered in this case be discussed, and it would be inconsistent with notions of judicial economy to do so.

1. Petitioner does not dispute that it was not in substantial compliance from July 29, 2009 through August 23, 2009.

2. Petitioner's noncompliance caused no actual harm but posed a risk for more than minimal harm to residents.

3. A CMP of $150 per day from July 29 through August 23, 2009, is a reasonable enforcement remedy for the noncompliance that did not cause actual harm but posed a risk for more than minimal harm.

The Statement of Deficiencies (SOD) for the survey that concluded on August 12, 2009, alleged that Petitioner was not in substantial compliance based on violation of eight regulations that caused no actual harm but posed a risk for more than minimal harm to residents. CMS Ex. 3. Petitioner stipulated at hearing that it was noncompliant with the eight regulatory requirements and that the noncompliance did not cause actual harm but posed a risk for more than minimal harm. Petitioner also stipulated that the noncompliance was a sufficient basis for the imposition of a CMP in the amount of $150 per day beginning July 29, 2009, and that the CMP in that amount was reasonable. Petitioner was unwilling to stipulate that noncompliance continued through August 23, 2009, but counsel for Petitioner stated that Petitioner would be presenting no evidence or argument on that issue. CMS agreed to the stipulations. Tr. at 88-94.

Accordingly, I conclude that Petitioner was not in substantial compliance from July 29 through August 23, 2009, based upon regulatory violations[4] that caused no actual harm but posed a risk for more than minimal harm. I also conclude that a $150 per day CMP from July 29 through August 23, 2009, is a reasonable enforcement remedy for the noncompliance.

The SOD also alleged noncompliance that posed immediate jeopardy to residents based on violations of 42 C.F.R. §§ 483.10(b)(11) (Tag F157), 483.25(m)(1) (Tag F332), and 483.25(m)(2) (Tag F333). CMS elected to proceed upon these alleged deficiencies and the $5,050 per day CMP, even though Petitioner conceded it was not in substantial compliance based on the other cited deficiencies.

4. Petitioner did not violate 42 C.F.R. § 483.10(b)(11)(Tag F157).

5. The declaration of immediate jeopardy based upon the alleged deficiency under Tag F157 was clearly erroneous.

Petitioner is obliged as a participant in the Medicare program, to protect and promote the rights of each of its residents. 42 C.F.R. § 483.10. Among the specific rights listed in the regulation is the right of the resident to be notified, to have his or her legal representative and interested family notified, and to have his or her physician consulted regarding

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[4] The regulations violated were 42 C.F.R. §§ 483.10(e) and 483.75(l)(4); 483.25; 483.25(d); 483.25(g)(2); 483.65(a); 483.65(b)(3); 483.75(j)(1); and 483.75(l)(1).

certain events. Notification and consultation are required for: (1) an accident that results in injury and may require physician intervention; (2) a significant change in the resident's physical, mental or psychosocial condition; (3) a need to significantly alter treatment; or (4) a decision to transfer or discharge the resident. The regulation requires that Petitioner immediately "inform the resident; consult with the resident's physician; and if known, notify the resident's legal representative or interested family" of any of the listed events. 42 C.F.R. § 483.10(b)(11)(i). "Immediately" means as soon as the accident, significant change, or need to alter treatment significantly is detected with no intervening interval of time. *Magnolia Estates Skilled Care*, DAB No. 2228, at 8-9 (2009). A "significant change" is defined as "deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications." 42 C.F.R. § 483.10(b)(11)(i)(B). Thus, a facility must immediately consult with the resident's physician not only when there is a life-threatening condition, but also when there is a non-emergency clinical complication such as the development of a stage II pressure sore. *Stone County Nursing & Rehab. Ctr.*, DAB No. 2276, at 5-6 (2009); *The Laurels at Forest Glenn*, DAB No. 2182, at 12 (2008). Significant alteration of treatment is defined as "a need to discontinue an existing form of treatment due to adverse consequence, or to commence a new form of treatment." 42 C.F.R. § 483.10(b)(11)(i)(C). The preamble to the final rule promulgating the regulation and also the CMS official interpretation of the regulation found in the State Operations Manual (SOM), state that the need to alter treatment significantly is either a need to stop a form of treatment due to adverse consequences such as an adverse drug reaction, or a need to commence a new form of treatment, procedure, or therapy not previously used to address a problem. SOM, app. PP, Tag F157; 56 *Fed. Reg.* 48,826, 48,833 (Sept. 26, 1991);[5] *The Laurels at Forest Glenn*, DAB No. 2182, at 12. The distinction between the requirement to inform and to consult has been recognized as being intentional and significant. The preamble to the final rule promulgating the regulation shows that the drafters' intended to require the facility to "inform" the resident, the resident's family, or representative of changes. However, the drafters intended to require that the facility actually "consult" with the resident's physician. 56 *Fed. Reg.* at 48,833. Appellate panels of the Board have concluded that the requirement to consult means more than simply notifying the resident's physician. "The requirement to consult means that the facility must engage in a dialogue with the physician about an appropriate response to the significant change or changes." *Stone County Nursing & Rehab. Ctr.*, DAB No. 2276, at 10; *Magnolia Estates Skilled Care*, DAB No. 2228, at 9.

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[5] The SOM and the preamble language do not have the force and effect of a statute or regulation. However, they are statements of the CMS interpretation and policy related to the statutory and regulatory participation requirements.

The surveyors allege in the SOD that Petitioner violated 42 C.F.R. § 483.10(b)(11) because Petitioner failed to notify the physicians of Residents 12, 18, and 20 when they had blood sugar readings below 60 and above 401. The surveyors allege that the violation posed immediate jeopardy for all of the facility's diabetic residents from July 29 to August 12, 2009. CMS Ex. 3, at 1-2. I conclude that CMS has failed to make a prima facie showing of noncompliance based on a violation of 42 C.F.R. § 483.10(b)(11) due to failure to consult the residents' physicians as the evidence does not show a significant change or a need to alter treatment significantly for any of the residents.

a. Facts

(i) Resident 12

The surveyors alleged that Resident 12 had a physician's order dated July 5, 2009, for sliding scale insulin.[6] The order required that, if the resident's blood sugar exceeded 400, he was to be given 10 units of insulin, and the resident's physician was to be called. The surveyors alleged that the Accucheck/Insulin Log for the resident from July 2009, shows that at 4:30 p.m. on July 10, 2009 his blood sugar was 430, but there is no record the physician was called. CMS Ex. 3, at 9.

Resident 12, a male, was 74 at the time of the survey. He was admitted to Petitioner on March 16, 2009, with multiple diagnoses, including Type II diabetes mellitus. CMS Ex. 7, at 27, 49. Resident 12 had an order that his blood sugar be checked twice each day at breakfast and dinner, and, if his blood sugar exceeded 400, he was to be given 10 units of insulin and his physician was to be called. The evidence presented by CMS shows that the order was issued June 21, 2009, though the evidence is consistent with a similar order having been in effect prior to June 21, 2009. CMS Ex. 7, at 5, 10, 11, 14, 21, 28, 33, 39, 40, 41. The evidence shows that on July 10, 2009 at 4:30 p.m. the resident's blood sugar was measured as 430, and he was given 10 units of sliding scale insulin. CMS Ex. 7, at 11, 14, 40. The evidence shows no other instance between June 1 and August 5, 2009, when the resident's blood sugar exceeded 400. CMS Ex. 7, at 5, 11, 14, 21, 33, 40. There were two other instances when the resident's blood sugar was between 351 and 400 and he required 10 units of insulin, June 9, 2009 at 5:00 p.m. and July 16, 2009 at 4:00 p.m. CMS Ex. 7, at 11, 14, 21, 40.

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[6] "Sliding scale" refers to the fact that the amount of insulin to be administered varies based on the resident's blood sugar reading.

(ii) Resident 18

The surveyors allege Resident 18 also had an order that required that the physician be called if the resident's blood sugar exceeded 400. The surveyors allege that a surveyor observed a nurse check Resident 18's blood sugar on August 3, 2009, and it was 432. The surveyor observed the nurse administer insulin. The surveyors allege that there was no order for the insulin (which is cited under two other deficiencies discussed hereafter), and there is no evidence that the physician was notified. CMS Ex. 3, at 10.

Resident 18, a male, was 83 at the time of the survey. He was admitted to Petitioner on July 18, 2007, with multiple diagnoses including Type II diabetes mellitus. CMS Ex. 9, at 5. Resident 18 had physician's orders dated March 2, 2009 and June 12, 2009, that specified his physician was to be called if his blood sugar exceeded 401, but the orders did not specify that Resident 18 was to receive sliding scale insulin when his blood sugar exceeded 401. CMS Ex. 9, at 9, 17, 36, 44, 46, 53. Accucheck/Insulin Log sheets for Resident 18 in evidence all show that he was to receive sliding scale insulin according to the standard sliding scale that is printed on each of the sheets. However, the standard sliding scale on the log sheets is different than the sliding scale ordered by Resident 18's physician in several respects. Significantly for purposes of this deficiency citation, the standard scale provides that, when blood sugar exceeds 401, the resident is to be given 12 units of regular insulin and the physician is to be called if blood sugar continues to exceed 401 after two hours. The Accucheck/Insulin Log sheets in evidence show that Resident 18's blood sugar exceeded 401, and he was given 12 units of insulin on 21 occasions – June 2, 3, 4, 8, 9, 11, 13, 14, 18, 20, 23, 24, 27, 29, July 2, 6, 9, 14, 15, 20, and August 3, 2009. CMS Ex. 9, at 11, 14, 20, 24 26, 28, 30, 32, 68, 70, 72, 74, 76, 78.

(iii) Resident 20

The surveyors allege that there were multiple instances in May, June, and July 2009, when Resident 20's blood sugar was less than 60 or greater than 400, but there is no evidence that the resident's physician was notified. CMS Ex. 3, at 6-9.

Resident 20, a male, was 87 at the time of the survey. He was admitted to Petitioner on February 10, 2009, with multiple diagnoses including Type II diabetes mellitus. CMS Ex. 11, at 150. The clinical records obtained by the surveyors and admitted as CMS Ex. 11 show that Resident 20 had a physician's order that his blood sugar level be checked before meals and at bedtime and for the administration of insulin on a sliding scale, but the order did not specify that the physician be notified when blood sugar was less than 60 or greater than 400. The physician signed these orders on May 4, 2009, June 1, 2009, July 1, 2009, and August 5, 2009. CMS Ex. 11, at 26, 178, 180, 186.

Accucheck/Insulin Log sheets for Resident 20 from May 2009 are not consistent in the sliding scale applicable for the resident. Some sheets include a hand-written sliding scale

order with lines drawn through the standard sliding scale. Other sheets from May 2009, reflect only the standard sliding scale. None of the sheets list the sliding scale order of the physician that originally was dated in February 2009, and subsequently reissued in May, June, July, and August 2009. CMS Ex. 11, at 179, 204-07, 265, 267, 279. The same observation applies to the Accucheck/Insulin Log sheets from June (CMS Ex. 11, at 199-203, 209-10, 281, 283, 317); July (CMS Ex. 11, at 212, 214, 216, 217, 269, 271, 303-05); and August 2009 (CMS Ex. 11, at 220, 222, 224-25, 273, 277, 293, 295, 297); except that the sheets for July and August 2009, instruct staff to use the standard sliding scale preprinted on the forms. On July 30, 2009, at 8:25 a.m., an order was written that stated that staff was to continue using the standard sliding scale and to continue to hold all scheduled insulin until further notice. CMS Ex. 11, at 77. This order suggests that staff had previously been using the standard sliding scale, but there is no order to that effect in evidence. It is also not clear whether the physician was referring to the order dated in February 2009 and reissued in May, June, July, and August 2009 as the "standing sliding scale" or whether he was referring to the sliding scale preprinted on Petitioner's forms. Even if the physician intended by his July 30, 2009 order for the sliding scale on Petitioner's forms to apply, that order was overridden when he signed the August 5, 2009 order listing the sliding scale originally implemented on February 10, 2009. CMS Ex. 11, at 26.

What is most significant for this deficiency is the frequency with which the resident's blood sugar was less than 60 and greater than 400. In May 2009, there are 4 recorded instances when the resident's blood sugar was less than 60 and 8 instances when it exceeded 400. CMS Ex. 11, at 204-05. In June 2009, there were 3 instances when blood sugar was less than 60 and 9 instances when it exceeded 400. CMS Ex. 11, at 209-10. In July 2009, there were 3 instances when the resident's blood sugar was less than 60 and 9 instances when it exceeded 400. CMS Ex. 11, at 212-15. Only part of the month of August 2009 is documented prior to the time the surveyor obtained the documents. However, from August 1 through 10, there are 7 recorded instances when the resident's blood sugar exceeded 400. CMS Ex. 11, at 220-24.

b. Analysis

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). 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 and that the violation posed a risk for more than minimal harm. The regulation CMS alleges was violated in this case requires that Petitioner immediately "inform the resident; consult with the resident's physician; and if known, notify the resident's legal representative or interested family" of: (1) an accident that results in injury and may require physician intervention; (2) a significant change in the resident's physical, mental or psychosocial condition; (3) a need to significantly alter

treatment; or (4) a decision to transfer or discharge the resident. 42 C.F.R. § 483.10(b)(11)(i). CMS does not allege that the violation here is based upon an accident, a decision to transfer or discharge, or a failure to inform the resident, the resident's family, or the resident's legal representative. CMS alleges that Petitioner violated the regulation because Petitioner failed to notify or inform the residents' physicians. The regulation does not address notifying or informing a resident's physician but, rather, imposes the obligation to consult the physician in certain circumstances. According to the regulation, the need to consult the physician is only triggered if there is a "significant change" in the resident's condition or there is a need to "significantly alter treatment." CMS does not specifically identify a significant change in the resident's conditions or a need to significantly alter treatment for the residents. CMS Br. at 15-18. CMS fails to make a prima facie showing of noncompliance because the evidence upon which CMS relies does not show a significant change or a need to significantly alter treatment.

When a penalty is proposed and appealed, CMS must make a prima facie case that the facility has failed to comply substantially with federal participation requirements. "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 Rehabilitation Center*, 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.

Hillman, 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 the Petitioner; and (3) show how the deficiencies it found amount to noncompliance that warrants an enforcement remedy, *i.e.*, that there was a risk for more than minimal harm due to the regulatory violation.

In *Evergreene Nursing Care Center*, DAB No. 2069 (2007), 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.
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> CMS makes a prima facie showing of noncompliance if the evidence CMS relies on is sufficient to support a decision in its favor absent an effective rebuttal. 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."

Evergreene, DAB No. 2069, at 7-8 (citations omitted).

Whether CMS makes a prima facie showing is determined by review of the credible evidence CMS presents to establish each element necessary to show that a facility is not in substantial compliance with a statutory or regulatory requirement of participation. To establish a prima facie case of noncompliance, the required basis for imposition of an enforcement remedy, CMS must show that the participation requirement was violated and that one or more residents suffered or were exposed to a risk for more than minimal harm. Petitioner disputes the factual basis for the CMS prima facie case. Petitioner preserved its argument that CMS failed to make a prima facie case by moving at the conclusion of the CMS case-in-chief for a judgment that CMS failed to make a prima facie showing. Tr. at 352-53. *Jennifer Matthew Nursing & Rehab. Ctr.,* DAB No. 2192, at 20-21, n.12 (2008).

The documentary evidence presented by CMS shows that Residents 12, 18, and 20 were diabetics and that their blood sugars fluctuated throughout the day. CMS concedes this point in the case of Resident 20. CMS Br. at 17. The evidence shows that the physicians for the residents were aware of the fluctuating blood sugars of each resident, and they had ordered the administration of insulin based on a sliding scale, in some instances in addition to and in other instances in lieu of regular administration of insulin. The sliding scales reflect that the physicians were aware of the possibility that blood sugar readings

might be less than 60 or greater than 400 and had given instructions for how those low and high readings were to be addressed. The clinical records for each of the residents introduced as evidence by CMS show that for each resident there were one or more instances when blood sugar was below or above the specified parameters. The evidence shows that the problem of low and high blood sugars was recognized and addressed by the treating physician for each of the three residents, months before the survey that concluded on August 12, 2009. The surveyors did not testify that they identified a significant change in the residents' conditions or that they identified a need to significantly alter treatment for the residents.

I conclude that the evidence upon which CMS relies does not show a significant change in condition or a need to significantly alter treatment for Residents 12, 18, or 20. Accordingly, I conclude that CMS has failed to make a prima facie showing of noncompliance based on a violation of 42 C.F.R. § 483.10(b)(11)(Tag F157).[7] I further conclude that the declaration of immediate jeopardy based upon the alleged deficiency was clearly erroneous.

6. Petitioner violated 42 C.F.R. § 483.25(m)(1)(Tag F332).

7. Petitioner did not show that the declaration of immediate jeopardy was clearly erroneous.

The surveyors allege in the SOD that Petitioner violated 42 C.F.R. § 483.25(m)(1), which requires that a facility ensure it is free of medication error rates of five percent or greater. The surveyors allege that 10 errors occurred in 49 opportunities for error, a rate of 20 percent. The surveyors allege that the failure to administer insulin as ordered and within 30 minutes prior to meals placed diabetic residents in immediate jeopardy. CMS Ex. 3, at 23-24, 29-30.

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[7] An argument could be made that the evidence shows Petitioner failed to comply with physicians' orders to notify the physician for these residents when blood sugars were outside certain parameters, and this seems to be the gist of the CMS argument. CMS Br. at 15-18. However, the regulation under consideration does not address or establish a requirement to comply with physicians' orders. Failure to follow physicians' orders might be a basis for an allegation that Petitioner violated participation requirements: to deliver services that meet professional standards of quality; to deliver care according to the resident's care plan; to deliver quality care; or to document that there was compliance with physicians' orders. However, Petitioner was not cited in the SOD for such deficiencies related to these residents or given notice by the SOD that it would need to defend those allegations, and I make no findings or conclusions in this regard.

Following are the ten alleged errors:

Example	Resident	Alleged Error	Date/Time	CMS Ex. 3
1	12	Received meal tray and began to eat 1 hour 19 minutes after 6 units of Novolin insulin administered.	8/2/2009, 4:03 p.m. – 5:22 p.m.	24
2	12	Megace 4 mg administered without order.	8/4/2009, 4:15 p.m.	25
3	17	Received meal tray 1 hour after 10 units of Novolin insulin administered.	8/3/2009, 4:35 p.m. - 5:35 p.m.	25
4	18	Received meal tray 1 hour 15 minutes after receiving 12 units Novolin insulin pursuant to sliding scale, and no order for 12 units.	8/3/2009, 4:15 p.m.- 5:30 p.m.	25-26
5	19	Received meal tray 1 hour and 30 minutes after 4 units Novolin insulin administered.	8/3/2009, 4:12 p.m.- 5:42 p.m.	27
6	11	Administered 330 mg (7.5cc) ferrous sulfate rather than 325 mg (7.38 cc) as ordered.	8/4/2009, 9:20 a.m.	28
7	11	Given multivitamin with iron rather than Thera-Tab.	8/4/2009, 9:30 a.m.	28
8	46	Given multivitamin rather than multivitamin with minerals as ordered.	8/5/2009, 7:35 a.m.	28-29
9	46	Administered 5 mg Methadone rather than 10 mg as ordered	8/5/2009, 7:35 a.m.	28-29
10	2	Eye drop (moisturizer/lubricant) applied to right eye rather than left eye as ordered.	8/3/2009, 1:25 p.m.	29

Participating long-term care facilities must ensure that each resident is provided and receives "the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the [resident's] comprehensive assessment and plan of care." 42 C.F.R. § 483.25. Regarding medication errors, the quality of care regulations require that the facility must ensure that:

> (1) It is free of medication error rates of five percent or greater; and
> (2) Residents are free of any significant medication errors.

42 C.F.R. § 483.25(m). The surveyors and CMS allege that Petitioner violated both prongs of the regulation. The alleged violation of 42 C.F.R. § 483.25(m)(2) is discussed separately hereafter.

The Guidance to Surveyors for Long Term Care Facilities, SOM app. PP, Tag F332 and F333[8] instructs surveyors that a medication error is:

> The *observed* preparation or administration of drugs or biologicals which is not in accordance with any of the following:
>
> 1. Physician's orders;
> 2 Manufacturer's specifications (not recommendations) regarding the preparation and administration of the drug or biological;
> 3. Accepted professional standards and principles which apply to professionals providing services. Accepted professional standards and principles include the various practice regulations in each State, and current commonly accepted health standards established by national organizations, boards, and councils. (*Emphasis added).*

No preparation error is alleged, only administration errors are cited by the surveyors.

The SOM explains that the medication error rate for purposes of determining whether there is a violation of 42 C.F.R. § 483.25(m)(1) is determined by dividing the number of observed errors by the number of opportunities for error and multiplying the quotient by 100, *i.e.*,

$$\text{Medication Error Rate} = \frac{\text{Number of Observed Errors}}{\text{Number of Opportunities}} \text{ X } 100$$

Surveyors are instructed that the error rate must actually be five percent or greater for a citation under 42 C.F.R. § 483.25(m)(1) and that rounding of a lower rate to five percent is not permitted. Surveyors are also instructed to use an observation technique to determine medication errors. Surveyors are to observe the administration of drugs, record what is observed, and reconcile the observations with the prescriber's drug orders to determine whether a medication error occurred. The SOM specifies that the

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[8] A very similar definition is set forth in the Survey Protocol for Long-Term Care Facilities, SOM, app. P, Sub-Task 5E, Medication Pass and Pharmacy Services (rev. 22, iss. 12-15-06, eff. 12-18-06).

"[d]etection of blank spaces on a medication administration record does not constitute detection of actual medication errors." SOM, app. PP, Tag F332 and F333.

The SOM provides additional instruction to surveyors for identifying errors related to the timing of administration of medications. In a subsection entitled "Determining Medication Errors," the SOM provides:

> **Timing Errors** -- If a drug is ordered before meals (AC) and administered after meals (PC), always count this as a medication error. Likewise, if a drug is ordered PC and is given AC, count as a medication error. Count a wrong time error if the drug is administered 60 minutes earlier or later than its scheduled time of administration, BUT ONLY IF THAT WRONG TIME ERROR CAN CAUSE THE RESIDENT DISCOMFORT OR JEOPARDIZE THE RESIDENT'S HEALTH AND SAFETY. Counting a drug with a long half-life (e.g., digoxin) as a wrong time error when it is 15 minutes late is improper because this drug has a long half-life (beyond 24 hours) and 15 minutes has no significant impact on the resident. The same is true for many other wrong time errors (except AC AND PC errors).
> To determine the scheduled time, examine the facility's policy relative to dosing schedules. The facility's policy should dictate when it administers a.m. doses, or when it administers the first dose in a 4-times-a-day dosing schedule.

SOM, app. PP, Tag F332 and F333 (emphasis in original). Petitioner argues that a timing error is not a medication error at all unless it involves a failure to administer a drug before or after a meal as ordered, or the drug is administered more than 60 minutes before or after its scheduled time and the wrong time error could cause the resident discomfort or jeopardize the resident's health and safety. P. Br. at 6. CMS does not take issue with Petitioner's interpretation. CMS Br. at 7. I agree with Petitioner's interpretation for the following reasons.

The regulation does not provide a definition for "significant medication error." Significant and non-significant, also referred to as insignificant, medication errors are described in detail in the SOM, app. PP, Tag F332 and F333. A significant medication error is "one which causes the resident discomfort or jeopardizes his or her health and safety" and other medication errors are "non-significant." SOM, app. PP, Tag F332 and F333. The SOM instructs surveyors that "significance" is a matter of professional judgment based on consideration of the specific resident's condition, the drug category, and the frequency of the error. SOM, app. PP, Tag F332 and F333. Both significant and insignificant errors are considered when determining the medication error rate under 42

C.F.R. § 483.25(m)(1). SOM, app. F332 and F333; *Park Manor Nursing Home*, DAB No. 2005, at 48 (2005). The issue, not addressed by the regulation, the SOM, or prior decisions of the Board, is the issue raised by Petitioner, *i.e.*, whether an error in the timing of administration of a drug is a medication error only if the error was a failure to administer within 60 minutes of the time prescribed and there was a potential for the timing error to cause a resident discomfort or jeopardize the resident's health and safety.

My review of the language of the SOM, Tags F332 and F333, and its organization leads me to conclude that Petitioner urges the correct interpretation of CMS policy for how to determine whether a timing error (wrong time error) amounted to a medication error that should be counted for purposes of application of 42 C.F.R. § 483.25(m)(1). The discussion of timing errors upon which Petitioner relies is set forth in a subsection of the discussion for Tags F332 and F333 entitled "Timing Errors" that is also the first subsection of a subsection entitled "Determining Medication Errors." The discussion of timing errors is not included within the sections that discuss significant and insignificant errors or that provide examples of such errors. The titles of the two subsections – "Determining Medication Errors" and "Timing Errors" – and their organization cause me to conclude that the purpose of the discussion was to instruct surveyors to determine whether a timing error was to be counted as a "medication error" or not. The purpose of the subsection was not to instruct surveyors how to determine whether a medication error was significant or insignificant. The first line of the subsection entitled "Timing Errors" states "[i]f a drug is ordered before meals (AC) and administered after meals (PC), always count this as a medication error." The sentence does not label such an error a "significant medication error," rather it states that such an error is a "medication error." Similarly, the second sentence states "[l]ikewise, if a drug is ordered PC and is given AC, count as a medication error." Again, the second sentence does not state that such an error is a significant medication error. The third sentence creates confusion because the drafters refer to a "wrong time error," and the drafters use the same language as that in of the definition of a "significant medication error." CMS instructs in the third sentence that surveyors should "[c]ount a wrong time error if the drug is administered 60 minutes earlier or later than its scheduled time of administration, BUT ONLY IF THAT WRONG TIME ERROR CAN CAUSE THE RESIDENT DISCOMFORT OR JEOPARDIZE THE RESIDENT'S HEALTH AND SAFETY." The emphasis appears in the original text, and I surmise it was used for emphasis. Despite the emphasis, the sentence is confusing because the text in capital letters is the same as the definition for a significant medication error. There are number of possible constructions that could be given to this confusing sentence. However, giving the drafters full credit for having been knowledgeable of the remaining text of the SOM under Tags F332 and F333, the logical construction for the sentence is that it instructs surveyors to count as a "medication error," only those errors in the timing of administration, *i.e.*, those that are more than 60 minutes early or late, that amount to a significant medication error. This construction makes sense for determination of whether or not there is a violation of 42 C.F.R. § 483.25(m)(1), because the counting of errors is necessary for determining whether or not the rate of error is five

percent or more. There is no need to count the number of medication errors to determine whether there is a violation of 42 C.F.R. § 483.25(m)(2), as the existence of even a single significant medication error constitutes a violation of the regulation. Furthermore, if a single significant medication error has the potential for more than minimal harm, it is noncompliance that will support an enforcement remedy. I conclude that the language of the SOM provides CMS policy guidance to surveyors that the following wrong time errors are counted as medication errors:

> 1. Failure to administer a medication before a meal or after a meal as ordered; and
>
> 2. Administration of a medication more than 60 minutes earlier or later than scheduled but, only if, such timing error amounts to a significant medication error, *i.e.*, it can cause the specific resident discomfort or jeopardizes the resident's health and safety.

Under the second prong, if a timing error amounts to a medication error, it is also a significant medication error and should, arguably, be cited as a violation of 42 C.F.R. § 483.25(m)(2) (Tag F333).

It is necessary to analyze each of the ten alleged errors (listed as examples in the foregoing table) to determine whether or not each is a medication error. According to the SOD the surveyors made 49 observations. CMS Ex. 3, at 23. Therefore, there is no regulatory violation so long as Petitioner had fewer than three medication errors.

In example 1, the surveyor alleges she observed that Resident 12 received his meal tray and began to eat 1 hour and 19 minutes after 6 units of Novolin insulin were administered. The surveyor alleges that the administration of the insulin more than 30 minutes prior to the meal is a medication error. CMS Ex. 3, at 24. The surveyor and CMS are in error, as this was a wrong time error, not a medication error. The surveyor does not allege the source for the requirement that insulin be administered not more than 30 minutes prior to a meal. Resident 12's physician's orders for Novolin R do not specify that the insulin must be administered within 30 minutes of a meal. CMS Ex. 7, at 10, 28, 39, 41. CMS did not present evidence of manufacturer's specifications or accepted professional standards and principles that require that Novolin R be administered no more than 30 minutes prior to a meal. Tr. at 225. Surveyor Penny Pope testified that, in her experience, Novolin R should be administered within 30 minutes of a meal although she admitted she did not actually review the manufacturer's instructions at the time she made the determination. Tr. at 118-20. I do not find that Surveyor Pope's recollection of manufacturer's literature related to Novolin R is sufficiently credible evidence of manufacturer's specifications regarding prescribing. I also do not accept her testimony as credible evidence of nursing standards and principles related to the administration of Novolin R in this case, as her testimony demonstrated a lack of

understanding of the impact of the administration of insulin and food upon an already very high blood sugar reading. Tr. at 123-24. Even if I accept the surveyors' allegation in the SOD and Surveyor Pope's testimony as sufficient evidence of the requirement that a meal be provided within 30 minutes of the administration of Novolin R, there is no medication error. A wrong time error is only counted as a medication error if the administration is not within 60 minutes of the scheduled time, and there is a potential to cause the resident discomfort or jeopardize the resident's health and safety. If I accept the surveyor's allegation that the time for administration is 30 minutes prior to a meal, then a wrong time error only becomes a medication error if a meal is not delivered within 1 hour and 30 minutes of the administration of the Novolin R. Thus, the surveyor's allegation does not on its face state a medication error as the allegation is that the resident actually began to eat at 1 hour and 19 minutes after the administration of Novolin R. Thus, example 1 as alleged by the surveyors is not a medication error.

In example 2, the surveyors allege that a surveyor observed that Resident 12 was administered four milligrams of Megace without an order. CMS Ex. 3, at 25. Petitioner asserts in its proposed finding of fact 25, that the citation of a deficiency related to Megace was in error. The testimony of Surveyor Penny Pope was that the reference in the SOD to 4 milligrams of Megace was in error, and it should have been 40 milligrams because Megace is only available in doses of 20 milligrams or 40 milligrams. Tr. at 106. Surveyor Pope did not testify that she observed the administration of Megace. Surveyor Pope did not testify how she knew that Megace was administered. Surveyor Pope did not testify how she knew that the SOD should have alleged that it was 40 milligrams of Megace, not 4 milligrams, other than to state that she knew Megace was only available in 20 and 40 milligram doses and that there was some discussion of the observations of this resident among the surveyors. According to the Resident Review Worksheet admitted as evidence by CMS, Freda Forsythe was the surveyor that made the observations of Resident 12, not Surveyor Pope. Surveyor Forsythe was not called to testify about her observations of what medication was administered to Resident 12. The evidence does not show how Surveyor Forsythe identified what is alleged to be Megace. The evidence does not show whether the medication administered was actually some other medication in a four milligram tablet, or whether Surveyor Forsythe simply made a typographical error. I do not accept the assertion in the SOD that Megace was administered as weighty evidence in light of the admitted error. Furthermore, no foundation was laid for the testimony of Surveyor Pope regarding this example, and I have no evidence of how she knew the information she testified to or whether her knowledge was reliably based. Thus, the interpretation of Surveyor Pope's testimony that 40 milligrams of Megace was administered to Resident 12 is not credible and entitled to no weight. I conclude that the evidence is insufficient to show that Resident 12 was given Megace in any quantity and that there was no medication error.

In example 3, the surveyors allege that Resident 17 received his meal tray one hour after he was given Novolin R insulin. CMS Ex. 3, at 25. Unlike Resident 12, Resident 17's

physician ordered that Novolin R be administered 30 minutes before meals. CMS Ex. 8, at 6. I conclude that the facts alleged show this was a wrong time error but not a medication error. There is no dispute that the insulin was delivered before the meal as ordered, and there is no medication error on that basis. Thus, a wrong time error only becomes a medication error if the administration of the drug is not within 60 minutes of the scheduled time and there is a potential to cause the resident discomfort or jeopardizes the resident's health and safety. The order was to administer Novolin R 30 minutes prior to a meal, and the insulin was administered before the meal. Therefore, in this example, a wrong time error only becomes a medication error if a meal was not delivered within 1 hour and 30 minutes of the administration of the Novolin R. The surveyor's allegation does not on its face allege a medication error, as the allegation is that the resident actually received his meal one hour after the administration of Novolin R. Accordingly, I conclude that example 3 is not a medication error.

In example 4, the surveyors allege two medication errors. The surveyors allege that Resident 18 received his meal tray 1 hour and 15 minutes after he was administered Novolin R insulin. CMS Ex. 3, at 25-26. The surveyor's observation is not disputed. The surveyor also alleges that the "2006 American Society of Consultant Pharmacists and Med-Pass" states that Novolin R should be administered 30 minutes prior to meals. CMS has not offered this document as evidence, and I do not accept the surveyor's reference to the source as sufficient evidence that the referenced document reflects accepted professional standards and principles. The source is also not cited in the other deficiencies involving the administration of Novolin. The physician order for Novolin R specifies that it is to be administered according to the sliding scale that is in the order. The order does not require that the Novolin be administered only within 30 minutes of a meal or that a meal must be served within 30 minutes of administration of the Novolin. CMS Ex. 9, at 9. If I accept the surveyor's assertion that Novolin should be administered 30 minutes prior to a meal, the allegation that a meal was not provided within 30 minutes of the administration of the Novolin is a wrong time error but not a medication error in this example. A wrong time error only becomes a medication error if the administration of the drug is not within 60 minutes of the scheduled time and there is a potential to cause the resident discomfort or jeopardizes the resident's health and safety. Therefore, in this example, a wrong time error becomes a medication error only if a meal is not delivered within 1 hour and 30 minutes of the administration of the Novolin R. The surveyor's allegation does not on its face allege a medication error, as the allegation is that the resident actually received his meal 1 hour and 15 minutes after the administration of Novolin R. Thus, I conclude the wrong time error did not amount to a medication error.

In example 4, the surveyor also alleges in the SOD that 12 units of Novolin were administered to Resident 18 due to a blood sugar reading of 432 but that there was no order for 12 units. CMS Ex. 3, at 26; Tr. at 110-14. I view the allegation that there was no order to administer 12 units of Novolin as a separate basis for a medication error under example 4. Petitioner argues that the sliding scale order for Resident 18 was consistent

with the facility sliding scale, and the facility sliding scale authorized administration of 12 units when blood sugar exceeded 400. P. Br. at 8-9. Petitioner is in error. The sliding scale ordered for Resident 18 on June 24, 2009, required that, if his blood sugar exceeded 401, his physician was to be notified, and the order did not authorize administration of 12 units of any insulin. CMS Ex. 9, at 9. Petitioner's clinical records show that the same sliding scale had been in effect for this resident since March 2009. CMS Ex. 9, at 44, 46, 53. Accucheck/Insulin Logs for Resident 12 indicate that the facility sliding scale is to be used and that the sliding scale provides that, if his blood sugar is above 401, the resident is to be given 12 units of regular insulin and, if on recheck after two hours, the blood sugar remains above 401, the physician is to be called. CMS Ex. 9, at 11, 14, 20, 24, 26, 28, 30, 32, 68, 70, 72, 74, 76, 78. Petitioner has presented no evidence that shows Resident 18's physician ordered that the facility sliding scale be used rather than the sliding scale he ordered as early as March 2009. The physician-ordered sliding scale and the facility sliding scale are clearly different. Accordingly, I conclude that the surveyor identified a medication error based upon the administration of 12 units of Novolin for a blood sugar reading of 432, when the applicable physician's order required that the physician be notified and did not authorize the administration of any insulin.

In example 5, the surveyors allege that Resident 19 received his meal tray 1 hour and 30 minutes after receiving four units of Novolog insulin. CMS Ex. 3, at 27. Resident 19 had an order for Novolog insulin to be used on a sliding scale. The order did not specify that Novolog was to be given 30 minutes prior to meals but did require that blood sugar be checked prior to meals. CMS Ex. 10, at 10, 23. CMS did not present evidence of manufacturer's specifications or accepted professional standards and principles that require that Novolog be administered no more than 30 minutes prior to a meal. Tr. at 225. Even if I accept the surveyors' allegation in the SOD as sufficient evidence of the requirement that a meal be provided within 30 minutes of the administration of Novolog, there is no medication error. A wrong time error is only counted as a medication error if the administration is not within 60 minutes of the scheduled time and there is a potential to cause the resident discomfort or jeopardize the resident's health and safety. If I accept the surveyor's allegation that the time for administration is 30 minutes prior to a meal, then a wrong time error only becomes a medication error if a meal is not delivered within 1 hour and 30 minutes of the administration of the Novolog. Thus, the surveyor's allegation does not on its face state a medication error, as the allegation is that the resident received his meal tray 1 hour and 30 minutes after the administration of Novolog. Accordingly, I conclude that example 5 is not a medication error.

In example 6, the surveyors allege that Resident 11 was administered 330 milligrams of ferrous sulfate rather than 325 milligrams as ordered. CMS Ex. 3, at 28. The surveyors' observation is not disputed by Petitioner. Resident 11's physician ordered on June 23, 2009, that the resident be given 325 milligrams or 7.5 cubic centimeters of ferrous sulfate through his feeding tube every day. CMS Ex. 6, at 4, 12; P. Ex. 1, at 21. The resident's physician also issued an order on June 23, 2009 for the resident to receive 7.4 milliliters

(one cubic centimeter is equal to one milliliter) of ferrous sulfate daily. CMS Ex. 6, at 8. Petitioner's argument does not rebut the allegation of the SOD. P. Br. at 7. Accordingly, I conclude that example 6 is a medication error.

In example 7, the surveyors allege that Resident 11 was given a multivitamin with iron rather than a Thera-Tab. CMS Ex. 3, at 28. Petitioner does not dispute the accuracy of the surveyor's observation. Petitioner does not specifically address this example in its post-hearing briefs. Resident 11's physician ordered one tablet of Thera-Tab via the resident's feeding tube each day. The physician authorized "generic equivalents . . . unless otherwise noted." CMS Ex. 6, at 4, 12. However, Petitioner did not present evidence that a multivitamin with iron is a generic equivalent that was authorized by the physician's order. Accordingly, I conclude that example 7 is a medication error.

In example 8, the surveyors allege that Resident 46 was given a multivitamin rather than a multivitamin with minerals as ordered. CMS Ex. 3, at 28-29. Petitioner does not specifically deny the surveyors' observations or address this example in its post-hearing brief. The clinical record shows that Resident 46's physician ordered that a multivitamin with minerals be administered every day. CMS Ex. 25, at 5, 6, 20. The physician authorized "generic equivalents . . . unless otherwise noted." CMS Ex. 25, at 6, 20. However, Petitioner did not present evidence that a multivitamin with minerals was authorized by the physician. I conclude that example 8 is a medication error.

In example 9, the surveyors allege that on August 5, 2008, a surveyor observed that Resident 46 was administered five milligrams of Methadone, rather than ten milligrams as ordered. CMS Ex. 3, at 28-29. Petitioner does not deny the surveyor's observations or address this example in its post-hearing brief. The clinical record includes copies of physician orders dated July 30, 2009, which required that effective August 2, 2009, Resident 46 was to receive 10 milligrams of Methadone every 12 hours. CMS Ex. 25, at 7, 21, 25. Accordingly, I conclude that example 9 is a medication error.

In example 10, the surveyors allege that a surveyor observed that Random Resident 2 was administered an eye drop in the right eye rather than the left eye as ordered. CMS Ex. 3, at 29. CMS did not present any clinical records for Random Resident 2. However, Petitioner does not deny the allegation or present evidence to rebut the surveyor's observations. Accordingly, I conclude that example 10 is also a medication error.

Based upon my review of the evidence, the surveyors correctly identified 6 medication errors out of 49 opportunities for error – an error rate of 12 percent. I conclude that Petitioner violated 42 C.F.R. § 483.25(m)(1)(Tag F332), because its medication error rate exceeded five percent during observed medication passes on August 2 through 5, 2009.

The surveyors alleged in the SOD and CMS determined that the failure to administer insulin as ordered by the physician and the failure to administer insulin within 30 minutes

of meals posed immediate jeopardy for diabetic residents from July 29, 2009 to August 12, 2009. CMS Ex. 3, at 23-24, 29-30. I have concluded that none of the timing errors amounted to medication errors in the examples cited in the SOD. Accordingly, I conclude that the timing errors did not pose immediate jeopardy.

I concluded that in example 4, however, the surveyor correctly identified as a medication error the administration of 12 units of Novolin due to a blood sugar reading of 432, but the physician's order required that he be notified for a blood sugar of over 401, and the order did not authorize the administration of any insulin. Petitioner did not specifically address whether or not the administration of a dose of insulin without an order posed immediate jeopardy. Petitioner argued that the declaration of immediate jeopardy is clearly erroneous because, at the hearing, the surveyors were unable to state the definition of immediate jeopardy. P. Br. at 14. I agree with Petitioner that the surveyors demonstrated a lack of knowledge of the meaning of the phrase "immediate jeopardy." Tr. at 127, 163, 297. However, it is not the surveyors' determination of immediate jeopardy that is in issue, it is the CMS determination that is subject to my review.

The CMS determination of immediate jeopardy must be upheld, unless Petitioner shows the declaration of immediate jeopardy clearly erroneous. 42 C.F.R. § 498.60(c)(2). Immediate jeopardy is "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. CMS's determination of immediate jeopardy is presumed to be correct, and Petitioner has a heavy burden to demonstrate clear error in that determination. *Yakima Valley Sch.* DAB No. 2422, at 8-10 (2011); *Cal Turner Extended Care Pavilion*, DAB No. 2384, at 13 (2011); *Maysville Nursing and Rehab. Facility*, DAB No. 2317, at 11 (2010); *Liberty Commons Nursing and Rehab. Ctr.– Johnston*, DAB No. 2031, at 18-19 (2006), *aff'd, Liberty Commons Nursing & Rehab. Ctr.–Johnson v. Leavitt*, 241 F. App'x 76 (4th Cir. 2007); *Brian Ctr. Health and Rehab./Goldsboro*, at 9 (*citing Barbourville Nursing Home*, DAB No. 1962, at 11 (2005)), *aff'd, Barbourville Nursing Home v. U.S. Dep't of Health & Human Srvs.*, 174 F. App'x 932 (6th Cir. 2006). Once CMS presents evidence supporting a finding of noncompliance, CMS does not need to offer evidence to support its determination that the noncompliance constitutes immediate jeopardy, rather, the burden is on the facility to show that that determination is clearly erroneous. *Cal Turner Extended Care Pavilion*, DAB No. 2384, at 13; *Liberty Commons Nursing & Rehab. Ctr.–Johnson*, 241 F. App'x 76, at 3-4 (4th Cir. 2007). Petitioner presented no weighty evidence that the administration of insulin, particularly 12 units, without a physician's order poses no risk for serious harm, injury, or death. Accordingly, I conclude that Petitioner has failed to meet its burden to show that the declaration of immediate jeopardy was clearly erroneous. Petitioner proposed a finding of fact that immediate jeopardy was corrected by no later than August 8, 2009, citing the testimony of DON Wehner (Tr. at 383-84). Petitioner's Proposed Findings of Fact, at 5, ¶ 33. DON Wehner testified that most of the plan of correction, other than some training, was completed by August 12, 2009. Tr. at 385-86.

Petitioner alleged completion dates for its plan of correction of August 5, 7, 10, 12, and 17. CMS Ex. 3, 24-29. The surveyors concluded that immediate jeopardy was abated on August 12, 2009, when the facility presented an acceptable allegation of compliance. CMS Ex. 3, at 30-32. Based on the testimony of DON Wehner and the plan of correction, I conclude that immediate jeopardy was abated on August 12, 2009, as the surveyors concluded.

8. Petitioner did not violate 42 C.F.R. § 483.25(m)(2)(Tag F333).

9. The declaration of immediate jeopardy based upon the alleged deficiency under Tag F333 was clearly erroneous.

The surveyors allege in the SOD that Petitioner violated 42 C.F.R. § 483.25(m)(2), which obligates Petitioner to ensure that its residents are free of any significant mediation errors. The surveyors alleged specifically that for 20 of 30 residents reviewed, Petitioner's staff failed to: perform blood sugar checks as ordered; administer correct dosages of sliding scale insulin as ordered; administer insulin within 30 minutes of meals; and obtain signed orders to administer insulin. The surveyors also alleged that staff's failures to administer insulin as ordered, to test blood sugar as ordered, and to notify physicians when blood sugars were below 60 or above 401 placed facility residents who required insulin in immediate jeopardy. CMS Ex. 3, at 32-33.

The SOM instructs surveyors that a significant medication error is one that causes a resident discomfort or jeopardizes his or her health or safety. Discomfort may depend upon the individual resident. The relative significance of medication errors is a matter of professional judgment that considers three factors: (1) resident condition; (2) drug category; and (3) frequency of the error. The SOM includes a list of medication errors and characterizes them as significant or non-significant. Insulin is not listed. Thus, there is no presumption that a medication error related to the administration of insulin is either significant or non-significant. SOM, app. PP, Tags F332 and 333.

Petitioner objects to this deficiency citation on grounds that the surveyors' findings were based upon record reviews and not actual observation of medication passes. P. Br. at 9-10. Petitioner is correct that the SOM instructs surveyors to use observation of one or more medication passes to determine medication errors. The SOM specifically instructs surveyors not to use paper review to determine medication errors as the detection of blank spaces on a medication administration record does not constitute the detection of actual medication errors. SOM app. PP, Tags F332 and F333. The surveyors' allegations in the SOD clearly show that, except for the examples of Resident 17, 18, and 19, all are based upon review of records and the surveyors' identification of omissions or blank spaces on medication administration records rather than the observation of actual errors and omissions in the administration of medications. CMS Ex. 3, at 39-67; Tr. at 186-87. I do not intend to suggest that errors in documentation may never be a basis for the

discovery of a significant medication error. However, in this case, the documentation errors as cited alone are not sufficient to satisfy the articulated CMS policy in the SOM and are insufficient for a prima facie showing of a violation 42 C.F.R. § 483.25(m)(2). For reasons already discussed under Tag F332, I also find no significant medication error in any wrong-time of administration example when insulin was administered within 60 minutes of the prescribed time so long as it was administered prior to or after a meal as ordered. Accordingly, further examination is required of the examples of Resident 17, 18, and 19 only.

The surveyors allege that on August 3, 2009, a surveyor observed that Resident 17 was administered six units of Novolin R. The surveyors allege that the resident had an order for 10 units of Novolin R, three times per day, 30 minutes before meals. The surveyors alleged that Resident 17 did not receive his meal tray and begin eating until 1 hour and 19 minutes after the insulin was administered. CMS Ex. 3, at 54. The wrong-time error did not amount to a medication error, as the insulin was administered before the meal and no more than 1 hour and 30 minutes prior to the meal being served. The surveyors also allege that Resident 17 received the incorrect dose of insulin. The surveyors' allegation regarding the incorrect dose is not clear, but I construe the allegation to be that the 6 units observed to be administered was incorrect, and the correct dose should have been 10 units. CMS Ex. 3, at 54. The clinical record in evidence shows that Resident 17 had an order for 10 units of Novolin R to be administered three times per day, 30 minutes before meals. He also had an order for 25 units of Lantus, another insulin, to be administered at bedtime. There is no order in evidence for Resident 17 to receive either sliding scale insulin or 6 units of insulin. CMS Ex. 8, at 6, 11, 18-29. Nevertheless, I do not find a medication error because the surveyors' observations of Resident 17, as alleged in the SOD, are in conflict and not credible. The surveyors identified only one resident as Resident 17 in this survey. CMS Ex. 4. Under Tag F332, the surveyors allege that at 4:35 p.m. on August 3, 2009, a surveyor saw a nurse administer 10 units of Novolin R to Resident 17. CMS Ex. 3, at 25. The administration of 10 units is consistent with the resident's orders. CMS Ex. 8, at 6. The clinical records placed in evidence by CMS show that staff also documented the administration of 10 units of Novolin R at 4:00 p.m. on August 3, 2009. CMS Ex. 8, at 11, 18, 28. However, under Tag F333, the surveyors allege that at 4:03 p.m. on August 3, 2009, a surveyor saw a nurse administer six units of Novolin R to Resident 17. CMS Ex. 3, at 54. CMS does not offer any explanation or attempt to resolve the inconsistent allegations of its surveyors. Accordingly, I conclude the evidence does not show a medication error occurred related to the administration of a wrong dose of Novolin R on August 3, 2009 at about 4:00 to 4:30 p.m.

The surveyors cite the example of Resident 19. The surveyors allege in the SOD that on August 3, 2009, a surveyor observed the administration of four units of Novolog insulin to Resident 19, without a physician's order. The surveyors also alleged that there was no signed physician's order for the administration of sliding scale insulin. CMS Ex. 3, at 55. The surveyors' allegations of fact are in error. The clinical records placed in evidence by

CMS show that Resident 19 had a physician's order dated July 27, 2009, for Novolog to be administered according to the sliding scale ordered by the physician on July 28, 2009. The order for Novolog was ordered to be discontinued effective August 5, 2009, and Novolin R was to be administered according to the physician's sliding scale thereafter. The orders are signed by the physician, albeit not until August 5, 2009. The surveyors do not allege what the resident's blood sugar reading was when the observation was made on August 3, 2009. However, the orders provide that 4 units of Novolog were to be administered for a blood sugar reading of 201 to 250, during the period the order was in effect from July 28 to August 5, 2009. CMS Ex. 10, at 10, 17, 20, 23. Accordingly, the evidence shows no medication error related to Resident 19 on August 3, 2009.

The surveyors cited the observed medication pass to Resident 18 on August 3, 2009, when he was given 12 units of Novolin R for a blood sugar of 432 without notification of the physician and without an order in the resident's record to administer the Novolin R. CMS Ex. 3, at 55. The same facts are also alleged under Tag F332. CMS Ex. 3, at 25-26. I concluded under Tag F332 that these facts constituted a medication error. The issue under Tag F333 is whether it was a significant medication error. In the example of Resident 18, the surveyors do not specifically allege that the resident was subject to experiencing discomfort or that his health or safety was jeopardized by receiving insulin without a physician order. CMS Ex. 3, at 55. However, a fair reading of the allegation that there was a significant medication error is that the surveyors intended to allege a potential for discomfort or that the resident's health or safety was jeopardized. As already noted there is no presumption established by the SOM that a medication error related to the administration of insulin is significant. CMS presents no competent evidence other than the opinions of the surveyors as reflected by the SOD that the medication error in question was significant. Surveyor Pope testified that she understood that the administration of insulin to the resident could cause his blood sugar to drop. Tr. at 113. She also testified to her opinion that the administration of insulin without an order could cause harm. Tr. at 138. Given the fact the resident's blood sugar was 432, lowering the blood sugar cannot credibly be characterized as harm. Tr. at 113, 138. Surveyor Melissa Thomas testified based upon her nursing credentials regarding the symptoms and risks for harm or death associated with high and low blood sugar and that a high blood sugar requires insulin to return it to a normal range. Tr. at 167-70, 216-17.

The evidence shows that Resident 18's physician ordered that he be contacted if the resident's blood sugar exceeded 401. The physician did not authorize the administration of any insulin if blood sugar exceeded 401. The same order was reauthorized by the physician's signature in May, June, and July, 2009. CMS Ex. 9, at 9, 44, 46. For some unexplained reason, facility staff used the facility standard sliding scale in June, July, and August 2009, rather than the sliding scale ordered by the physician. Pursuant to the facility standard sliding scale, if blood sugar exceeded 401 staff was to administer 12 units of regular insulin, recheck blood sugar in two hours, and call the physician if the blood sugar still exceeded 401. Petitioner's failure to ensure staff complied with the

physician's ordered sliding scale rather than applying the facility standard, constitutes a medication error. I conclude, however, that, in the case of Resident 18, the medication error did not have the potential to cause Resident 18 discomfort or pose a health and safety risk and, therefore, did not amount to a significant medication error. I conclude that there was no potential for discomfort or a health and safety risk for two reasons. The evidence shows that the standard sliding scale had been used with Resident 18, albeit in error, for several months with no evidence of any discomfort or health or safety risk. Further, the evidence shows many instances in June, July, and August 2009, when the physician was called for blood sugar readings of "Hi" and above 401, with the physician ordering from 12 to 25 units of insulin. CMS Ex. 9, at 11, 14, 20, 21, 24, 25-27, 28, 30, 32, 64-66, 68, 70, 72-76, 78-79, 81. Therefore, the administration of 12 units of insulin for a blood sugar reading of 432 observed by the surveyors was consistent with past orders of the physician. While the medication error is not excused by the fact that in past instances of blood sugar above 401 the physician ordered 12 units, it is more likely than not that the administration of 12 units was not going to cause discomfort or pose a risk to Resident 18's health and safety but rather lower the resident's high blood sugar to a safer range as such a dose had done in the past.

Accordingly, I conclude that there is no significant medication error in violation of 42 C.F.R. § 483.25(m)(2)(Tag F333). I further conclude that the declaration of immediate jeopardy based upon this alleged violation was, therefore, clearly erroneous.

10. The CMP of $5,050 per day from July 29, 2009 through August 11, 2009, is not reasonable.

11. A CMP of $3,050 per day from July 29, 2009 through August 11, 2009, is a reasonable enforcement remedy.

I concluded based on the stipulations of the parties that Petitioner was not in substantial compliance from July 29 through August 23, 2009, based upon regulatory violations that caused no actual harm but posed a risk for more than minimal harm to Petitioner's residents. I also concluded based on the stipulations of the parties that a $150 per day CMP from July 29 through August 23, 2009, is a reasonable enforcement remedy for the noncompliance. Based on consideration of the entire record, I have also concluded that Petitioner violated 42 C.F.R. § 483.25(m)(1)(Tag F332) and that Petitioner has failed to show that the CMS determination that the violation posed immediate jeopardy from July 29, 2009 through August 11, 2009 was clearly erroneous.

If a facility is not in substantial compliance with program requirements, CMS has the authority to impose one or more of the enforcement remedies listed in 42 C.F.R. § 488.406, including a CMP. CMS may impose a daily CMP for the number of days that the facility is not in compliance, or a per instance CMP for each instance that a facility is not in substantial compliance, whether or not the deficiencies pose immediate jeopardy.

42 C.F.R. § 488.430(a). CMPs that may be imposed against a facility on a per day basis are divided into two ranges. The upper range of CMPs is $3,050 per day to $10,000 per day and is reserved for deficiencies that pose immediate jeopardy to a facility's residents and, in some circumstances, for repeated deficiencies. The lower range is from $50 to $3,000 per day and is authorized for noncompliance that does not pose immediate jeopardy but, has the potential for more than minimal harm. 42 C.F.R. §§ 488.408, .438(a)(1)(i), (d)(2). The parties stipulated that the $150 CMP was reasonable for the noncompliance that did not posed immediate jeopardy. Because I have concluded that Petitioner did not show that the CMS determination of immediate jeopardy from July 29 through August 11, 2009 was clearly erroneous, I have to make a determination related to the reasonableness of the CMP in the upper range.

If I conclude, as I have in this case, that there is a basis for the imposition of an enforcement remedy and the remedy proposed is a CMP, 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 electing 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 noncompliance, 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 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. and Specialty Care Ctr.*, DAB No. 1629 (1997).

CMS proposed to impose a CMP of $5,050 per day for the period July 29 through August 11, 2009, based on consideration of three regulatory violations alleged by the surveyors, each with multiple examples. I have concluded that the evidence shows only a single

regulatory violation for which Petitioner has failed to show the CMS determination of immediate jeopardy was clearly erroneous. Thus, when applying the regulatory factors, I do so only in the context of the noncompliance under Tag F332. CMS does not cite to any history of noncompliance. CMS Br. at 20-22. Petitioner does not allege that its financial condition should be considered in determining the reasonableness of the proposed CMP. P. Br. at 15-17. In concluding that Petitioner violated 42 C.F.R. § 483.25(m)(1)(Tag F332), I found that Petitioner had a medication error rate of 12 percent during observed medication passes to multiple residents. A 12 percent error rate is significant, even though there was fortunately no evidence of actual harm to a resident due to the errors. The evidence shows that the deficiency was widespread. Petitioner was clearly culpable in its failure to ensure accuracy in the administration of medications to its residents. It may be argued that the remedial purpose for imposing enforcement remedies was satisfied by Petitioner's prompt correction of the noncompliance, Petitioner's admission of noncompliance, and Petitioner's stipulation to the reasonableness of a CMP in the lower range. But, the CMS election to proceed on the alleged noncompliance for which the agency determined there was immediate jeopardy, even though the remedial purposes of the Act and regulations may have been achieved prior to the hearing in this case, is not subject to my review. In considering the reasonableness of the CMP relative to the remedial purpose of the Act and regulations and all the regulatory factors, however, I conclude that a CMP of $5,050 per day is not reasonable. I conclude that a CMP of $3,050 per day for the noncompliance that posed immediate jeopardy during the period July 29 through August 11, 2009, the lowest amount permitted for immediate jeopardy, is reasonable.

Accordingly, I conclude that a CMP of $3,050 per day from July 29 through August 11, 2009 and $150 per day from August 12 through August 23, 2009, is a reasonable enforcement remedy in this case. Petitioner's ineligibility to be approved to conduct a NATCEP for two years after the date of the survey was by operation of the regulations. The DPNA and termination were not effectuated in this case.

III. Conclusion

For the foregoing reasons, I conclude that: Petitioner was not in substantial compliance with program participation requirements from July 29, 2009 through August 23, 2009; there is a basis for the imposition of an enforcement remedy; and a CMP of $3,050 per day from July 29, 2009 through August 11, 2009 and $150 per day from August 12 through August 23, 2009, is a reasonable enforcement remedy.

/s/
Keith W. Sickendick
Administrative Law Judge