Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Lakeport Skilled Nursing Center, Inc.
(CCN: 05-5499),

Petitioner

v.

Centers for Medicare and Medicaid Services.

Docket No. C-09-236

Decision No. CR2385

Date: June 21, 2011

DECISION

Petitioner, Lakeport Skilled Nursing Center, Inc., was not in substantial compliance with program participation requirements from October 27, 2008 through December 21, 2008, due to a violation of 42 C.F.R. § 483.25 (Tag F309).[1] There is a basis for the imposition of enforcement remedies. The following enforcement remedies are reasonable: a civil money penalty (CMP) of $5,000 for October 27, 2008 and a CMP of $1,000 per day from October 28, 2008 through December 21, 2008, for a total CMP of $60,000; and a denial of payment for new admissions (DPNA) from December 20, 2008 through December 21, 2008. Petitioner was also ineligible to conduct a Nurse Aide Training and Competency Evaluation Program (NATCEP) for a period of two years beginning October 28, 2008.

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[1] References are to the version of the Code of Federal Regulations (C.F.R.) in effect at the time of the survey, unless otherwise indicated.

I. Background

Petitioner is located in Lakeport, California, and participates in Medicare as a skilled nursing facility (SNF) and the state Medicaid program as a nursing facility (NF). On October 28, 2008, Petitioner was surveyed by the California Department of Public Health (state agency) and found not in substantial compliance with program participation requirements. A revisit survey determined that Petitioner returned to substantial compliance effective December 22, 2008. Joint Stipulation of Undisputed Facts (Jt. Stip.); Tr. at 41.

The Centers for Medicare and Medicaid Services (CMS) notified Petitioner by letters dated December 5, 2008 and February 13, 2009, that it was imposing the following enforcement remedies: a CMP of $5,000 for one day of immediate jeopardy on October 27, 2008; a CMP of $1,000 per day effective October 28, 2008, continuing until Petitioner returned to substantial compliance or its provider agreement was terminated; and a DPNA effective December 20, 2008, continuing until Petitioner returned to substantial compliance or was terminated. CMS also advised Petitioner that it could not be approved to conduct a NATCEP for two years and that any prior approval would be withdrawn.[2] In its February 13, 2009 letter, CMS notified Petitioner that a revisit survey concluded that Petitioner returned to substantial compliance with program participation requirements effective December 22, 2008. Jt. Stip.; CMS Exhibit (CMS Ex.) 5.

Petitioner requested a hearing before an administrative law judge (ALJ) by letter dated February 2, 2009. The case was docketed as C-09-236 and assigned to me for hearing and decision. On November 18 and 19, 2009, a hearing was convened at Sacramento, California, and a 569-page transcript (Tr.) of the proceedings was prepared. CMS offered CMS exhibits (Exs.) 1 through 16, which were admitted as evidence. Tr. at 21-23. Petitioner offered Petitioner exhibits (P. Exs.) 1 through 14, which were admitted as evidence. Tr. at 23-30. CMS called as witnesses: Surveyor Barbara Ebert, RN; and Surveyor John Motter, RN. Petitioner called as witnesses: Susan Acquisto, RN; and Bennett Zier, M.D. The parties filed post-hearing briefs (CMS Br. and P. Br., respectively), but both parties waived the filing of a reply brief.

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[2] Petitioner did not have a NATCEP at the time of the survey. Tr. at 39-40.

II. Discussion

A. Issues

The issues in this case are:

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

B. Applicable Law

The statutory and regulatory requirements for participation by a long-term care facility are found at sections 1819 (SNF) and 1919 (NF) of the Act and at 42 C.F.R. Part 483. Section 1819(h)(2) of the Act vests the Secretary of Health and Human Services (Secretary) with authority 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.[3] Pursuant to section 1819(h)(2)(C) of the Act, the Secretary may continue Medicare payments to a SNF not longer than six months after the date the facility is first found not in compliance with participation requirements. Pursuant to Act section 1819(h)(2)(D), if a SNF does not return to compliance with participation requirements within three months, the Secretary must deny payments for all individuals admitted to the facility after that date – commonly referred to as the mandatory or statutory DPNA. In addition to the authority to terminate a noncompliant SNF's participation in Medicare, the Act 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 failure to meet a condition for participation or a violation of a condition for participation established by sections

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[3] Section 1919(h)(2) of the Act gives similar 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.

1819(b), (c), and (d) of the Act or the Secretary's regulations at 42 C.F.R. Part 483, subpart B. 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 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 a CMP, $50 per day to $3,000 per day, is reserved for deficiencies that do not constitute 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 would be 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. 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 established by the Secretary and a process for reviewing and re-approving those programs using criteria set by the Secretary. 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. 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 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" exists if surveyors conclude that there was one or more deficiencies related to the 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 pose immediate jeopardy, constitute a pattern of or widespread actual harm that does not amount to immediate jeopardy, or constitute a widespread potential for more than minimal harm that does not amount to immediate jeopardy, without 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. *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 that CMS determined 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); *see Hillman Rehab. Ctr.*, DAB No. 1611 (1997), No. 98-3789, 1999 WL 34813783 (D.N.J. May 13, 1999).

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. CMS alleges based upon the survey on October 28, 2008, that Petitioner was not in substantial compliance with program participation requirements from October 27, 2008 through December 21, 2008, based upon a violation of 42 C.F.R. § 483.25 (Tag F309), at a scope and severity (s/s) of K, which represents immediate jeopardy. I conclude that Petitioner violated 42 C.F.R. § 483.25 (Tag F309) as alleged by the survey completed on October 28, 2008. I conclude that Petitioner has not shown that the

determination that the violation posed immediate jeopardy on October 27, 2008, was clearly erroneous. I also conclude that the enforcement remedies proposed by CMS are reasonable.

I have carefully considered all the evidence, including the documents and the testimony at hearing, and the arguments of both parties, even though not all may be specifically discussed in this decision. I discuss the credible evidence given the greatest weight in my decision-making.[4] 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. Petitioner violated 42 C.F.R. § 483.25 (Tag F309) from October 27, 2008 through December 21, 2008.

2. Petitioner's violation of 42 C.F.R. § 483.25, posed a risk for more than minimal harm.

3. Petitioner has not shown that the determination that the violation posed immediate jeopardy on October 27, 2008, was clearly erroneous.

4. There is a basis for the imposition of an enforcement remedy.

Petitioner is obligated by the quality of care regulation to ensure that each resident receives "necessary care and services to attain and maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care." 42 C.F.R. § 483.25.

The surveyor alleged in the Statement of Deficiencies (SOD) that Petitioner violated 42 C.F.R. § 483.25, because staff failed to comply with physicians' orders to:

- Administer regular insulin for Residents 2, 3, and 4;

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[4] "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.

- Administer Glucagon® to Residents 4, 5, and 6; and

- Notify the residents' physicians when the residents had blood sugar readings above or below certain readings.

The surveyor also alleged that Petitioner's staff failed to:

- Clarify incomplete physicians' orders related to the use of Glucagon or glucose gel for Residents 2, 4, 5, and 6;

- Assess Residents 2, 3, 4, 5, and 6 for hyperglycemic and hypoglycemic reactions; and

- Develop a care plan for Resident 2 to address his agitation related to high or low blood sugar.

According to the surveyor, the failures of Petitioner's staff placed the residents involved at risk for diabetic coma or brain damage – serious harm that amounted to immediate jeopardy. CMS Ex. 1, at 1-2. Based upon the following facts related to Residents 2, 3, 4, 5, and 6, I conclude that CMS has made a *prima facie* showing that Petitioner failed to deliver necessary care and services to those residents, posing a risk for more than minimal harm. I further conclude that Petitioner has failed to rebut the evidence that shows its staff failed to comply with physicians' orders for the management of the residents' diabetes.[5] Petitioner has also failed to show that the declaration of immediate jeopardy was clearly erroneous.

a. Facts

(i) Resident 2

Resident 2, a male, was 54 years old at the time of the survey. He was admitted to Petitioner's facility on November 13, 2004, and then readmitted on December 20, 2007, with diagnoses that included Type 1 diabetes mellitus that was uncontrolled, acute necrosis of the liver, acute pancreatitis, anemia, neuralgia, chronic renal failure, depressive disorder, drug dependence, dementia without behavioral disorder, esophageal reflex, and insomnia. CMS Ex. 11, at 12; P. Ex. 7, at 1, 3, 9. The resident had a history

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[5] Because I conclude that failure to follow physicians' orders constituted a deficiency, I conclude it is not necessary to discuss the alternate grounds cited by the surveyor, *i.e.*, failure to clarify orders, failure to assess residents, and failure to develop a care plan for Resident 2.

of complications associated with diabetes, including episodes of hypoglycemia and a previous coma. His diabetes was challenging to manage, and he was considered a brittle diabetic.[6] P. Ex. 7, at 3-4, 7, 16-20, 22; Tr. at 520-21.

Resident 2's care plan listed as a problem his potential for injury related to frequent hypoglycemic and hyperglycemic events. The care plan directed staff to observe the resident for signs and symptoms of hypoglycemia (low blood sugar), administer medications, and report abnormal laboratory values promptly. The care plan required that staff notify the resident's physician if the resident's blood glucose[7] level was outside certain parameters, but the parameters are unclear on the care plan. An undated entry required notification of the physician if the resident's blood sugar was less than 70 or greater than 300.[8] An entry dated December 28, 2005, required notification if his blood sugar was less than 60 or greater than 400. However, on the copy of the care plan introduced as evidence by Petitioner, a line was stricken through the number 60 and 70 was written above the number 60. The copy of the care plan offered by CMS was obtained by the surveyor during the survey, and I find that the direction to report blood sugar less than 60 was changed after the surveyor obtained the copy of the care plan. However, it is not possible to decide based on entries on the care plan whether the order in effect at the time of the survey was to report when the blood sugar was less than 70 or greater than 300 or less than 60 or greater than 400. The copy of the care plan introduced as evidence by Petitioner includes an entry that required checking the resident's blood sugar by finger stick four times per day. The date of the entry is February 18, but the year is indecipherable. P. Ex. 7, at 8. The copy of the care plan obtained by the surveyor and introduced as evidence by CMS does not include the same entry. CMS Ex. 11, at 12; P. Ex. 7, at 8. The care plan is simply not clear as to what care and services Petitioner's staff was to deliver to Resident 2.

Resident 2's Medication Administration Record (MAR) for October 2008, reflects that staff was checking the resident's blood sugar levels three times each day at 6:30 a.m., 11:30 a.m., and 4:30 p.m. The MAR listed an order dated May 20, 2008, for sliding scale

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[6] The term brittle diabetic is used to refer to diabetes that is hard to control, with wide swings in blood glucose levels, and that requires more careful monitoring for proper management. Tr. at 501-02, 520-21.

[7] The phrases "blood glucose level" and "blood sugar level" mean the same thing, i.e., the amount of glucose or sugar present in the blood.

[8] The standard unit of measurement for blood sugar in the United States is milligrams per deciliter (mg/dL), and it is presumed that this is the unit intended based on the numbers used in the order. Tr. at 312.

insulin (the amount to be administered was determined by the blood sugar reading). If blood sugar exceeded 400 the physician was to be called, but if his blood sugar was "low" the short acting insulin the resident had been receiving since April 29, 2008, was to be held. The MAR reflects an order dated December 20, 2007, that Resident 2 was to receive a Med Pass 2.0® and juice to increase blood sugar if he was alert and able to swallow without difficulty. His blood sugar was to be assessed again twenty minutes after administration of the Med Pass and juice. The order on the MAR does not indicate the low blood sugar level that was intended to trigger the administration of Med Pass and juice, and the MAR does not indicate the quantity of Med Pass and juice to administer. The MAR includes an order dated December 20, 2007, that if Resident 2 cannot tolerate the Med Pass and juice by mouth, he was to receive an injection of Glucagon, but the order does not indicate the amount of Glucagon to be injected. CMS Ex. 11, at 3-4, 6. The physician's orders sheet lists the same orders as the MAR and provide no more detail than appears on the MAR. P. Ex. 7, at 14. However, the physician orders sheet lists an order dated December 20, 2007, which does not appear on the MAR – an order that glucose gel was to be placed in Resident 2's mouth as necessary if his blood glucose was less than 70. A note on the MAR shows that on October 14, Resident 2's blood sugar was 51, and he was given orange juice and Med Pass, not glucose gel as ordered. A note dated October 17, 2008, reflects a blood sugar of 27 and that the resident was responsive. The note does not indicate that the resident was unable to tolerate glucose gel in his mouth as ordered, but he was given Glucagon by injection. A note dated October 27, 2008, shows the resident had a blood sugar of 52 and that he was responsive. The resident was given orange juice, Med Pass, and a sandwich, not glucose gel as ordered. CMS Ex. 11, at 7. There is no evidence that glucose gel was attempted on October 14, 17, or 27, 2008, when the resident's blood sugar was below 70, contrary to the physician's order. A note from October 21, 2008, shows that the resident's blood sugar was 420, the physician was notified, no new order was received, and staff was to continue insulin as ordered. CMS Ex. 11, at 8. The MAR shows that Resident 2's blood glucose level was less than 60 or greater than 400, eight times: 59 on October 3 at 6:30 a.m.; 436 on October 5 at 6:30 a.m.; 52 on October 14 at 6:30 a.m.; 58 on October 14 at 4:30 p.m.; 27 on October 17 at 6:30 a.m.; 420 on October 21 at 6:30 a.m.; 55, 43, and 80 on October 23 at[9] 4:30 p.m.; and 52 on October 27 at 6:30 p.m. There is no documentary evidence that staff notified the resident's physician when the resident's blood glucose results were outside the parameters of 60 and 400, except on October 21 when the blood sugar was 420 (CMS Ex. 11, at 8). The MAR and Nurse's Notes entries in evidence do not reflect that Med Pass, juice, or glucose gel or injection were used for any of the instances of low

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[9] Surveyor Ebert agreed on cross-examination that the nurses she interviewed understood that the parameters were less than 60 or greater than 400. Tr. at 186-88. On November 24, 2008, after the survey, it was ordered that the physician be notified if the resident's blood sugar was less than 60 or greater than 400. P. Ex. 7, at 14.

blood sugar except, as already noted, on October 14, 17, and 27. Staff also failed to document on the October 2008 MAR Resident 2's blood glucose levels on October 10, 2008 at 6:30 a.m., October 15 at 6:30 a.m., and October 24 at 6:30 a.m. or that he received his insulin as ordered at those times. CMS Ex. 11, at 3; P. Ex. 7, at 30. Petitioner has not presented evidence that the resident's blood sugar was actually tested or that the resident was provided insulin at those times.[10]

(ii) Resident 3

Resident 3, a female, was 79 years old at the time of the survey. She was admitted to Petitioner on August 27, 2007. Her diagnoses included uncontrolled diabetes mellitus, dementia, and a variety of mental impairments. CMS Ex. 12, at 2, 6; P. Ex. 8, at 1, 4. She was characterized as a brittle diabetic. P. Ex. 8, at 7. Resident 3 had care plans for altered nutritional status manifested by a history of weight loss, and she had a therapeutic diet for hypertension and for potential injury due to peripheral neuropathies, hypoglycemia, impaired skin integrity, sensory alteration, and visual impairment due to diabetic retinopathy. P. Ex. 8, at 2-6. The care plan related to hypoglycemia and directed staff to: monitor the resident's blood glucose as the physician ordered and as needed; administer the resident's medication as ordered; obtain laboratory testing and report abnormal values promptly; and observe the resident for signs and symptoms of hypoglycemia and hyperglycemia. P. Ex. 8, at 6.

Resident 3's October 2008 MAR listed a physician's order dated May 22, 2008, which required staff to obtain the resident's blood glucose levels prior to meals. The order required notification of the physician's nurse practitioner if the resident's blood sugar was less than 60 or greater than 350. CMS Ex. 12, at 12; P. Ex. 8, at 14. A June 25, 2008-physician's order required insulin prior to meals and an order dated May 22, 2008, required a different type of insulin prior to bed. CMS Ex. 12, at 11-12; P. Ex. 8, at 13-14. The MAR reflects that the resident had an order dated December 4, 2007 for glucose gel in her mouth as needed if her blood sugar was below a certain level, but the number is obscured by the copying of the document. The MAR reflects an order for a Glucagon emergency kit that administers one milligram by injection, as needed, if her blood glucose was less than 70 and the resident was not responding to glucose. CMS Ex. 12, at 15.

A note on the MAR, dated October 3, 2008, indicates that the nurse practitioner was

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[10] Petitioner's attempt to use its expert witness to establish based upon subsequent blood sugar levels that insulin was administered is not credible. The MAR shows significant variability in recorded blood glucose levels, even when the MAR is annotated to show that insulin was appropriately given. CMS Ex. 11, at 3.

notified because the resident's blood sugar was high, although the actual numeric reading is not in the note, and no new order was received. A nurse's note reports that another resident gave Resident 3 a piece of cake and that her blood sugar was high, but the actual number is not reported. CMS Ex. 12, at 13, 18; P. Ex. 8, at 11. A note dated October 5, 2008, indicates the resident's blood sugar was 404 and that she had signs and symptoms of hyperglycemia. The note indicates that the resident's husband brought in sweets. The physician was contacted but no new order was received. CMS Ex. 12, at 13. A Nurse's Notes entry on October 6, 2008 at 8:00 p.m. indicates that the resident's blood sugar was 273. CMS Ex. 12, at 18; P. Ex. 8, at 11. A Nurse's Notes entry dated October 20, 2008 at 1:15 p.m. indicates that Resident 3' blood sugar was 406 at 11:30 a.m. and that the nurse practitioner was notified, no new orders were received, and staff would continue to monitor. P. Ex. 8, at 12; CMS Ex. 12, at 20.

The MAR does not show that Resident 3 received her insulin prior to lunch on October 18, 2008. At 4:00 p.m. on October 18, 2008, the resident's blood glucose level was 403, but there is no evidence that the physician or nurse practitioner were called. Although a nurse's note indicates the physician was in the evening of October 18, the evidence does not show the high blood sugar was reported. CMS Ex. 12, at 12, 19; P. Ex. 8, at 10, 14. The evidence shows that either the physician or nurse practitioner was notified on October 3, 5, and 20, 2008 when the resident's blood sugar exceeded 350. But there is no evidence of notice to the physician or nurse practitioner for the instances when the resident's blood sugar exceeded 350 on October 1, 4, 6, 7, 10, 12, 14, 18, 19, 22, 23, or 26, 2008. CMS Ex. 12, at 11-12; P. Ex. 8, at 13-14.

(iii) Resident 4

Resident 4, a male, was 39 at the time of the survey. He was initially admitted to Petitioner's facility on September 18, 2006, and readmitted on July 17, 2008. His diagnoses included uncontrolled diabetes mellitus, a history of brain injury and convulsions, renal problems, and pernicious anemia and malnutrition. CMS Ex. 13, at 2, 6; P. Ex. 9, at 1. The resident suffered the brain injury during a motor vehicle wreck in June 2008, while on the way to dialysis. His cognitive ability and activities of daily living were severely limited when he was readmitted to Petitioner's facility in July 2008, and he was non-ambulatory. CMS Ex. 13, at 3; P. Ex. 9, at 2-3.

The resident's October 2008 MAR listed an order dated July 17, 2008, that required that the resident receive insulin on a sliding scale, depending upon his blood sugar level which staff was to assess four times during the day. The order, as recorded on the MAR, required notification of the physician if the resident's blood sugar exceeded 400. The MAR listed an order dated July 17, 2008, for glucose gel to be given orally if the resident's blood sugar was less than 70. The MAR reflects an order dated July 17, 2008, for the resident to receive one milligram of Glucagon by injection if his blood glucose was less than 70 and he did not respond to the glucose gel. The MAR does not reflect an

order to contact the physician if his blood sugar was less than 70. CMS Ex. 13, at 11-12; P. Ex. 9, at 4. The MAR also included an order for another type of insulin that was administered in a fixed amount and not on a sliding scale. CMS Ex. 13, at 15.

Notes on the MAR show that on October 20, 2008, the resident's blood sugar was taken upon his return from dialysis, and his regular insulin was held. CMS Ex. 13, at 13. The entry does not reflect the resident's blood sugar reading or that the physician was contacted and ordered holding the insulin. The orders recorded on the copies of the October MAR in evidence do not indicate insulin should be held based on a certain blood sugar level. A note dated October 27, 2008 at 6:00 a.m., indicates that the resident's blood glucose was 60 and that he was given juice and applesauce. The entry does not reflect that the resident was given glucose gel by mouth as ordered. CMS Ex. 13, at 13. The MAR also does not show that glucose gel was administered on October 27, 2008. CMS Ex. 13, at 12. Notes on the MAR do show that glucose gel was given as ordered when the resident's blood sugar was below 70 on October 1, 7, and 15, 2008, and the administration of gel is also recorded on the MAR. CMS Ex. 13, at 12, 14. The MAR reflects that Resident 3's blood sugar was 408 at 8:00 p.m. on October 20, but there is no evidence the physician was notified as ordered. The MAR also reflects that the resident's blood sugar was below 70 on October 10, 16, 18, and 19, 2008, but the MAR does not reflect that glucose gel was administered as ordered. CMS Ex. 13, at 11; P. Ex. 9, at 4.

(iv) Resident 5

Resident 5, a male, was 80 years old at the time of the survey. He was admitted to Petitioner's facility on April 21, 2006, and readmitted on October 9, 2008, with diagnoses that included uncontrolled diabetes mellitus and dementia. CMS Ex. 14 at 2, 5; P. Ex. 1, at 1.

Resident 5's October 2008 MAR included an order dated October 9, 2008, that he be given insulin on a sliding scale depending upon his blood sugar level and that his physician be contacted if his blood sugar was less than 60 or greater than 400. CMS Ex. 14, at 7; P. Ex. 10, at 2. He also had an order dated October 9, 2008, for glucose gel to be given orally if his blood sugar was below 70, and for one milligram of Glucagon by injection if his blood sugar was below 70 and he was not responding to glucose gel. CMS Ex. 14, at 8-9; P. Ex. 10, at 3-4; Tr. at 135. Notes on the MAR indicate that on October 22, 2008, Resident 5 was given orange juice and a snack, but whether that was for low blood sugar is not indicated and no low blood sugar is recorded on the MAR for that date. CMS Ex. 14, at 7, 10. A note on October 25, at either 6:00 p.m. or 7:00 p.m., reflects that the resident was given glucose gel for a blood glucose reading of 49, but the note does not indicate that the physician was called as ordered. CMS Ex. 14, at 11. The MAR does not show that the resident's blood sugar was checked or that he was given

insulin at 11:30 a.m. on October 12, or that he was given insulin at 4:30 pm on October 16, even though the order required he receive six units for a blood sugar reading of 195.[11]

(v) Resident 6

Resident 6, a female, was 80 years old at the time of the survey. She was admitted to Petitioner's facility on April 6, 2007, with diagnoses that included uncontrolled diabetes mellitus and Parkinsonism. CMS Ex. 15, at 2, 5; P. Ex. 11, at 1, 4.

Resident 6's October 2008 MAR lists an order dated April 6, 2007, for sliding scale insulin based on her blood glucose level. The order required that the physician be notified if her blood glucose was below 60 or greater than 400. An order dated May 29, 2007, required the administration of Lantus® insulin at 4:30 p.m., but it was not to be given if her blood sugar was less than 100. Orders dated May 23, 2007, required oral administration of glucose gel as necessary for blood sugar under 70 or the administration of Glucagon, one milligram, by injection, if her blood sugar was less than 70 and the resident did not respond to the glucose gel. An order dated August 9, 2007, added glipizide, twice each day, but it was to be held if her blood glucose was less than 100. CMS Ex. 15, at 7-11; P. Ex. 11, at 6-10.

The resident's MAR reflects that her blood sugar was less than 70 on October 3, 4, 5, 12, 18, 20, 22, and 27, 2008, but there is no evidence that she was given glucose gel or Glucagon. Furthermore, on October 12, 20, and 27, 2008, her blood glucose was recorded as being below 60, and there is no evidence that the physician was notified. CMS Ex. 15, at 8-12; P. Ex. 11, at 7-11.

(vi) Harm

The government's and Petitioner's witnesses acknowledge a risk for harm due to both hyperglycemia (high blood sugar) and hypoglycemia (low blood sugar). In this case, the evidence supports a finding that high or low blood sugar for these individual residents is denoted by the parameters set by the physician for notifying him or her. The testimony indicates that the most significant risk is related to hypoglycemia, when a resident may suffer brain damage and/or enter a coma. Tr. at 308-14, 437-38, 480-83, 502-03, 510-11, 547, 552-54.

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[11] An entry on the MAR for 6:30 p.m. on October 12, 2008, is unclear. The surveyor testified it could be either "62" or "162." She agreed on cross-examination that the amount of insulin given was consistent with blood glucose of 162. Counsel for CMS stipulated and agreed that the entry was 162. I find, for purposes of this decision, that the entry is "162." CMS Ex. 14, at 7; Tr. at 135, 224-25, 419.

b. Analysis

The survey was triggered by a report by Petitioner to the state agency regarding an incident of alleged resident-to-resident abuse involving Resident 2 on October 23, 2008. Surveyor Barbara Ebert testified that she was directed to conduct the complaint investigation and it commenced on October 27 and ended on October 28, 2008. Tr. at 52-53, 150. Surveyor Ebert testified that she chose to cite a deficiency under Tag F309, as the evidence did not show that staff was following physician's orders for the administration of insulin and for notifying the physician when blood glucose was measured as being outside certain parameters. Tr. at 109. She expanded her sample beyond Resident 2, as she had concerns about how Resident 2 was being monitored. Tr. at 110. She concluded that immediate jeopardy existed on October 27, 2008, and immediate jeopardy was abated as of October 28, 2008; however, Petitioner remained out of substantial compliance. Tr. at 110, 141-42. John Motter, RN, Nurse Consultant for CMS, testified that he reviewed the SOD on behalf of CMS and that he concurred with the deficiency citation and the immediate jeopardy determination. He testified that the multiple failures of Petitioner's staff to follow physicians' orders support his conclusion that there was immediate jeopardy. Tr. at 299-300. He testified that a resident who suffers hypoglycemia is at risk for entering a coma, and a resident experiencing hyperglycemia is also at risk for symptoms. He testified that failure to follow physicians' orders violates the standard of nursing care. Tr. at 308-14.

I conclude that CMS has made a *prima facie* showing of a violation of 42 C.F.R. § 483.25 (Tag F309) and that the violation posed a risk for more than minimal harm. The evidence shows multiple violations of physicians' orders related to the treatment of the residents' diabetes. The evidence that a physician ordered certain care and services triggers a rebuttable presumption that the care and services ordered are necessary care and services within the meaning of 42 C.F.R. § 483.25. The absence of evidence, such as documentation or testimony of the care giver, that ordered care and services were actually delivered, triggers an inference that care or services were not provided as ordered. The burden is upon Petitioner to rebut the CMS *prima facie* case by showing that necessary care and services were delivered. Petitioner fails to meet its burden in this case.

Resident 2's care planning team recognized in his care plan that he was at risk for hypoglycemia. But, the copies of the resident's care plans in evidence are a mess of undated and unclear directions as to what care and services staff was to deliver to prevent or mitigate the effects of hypoglycemia and when to notify the physician. Resident 2 had an order dated December 20, 2007, that he was to be given glucose gel if his blood sugar was less than 70. The order to use glucose gel is not listed on his October 2008 MAR. Thus, it is not surprising that on October 14, 17, and 27, 2008, staff violated the physician's order to administer glucose gel if the resident's blood sugar was less than 70. Resident 2's MAR shows that his blood glucose level was less than 60 or greater than 400, eight times. However, there is no documentary evidence that staff notified the

resident's physician when the resident's blood glucose results were outside the parameters of 60 and 400, except on October 21 when the blood sugar was 420 (CMS Ex. 11, at 8). The MAR and Nurse's Notes entries in evidence do not reflect that any ordered interventions were used for any of the instances of low blood sugar except, as already noted, on October 14, 17, and 27, and on those dates staff failed to comply with the order to use glucose gel.

Resident 3's October 2008 MAR does not show that she received her ordered insulin prior to lunch on October 18, 2008, and Petitioner presents no evidence to show she did. There is no evidence that her physician or nurse practitioner were notified later that day when her blood sugar was 403, contrary to her physician's order. There is also no evidence that either the physician or nurse practitioner were notified in accordance with a physician's order, when the resident's blood sugar exceeded 350 at least a dozen other times in October.

Resident 4's MAR shows that on October 20, 2008, his ordered insulin was held, but there is no evidence of an order that staff was permitted to decide not to administer his insulin. On October 27, 2008 at 6:00 a.m., staff responded to a low blood glucose reading by giving him juice and applesauce, not glucose gel as was ordered by the resident's physician. There is no evidence that Resident 3's physician was notified when the resident's blood sugar was 408 at 8:00 p.m. on October 20. There is no evidence that Resident 3 was given glucose gel as ordered on October 10, 16, 18, or 19, 2008 when his blood glucose was below 70.

On October 25, 2008, Resident 5 was given glucose gel as ordered when his blood glucose reading was 49, but there is no evidence that staff called the physician as required by the physician's order. There is no evidence that Resident 5 received his insulin at 11:30 a.m. on October 12, 2008 or at 4:30 p.m. on October 16, 2008.

Resident 6 had a blood sugar reading of less than 70 eight times in October 2008, and there is no evidence that she was given glucose gel or an injection of Glucagon. There is also no evidence that her physician was notified when her blood glucose was below 60 on three days in October 2008.

Petitioner did not present evidence to show that physicians were notified as ordered, that glucose gel was administered as ordered, or that insulin was given for any of the foregoing instances. Furthermore, there is no dispute among the experts who testified that the hypoglycemic incidents pose a risk for more than minimal harm due to the potential for brain damage and coma. The evidence also shows that hyperglycemic incidents pose a risk for more than minimal harm due to the potential for damage to the eyes, kidneys, and nerves. Accordingly, Petitioner has not rebutted the CMS *prima facie* case.

Petitioner urges that the errors in this case are simply documentation errors. However, Petitioner does not offer any fact witnesses, such as direct care staff or physicians to testify that care and services were delivered as ordered. Petitioner's fall back defense is that the omissions reflected by its documents did not cause more than minimal harm and/or that there was no immediate jeopardy. Petitioner called two expert witnesses to testify, Susan Acquisto, RN, and Bennett Zier, M.D.[12] In weighing their opinions, I consider that neither had a treatment relationship with any of the residents involved, neither examined any of the residents, neither interviewed the resident's physicians, and neither interviewed direct care staff. The experts' knowledge of the individual residents involved was limited to their review of whatever clinical records were provided by Petitioner, and it is not clear that those records were either more extensive or clearer than the limited clinical records in evidence before me. Tr. at 332, 498-500.

Nurse Acquisto opined that Resident 2 received appropriate treatment and that there was no harm. Tr. at 333. She testified that it is nursing standard of practice to use juice or applesauce to raise low blood sugar. She implied that it may be acceptable for a nurse to attempt juice or a supplement and, if it does not work, to then comply with orders for glucose gel or Glucagon. Tr. at 399, 402, 408-11. I do not find her testimony credible to the extent that it may be interpreted to mean that it is acceptable for staff to violate a specific physician's order. Nurse Acquisto agreed on my examination that it is not a matter within a nurse's discretion to withhold ordered insulin without a specific order. Tr. at 415. Nurse Acquisto testified that she saw no risk for more than minimal harm to residents 2, 3, 4, 5, and 6. Tr. at 426-28. Nurse Acquisto agreed on cross-examination that high or low blood sugar can have complications, and low blood sugar is most critical as it can lead to coma. Tr. at 437-38. She also testified that if staff calls the physician, it should be noted in the nurse's notes or the MAR. Tr. at 444-45. Nurse Acquisto testified that there is no risk for serious harm or death associated with a single missed dose of insulin. She testified however that whether or not a missed dose may cause some harm depends upon the resident. She agreed that it is important for a brittle diabetic to receive every dose of insulin and for their blood sugars to be monitored. Tr. at 475-79. She agreed that low or high blood sugar if allowed to continue could cause serious harm or death. Tr. at 480-83. I do not find credible or weighty the opinions of Nurse Acquisto that none of the residents were at risk for serious harm due to staff's failures to comply with physicians' orders. In addition to having no treatment relationship and with her knowledge of the residents limited to Petitioner's records, Nurse Acquisto's opinions expressed during testimony are inconsistent.

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[12] Nurse Acquisto was qualified at hearing as an expert in the area of nursing standards of practice. Dr. Zier was qualified at hearing as an expert in the area of geriatric medicine and internal medicine. Tr. at 331, 500; P. Exs. 12, 13.

Petitioner called Bennett G. Zier, M.D. to testify. Tr. at 494-500; P. Ex. 13. He testified that current literature indicates that tight control of blood sugar may not be optimal particularly for older residents with a long history of diabetes. Rather, it may be better to allow higher blood sugar, *i.e.*, mild hyperglycemia, to avoid increased hypoglycemic episodes when a resident could have significant brain damage. He typically orders that staff call him if a resident's blood sugar is below 50 or over 400 or 500. He considers hypoglycemia to be a blood glucose level below 50, but he recognized that physicians vary in their opinions as to what constitutes hypoglycemia. Tr. at 502-03, 510-11. Dr. Zier opined that Resident 2 was not in immediate jeopardy as he could see no possible connection between the alleged verbal altercation and hypoglycemia. Tr. at 504. He opined that missing one dose of insulin is likely to have little effect. Tr. at 511-12. Dr. Zier could not define the phrase "immediate jeopardy" when asked. Tr. at 513. He opined that Resident 2 suffered no adverse effects from any missed doses of insulin. Tr. 513-15. He testified that Resident 2's "A1c" level (a measure of average blood glucose level over a period) was normal and, thus, he concluded that Resident 2 received good care, at least during the three months following the survey, the period assessed by the A1c level in evidence. Tr. at 516-20. Dr. Zier opined that there was no immediate jeopardy related to Resident 3 or adverse effect related to one missed dose of insulin. Tr. at 521-22, 524-25. Dr. Zier testified regarding Resident 4 that there was no immediate jeopardy and no adverse effect. Tr. at 529-30. He testified that Resident 6 was not in immediate jeopardy. Tr. at 531. He testified that all residents received necessary care and services. Tr. at 531. He testified on cross-examination that he understood actual harm was not necessary for immediate jeopardy and he reconfirmed his earlier opinions that there was no harm and no immediate jeopardy, and no potential for harm for the residents. Tr. at 544. Dr. Zier testified that with tight control of blood sugars the progression of kidney disease, eye disease, and nerve disease is slowed, but the incidence of hypoglycemia is increased as much as threefold, and hypoglycemia causes brain damage. Tr. at 547. Dr. Zier testified in response to my questioning that his concern with hypoglycemia is the risk for brain damage. He agreed that hyperglycemia causes organ damage. Tr. at 552-54. I do not find Dr. Zier's testimony that there was no harm and no immediate jeopardy to be credible. Dr. Zier agreed that hypoglycemia presents a risk for brain damage. He did not explain how brain damage is not serious harm. He also did not address how failures of staff to follow physicians' orders in administering insulin and responding to the low blood sugars of these residents did not place the residents at risk for hypoglycemia and related serious harm.

Petitioner has failed to rebut the *prima facie* showing that it violated 42 C.F.R. § 483.25 (Tag F309) and that the violation posed a risk for more than minimal harm. I also conclude that Petitioner has failed to show that the declaration of immediate jeopardy was clearly erroneous. The evidence that Resident's 2, 4, 5, and 6 had low blood sugar readings in October is not disputed. The evidence shows multiple instances that staff failed to act in compliance with physicians' orders to treat the residents' low blood sugars. The experts agree that low blood sugar may cause brain damage. Petitioner has

not rebutted the evidence or shown that the risk for brain damage is not a risk for serious harm.

The state agency found, based upon a revisit survey completed on December 22, 2008, that Petitioner returned to substantial compliance with program participation requirements on that date. CMS Ex. 5, at 14. Petitioner urges me to find that it returned to substantial compliance on December 1, 2008, the date that the state agency accepted the plan of correction and the date Petitioner alleged in its plan of correction that it had fully implemented the plan. CMS Ex. 1, at 3-4. However, Petitioner does not explain how I might reach the conclusion it seeks. Petitioner only states that December 1 was when the plan of correction was submitted to, and accepted by, the state agency. P. Br. at 3. The Secretary has provided by regulation that enforcement remedies generally continue until a facility achieves substantial compliance as determined by a revisit survey or based on the examination of credible written evidence that can be verified without an on-site visit; or the facility's provider agreement is terminated. 42 C.F.R. § 488.454(a). The regulation further provides that if a facility can show by documentation acceptable to CMS or the state agency that it achieve and is capable of maintaining substantial compliance prior to the date of a revisit survey, the remedies terminate on the date that CMS or the state can verify substantial compliance was achieved and can be maintained. 42 C.F.R. § 488.454(e). Thus, once a facility has been found to be out of substantial compliance, it remains so until it shows by acceptable evidence that it has achieved and can maintain substantial compliance. Petitioner cannot simply rely upon the fact that the state agency accepted the plan of correction, as acceptance of the plan is not tantamount to a certification of compliance. 42 C.F.R. § 488.330. Petitioner needs to show by some evidence that it completely implemented its plan of correction prior to the date of the revisit or the date of substantial compliance found by the state agency or CMS. Petitioner has not presented the required evidence. I conclude that Petitioner did not return to substantial compliance prior to December 22, 2008.

5. Petitioner's challenge of the Secretary's regulations is not subject to my review.

Petitioner alleges in its Request for Hearing (page 3) and in its brief (P. Br. at 18-19) that: the administrative survey and adjudication processes violated its rights to due process; the regulations of the Secretary that establish the processes violate due process because they are vague and do not provide adequate opportunity to be heard before financial penalties take effect; the State Operations Manual (SOM), CMS Publication 100-07, was not promulgated after notice and comment rule-making under the Administrative Procedures Act (APA), 5 U.S.C. § 500 *et seq*.; any actions taken pursuant to that document are *void ab initio.*

Petitioner's challenge of the Secretary's regulations raises no issues within my authority to review. However, the process that Petitioner has been provided in this matter is that

provided for and due under the applicable regulations. Petitioner has received a hearing on the record as required by the Act and consistent with the requirements of APA. Petitioner has identified no specific process or procedure that offends the Secretary's regulations, the Act, or the APA.

Petitioner is correct that the SOM was not promulgated as a regulation under APA procedures. For that reason, the SOM is treated only as a policy statement of the Secretary and CMS, not a regulation. The SOM does not have the force and effect of law, and it is not applied as law. However, the provisions of the Act and regulations interpreted by the SOM clearly are law and are enforceable as such. *Northwest Tissue Ctr. v. Shalala*, 1 F.3d 522 (7th Cir. 1993); *State of Ind. by the Ind. Dep't of Pub. Welfare v. Sullivan*, 934 F.2d 853 (7th Cir. 1991). Thus, while the Secretary may not seek to enforce the provisions of the SOM, she may seek to enforce the provisions of the Act or regulations as interpreted by the SOM.

6. The following enforcement remedies are reasonable: a CMP of $5,000 for October 27, 2008; a CMP of $1,000 per day from October 28, 2008 through December 21, 2008; and a DPNA from December 20, 2008 through December 21, 2008.

I have concluded that Petitioner violated 42 C.F.R. § 483.25 and that the violation posed a risk for more than minimal harm to one or more facility residents. I have also concluded that the declaration of immediate jeopardy for one day has not been shown to be 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 and a DPNA. CMS may impose a CMP for the number of days that the facility is not in compliance or a 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). The upper range of CMPs authorized is $3,050 per day to $10,000 per day and CMPs in that range are limited to 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) and (d)(2). The lower range authorized for CMPs is $50 per day to $3,000 per day. CMPs in the lower range are not imposed for deficiencies that constitute immediate jeopardy but may be imposed for deficiencies that either cause actual harm to residents, or cause no actual harm but have the potential for causing more than minimal harm. 42 C.F.R. § 488.438(a)(1)(ii). The violation of 42 C.F.R. § 483.25 in this case posed more than minimal harm, and the violation provides the basis for enforcement remedies. A CMP in the upper range is authorized for the one day of immediate jeopardy, and a CMP in the lower range is authorized for the other days until Petitioner returned to substantial compliance.

When 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). I may not: (1) set the CMP at zero or reduce it to zero; (2) review the exercise of discretion by CMS in selecting a CMP as an enforcement remedy; or (3) consider factors other than those 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 facilities 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. & Specialty Care Ctr.*, DAB No. 1629 (1997).

CMS presented unrebutted evidence that Petitioner has been cited for deficiencies by past surveys, but there are no deficiencies previously cited under 42 C.F.R. § 483.25 (Tag F309). CMS Ex. 3. Petitioner has not presented any evidence that it is unable to pay the CMP. The deficiency cited is serious and the evidence shows that the residents were exposed to the potential for serious harm due to Petitioner's failure to ensure staff followed physicians' orders. Culpability is defined by the regulation as "neglect, indifference or disregard for resident care, comfort or safety." 42 C.F.R. § 483.438(f)(4). The regulation also provides that the absence of culpability is not a mitigating factor for reducing the amount of a penalty. Petitioner was culpable for the failure of its staff to follow physicians' orders. The evidence shows more than a single failure. Indeed, the evidence shows multiple failures with just the residents cited, and that these failures constituted a pattern of noncompliance with physicians' orders. Failure to adhere to the physicians' orders deprived the residents of care and services necessary for control of their diabetes and for the residents to achieve and maintain the highest practicable physical, mental, and psychosocial well-being. I conclude that a $5,000 CMP for one day of immediate jeopardy, which is at the low end of the upper range, is not unreasonable. The $1,000 per day CMP, effective October 28, 2008 through December 21, 2008, is also

not unreasonable given the seriousness of the deficiency, and the culpability of the facility. CMS had authority to impose the discretionary DPNA because Petitioner was not in substantial compliance, and I have no authority to review the choice of that remedy.

Petitioner argues that the CMP is unreasonable because there was no deficiency and, if there was, immediate jeopardy was clearly erroneous. P. Br. at 17-18. Those arguments are without merit for reasons that I have already discussed in detail. Petitioner also argues that the CMP of $5,000 is unreasonable as it is based on a single deficiency. P. Br. at 18. Although there was only a single deficiency cited, there are multiple examples of the deficiency. Based upon my analysis of the regulatory factors, the CMP of $5,000 is not unreasonable considering the purpose for enforcement remedies. Petitioner argues in its Request for Hearing (page 2) that CMS failed to consider the factors required by the regulation at 42 C.F.R. § 488.438(f). I do not review whether or how CMS evaluated the regulatory factors. Rather, I conduct a *de novo* review of the factors to determine the reasonableness of the CMP imposed.

III. Conclusion

For the foregoing reasons, Petitioner was not in substantial compliance with program participation requirements from October 27, 2008 through December 21 2008, and there is a basis for the imposition of enforcement remedies. The following enforcement remedies are reasonable: a CMP of $5,000 for one day of immediate jeopardy on October 27, 2008; a CMP of $1,000 per day from October 28, 2008 through December 21, 2008; and a DPNA from December 20, 2008 through December 21, 2008.

/s/
Keith Sickendick
Administrative Law Judge