Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Covington Court Health and Rehabilitation Center (CCN: 04-5363),

Petitioner,

v.

Centers for Medicare and Medicaid Services.

Docket No. C-11-395

Decision No. CR2600

Date: September 13, 2012

DECISION

Petitioner Covington Court Health and Rehabilitation Center challenges the determination of the Centers for Medicare and Medicaid Services (CMS) that it was not in substantial compliance with program participation requirements. Petitioner also challenges CMS's imposition of a per-instance civil money penalty (PICMP) in the amount of \$10,000. For the reasons discussed below, I find Petitioner was not in substantial compliance with program participation requirements, and that a PICMP of \$10,000 is a reasonable enforcement remedy.

I. Background

Petitioner is a skilled nursing facility located in Fort Smith, Arkansas. The Arkansas Department of Human Services, Office of Long Term Care (state agency), conducted a complaint survey of Petitioner on January 21, 2011, and found Petitioner to be out of substantial compliance with the participation requirements at 42 C.F.R.

§ 483.10(b)(11) (Tag F157, scope and severity level D); 42 C.F.R. § 483.25 (Tag F309, scope and severity level J); 42 C.F.R. § 483.25(l) (Tag F329, scope and severity level E); 42 C.F.R. § 483.25(m)(2) (Tag F333, scope and severity level E); and 42 C.F.R. § 483.75(j)(2)(ii) (Tag F505, scope and severity level E).

By letter dated February 16, 2011, CMS notified Petitioner that it was imposing the following remedies: a PICMP of \$10,000 for the deficiency at Tag F309; a denial of payment for new admissions (DPNA) beginning March 3, 2011, and continuing until the day before Petitioner achieved substantial compliance or its provider agreement was terminated; and termination of Petitioner's provider agreement unless Petitioner achieved substantial compliance before April 21, 2011. CMS Ex. 6.

CMS advised Petitioner by letter dated March 3, 2011, that the PICMP of \$10,000 for Tag F309, was rescinded, and that the effective date of the DPNA was changed from March 3, 2011, to April 21, 2011. The letter also advised Petitioner that its provider agreement would still be terminated effective April 21, 2011, unless it achieved substantial compliance by that date. CMS Ex. 5.

In another letter dated March 8, 2011, CMS advised Petitioner that the PICMP of \$10,000 that had been rescinded for Tag F309, was reinstated. The letter also advised Petitioner that the other remedies, termination of its provider agreement and the DPNA, remained unchanged. CMS Ex. 4.

By letter dated April 1, 2011, CMS notified Petitioner that, based on a survey conducted on March 17, 2011, it found Petitioner to be out of substantial compliance with the participation requirement at 42 C.F.R. § 483.25(m)(2) (Tag F333, scope and severity level D). CMS stated that the following enforcement remedies were imposed: the DPNA was effective April 21, 2011; the PICMP of \$10,000 for Tag F309 was already imposed; and termination of Petitioner's provider agreement would now be effective June 21, 2011.¹ CMS Ex. 2.

By letter dated April 15, 2011, CMS notified Petitioner that it had achieved substantial compliance with the requirements for Medicare participation. CMS advised Petitioner that it had rescinded the termination of Petitioner's Medicare/Medicaid provider

¹ At the top of the notice letter dated April 1, 2011, CMS advised Petitioner, in boldface capital letters, that this letter superceded a notice that CMS had sent on March 31, 2011. CMS indicated that the only difference between the two letters was that it corrected the effective date of the DPNA. CMS Ex. 2, at 1. I note that the record also contains CMS's March 31, 2011 letter. CMS Ex. 3.

agreement and also rescinded the DPNA. CMS stated that the PICMP of \$10,000 had already been imposed. CMS Ex. 1.

Petitioner requested a hearing by letter dated April 15, 2011. The case was docketed as C-11-395 and assigned to me for hearing and decision on April 19, 2011.

I conducted an in-person hearing in Little Rock, Arkansas on September 27-28, 2011. CMS offered exhibits (CMS Exs.) 1 through 37, which I admitted into evidence. Transcript (Tr.) 20. Petitioner offered exhibits (P. Exs.) 1, and 3 through 40, which I admitted. Tr. 21. On September 16, 2011, Petitioner took the deposition of Dr. Phillip Bobo, which was offered as P. Ex. 40 and admitted at the hearing. On September 21, 2011, CMS took the deposition of Dr. Bruce Biller, and offered his deposition as CMS Ex. 38, which I admitted into evidence. On November 29, 2011, Petitioner took the deposition of Toava McGahan-Howard, Certified Nurse Aide (CNA), and offered her deposition as P. Ex. 41, which I admitted into evidence.

CMS called the following witnesses: Surveyor Linda Schneider, R.N. and Theresa Bennett, R.N. Petitioner called the following witnesses: John Hopkins; Dr. Randall Beallis; Patricia Fashing, Licensed Practical Nurse (LPN); and Thomas Martini, R.N. The parties filed post-hearing briefs (P. Br. and CMS Br.) and post-hearing reply briefs.

II. Issues

The issues in this case are:

1. Whether Petitioner was out of substantial compliance with participation requirements; and

2. Whether the remedies imposed are reasonable.

III. 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 Social Security Act (Act) and at 42 C.F.R. Part 483.² 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

² All references are to the 2011 version of the Code of Federal Regulations (C.F.R.), which was in effect at the time of the survey.

established by sections 1819(b), (c), and (d) of the Act.³ Pursuant to 1819(h)(2)(C), 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 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 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. 42 C.F.R. § 488.301. State survey agencies survey facilities that participate in Medicare on behalf of CMS to determine whether the facilities are complying with federal participation requirements. 42 C.F.R. §§ 488.10-.28, 488.300-.335. The regulations specify the enforcement remedies that CMS may impose if a facility is not in substantial compliance with Medicare requirements. 42 C.F.R. § 488.406.

CMS may impose a CMP for the number of days a facility is not in substantial compliance or for each instance of noncompliance. 42 C.F.R. § 488.430(a). 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

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.

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). A per instance CMP may range from \$1000 to \$10,000, and the range is not affected by the presence of immediate jeopardy. 42 C.F.R. § 488.438(a)(2).

The Act and regulations make a hearing before an administrative law judge (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, is 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 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 Ctr.*, DAB No. 1904 (2004), *aff'd*, 129 F. App'x. 181 (6th Cir. 2005); *Batavia Nursing & Convalescent Inn*, DAB No. 1911 (2004); *Emerald Oaks*, DAB No. 1800; *Cross Creek Health Care Ctr.*, DAB No. 1665 (1998); *see Hillman Rehab. Ctr.*, DAB No. 1611 (1997), *aff'd*, No. 98-3789, 1999 WL 34813783 (D.N.J. May 13, 1999).

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

A. Petitioner was not in substantial compliance with 42 C.F.R. § 483.25 (Tag F309) (quality of care).⁴

Under the statute and the "quality of care" regulation, each resident must receive and the facility must provide the necessary care and services to allow a resident 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. Act § 1819(b)(2); 42 C.F.R. § 483.25.

CMS's allegations of noncompliance with 42 C.F.R. § 483.25 center on the care provided to two diabetic residents, R5 and R6, who were also wife and husband, respectively. The Statement of Deficiencies (SOD) alleges, based on record review and interview, that Petitioner failed to ensure that its staff identified that R5 had significantly low blood sugar results, along with serious deterioration in her physical and mental condition, such that there existed an emergency situation requiring the prompt notification of emergency medical services. The SOD alleges also that Petitioner failed to ensure that the physician was promptly consulted when R6 had significantly low blood sugar results and failed to ensure that his blood sugar was monitored to ensure that there was no further drop in his blood sugar level. CMS Ex. 7, at 9.

Facts Relating to Resident 5

R5 was a 75-year old woman who was admitted to the facility on January 23, 2010, with diagnoses that included uncontrolled diabetes mellitus, cerebral vascular accident, osteoporosis, hypertension, esophageal reflux, and amputation of a toe. CMS Ex. 9; see CMS Ex. 12; P. Ex. 14, at 5. R5's Minimum Data Set (MDS) with an assessment reference date of January 29, 2010, indicates that R5 had short-term and long-term memory problems, had some difficulty with decision-making, used a wheelchair most of the time, required assistance with her activities of daily living, and was on a therapeutic

⁴ The only deficiency citation at issue in this case is the one under 42 C.F.R. § 483.25, Tag F309. Although CMS alleged a deficiency under 42 C.F.R. § 483.10(b)(11), Tag F157 ("failure to notify physician of significant change"), CMS chose not to impose any remedies against Petitioner based on this citation. See CMS Reply at 2. As I discuss below, the evidence shows that Petitioner failed to notify the residents' physician immediately as required when their blood sugar levels were significantly low. However, CMS's case treats this failure as part of a bigger picture showing a violation of 42 C.F.R. § 483.25, Tag F309.

diet. P. Ex. 14, at 3, 6, 13. Petitioner updated R5's MDS on February 2, 2010, September 16, 2010, and November 14, 2010. P. Ex. 14, at 18-63; P. Br. at 15.

R5's care plan identified as a problem her potential for weight loss related to her diabetic diet and dementia. Among other approaches, the plan directed staff to: notify physician of significant weight loss; observe for changes in appetite; weigh per schedule and as needed; provide diet as ordered; provide with food/beverage preferences; encourage to eat; offer alternate if meal is refused or less than 50% of meal is consumed; provide snacks or supplements; observe for signs and symptoms of hypoglycemia (low blood sugar) and hyperglycemia (high blood sugar); consult with the registered dietician as needed; and keep resident/responsible party informed. CMS Ex. 11, at 4-5.

At the October and November 2010 monthly exams, R5's treating physician, Dr. Randall Beallis, documented that R5 had stable vital signs, and her lungs and heart showed no abnormalities. CMS Ex. 14, at 7-8.

R5's physician orders dated October 11, 2010, stated that Petitioner's staff was to notify R5's physician immediately if her capillary blood glucose (CBG)⁵ level was below 40 or higher than 400. P. Ex. 6, at 30; CMS Ex. 12, at 1; CMS Ex. 14, at 1.

A nursing note dated November 14, 2010, at 8:15 a.m., states that R5's CBG level was measured at 7:00 a.m., and registered 76. Nursing staff administered 16 units of Novolin 70-30, which is "intermediate insulin." P. Ex. 10, at 1; CMS Ex. 13, at 1; P. Ex. 11, at 87; CMS Ex. 12, at 2.⁶ At 11:30 a.m., R5's CBG level was 285. P. Ex. 10, at 1; CMS Ex. 13, at 1. Nursing staff administered three units of Novolin R 100, which is fast-acting insulin given based on a sliding scale. P. Ex. 10, at 1; CMS Ex. 13, at 1; P. Ex. 11, at 88; CMS Ex. 12, at 3; Tr. 133-35.

In another November 14, 2010 nursing note at 11:33 p.m., LPN Ronald Llemit stated that, around 4:30 p.m., R5 was awake, alert and oriented. Her respirations were normal and unlabored, with no shortness of breath. LPN Llemit noted that R5 was able to make her needs known to staff. He documented that R5's CBG level measured 214. P. Ex. 10, at 1; CMS Ex. 13, at 1. LPN Llemit administered two units of Novolin R 100 (sliding

⁵ The phrases "blood glucose level" and "blood sugar level" are interchangeable and mean the amount of glucose or sugar present in the blood.

⁶ Intermediate insulin works for a much longer period of time and can stay in the body for up to 24 hours. Tr. 134.

scale) insulin and twelve units of Novolin 70-30 insulin. P. Ex. 11, at 88; CMS Ex. 12, at 3; CMS Ex. 20, at 1; Tr. 133. LPN Llemit noted that R5 refused to eat dinner.⁷ He encouraged R5 to drink the supplement Ensure and R5 refused. P. Ex. 10, at 1; P. Ex. 21, at 6; CMS Ex. 13, at 1.

Apparently, around 5 p.m., R5 refused dinner in the dining room again and also again refused to drink Ensure. P. Ex. 21, at 6. On R5's meal charting record, which shows the percentage of meals consumed, LPN Llemit wrote a "0" in the box corresponding to the 5:00 p.m. dinner to indicate that R5 had nothing to eat. P. Ex. 12, at 10.

Sometime between 8:10 and 8:30 p.m., R6 (R5's husband and roommate at the facility), stood in the hallway and called for help for R5.⁸ CMS Ex. 19, at 2, 4. It appears that staff members LPN Llemit, CNA McGahan-Howard, and CNA Alyssa Regnier, entered R5's room. See P. Ex. 21, at 4; CMS Br. at 5. According to LPN Llemit's nursing notes, R5 had "cold, clammy skin" and was "unresponsive to stimuli and verbal command." P. Ex. 10, at 1; CMS Ex. 13, at 1.

CNA McGahan-Howard left R5's room to retrieve the facility's manual vital signs equipment. CMS Ex. 30, at 26. LPN Llemit stated in an interview that he told the CNAs to obtain R5's vital signs, but they couldn't feel a pulse. LPN Llemit stated that he "did a pulse ox & it was [not] reading."⁹ CMS Ex. 30, at 22. According to CNA McGahan-Howard, R5's pulse was "faint." P. Ex. 41, at 24. LPN Llemit checked R5's CBG level, and his nursing notes state that her blood sugar level was 39 at 8:30 p.m. P. Ex. 10, at 1; CMS Ex. 13, at 1. Although R5 had a physician's order requiring staff to notify her physician if her blood sugar level measured less than 40, Petitioner's staff did not notify

⁷ Petitioner claims that R5 said that she had eaten pizza and also claims that R5's family brought her a dinner of coleslaw, baked beans, and fish. P. Br. at 5; see P. Ex. 41, at 10-11, 13. As I discuss further below, there is no documentary evidence in the record that R5 ate anything on the evening of November 14, 2010, following her afternoon dosage of insulin.

⁸ I note that the parties do not agree on the exact time when R5's husband, R6, called out for assistance for R5. Based on the record, I find that R6 called for help sometime between 8:10 p.m. and 8:30 p.m. More specificity in fixing the time does not appear to be material.

⁹ Although LPN Llemit stated that the pulse ox "was [not] reading," it is apparent that what he meant is that the pulse oximeter was not giving a reading when it was attached to R5's finger.

R5's physician. Instead, CNA McGahan-Howard stated that she ran to the kitchen to get orange juice, LPN Llemit attempted to get R5 to drink the orange juice, but she was not able to drink it. P. Ex. 41, at 28-29. Staff were unable to get a blood pressure reading or a pulse oximeter reading for R5, so CNA McGahan-Howard went to another wing of the facility to retrieve a second vital signs machine. P. Ex. 41, at 29, 102, 107. LPN Llemit and CNA Regnier obtained an oxygen canister and a nasal cannula from different supply closets. They hooked up the equipment and began to administer oxygen to R5.

According to R5's son, LPN Llemit called him at 8:24 p.m. to tell him about his mother's condition. R5's son states that he arrived at the facility within 15-20 minutes, and discovered that his mother was unconscious. CMS Ex. 30, at 35.

Around 8:40 p.m., LPN Llemit called R5's physician, Dr. Beallis. CMS Ex. 30, at 22. According to LPN Llemit, he told Dr. Beallis that R5 was unresponsive, her blood sugar was 39, her vital signs were unreadable via pulse oximetry, and he could not feel a pulse on R5. CMS Ex. 30, at 22. Dr. Beallis gave an order for a Glucagon injection and to reassess R5 after fifteen minutes.¹⁰ CMS Ex. 30, at 22. LPN Llemit obtained the Glucagon from the facility's emergency kit, which was kept in a locked room, returned to R5's room and administered the injection around 8:45 p.m., according to the facility's own timeline as provided to CMS. CMS Ex. 20. At 9:00 p.m., LPN Llemit measured R5's CBG level, and it had dropped to 26 following the Glucagon injection. P. Ex. 10, at 1; CMS Ex. 13, at 1. LPN Llemit reportedly called Petitioner's DON and Dr. Beallis, who ordered staff to call Emergency Medical Services (EMS) for R5. See P. Ex. 25, at 2. At 9:03 p.m., LPN Llemit called EMS. P. Ex. 20, at 5; CMS Ex. 16, at 5. EMS arrived at the facility at 9:11 p.m. P. Ex. 20, at 5; CMS Ex. 16, at 5. According to paramedic John Hopkins, when he arrived on the scene, he assessed R5 and found her respirations were "very shallow and weak." Tr. 200. He noted that R5 was unresponsive and he could not really detect a pulse. P. Ex. 20, at 4; Tr. 200. Mr. Hopkins measured R5's blood sugar, and found that it was 29. P. Ex. 20, at 4; CMS Ex. 16, at 4; Tr. 198. At 9:14 p.m., the paramedics gave a "D 50 IV push" (intravenous administration of Dextrose 50). P. Ex. 20, at 4, CMS Ex. 16, at 4. There was no change in R5's condition as a result of the D 50. P. Ex. 20, at 4; CMS Ex. 16, at 4; Tr. 200-01. The parametrics then moved R5 to the ambulance, placed her on the cardiac monitor, and shocked her with a defibrillator. R5 went into asystole (no pulse), and the paramedics started CPR and administered epinephrine and atropine. R5 still had no pulse, and the paramedics continued CPR and transported R5 to the emergency room. P. Ex. 20, at 4; CMS Ex. 16, at 4; Tr. 201. R5 was pronounced dead at 10:14 p.m. at the hospital. CMS Ex. 17, at 7-9, 15.

¹⁰ Glucagon is a medication that increases blood glucose.

Facts Relating to Resident 6

R6 was a 76-year old man who was admitted to Petitioner's facility on December 12, 2008. CMS Ex. 21. His diagnoses included cerebrovascular accident, uncontrolled diabetes mellitus, hypertension, chronic airway obstruction, obesity, and depression. CMS Ex. 21. Like his wife (R5), R6 had a physician's order that required Petitioner's staff to notify his physician immediately if his blood sugar level dropped below 40. CMS Ex. 26, at 1, CMS Ex. 24, at 7.

On October 31, 2010, at 4:30 p.m., LPN Llemit documented on R6's Medication Administration Record (MAR) that his blood sugar level was 37. CMS Ex. 24, at 7. A review of the nursing notes indicates that, for October 31, 2010, there is no entry stating that R6 had a blood sugar reading of 37 at 4:30 p.m. CMS Ex. 25, at 5. The record contains no evidence that staff immediately contacted R6's physician to inform him that R6's blood sugar level had dropped below 40.

Discussion

Petitioner agrees that R5's condition was "very serious" on the night of November 14, 2010, but contends that CMS "overstates the gravity of the situation." P. Br. at 24. Petitioner asserts that its staff acted timely and competently in providing treatment to R5, including promptly calling EMS, and that her death was "unavoidable." P. Br. at 11. Petitioner also contends that its staff provided necessary diabetic dietary care and services to R5.

The record does not support Petitioner's contentions. There can be no dispute that R5 experienced a life-threatening diabetic crisis on the night of November 14, 2010, nor can it be disputed that the change in her condition required immediate emergency medical attention. The record shows that Petitioner's staff failed to notify R5's physician immediately when her blood sugar fell below 40, as explicitly required under his standing orders. Moreover, Petitioner's staff failed to monitor R5's meal intake adequately after she received her afternoon dosage of insulin. Contrary to Petitioner's claim, I find that its staff did not act with any urgency despite R5's critical condition, and failed to call 911 immediately to obtain emergency medical services for R5. Given the obvious — that critical time was lost because of Petitioner's staff's delay in calling 911 — it is impossible to conclude with any confidence at all that R5's death was "unavoidable" as Petitioner suggests.

Because R5 was a diabetic, she required close monitoring of her blood sugar levels and her meal intake. Her care plan directed staff to, among other things, offer alternates if she refused a meal or if she consumed less than 50% of an offered meal, provide snacks or supplements, and observe her for signs and symptoms of hypoglycemia and

hyperglycemia. CMS Ex. 11, at 5. R5 also had a physician's order that required staff to notify her physician immediately if her blood glucose level fell below 40 or higher than 400. P. Ex. 6, at 30; CMS Ex. 12, at 1; CMS Ex. 14, at 1; Tr. 286.

As stated above, on the night of November 14, 2010, sometime between 8:10 and 8:30 p.m., R6 (husband of R5) called out for help, and Petitioner's staff found R5 with "cold, clammy skin" and "unresponsive to stimuli and verbal command." P. Ex. 10, at 1; CMS Ex. 13, at 1. Petitioner's staff was unable to obtain R5's vital signs.¹¹ LPN Llemit stated that the CNAs could not feel a pulse and that the pulse oximeter was not giving a reading. CMS Ex. 30, at 22. CNA McGahan-Howard, however, said that R5's pulse was "faint." Staff went to retrieve another vital signs machine from another wing of the facility. LPN Llemit checked R5's CBG level, and it was 39 at 8:30 p.m. P. Ex. 10, at 1; CMS Ex. 13, at 1. LPN Llemit and CNA Regnier then left R5's room to get an oxygen canister and a nasal cannula, returned, hooked up the equipment, and administered oxygen to R5. P. Ex. 10, at 1; CMS Ex. 13, at 1.

It was Petitioner's staff's obligation under Dr. Beallis' standing order to notify him *immediately* when R5's blood sugar level dropped below 40. However, they failed to follow this order. According to Dr. Beallis' signed affidavit, LPN Llemit called Dr. Beallis "at approximately 8:40 p.m. and notified [him] that Resident #5's CBG was 39." P. Ex. 25, at 1; Tr. 287. Petitioner acknowledges that ten minutes passed before LPN Llemit called Dr. Beallis to notify him of R5's condition.¹² P. Br. at 26; P. Reply at 11. In Petitioner's view, because CMS presented no evidence as to how "immediate" should be defined, the question is whether a ten-minute delay was "reasonable" in light of the fact that LPN Llemit had to first retrieve the proper equipment and then test R5's CBG level. P. Br. at 26; P. Reply at 11.

I do not find Petitioner's staff's ten-minute delay in notifying Dr. Beallis to be "reasonable." There can be no dispute that the fact that R5 had a blood sugar of 39

¹¹ According to Petitioner, one of its CNAs obtained R5's vital signs, and wrote them down on a piece of paper. P. Br. at 28-29. I find no support for this in the record as Petitioner has not offered any "piece of paper" into evidence documenting R5's vital signs on the night of November 14, 2010.

¹² I note that Petitioner also claims elsewhere in its posthearing brief that LPN Llemit called Dr. Beallis around 8:36 p.m. P. Br. at 8. Other than LPN Llemit's self-serving statement, the time of 8:36 p.m. is not substantiated in any way by any documentary evidence. P. Ex. 21, at 6.

required <u>immediate</u> physician involvement. At the hearing, Dr. Beallis himself testified, "in the case of a low blood sugar, that needs to be addressed absolutely immediately." Tr. 262. Petitioner has offered no compelling reason to explain the delay in calling Dr. Beallis, other than to argue that LPN Llemit was unavailable because he was running about the facility getting equipment. It hardly needs pointing out that if LPN Llemit was too busy with other tasks to call Dr. Beallis, there were other staff present who would have had the ability and opportunity to contact Dr. Beallis "absolutely immediately" when R5's blood sugar was found to register 39 around 8:30 p.m. Instead, for whatever reason, while R5 remained unresponsive and her physical condition continued to deteriorate, ten critical minutes passed before staff took any action. By failing to follow Dr. Beallis' standing order to immediately notify him of R5's significantly low blood sugar level, Petitioner's staff failed to provide R5 with necessary care and services, in violation of 42 C.F.R. § 483.25.

Moreover, given the life-threatening circumstances faced by R5, I find that Petitioner's staff failed to seek emergency medical services for her immediately so that she could be transported to the hospital. In maintaining that there was no delay in calling 911 for R5, Petitioner claims that its staff were required under Dr. Beallis' standing order to first notify him of R5's CBG level and that to do anything else would have been "at odds with ensuring that residents receive consistent care." P. Br. at 22. According to Petitioner, there exists a "chain of medical authority" and that where a physician's order is in place that relates to symptoms a resident may be experiencing, then it would be a violation of the physician's order for a nurse to also call EMS in addition to notifying the physician. P. Reply at 7. Petitioner contends also that its nursing staff did not have the medical training to determine whether it was appropriate to call EMS for R5, and that it was a decision best left to Dr. Beallis.

In Petitioner's view, once LPN Llemit notified Dr. Beallis of R5's condition, then calling EMS was essentially no longer an option for LPN Llemit. Dr. Beallis testified that LPN Llemit told him that R5 was "groggy" and had a blood sugar of 39, and based on this information, he ordered a Glucagon injection and told LPN Llemit to reassess her after 15 minutes. Dr. Beallis instructed LPN Llemit to call him back if the Glucagon did not raise R5's blood sugar. Tr. 262, 266, 279-80, 303-03; P. Ex. 25, at 1-2. When asked why he did not order LPN Llemit to call EMS immediately when he was contacted, Dr. Beallis testified that it was "not the appropriate thing to do." Tr. 267. According to Dr. Beallis, Glucagon "is a successful treatment at least 99 out of 100 times for hypoglycemia" and if nursing staff were to call EMS in every instance when a resident had low blood sugar, then "you'd be calling EMS all the time inappropriately." Tr. 267.

Dr. Beallis testified that the only time that it would be acceptable for a nurse to call EMS without first obtaining the order from him would be in a life-threatening situation. Tr. 268-69. According to Dr. Beallis, a situation where someone was "actively bleeding" or did not have a pulse would warrant an immediate call to EMS by nursing staff. Tr. 269.

Dr. Beallis also stated that if someone had low blood sugar and was completely unconscious, then he would give the order to "[c]all EMS and administer Glucagon." Tr. 263.

As the record shows, in R5's case, the Glucagon treatment was not successful, and R5's CBG level, when measured again at 9:00 p.m. following the injection, had dropped to 26. P. Ex. 10, at 1; CMS Ex. 13, at 1. After being made aware in a second phone call from LPN Llemit that R5's blood sugar level had fallen even further, Dr. Beallis finally ordered nursing staff to call EMS. Tr. 266-67.

In addition to the testimony of Dr. Beallis, Petitioner offered the testimony through sworn deposition of Dr. Phillip Bobo. P. Ex. 40. I note that although Petitioner offered Dr. Bobo as an expert in "[e]mergency medicine, geriatric care, and nursing facility operational medical policies and care," CMS objected to his being qualified as an expert in geriatric care. P. Ex. 40, at 11-13. Dr. Bobo testified that Petitioner's nursing staff followed Dr. Beallis' orders and "did everything that they could do." P. Ex. 40, at 64-65, 66. He testified that when a nurse reports that a patient has a blood sugar of less than forty, and is not alert, then a physician can either order D50W IV or Glucagon in order to raise the blood sugar. P. Ex. 40 at 32-34. He opined that a situation where a resident has a blood sugar of below forty would not necessarily warrant calling EMS. P. Ex. 40, at 35. According to Dr. Bobo, "if you call EMS right away, then you're not addressing the immediate problem. I mean, you might call them, but you've got to address this problem with actions by the nursing staff and what they can do and they have the capability of doing." P. Ex. 40, at 36. In describing the condition of a patient who has a blood sugar of below forty, Dr. Bobo stated:

Well, they are going to be mentally confused, may even be comatose, probably are comatose at forty. . . . And you stay in a comatose state long enough, you may even have impaired breathing. It can affect every organ system. But usually this is – the first thing that goes is the cerebral – the neurological status of the patient deteriorates.

P. Ex. 40, at 38. When asked if a blood sugar of below forty is manageable or if it is always a critical event, Dr. Bobo opined that "it can be managed" and noted that "blood sugars less than forty occur all the time, and they are treated and they respond, and they're fine." P. Ex. 40, at 38.

Dr. Bobo acknowledged that Petitioner's staff could also have called 911 at the same time they called Dr. Beallis to notify him that R5's blood sugar was below forty. P. Ex. 40, at 90. He stated further, "you can call 911 any time you want to if you so desire to call 911, but it's not in the policy for them to call 911, and it's not the doctor's order to call 911." P. Ex. 40, at 91. When asked who could have called 911, Dr. Bobo stated that

"[a]nyone could call 911" and admitted that, among the two CNAs and one LPN who were attending to R5 on November 14, any one of them could have called 911. P. Ex. 40, at 92-93.

In support of its position that Petitioner's staff should have immediately contacted EMS for R5, CMS relies on the deposition testimony of Dr. Bruce Biller, who was qualified as an expert in endocrinology and internal medicine. Tr. 10. Dr. Biller testified that R5's blood sugar level of 39 indicated that she was experiencing "severe hypoglycemia." Tr. 22. Dr. Biller testified:

[R5] was found semiconscious with clear-cut symptoms evident of hypoglycemia in a setting of a blood glucose of either 39 or 27, depending on the sequence that you choose to find. Clearly it is a medical emergency. At that point the next thing that should have happened is calling EMS, unquestionably. . . . Calling EMS is step one. Step two should have been calling the doctor. Neither of those happened then.

CMS Ex. 38, at 24.

In describing R5's condition, Dr. Biller testified further:

So we have now a situation where we have someone who is undetectable vital signs, no detectable O2 on the pulse ox, and barely breathing. This is a clear-cut medical emergency. Call EMS, is step one.

CMS Ex. 38, at 25-26.

Besides being very critical of how Petitioner's staff responded to R5's medical emergency, Dr. Biller also expressed his opinion that Dr. Beallis did not act appropriately in the situation. Referring to Dr. Beallis' order to give a Glucagon injection to R5, Dr. Biller testified:

[t]he doctor should have given the order to call the EMS at that point, since it had not been called up until that point. That's step one, get EMS. And step two is give glucagon once. Instead, the order was give glucagon and call me back in 15 minutes.

CMS Ex. 38, at 26; see CMS Ex. 38, at 51-52.

When asked if LPN Llemit's call to Dr. Beallis around 8:39 p.m. constituted "immediate contact," Dr. Biller responded, "No." CMS Ex. 38, at 51. When asked "what would constitute immediate contact to the doctor," Dr. Biller emphasized again that "in his professional opinion once the patient was found as she was in an extreme hypoglycemic state, step one is call EMS; and immediate next step is call the doctor." CMS Ex. 38, at 51. Dr. Biller pointed out that a call to EMS would take "less than a minute" and noted that EMS, when contacted, came on site in roughly ten minutes. CMS Ex. 38, at 51. Dr. Biller opined that Petitioner's staff did not give R5 "optimal care," stressing the fact that staff failed to call "EMS at various times when they could have, should have been called, including the very beginning of this, the recognition of it being severe hypoglycemia." CMS Ex. 38, at 57.

Weighing the testimony offered by Dr. Bobo and Dr. Biller, I find that the opinions of Dr. Biller are entitled to more weight. Dr. Biller's credible testimony indicates that R5's condition on the night of November 14 presented a medical emergency and that Petitioner's staff failed to recognize it as such. Dr. Biller testified that Petitioner's staff should have called EMS immediately, and then called Dr. Beallis. I am not persuaded by Dr. Bobo's testimony that R5's condition did not warrant calling EMS immediately. Dr. Bobo opined that it was not necessary to call EMS when a patient has a blood sugar level of below forty. However, he also stated that serious harm can result if a patient has a blood sugar level of below forty, noting that there is a potential for coma and neurological damage. Dr. Bobo's testimony is clearly contradictory. Moreover, I find somewhat troubling his apparently-nonchalant view that, even though R5 was found nonresponsive and hypoglycemic, calling EMS was not necessarily required since it was not part of Dr. Beallis' order. As testified by Dr. Biller, R5 had "undetectable vital signs, no detectable O2 on the pulse ox, and [was] barely breathing. This is a clear-cut medical emergency." That Dr. Bobo did not view the totality of R5's symptoms as being indicative of a medical emergency is simply not consistent with the clinical evidence, and that inconsistency renders his testimony unreliable in my analysis of this situation. There can be no question that, as Dr. Biller correctly recognized and forcefully asserted, R5 was in critical condition and EMS should have been immediately contacted by Petitioner's staff.

I have also discounted Dr. Bobo's opinion that Petitioner's staff complied with Dr. Beallis' orders. In opining that staff "followed the physician's orders to the tee" (P. Ex. 40, at 64), Dr. Bobo chooses to ignore what the evidence clearly shows – that Petitioner's staff failed to contact Dr. Beallis *immediately* when R5's blood sugar fell below 40, as they were *required* to do under his standing order. Dr. Biller, on the other hand, held the entirely opposite view to that of Dr. Bobo, expressing the opinion that Petitioner's staff failed to carry out Dr. Beallis' order and failed to call EMS timely, I agree with — and accept as the more credible — Dr. Biller's opinion. It is evident that even though R5 was unresponsive and suffering what most likely was a diabetic crisis due to her

abnormally low blood sugar level, no one on Petitioner's staff took immediate action to call EMS or Dr. Beallis. Rather, staff acted in a disorganized fashion, running to-and-fro in search of equipment, and their response to R5's emergency can only be described as confused, disorganized, and tragically inadequate.

Further, I find Petitioner's argument that nursing facility staff do not possess the ability or training to recognize an emergency situation or call 911 to be completely at odds with how one would expect reasonable nursing facility staff to act in an emergency situation. In fact, Petitioner's own witness, Dr. Bobo, testified that it would have been appropriate for either the CNAs or LPNs to call EMS for R5. As Dr. Bobo stated, "[a]nyone could call 911," and he admitted that, among the two CNAs and one LPN who were attending to R5 on November 14, any one of them could have called 911. P. Ex. 40, at 92-93. Dr. Biller also testified that LPNs are trained to recognize emergency situations and that it is within the scope of their duty to call EMS if an emergency situation arises. CMS Ex. 38, at 30.

I note that even Petitioner's own Director of Nursing, Susie Shaw, stated that if a resident had a blood sugar level of 39, and was cold, clammy, and unresponsive, staff should "call 911, call MD & tell him what [the resident's] condition is & that [the resident] has been sent to hospital." CMS Ex. 30, at 29. In DON Shaw's view, nursing staff would be acting within the scope of their duties in calling both 911 and a resident's physician in an emergency situation. She did not indicate that there were any restrictions on who could call 911. Based on the statements of Dr. Bobo, Dr. Biller, and DON Shaw, there can be little doubt that Petitioner's nursing staff was entirely capable of calling 911 on its own initiative, and that doing so would not in any way have been inconsistent with their obligations as caregivers. I find Petitioner's position that calling EMS for R5 was "a decision best left to a physician" (P. Br. at 25) is wholly unsupported in the record. As CMS points out, given the emergency circumstances, Petitioner's staff could have simultaneously called EMS and immediately notified Dr. Beallis of R5's low blood sugar – they were not mutually exclusive events, and I have been shown no evidence or rational argument to suggest that they were.

As further evidence that Petitioner failed to provide necessary care and services to R5, CMS contends that the record also shows that Petitioner's staff failed adequately to monitor R5's meal intake on November 14, 2010, and failed to implement the interventions in her care plan after she twice refused to eat. As stated above, around 4:30 p.m. on November 14, R5 received her afternoon dosage of insulin. R5 refused to eat her dinner and also refused a can of the dietary supplement Ensure. P. Ex. 10, at 1; CMS Ex. 13, at 1. Around 5:00 p.m., LPN Llemit again offered R5 dinner and Ensure, and she again refused both. P. Ex. 21, at 6.

With respect to her diabetes, R5's care plan required staff, among other things, to provide her a diet as ordered, to provide her with food and beverage preferences, to encourage her

to eat, to offer alternative meals if she refused or ate less than 50% of a meal, to provide snacks or supplements, and to keep her responsible party informed. CMS Ex. 11, at 4-5. Thus, when R5 refused her dinner and the offered Ensure, an option under her care plan would have been for LPN Llemit to offer her an alternate meal. Alternatively, LPN Llemit could have offered R5 a snack. He did neither. Instead, according to the nursing notes, some little while later around 5:00 p.m., LPN Llemit offered R5 the same meal and again offered Ensure. As she had before, R5 refused. LPN Llemit again failed to offer R5 an alternate meal or provide snacks. Under R5's care plan, LPN Llemit was also required to notify her responsible party that R5 was refusing to eat after receiving insulin. He did not do this either. I note that LPN Llemit did call R5's son later, in the 8:00 p.m. hour; however, the purpose of that call was to inform him of the fact that his mother was suddenly in very critical condition.

In its defense, Petitioner argues that CNA Howard saw R5 eat dinner on November 14, 2010. According to CNA Howard, between 5:10 and 5:30 p.m., R5 ate coleslaw, baked beans, and barbecued fish that her family had provided to her. P. Br. at 5. Petitioner contends that R5 refused a snack an hour later because she was still eating her dinner. P. Br. at 5. Furthermore, Petitioner asserts that CNA Howard stated that she recorded that R5 ate 75% of her dinner on November 14, and that the notation on Petitioner's meal charting record that R5 ate nothing is incorrect or was somehow altered. P. Br. at 6.

I do not find CNA Howard's testimony credible and decline to rely on it at all. Petitioner has offered no independent evidence for the idea that R5 ate some fish or other food brought to her by her family. Such evidence, if it existed, would certainly not have been difficult to develop and present. I have no reason to question LPN Llemit's nursing notes where he documented that R5 "refused to eat" her dinner and also "refused" to drink Ensure on the evening of November 14, 2010. See P. Ex. 10, at 1. Moreover, Petitioner has offered no reason for anyone to have altered the meal charting documentation — much less proof even hinting at such an alteration — which clearly shows that R5 ate "0%" of her dinner.

However, even if R5 had eaten something at dinner, Petitioner's staff and her physician ought to have been aware of her meal intake and accurately recorded it. Tracking R5's diet and what she ate was crucial given the fact that R5 was known to be diabetic and in need of very close monitoring.

Assuming that R5 did *not* eat any dinner or drink her supplement, which is what the record strongly indicates based on Petitioner's own records, I find that Petitioner's staff failed to implement the careplanned interventions after R5 refused to eat. It was incumbent upon Petitioner's staff to ensure that R5 ate enough food after she received her afternoon dosage of insulin so that her blood sugar levels remained stable. However, the record shows that staff did not adequately respond to R5's refusal to eat, thereby exposing her to the risk of developing severe hypoglycemia.

CMS's expert witness, Dr. Biller, testified that a long-time diabetic who missed a meal or refused to eat or drink after receiving insulin would have a "high risk" of being in a life-threatening situation. CMS Ex. 38, at 97-98. Dr. Biller testified further that after R5 refused to eat, Petitioner's staff failed to respond appropriately since they did not "develop an alternative group of strategies that could be quickly tried and while [R5] was not yet having symptoms of hypoglycemia, which was, in my professional judgment, a serious and real threat to her." CMS Ex. 38, at 98. Additionally, according to Petitioner's witness, LPN Fashing, an LPN is trained to understand that there is a good potential for a hypoglycemic episode "if a diabetic patient receives a full dosage of insulin and does not eat." Tr. 330. LPN Fashing testified further that in the event of a refusal to eat by R5 after she received insulin, then staff could implement the care plan approaches to address the situation at the time that she refused the meal. Tr. 334.

In addition to their tepid response to R5's refusal to eat, I note that the staff also failed to notify R5's physician, Dr. Beallis, that she had refused to eat dinner. At the hearing, Dr. Beallis admitted that no one called him either time when R5 refused her dinner. Tr. 286. As discussed above, LPN Llemit called Dr. Beallis several hours later, to inform him that R5's blood sugar level had dropped to 39. Even then, it is not clear whether Dr. Beallis was informed that R5 had not eaten anything since receiving her afternoon dosage of insulin. In his affidavit, Dr. Beallis states that he was told that R5's blood sugar was 39, but gives no indication that he was aware that R5 had not eaten anything for several hours. P. Ex. 25, at 1-2.¹³

Clearly, R5 was at risk for a severe hypoglycemic episode due to her refusal to eat. Her situation was made more perilous in light of the fact that she had received her afternoon dosage of insulin shortly before her refusal of dinner. I find that Petitioner's staff did little to ensure that R5 ate something and failed to implement the approaches specified in her care plan. As a result, Petitioner's staff failed to provide R5 with necessary care and services to address her diabetic dietary needs, in violation of 42 C.F.R. § 483.25.

¹³ Although Dr. Beallis maintained that he was given accurate and complete information regarding R5's condition from LPN Llemit (Tr. 262-63), his position seems rather disingenuous in light of the fact that he may not have had any idea that R5 had not eaten for several hours. Dr. Beallis testified that "the amount that [R5] ate [was] a medical concern for" him (Tr. 256), and stated that having accurate information about R5's meal intake would have been relevant to monitoring her for hypoglycemia and hyperglycemia. If he was unaware that R5 had not eaten anything after receiving insulin, then the information he received about R5's condition would have been neither accurate nor complete.

Finally, CMS also contends that Petitioner failed to follow its own policies in treating R5. CMS notes that Petitioner's internal Nursing Procedures Manual contained policies that addressed diabetic coma/insulin shock and change in a resident's medical condition. P. Ex. 1, at 1-3, 6-8. Inasmuch as I have concluded that Petitioner violated 42 C.F.R. § 483.25 based on its failure to follow R5's physician's order, failure to timely contact EMS, and its failure to monitor her meal intake, I do not find it necessary to address CMS's argument that Petitioner's staff acted in a manner inconsistent with its own policies.

With respect to R6, who is the husband of R5, Petitioner concedes that its staff did not notify Dr. Beallis when R6 had a blood sugar level of less than 40, as required by his order, but characterizes this failing as possibly a transcription error on R6's MAR. Petitioner asserts further that there was no risk of harm at all to R6 as a result of this failure.

Like his wife (R5), R6 also suffered from diabetes mellitus. As with R5, there was an explicit standing order in R6's chart from Dr. Beallis that required staff to notify him immediately if R6's blood sugar level fell below 40. As documented on R6's MAR, his blood sugar level dropped to 37 on October 31, 2010. Dr. Beallis was not notified by staff of this event, nor were there any interventions put in place to address R6's blood sugar reading of 37 or monitor it further.

Petitioner has offered no real explanation for its staff's failure to contact Dr. Beallis on October 31. Instead, Petitioner poses the theory that R6's low blood sugar reading of 37 "charted in the MAR was an error." P. Br. at 32. According to Petitioner, because R6 did not experience any signs or symptoms of hypoglycemia, his blood sugar level reading could not truly have been 37. Petitioner posits that LPN Llemit most likely incorrectly entered R6's blood sugar level into the computer, and then failed to have the error corrected. P. Br. at 32.

Petitioner's arguments are not credible as they are without support in the evidence. In claiming that a transcription error occurred, Petitioner has offered only speculation and conjecture, with no actual proof. There is no corroborating evidence that a documentation error occurred and that the MAR does not accurately reflect R6's blood sugar reading for October 31, 2010. In fact, when asked about R6's blood sugar level of 37, Dr. Beallis made no mention of any transcription error on the MAR, but instead acknowledged that he was not notified of the low blood sugar reading and was unaware of it "for a couple of months after it happened." Tr. 276.

Moreover, the fact that R6 did not suffer any apparent or obvious harm due to Petitioner's staff's failure to notify the physician does not in any way absolve Petitioner of its obligation to comply with the physician's orders. Petitioner's staff had a duty to notify Dr. Beallis immediately if R6's blood sugar dropped below 40. There can be no dispute

at this point in the discussion of the facts that R6's low blood sugar reading potentially could have resulted in a severe — and as this record sadly shows — life-threatening hypoglycemic episode, putting him at risk for grave consequences. Petitioner's staff failed to notify Dr. Beallis as required by his order, and consequently, I find that Petitioner failed to provide R6 with the necessary care and services as required by 42 C.F.R. § 483.25.

B. CMS's determination of immediate jeopardy level noncompliance is not clearly erroneous.

CMS concluded that the violation of 42 C.F.R. § 483.25 posed immediate jeopardy. However, because CMS imposed a PICMP in this case, and not a per-day CMP, I need not consider CMS's finding that the deficiencies here constituted immediate jeopardy. CMS recognizes as much, for it states in its prehearing brief, "The presence of 'immediate jeopardy' is not a regulatory prerequisite for imposing a per-instance CMP and is not at issue in this case." CMS Prehearing Br. at 21.

The regulations are clear that the scope and severity determination of immediate jeopardy can be appealed but only if the range of CMP that can be imposed could change or if the facility's nurse aide training program would be affected due to a finding of substandard quality of care. 42 C.F.R. §§ 498.3(b)(14)(i), (ii) and 498.3(d)(10)(i), (ii). It does not appear that Petitioner had a nurse aide training program. Further, there is but a single range for PICMPs and the amount of a PICMP is not affected by whether or not there is immediate jeopardy. 42 C.F.R. §§ 488.408; 488.438. Thus, the immediate jeopardy finding is not subject to appeal or my review in this case. However, to the extent that a declaration of immediate jeopardy reflects upon the seriousness of the deficiency, it is reasonable to consider whether immediate jeopardy existed as an evidentiary matter.

Immediate jeopardy is defined as a situation in which a facility'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 as to the level of noncompliance must be upheld unless it is clearly erroneous. 42 C.F.R. § 498.60(c). Under the clearly erroneous standard, CMS's immediate jeopardy finding is presumed to be correct, and the facility has a heavy burden to overturn it. *Stone County Nursing & Rehabilitation Center*, DAB No. 2276, at 17 (2009); *Edgemont Healthcare*, DAB No. 2202, at 20 (2008); *Daughters of Miriam Center*, DAB No. 2067, at 7 (2007).

Petitioner placed R5 and R6 in immediate jeopardy when its staff failed to notify their physician when they had significantly low blood sugar readings, in violation of his standing orders. As a result, R5 experienced a diabetic crisis — a severe hypoglycemic episode – and thus suffered actual harm. In addition to the delay in contacting her physician, Petitioner's staff also failed to respond appropriately once they were aware of R5's deteriorating condition. Although R5's unresponsiveness and life-threatening

symptoms clearly created an emergency situation, staff delayed in calling EMS, causing critical time to be lost. With respect to R6, Petitioner's failure to follow physician's orders placed him at risk of serious harm as he could have suffered a severe hypoglycemic episode much as his wife did, with the obvious risk of similarly-tragic results. CMS's immediate jeopardy finding is thus not clearly erroneous.

C. The \$10,000 PICMP imposed is reasonable.

I have concluded that Petitioner was not in substantial compliance with all program participation requirements due to a violation of 42 C.F.R. § 483.25, Tag F309. Therefore, there is a basis for CMS to impose one or more of the enforcement remedies listed in 42 C.F.R. § 488.406, including a PICMP for each instance that a facility is not in substantial compliance. 42 C.F.R. § 499.430(a). CMS is authorized to impose a PICMP from \$1000 to \$10,000 per instance. 42 C.F.R. § 488.438(a)(2). Unlike a per-day CMP, a finding of immediate jeopardy is not required to impose the maximum PICMP. In this case, CMS has imposed a PICMP of \$10,000.

My review of the reasonableness of the PICMP imposed is *de novo* and is based upon the evidence in the record before me. In determining the reasonableness, I apply the factors listed at 42 C.F.R. § 488.438(f) which are: (1) the facility's history of noncompliance; (2) the facility's financial condition; (3) factors specified at 42 C.F.R. § 488.404; and (4) the facility's degree of culpability, which includes neglect, indifference, or disregard for resident care, comfort or safety. The absence of culpability is not a mitigating factor. The factors at 42 C.F.R. § 488.404 include: (1) the scope and severity of the deficiency; (2) the relationship of the deficiency to other deficiencies resulting in noncompliance; and (3) the facility's prior history of noncompliance in general and specifically with reference to the cited deficiencies.

Petitioner argues that the \$10,000 PICMP imposed by CMS is unreasonable. Petitioner contends that it does not have a history of noncompliance, that the deficiency was isolated to two residents and was of limited scope, and that its culpability, if any, is limited. P. Br. at 32-33.

Contrary to Petitioner's assertions, the record shows, based on documentation submitted by CMS, that the facility has a history of substantial noncompliance. CMS Ex. 35. In the past years, Petitioner has been cited under various tags at several surveys. At an April 30, 2010 survey, Petitioner was cited, among other things, for failing to be in substantial compliance with Tag F323 (accident hazards) at the "K" level of scope and severity. CMS Ex. 35, at 1. At a June 2010 survey, Petitioner was cited, among other things, for failing to be in substantial compliance with Tag F441 (infection control) at the "F" level of scope and severity, and Tag F309, the tag at issue in this case, at the "D" level of scope and severity. CMS Ex. 35, at 6. Petitioner has also been cited in the past for life safety code violations. CMS Ex. 35, at 2-3. I conclude that the deficiencies were serious and that Petitioner was culpable. That only two residents were involved does not make the deficiencies less serious. In fact, considering that one resident, R5, suffered a severe hypoglycemic episode and another resident, R6, could potentially have suffered serious harm, it is fortunate that Petitioner's staff's failings in care did not involve more residents. R5 and R6 were diabetics on insulin regimens, and it was Petitioner's staff's duty to carefully monitor their diets and condition and notify the physician when they had abnormal blood sugar readings pursuant to his explicit orders. Petitioner's staff failed to discharge that duty, and for this they are culpable. Moreover, as discussed above, I have concluded that Petitioner's staff's exhibited further failings in their treatment of R5, as demonstrated by the failure to immediately call EMS when she exhibited life-threatening symptoms and her condition had clearly turned for the worse.

In an attempt to limit its culpability, Petitioner shifts blame to R5 as being partly responsible for the fact that she had a hypoglycemic episode. In its prehearing brief, Petitioner states, "[R5] contributed to the hypoglycemic episode that unfortunately ended with her death." P. Pre-hearing Br. at 15. According to Petitioner, R5 was noncompliant with her diet, sometimes ate pizza that her son brought her, and this would cause her blood sugar levels to fluctuate, "creat[ing] a medical situation that [Petitioner] had to manage." P. Pre-hearing Br. at 12. As stated above, R5's care plan contained interventions that Petitioner's staff were required to implement if she refused meals. These interventions included offering her alternate meals if she refused or ate less than 50% of a meal, providing snacks or supplements, and keeping her responsible party informed. Other than offering R5 the same meal and Ensure twice on the evening of November 14, 2010 when she refused to eat dinner, Petitioner's staff did not attempt any other careplanned approaches. I find that blaming R5 for its own staff's failure to institute the other interventions listed in the care plan is a less-than-admirable strategy on Petitioner's part. It was Petitioner's duty — put plainly, it was Petitioner's job — to provide care for R5 in accordance with the care plan it had prepared for her. 42 C.F.R. § 483.25. Petitioner failed to do this, and is thus entirely culpable.

Petitioner has not asserted that its financial condition is such that it cannot pay the PICMP and has presented no evidence of its financial condition.

A \$10,000 PICMP is the maximum amount of PICMP that CMS may impose for an instance of non-compliance. I conclude that the \$10,000 PICMP is reasonable in light of the relevant factors.

V. Conclusion

For the foregoing reasons, I conclude that Petitioner was not in substantial compliance with program participation requirements due to a violation of 42 C.F.R. § 483.25, cited as Tag F309. The \$10,000 PICMP is a reasonable enforcement remedy.

/s/ Richard J. Smith Administrative Law Judge