Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

In the Case of:)	
Magnolia Estates Skilled Care)	Date: June 13, 2008
(CCN: 34-5288),)	
)	
Petitioner,)	
- V)	Docket No. C-06-192
)	Decision No. CR1804
Centers for Medicare & Medicaid)	
Services.)	
)	

Civil Remedies Division

DECISION

Petitioner, Magnolia Estates Skilled Care, violated 42 C.F.R. §§ 483.10(b)(11); 483.25; 483.25(m)(1) and 483.65(a);¹ and 483.75, as alleged by the Centers for Medicare & Medicaid Services (CMS), based upon the survey completed at the facility on October 20, 2005. The civil money penalties (CMP) of \$3050 per day during the period July 25 through October 19, 2005 and \$50 per day for the period October 20 through November 12, 2005, are reasonable.

I. Background

Petitioner is a long-term care facility, located in Spencer, North Carolina, and certified to participate in the Medicare program as a skilled nursing facility (SNF) and the Medicaid program as a nursing facility (NF). The North Carolina Department of Health and Human Services, Division of Facility Services (the state agency), conducted a survey of Petitioner's facility October 17 through 20, 2005, the results of which are reported in a Statement of Deficiencies (SOD) dated October 20, 2005. CMS Exhibit (CMS Ex.) 3; Petitioner's Exhibit (P. Ex. 2); Joint Stipulation dated May 10, 2006 (Jt. Stip.). CMS notified Petitioner by letter dated November 8, 2005, that it was imposing a CMP of \$3050 per day effective July 25, 2005 and continuing through October 19, 2005, and a

¹ All references are to the revision of the Code of Federal Regulations (C.F.R.) in effect at the time of the surveys, unless otherwise indicated.

CMP of \$50 per day effective October 20, 2005 and continuing until Petitioner achieved substantial compliance with program requirements; a denial of payments (DPNA) effective January 20, 2006; and termination effective April 20, 2006. Jt. Stip.; CMS Ex. 1; P. Ex. 1. A revisit survey determined that Petitioner returned to substantial compliance on November 13, 2005, and the DPNA and termination were rescinded. P. Ex. 5.

Petitioner timely requested a hearing by an administrative law judge (ALJ) on January 5, 2006. The case was assigned to me for hearing and decision on February 8, 2006, and a Notice of Case Assignment and Prehearing Case Development Order was issued at my direction on that date. I convened a hearing in Charlotte, North Carolina on August 22 and 23, 2006. A two volume 395-page transcript (Tr.) was prepared and made available to the parties.² CMS offered and I admitted CMS exhibits 1 through 32 (Tr. 17) and Petitioner offered and I admitted Petitioner exhibits 1 through 42 (Tr. 24). CMS filed a post-hearing brief (CMS Brief) and a reply brief (CMS Reply). Petitioner also filed a post-hearing brief (P. Brief) and a reply brief (P. Reply).

II. Discussion

A. Findings of Fact

The following findings of fact are based upon the parties' joint stipulation, the testimony at hearing, and the exhibits admitted. Citations to exhibit numbers related to each finding of fact may be found in the analysis section of this decision if not indicated here.

² Petitioner indicates in its reply to the CMS post-hearing brief that counsel for Petitioner had difficulty locating in the transcript the specific pages cited by CMS in its briefs. P. Reply at 2, n.1. Petitioner does not assert any prejudice or request any relief. I had no difficulty locating references to transcript pages cited by CMS. I did, however, initially have difficulty with Petitioner's references to the transcript. Volume I of the transcript, which includes the proceedings from August 22, 2006, has pages 1 through 241. Volume II of the transcript, which includes the proceedings from August 23, 2006, begins with page number 242 and, in the electronic version, pages 386 through 395 are incorrectly numbered 243 through 252. (The hard copy of the transcript is similarly misnumbered.) CMS cites to the transcript are consistent with the actual numbering of the transcript pages. Petitioner's cites to the pages of Volume II are in error. In its reply brief at pages 2 and 3, Petitioner refers, for example to pages 52, 55, 71, and 75 in Volume II. Petitioner makes the same error in its post-hearing brief at page 17 for example, referring to pages 94-96 as being in Volume II. After comparing Petitioner's cites in its briefs with Volume II of the transcript, I determined that Petitioner's cites to Volume II of the transcript were easily located by adding 235 to whatever page number from Volume II Petitioner cited. I conclude there was no error in the transcript that caused prejudice to Petitioner or that required correction.

- Resident 1, the resident who is the subject of the deficiencies alleged by CMS, was admitted to Petitioner's facility on January 22, 2002, at the age of 45 with diagnoses including Huntington's Chorea, cerebral degeneration, and insomnia. P. Ex. 33, at 1.
- 2. Huntington's Chorea is a progressive disorder that involves involuntary movements of the extremities as well as cognitive impairment and, in Resident 1's case, her cognitive impairment had progressed to the point where she was unable to communicate in any meaningful manner and she was fed by tube. P. Ex. 33, at 7-11; Tr. 289.
- 3. Resident 1 was totally dependent on Petitioner for her care. P. Ex. 33.
- 4. Resident 1 had an elevated temperature and seizure on May 25, 2004, and was prescribed Valium or its generic, Diazepam, by intramuscular injection, as needed. P. Ex. 9, at 2; P. Ex. 33, at 23, 426.
- 5. Resident 1's care plan dated January 19, 2004, includes a note under "short term goal" that states that seizure activity was noted on October 8, 2004. CMS Ex. 16, at 4; P. Ex. 8, at 4; P. Ex. 33, at 409.
- 6. Resident 1's care plan dated January 19, 2004, included the intervention that her bed's side rails were padded to prevent injuries related to her involuntary movements. CMS Ex. 16, at 2; P. Ex. 8, at 2.
- 7. Nurse's Notes from July 24, 2005 show that at 5:30 p.m., A. Higgins, RN, witnessed Resident 1 having a "petit mal seizure" with jerking movements up and down of the extremities; she noted that the padded side rails were up; she remained at Resident 1's bedside until the seizure ceased; she assessed Resident 1 and noted no injury; she positioned Resident 1's body on her side; she administered Valium pursuant to the physician's standing order; and she noted that she would continue to monitor Resident 1 for seizure activity. CMS Ex. 5, at 1; P. Ex. 33, at 383.
- 8. Nurse's Notes from July 25, 2005 show:
 - a. At 12:45 a.m. RN Higgins assessed Resident 1 and found her jerking at intervals with pupils dilated and fixed and staring episodes were noted.
 - RN Higgins paged the doctor on call about Resident 1's pupils and her elevated pulse; the Physician's assistant (PA) for Resident 1's doctor, Dr. Nickerson, who also is the facility medical director, took the call.

- c. Nurse Higgins informed the PA about the pupils, the elevated pulse, and the events that occurred during and after the seizure; the PA indicated he would call the physician on call, Dr. Kirtley, to determine what follow-up was needed.
- d. At 12:50 a.m., Dr. Kirtley, the on-call physician for Resident 1's physician, called back, an update was given, and he told the nurse to continue to monitor and to have Resident 1 evaluated by neurology because she could be having a different type of seizure.
- e. At 9:40 a.m., Lisa Hodges, Licensed Practical Nurse (LPN), noted that she called the Geriatric Nurse Practitioner (NP), Caroline Adams, who worked for Dr. Nickerson, Resident 1's physician and Petitioner's medical director, to inform her about Resident 1's seizure episodes, her current condition, and the order for a neurology consult.
- f. NP Adams, who usually cared for Resident 1 (Tr. 370), cancelled the order for the neurology consult and instead ordered that 100 mg of Dilantin be administered through the resident's feeding tube.
- g. LPN Hodges noted at 2:35 p.m that she contacted Resident 1's family about the seizure episodes and the "new orders" and that she noted a small purple bruise on Resident 1's right knee due to the seizure activity.
- h. At 10:10 p.m., Kim McCorkle, LPN, was called to Resident 1's room by the Certified Nursing Assistant (CNA) and she found Resident 1's right knee was swollen and bruised with a reddened area to the right knee that was bleeding.
- i. At 10:15 p.m., LPN McCorkle noted that she called Dr. Nickerson and made him aware of the knee and that he gave her a telephone order for an x-ray and to keep the right knee propped-up; he wanted the results of the x-ray called in to his office and informed her that it was okay to get the x-ray in the morning.
- j. LPN McCorkle also noted at 10:15 p.m. that she called and made an appointment for the mobile x-ray to come to the facility on July 26, 2005; and she noted that the bed side rail remained padded.

k. At 10:30 p.m., LPN McCorkle indicated that she applied a pressure dressing to the right knee due to a small amount of bleeding and she also wrote:
"Tip of bone through skin. Will continue to monitor."

CMS Ex. 5, at 2-4; P. Ex. 33, at 380-83.

- 9. Nurse's Notes for July 26, 2005 show:
 - a. Notes with the time 4:50 a.m. and 11 a.m. indicate presence of blood on the gauze and a small amount of some breakthrough bleeding; the 11 a.m. note also indicates that routine pain medication and comfort measures continued.
 - b. The mobile x-ray arrived at 12:40 p.m. to X-ray Resident 1's right knee and at 2 p.m. the facility received the x-ray report that showed Resident 1 had a comminuted fracture of the right distal femur just above the knee.
 - c. NP Adams was notified of the x-ray report and she provided new orders to consult with an orthopedist for a "splint (immobilizer)." CMS Ex. 5, at 5; P. Ex. 33, at 379.
 - d. An appointment was made for Resident 1 to see Dr. Mason for a splint immobilizer on July 27, 2005 at 10:30 a.m. CMS Ex. 5, at 5; P. Ex. 33, at 379.
 - e. A note timed 10:30 p.m indicates Resident 1 was resting quietly, her dressing was dry and intact with no drainage noted, routine pain medication was given, and no signs or symptoms of pain were noted.

CMS Ex. 5, at 4-5; P. Ex. 33, at 379-80; Tr. 173.

- 10. Nurse's Notes for July 27, 2005, show:
 - a. A note timed 4:55 a.m. indicates that Resident 1 had increased alertness during the night shift and that the dressing on her right knee was dry and intact.
 - b. An 8:00 a.m. note indicates that Resident 1's right knee was bleeding though the dressing and when the dressing was removed there was a purple bruise and bone was exposed; a protective dressing was applied and she was given routine pain medication.
 - c. Resident 1 left the facility at 9:45 a.m. and was transported to the doctor's appointment in the facility van in a geri chair.

d. At 12:00 p.m., the orthopedist's office called the facility and advised that Resident 1 was being transferred to the hospital for femur debridement and open reduction surgery.

CMS Ex. 5, at 5-6; P. Ex. 33, at 378; Tr. 378-79.

11. Dr. Mason's notes and operative report from July 27, 2005, show that Resident 1's fractured right femur had perforated the medial skin and that the resident was reacting to pain from the fracture site.³ P. Exs. 14, 15, and 16.

B. Conclusions of Law

- 1. Petitioner violated 42 C.F.R. § 483.10(b)(11) (Tag F157).
- 2. Petitioner violated 42 C.F.R. § 483.25 (Tag F309).
- 3. Petitioner violated 42 C.F.R. § 483.75 (Tag F490).
- 4. The determination that Petitioner's violation of 42 C.F.R. §§ 483.10(b)(11), 483.25, and 483.75 posed immediate jeopardy was not clearly erroneous.
- 5. Petitioner was not in compliance with program participation requirements from July 25, 2005 through November 12, 2005.
- 6. A \$3050 per day CMP for the period of immediate jeopardy of July 25, 2005 through October 19, 2005 and a \$50 per day CMP for the period of October 20 through November 12, 2005, are reasonable.

³ Resident 1 returned to the facility on July 28, 2005 after the surgery with a splint/immobilizer and ace wrap on the right knee with orders that neither the wrap nor splint were to be loosened or removed by staff; there also was an order for pain medication and IV antibiotic therapy. CMS Ex. 5, at 7; P. Ex. 33, at 377. Nurse's Notes reflect only two instances over the next few days when, despite the immobilizer, Resident 1 moved the leg; otherwise the immobilizer was intact. CMS Ex. 5, at 11, 12; P. Ex. 33, at 374-75. A note dated August 6, 2005, indicates that Resident 1 was very non-compliant with keeping her injured leg straight due to her disease process. CMS Ex. 5, at 18; P. Ex. 33, at 368. After follow-up visits to the orthopedist, Dr. Mason, on August 4 and August 8, 2005, his notes show that he ordered an above the knee amputation of Resident 1's right leg because the femur was still protruding through the skin and he determined that a cast would not be effective to permit healing. CMS Ex. 32, at 11; P. Ex. 20.

C. Issues

The issues in this case are:

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

Whether the remedy imposed is reasonable.

D. Applicable Law

Petitioner is a long-term care facility participating in the federal Medicare program as a SNF and in the state Medicaid program as a NF. The statutory and regulatory requirements for participation by a long-term care facility are found at sections 1819 and 1919 of the Social Security Act (Act) and at 42 C.F.R. Part 483. Sections 1819 and 1919 of the Act vest the Secretary of the Department of Health and Human Services with authority to impose civil money penalties against a long-term care facility for failure to comply substantially with federal participation requirements.

Pursuant to the Act, 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 the Secretary through his regulations at 42 C.F.R. Part 483. Facilities that participate in Medicare may be surveyed on behalf of CMS by state survey agencies in order to determine whether the facilities are complying with federal participation requirements. 42 C.F.R. §§ 488.10-488.28, 488.300-488.335. Pursuant to 42 C.F.R. Part 488, CMS may impose a per instance or per day CMP against a long-term care facility when a state survey agency concludes that the facility is not complying substantially with federal participation requirements. 42 C.F.R. §§ 488.406; 488.408; 488.430. The regulations in 42 C.F.R. Part 488 also give CMS a number of other remedies that can be imposed if a facility is not in compliance with Medicare requirements. Id.

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 CMP, of from \$3050 per day to \$10,000 per day, is reserved for deficiencies that constitute 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). The lower range of CMP, from \$50 per day to \$3000 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). Pursuant to 42 C.F.R. § 488.301, "(*i*)mmediate 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." (emphasis in original).

The Act and regulations make a hearing before an ALJ available to a long-term care facility against which CMS has determined to impose a CMP. Act, section 1128A(c)(2); 42 C.F.R. §§ 488.408(g); 498.3(b)(13). The hearing before an ALJ is a *de novo* proceeding. Anesthesiologists Affiliated, et al, DAB CR65 (1990), aff'd, 941 F.2d 678 (8th Cir. 1991); Emerald Oaks, DAB No. 1800, at 11 (2001); Beechwood Sanitarium, DAB No. 1906 (2004); Cal Turner Extended Care, DAB No. 2030 (2006); The Residence at Salem Woods, DAB No. 2052, (2006). A facility has a right to appeal a "certification of noncompliance leading to an enforcement remedy." 42 C.F.R. § 488.408(g)(1); see also 42 C.F.R. §§ 488.330(e) and 498.3. However, the choice of remedies by CMS 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 found by CMS if a successful challenge would affect the amount of the CMP that could be collected by CMS or impact upon the facility's Nurse Aid Training and Competency Evaluation Programs (NATCEP). 42 C.F.R. §§ 498.3(b)(14) and (d)(10)(i). CMS's determination as to the level of noncompliance "must be upheld unless it is clearly erroneous." 42 C.F.R. § 498.60(c)(2). This includes CMS's finding of immediate jeopardy. Woodstock Care Center, DAB No. 1726, at 9, 38 (2000), aff'd, Woodstock Care Center v. Thompson, 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). Review of a CMP by an ALJ is governed by 42 C.F.R. § 488.438(e).

When a penalty is proposed and appealed, CMS must make a *prima facie* case that the facility has failed to comply substantially with federal participation requirements. "*Prima facie*" means that the evidence is "(s)ufficient to establish a fact or raise a presumption unless disproved or rebutted. *Black's Law Dictionary* 1228 (8th ed. 2004). *See also Hillman Rehabilitation Center*, DAB No. 1611, at 8 (1997), *aff'd Hillman Rehabilitation Center v. U.S. Dept. of Health and Human Services*, No. 98-3789 (GEB) (D.N.J. May 13, 1999). To prevail, a long-term care facility must overcome CMS's showing by a preponderance of the evidence. *Batavia Nursing and Convalescent Center*, DAB No. 1904 (2004); *Batavia Nursing and Convalescent Inn*, DAB No. 1911 (2004) *aff'd*, *Batavia Nursing & Convalescent Ctr. v. Thompson*, No. 04-3687 (6th Cir. Aug. 3, 2005); *Emerald Oaks*, DAB No. 1800 (2001); *Cross Creek Health Care Center*, DAB No. 1665 (1998); *Hillman Rehabilitation Center*, DAB No. 1611.

E. Analysis

1. Petitioner violated 42 C.F.R. §§ 483.10(b)(11) (Tag F157), 483.25 (Tag F309), and 483.75 (Tag F490), and its violation of these participation requirements posed immediate jeopardy.⁴

Based on a single set of facts involving Resident 1, the surveyors concluded and CMS alleges that Petitioner violated 42 C.F.R. §§ 483.10(b)(11) (Tag F157), 483.25 (Tag F309) and 483.75 (Tag F490), and that these violations posed immediate jeopardy. Thus, CMS argues, Petitioner was not in substantial compliance with program participation requirements.

a. Facts.

There is little dispute as to most of the facts. Resident 1 was admitted to Petitioner's facility in January 2002 at the age of 45, with diagnosis of Huntington's chorea, cerebella degeneration, and insomnia. Her Huntington's chorea involved uncontrolled movement of her extremities. P. Ex. 33, at 1-2, 11. By January 2005, Resident 1's cognitive impairment had progressed to the point where she was unable to communicate. Tr. 289; P. Ex 33, at 7-11. Petitioner's clinical records for Resident 1 show that she suffered from seizures as early as May 2004, for which she was prescribed Valium by intramuscular injection.⁵ CMS Ex. 16, at 4; P. Ex. 8, at 4; P. Ex. 9, at 2; P. Ex. 33, at 23, 409, 426. On July 24, 2005, at 5:30 p.m., RN Higgins observed Resident 1 having a seizure that she characterized in her notes as petit mal.⁶ CMS Ex. 5, at 1; P. Ex. 33, at 383. Resident 1

⁵ I do not find a separate diagnosis of a seizure disorder in Petitioner's clinical records. Of course, Resident 1's doctor may have attributed her seizures to her cerebral degeneration, which is a listed diagnosis.

⁴ The surveyors also cited Petitioner for violations of 42 C.F.R. §§ 483.25(m)(1) (Tag F332); 483.65(a) (Tag F441); and 483.75(o)(2)-(4) (Tag F521). The surveyors alleged that each of these deficiencies caused no actual harm but that each had the potential for more than minimal harm without immediate jeopardy. CMS Ex. 3, at 54, 57, 66. In the interest of judicial economy, I elect not to address the merits of these alleged deficiencies. The proposed CMP in this case is \$3050 per day, which is in the range of CMPs that may be imposed only for deficiencies that pose immediate jeopardy. My findings and conclusions in this case are that Petitioner committed three violations that posed immediate jeopardy and those deficiencies are a sufficient basis for the imposition of the enforcement remedy proposed by CMS.

⁶ Petitioner's witness, LPN Lisa Hodges, a facility employee, testified that Resident 1's involuntary movements due to her Huntington's chorea were distinguishable (continued...)

was again noted to have a seizure at 12:45 a.m. on July 25, 2005, and her physician's office was notified and a neurology consult was ordered because the resident's seizure manifested differently than prior seizure activity. Resident 1's physician's office was again contacted at 9:00 a.m. on July 25, 2005, and the nurse practitioner ordered that the neurology consult be cancelled and that Resident 1 be given Dilantin via her feeding tube. CMS Ex. 5, at 2-3; P. Ex. 33, at 381-82. A Nurse's Note entry at 2:35 p.m on July 25, 2005, indicates that Resident 1's family was notified of her seizures, that her medication for seizures had changed, and that a small bruise was noted on her knee that was attributed in the Nurse's Notes to the morning seizure activity. CMS Ex. 5, at 3; P. Ex. 33, at 381. The nurse's note from 12:45 a.m. that records the seizure activity observed about that time (CMS Ex. 5, at 2; P. Ex. 33, at 382) does not mention bruising. The nurse's notes at 12:50 a.m., 9:00 a.m., and 9:40 a.m. on July 25, 2005 (CMS Ex. 5, at 2-3; P. Ex. 33, at 381-82) do not mention a bruise. Significantly, the notes from 12:50 a.m. and 9:40 a.m., which record the nurse's calls to the on-call physician and the nurse practitioner, do not mention that any bruising was observed or reported.

A note at 10:10 p.m. on July 25, 2005, by LPN McCorkle, indicates that she was called to the resident's room by the CNA to examine Resident 1's right knee. She recorded in her note that Resident 1's right knee was swollen and bruised, with bleeding. At 10:15 p.m. a note shows that Resident 1's physician was notified and he ordered an x-ray and to try and keep Resident 1's knee propped-up. The note indicates that the physician wanted the results of the x-ray called to his office and that it was acceptable to get the x-ray in the morning by the mobile x-ray company. The note further indicated that the x-ray provider was called and the appointment made for July 26, 2005. The nurse's note does not state that Dr. Nickerson was advised of the bleeding, bruising or swelling, and there is no order recorded specifically related to treatment for the bleeding. CMS Ex. 5, at 4; P. Ex. 33, at 380. LPN McCorkle testified, however, that she called Dr. Nickerson because the bruise had changed color, there was a small amount of blood, and she could feel the tip of bone through the skin when she ran her hand over the area. She also testified that she could not determine whether the bone was actually protruding through the skin. Tr. 290. A note from 10:30 p.m. records that a pressure dressing was applied to the resident's right knee due to a "small amount of bleeding." The note also states: "Tip of bone through skin. Will continue to monitor." CMS Ex. 5, at 4; P. Ex. 33, at 380. LPN McCorkle testified that after her conversation with Dr. Nickerson she called him again at 10:30 p.m. She testified that the reason she called him a second time was that she thought he might reconsider and send Resident 1 to the hospital; she stated, "it was his call . . . I can't do nothing about an order." Tr. 296; 314. She also testified that she discussed the bone protrusion with Dr. Nickerson, although that too was not included in her notes. Tr. 296. No call at 10:30 p.m. is recorded in the Nurse's Notes on July 25, 2005. CMS Ex. 5, at 4; P. Ex. 33, at 380; Tr. 292, 296. LPN McCorkle prepared a statement dated October 18,

⁶(...continued)

from movements associated with her seizure activity. Tr. 357-63, 370-71.

2007, nearly three months after the incident and during the survey, in which she states a that a small piece of bone was protruding through the skin, that she called Dr. Nickerson a second time to advise him about the bone and that a pressure dressing was applied, and that he told her to continue to monitor and keep the knee propped. CMS Ex. 32, at 311-312. Dr. Nickerson did not appear and testify at hearing.

The next Nurse's Note entry following the entry at 10:30 p.m. on July 25, is timed 4:50 a.m. on July 26, 2005. The note states that the dressing on Resident 1's right knee was intact but blood stained and not saturated. The next entry at 11:00 a.m. indicates that the dressing was intact with some breakthrough bleeding apparent. The resident's right leg was x-rayed sometime after 12:40 p.m. and the results, reported at 2:00 p.m. on July 26, 2005, show that she had a fractured distal femur. Resident 1's physician's office was notified of the x-ray results and she was scheduled to see an orthopedist for a splint/immobilizer on July 27, 2005 at 10:30 a.m.

A note at 8:00 a.m. on July 27, 2005 indicates that there was bleeding through the dressing on the right knee and when the dressing was removed there was a bruise and bone was exposed.⁷ The wound was redressed and Resident 1 was sent to her orthopedic appointment at 9:45 a.m. by facility van. P. Ex. 33, at 378. Subsequently, the orthopedist called the facility and advised that Resident 1 was being transferred to the hospital for femur debridement and open reduction surgery. She returned from the hospital on July 28, 2005 after the surgery with a splint/immobilizer and ace wrap on the right knee that was not to be loosened or removed and an order for pain medication and intravenous antibiotics. The notes reflect two instances over the next few days when, despite the immobilizer on the right leg, Resident 1 moved the leg; otherwise, the immobilizer was intact. P. Ex. 33, at 375, 374. The notes from July 31 through August 4, 2005 do not indicate any problems with her right knee and indicate the immobilizer was in place. She was transported on August 4, 2005 in her geri chair by facility van to the orthopedist's office. She was returned the same day with new orders for antibiotic treatment. P. Ex. 33, at 370. On August 8, 2005, Resident 1's orthopedist ordered that Resident 1 undergo an above the knee amputation of the right leg.⁸ She was transported to the hospital and the amputation was performed August 10, 2005, and she was returned to the facility on August 11, 2005. P. Ex. 33, at 364. Petitioner does not dispute resident broke her leg making contact with the side rail or some other part of the bed. Tr. 45, 50-51.

⁷ LPN Hodges, who changed the dressing on the morning of July 27, 2005, testified that she had been told by the nurse from the previous shift that Resident 1's "bone was showing." Tr. 330.

⁸ The orthopedist determined on the August 8, 2005 revisit that the femur was still protruding through the medial skin and that a cast would not work. He therefore scheduled the resident for an above-the-knee amputation on August 10, 2005. P. Ex. 33, at 69.

b. The facts establish a violation of 42 C.F.R. § 483.10(b)(11).

Section 483.10(b)(11)(i) of 42 C.F.R. entitled, "Resident rights," requires:

(11) Notification of changes. (i) A facility must immediately inform the resident; consult with the resident's physician; and if known, notify the resident's legal respresentative (sic) or an interested family member when there is --

(A) An accident involving the resident which results in injury and has the potential for requiring physician intervention;

(B) A significant change in the resident's physical, mental, or psychosocial status (i.e., a deterioration in health, mental, or psychosocial status in either life-threatening conditions or clinical complications);

(C) A need to alter treatment significantly (i.e., a need to discontinue an existing form of treatment due to adverse consequences, or to commence a new form of treatment); or

(D) A decision to transfer or discharge the resident from the facility as specified in Sec. 483.12(a).

The regulatory requirements are clearly stated, yet they are often misquoted and misconstrued.⁹ Among the resident rights recognized by the regulation is that the facility "**must immediately . . . consult with the resident's physician** . . . when there is a significant change in the resident's physical, mental, or psychosocial status" (meaning a deterioration in the resident's condition). 42 C.F.R. § 483.10(b)(11)(emphasis added). The requirement is not discretionary and it requires more than merely informing or notifying the physician, which is evident from the plain language of the regulation. The drafters chose the language carefully. The regulation is specific that the facility is required to **immediately "inform** the resident; **consult** the physician; and . . . **notify** the legal representative or an interested family member." *Id*. (emphasis added). The preamble to the final rule indicates the drafters' specific intention that the facility should "inform" the resident of the changes that have occurred but should "consult with the physician about actions that are needed." 56 Fed. Reg. 48,826, at 48,833 (Sept. 26, 1991). Thus, it is clear from the language of the regulation and its history that the

⁹ Petitioner incorrectly quotes the language of 42 C.F.R. § 483.10(b)(11) as stating that a facility must "inform the resident's physician" rather than quoting the actual language of the regulation that the facility must "consult with the resident's physician." P. Brief at 6.

requirement of the regulation to consult means more than to simply notify. Consultation requires a dialogue with and a responsive directive from the resident's physician as to what actions are needed; it is not enough to merely notify the physician of the resident's change in condition. Nor is it enough to leave just a message for the physician. Also, the facility must provide the physician with all the information necessary to properly assess any changes to the resident's condition and what course of action is necessary. Failure to provide even one aspect of the change in a resident's condition can significantly impact whether the physician has been properly consulted.

The regulation also requires consultation "immediately" upon discernment of a change in condition of the resident. The use of the term "immediately" in the regulatory requirement indicates that consultation is expected to be done as soon as the change is detected, without any intervening interval of time. It does not mean that the facility can wait hours or days before consulting with the physician. The preamble to the final rule indicates that originally the proposed rule granted the facility up to 24 hours in which to notify the resident's physician and the legal representative or family. However, after the receipt of comments that time is of the essence in such circumstances, the final rule amended that provision to require that the physician and legal representative or family be consulted/notified immediately. 56 Fed. Reg. 48,826, 48,833 (Sept. 26, 1991). The point of using the word "immediately" was the recognition that in such situations a delay could result in a situation where a resident is beyond recovery or dies. Furthermore, when we balance the relative inconvenience to a physician and the facility staff to consult about a resident's change in condition with the possibility for dire consequences to the resident if the physician is not consulted, it seems that any inconvenience certainly is inconsequential and outweighed by the potential for significant harm if the facility fails to consult the physician.¹⁰ This regulatory requirement is included in the regulation entitled "Resident rights" and the requirements of this specific regulation provide that every resident has the right to a dignified existence and access to and communication with persons and services inside and outside the facility. Therefore, the regulatory requirements make inconsequential any inconvenience under the regulation to the resident's physician or to the facility staff when compared to the protection and facilitation of the rights of the resident. See 56 Fed. Reg. 48,826, at 48,834 (Sept, 26, 1991).

Furthermore, the regulation does not allow the facility to pick and choose whom to notify and whom to consult. Rather, it requires the facility to immediately inform the resident, consult the physician **and** notify the resident's legal representative or interested family member.

¹⁰ It is better to err on the side of consulting a physician regarding a change in a resident's condition rather than not or debating about whether the change is significant, particularly since nursing home staff may not be qualified or competent to identify the significance of signs and symptoms.

The surveyors allege in the SOD that Petitioner violated 42 C.F.R. § 483.10(b)(11) because: (1) Resident 1's physician was not immediately notified of the need to use a pressure dressing for bleeding and that the bone was protruding through the skin at Resident 1's right knee, which posed immediate jeopardy; and (2) Petitioner failed to notify the family of the seizure activity and right knee injury until the day after the incident.¹¹ CMS Ex. 3, at 2.

Based upon the evidence presented by CMS, I have no difficulty concluding that CMS has made a prima facie showing of a violation of 42 C.F.R. § 483.10(b)(11). Resident 1 experienced a seizure that her care giver believed was different from past seizures, indicating possible need to commence a new form of treatment. Petitioner's nurse did consult with the on-call physician who ordered a neurology consult and the nurse practitioner who cancelled the order for a neurology consult and ordered that dilantin be administered. Thus, Petitioner's staff did consult with the physician or the physician's nurse practitioner regarding the seizure activity. However, CMS presented Petitioner's clinical records for Resident 1, and those records do not show that a physician was immediately consulted regarding the bleeding at the right knee of such volume that a pressure dressing was required or that nursing staff could feel the tip of Resident 1's broken right femur pressing against the skin or protruding through the skin. The bruising to the right knee, the bleeding at the right knee, and the protruding bone, whether just pressing under the skin or actually protruding through the skin, were obvious signs that Resident 1 had experienced a displaced fracture of her right femur. The occurrence of the fracture is evidence of an accident, a significant change, or a need to alter treatment, the three triggers for consultation specified in 42 C.F.R. § 483.10(b)(11). The evidence related to the incident offered by CMS, Petitioner's clinical records for Resident 1, do not show that consultation occurred.

Regarding notification of the family, Petitioner does not dispute that the family was not notified regarding the seizure activity, the orders of the on-call physician, the orders of the nurse practitioner, and the signs of a displaced and open fracture until 2:35 p.m. on

¹¹ Petitioner was not cited by the surveyors for failure to properly assess and care plan for Resident 1 to reduce her risk of injury and such a charge is not before me. Also not before me, is any charge that Petitioner failed to adequately assess, care plan, or implement interventions for Resident 1's Huntington's chorea or her seizures. Tr. 37-63.

July 25, 2005.¹² Thus, Petitioner did not contact the family immediately and a violation has been established.¹³

I have reviewed the exhibits and the testimony and conclude that Petitioner has failed to show that it was in substantial compliance with 42 C.F.R. § 483.10(b)(11) or that it has some affirmative defense that would excuse its violation.

The evidence is undisputed that at 2:35 p.m. on July 25, 2005, Resident 1's mother was advised by Petitioner's staff that her daughter had a seizure and had a bruise on her right knee that was attributed to seizure activity just after midnight that morning. The existence of the bruise is not recorded earlier in the Nurse's Notes but must have been observed sometime between the seizure activity around 12:45 a.m. and the call to the mother. Approximately eight hours later at 10:10 p.m. on July 25, 2005, a Nurse's Note signed by LPN McCorkle indicates that Resident 1's right knee was bruised, swollen, and bleeding. At 10:15 p.m., Dr. Nickerson was called and he gave orders to get an x-ray the next day and to keep the right knee propped-up. The note does not show what specifically Dr. Nickerson was told. LPN McCorkle made the next Nurse's Note entry at 10:30 p.m., 15 minutes after her entry regarding her conversation with Dr. Nickerson. Her 10:30 p.m. entry indicates that she applied a pressure dressing and that she could feel the tip of bone through the skin. Petitioner's clinical records do not show that after feeling the tip of bone LPN McCorkle called Dr. Nickerson to let him know about the bleeding and the bone and to see if he wanted to change his orders.

LPN McCorkle did prepare a written statement dated October 18, 2005 (CMS Ex. 32), during the period of the survey, which was October 17 through 20, 2005. Jt. Stip. ¶ 4. LPN McCorkle states in her written statement that she was called to Resident 1's room where she observed bright red blood on the pad and skin of Resident 1's right knee; swelling of the right knee; and a quarter-size red bruise on the right knee. She also observed a small protruding bone but no skin break that she could find. She wrote that she called the hospital and was connected with Dr. Nickerson who she told about the blood, but no active bleeding; swelling; and protruding bone, but no skin break. She wrote that

¹² The surveyors do not allege that the failure to notify the family immediately posed immediate jeopardy as they did regarding the failure to consult with the physician. Nevertheless, Resident 1 was unable to communicate or, presumably, to participate in medical decision-making with her physician or the physician's extender. Thus, the importance of immediate notification should not be minimized.

¹³ Petitioner argues regarding notification of the family that there was no significant change that required notification until approximately 2:30 p.m. on July 25, 2005, and that the family was notified at that time. P. Brief at 6-7. I conclude that this argument is without merit as I conclude that the significant change was apparent in the early morning of July 25, 2005, based upon the facts discussed herein.

the doctor ordered x-rays to be done the next day and to keep the right knee propped-up. She states in her written statement that she was later called back to Resident 1's room by the CNA and she observed a small piece of bone protruding through the skin; she applied a dressing and a pressure wrap; and then called the physician again to make him aware of the bone protruding through the skin and that she applied a pressure dressing; and the doctor told her to monitor and keep the knee propped-up. CMS Ex. 32. LPN McCorkle testified consistently with her written statement. Tr. 273-80; 302-11. She testified that she called Dr. Nickerson a second time because she thought he might change his order and send Resident 1 to the hospital. Tr. 315-16. She testified that she thought the blood may have come from a skin tear, but she searched and could not find one. Tr. 302. However, she also testified that she assumed the bone must have broken through the skin because the blood had to be coming from somewhere but she could not find an open wound. Tr. 281-82. She testified that when she felt the piece of bone, she thought the bone might be out of place but she did not think about it being broken. Tr. 306-07.

Petitioner relies upon the statement and testimony of LPN McCorkle to establish Dr. Nickerson was consulted and to shift the blame for inaction to him. However, I do not find the testimony of LPN McCorkle or her recollection of events credible compared with the contemporaneous records related to the events. As a nurse, LPN McCorkle surely could recognize that feeling the tip of a bone through the skin is not normal but rather a good sign that the femur was broken and displaced. In response to questions from Petitioner's attorney, she testified that she thought the bone had broken through skin and was the source of the blood on Resident 1's incontinence pad, which provoked her to call Dr. Nickerson a second time. However, in response to my questions, she indicated she thought the blood might have come from a skin tear and that she thought the femur, the largest bone in the human body, was simply displaced but not broken, despite the fact she thought the bone she could feel was approximately the size of a pencil eraser. It strains credibility to believe that LPN McCorkle found blood in the area, understood she needed to apply a pressure dressing rather than a band-aid, but did not realize that that most likely indicted that the tip of bone she felt had punctured the skin. Upon learning this information, Dr. Nickerson likely would have changed his order to wait for an x-ray or to attempt to elevate the right knee, which certainly sounds painful if not completely contraindicated. Furthermore, LPN McCorkle admitted on cross-examination that a fracture with bone protruding through the skin is a significant change of status, an emergency situation which required immediate treatment, and that there was a risk of infection due to the open wound. Tr. 288-89. Perhaps most surprising and troubling was her testimony in response to my questioning that she could have sent Resident 1 to the hospital without an order from Dr. Nickerson, but she did not think it was warranted. Tr. 316. If I accept this testimony as true, then its not likely that she called Dr. Nickerson a second time believing he would change his mind and order Resident 1 to the hospital. Considering Petitioner's clinical records and the inconsistencies, I conclude it not credible that LPN McCorkle contacted Dr. Nickerson a second time or that she ever made clear to him the obvious signs of an open fracture of Resident 1's right femur. I find her testimony not credible to establish that she consulted with Dr. Nickerson about the best plan for emergent care.

Petitioner argues that on July 27, 2005, the physician and nurse practitioner signed the incident report prepared by the Director of Nursing (DON) on July 26, 2005. P. Brief at 13. Petitioner argues that by signing the report, they indicated their agreement with the representation in the report that LPN McCorkle notified them of the possible protruding bone. This argument has no merit. Assuming the doctor or nurse practitioner read the report before signing, the report is neither clear nor accurate. The report indicates that the incident occurred July 26, 2005, at 2:00 p.m. P. Ex. 28, at 1, 2, 3. The report indicates that NP Adams was called at 2:00 p.m. on July 26, 2005 and that Resident 1's mother was contacted at 2:15 p.m. on July 26, 2005. P. Ex. 28, at 1. Hand-written entries under the section "Final Disposition" on the first page of the report state that family and the on-duty physician were notified of swelling and potential small bone protrusion, but does not state specifically when the notices occurred. P. Ex. 28, at 1. Under the description of the event, there is no mention of any bone protruding. P. Ex. 28, at 1. There is a hand-written note on the third page of the report that refers to July 25, 2005, 10:10 p.m., LPN McCorkle reported the right knee was swollen, with bruising, possible small splinter of bone showing, and that the "M.D." was made aware. P. Ex. 28, at 3. However, neither Dr. Nickerson nor NP Adams signed this page of the report or otherwise acknowledge that LPN McCorkle consulted with them about the possibility of an open fracture.

Furthermore, Petitioner's admission that the DON, the physician's Nurse Practitioner, and the Administrator were all aware that Resident 1's fractured femur was protruding through the skin as of 2:00 p.m. on July 26, 2005, supports the CMS position that Petitioner was in violation of its duty to consult the physician and to deliver necessary care and services. Given the admitted risk for infection, when the DON learned of the possible bone protrusion, the DON should have made sure Resident 1 was sent to the hospital instead of waiting another day for her to be taken to the orthopedist's office by facility van, as if Resident 1 was going to an ordinary doctor's appointment. Even absent a protruding bone, I question why Resident 1 was not transported to the hospital immediately upon receipt of the x-ray report at 2:00 p.m. on July 26, 2005, that showed fracture of the femur. Clearly, the facility staff were not in a position to treat the fracture and should have taken immediate action to make sure Resident 1 was seen by someone who could provide necessary treatment. This is all the more troublesome considering Resident 1's inability to communicate, particularly that she was in pain, and to make her needs known. In such circumstances the facility has even a greater duty to make sure the resident's needs and rights are met and protected. Petitioner's clinical records show that between 12:45 a.m on July 25, 2005 and when she was sent to be seen by Dr. Mason at 9:45 a.m. on July 27, 2005, Resident 1 showed no signs of pain and received her routine dose of Loritab, a pain medication. CMS Ex. 5, at 2-6. Staff's assessment of Resident 1's pain is questionable however, given the seriousness of the fracture, her inability to communicate, and the fact

that Dr. Mason reported that the resident showed signs of pain in her right leg. P. Ex. 15, at 2.

Accordingly, I conclude that Petitioner violated 42 C.F.R. § 483.10(b)(11).

c. The facts establish a violation of 42 C.F.R. § 483.25.

The general quality of care regulation, 42 C.F.R. § 483.25, requires that each resident receive, and the participating facility must provide, the necessary care and services to attain or maintain a resident's highest practicable physical, mental, and psychosocial well-being, in accordance with the resident's comprehensive assessment and plan of care.

The facts already discussed regarding Resident 1 also show that Petitioner was in violation of 42 C.F.R. § 483.25. Resident 1 did not receive, because the facility did not provide, the necessary care and services for Resident 1 to attain or maintain her highest practicable physical, mental, and psychosocial well-being, in accordance with her comprehensive assessment and plan of care.

The facts show that sometime, perhaps as early as 12:45 a.m. on July 25, 2005, Resident 1 broke her right femur above the knee. Either immediately, or perhaps during the morning or afternoon of July 25, 2005, the fracture of the femur became separated or displaced. The tip of the displaced bone subsequently punctured the skin above the knee, with evident bruising and bleeding. A CNA noticed the bruising and bleeding in the late evening on July 25, 2005, just about the time of the rush of the evening shift change. The CNA called for LPN McCorkle who observed the bruising and blood and called Dr. Nickerson, Resident 1's physician and the facility Medical Director. What LPN McCorkle told Dr. Nickerson was disputed by the parties and whether she called him once or twice was also disputed; however, as discussed above, I have resolved that dispute. It is not disputed that the order LPN McCorkle received was to have Resident 1's leg x-rayed the next day and to keep the knee elevated. LPN McCorkle did not believe that Resident 1's condition warranted sending her to the emergency room, although she admitted she could have. Tr. 316. Rather, she busied herself getting ready for the shift change with her relief nurse so she could go home. Tr. 308-10.

The bottom-line on this deficiency is that Resident 1 was not seen by any physician, let alone the orthopedist, until the early afternoon of July 27, 2005, some 38 hours after the bone was first noted to be protruding. Upon examination of Resident 1's leg, the orthopedist immediately had her transferred to the hospital for surgery to attempt to treat the fracture. I have no difficulty finding that these facts show that Petitioner failed to deliver necessary care and services to Resident 1 in violation of 42 C.F.R. § 483.25. The fact that Petitioner did not determine it was necessary to obtain emergency treatment more promptly is no defense and is, in fact, indefensible.

d. The facts establish a violation of 42 C.F.R. § 483.75.

The Secretary also requires by regulation that participating facilities be "administered in a manner that enables it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental and psychosocial well-being of each resident." 42 C.F.R. § 483.75 (Tag F490).

The surveyors allege that Petitioner violated this regulation because Petitioner failed to ensure systems were in place to provide optimal care and services for each resident, as evidenced by Petitioner's failure to consult with Resident 1's physician and family and to provide necessary care and services for Resident 1. CMS Ex. 3, at 60. The surveyors' charge of violation of 42 C.F.R. § 483.75, is derivative of the violations of 42 C.F.R. §§ 483.10(b)(11) and 483.25, already discussed. Appellate panels of the Departmental Appeals Board (the Board) have approved derivative deficiencies cited under 42 C.F.R. § 483.75, in prior cases. *See Cross Creek Health Care Center*, DAB No. 1665 (1998); *Asbury Center at Johnson City*, DAB No. 1815 (2002); and *Eastwood Convalescent Center*, DAB No. 2088 (2007).

Petitioner argues that "[o]ne alleged failure to care for one resident in one instance, even if proven, does not establish that a facility lacked an appropriate system." P. Brief at 18. Petitioner points out that it had policies in place, standing orders were on record and used, Resident 1 was monitored, there were repeated communications with the physician or physician's extender, orders given were implemented, and an incident report was completed. P. Brief at 18-19. Petitioner misses the point that despite its policies, the standing orders, communication, implementation of orders, and the incident report, Resident 1 had a displaced fracture of the right femur which punctured the skin from July 25 to July 27, 2005, that was not properly treated. Petitioner's systems, even if in place, were not effective to prevent the violations I have already discussed. I conclude that Petitioner was not administered in a manner so that its resources were used effectively to help Resident 1 attain her highest practicable physical, mental and psychosocial wellbeing. Accordingly, Petitioner violated 42 C.F.R. § 483.75.

e. CMS's determination that the violations of 42 C.F.R. §§ 483.10(b(11) (Tag F157), 483.25 (Tag F309), and 483.75 (Tag F490) posed immediate jeopardy to its residents was not clearly erroneous.

The surveyors allege in the SOD under Tags F157, F309, and F490, that immediate jeopardy began on July 25, 2005, that the immediate jeopardy was identified by the surveyors on October 18, 2005, that Petitioner's Administrator was notified of the immediate jeopardy on October 18, 2005, and that the immediate jeopardy was removed on October 20, 2005, when Petitioner put in place "a plan of correction to ensure that the

physician would be notified of acute episodes in timely manner."¹⁴ CMS Ex. 3, at 2, 30, 60-61.

The issue is whether the immediate jeopardy finding was "clearly erroneous." Immediate jeopardy exists if the facility's noncompliance 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 a facility's noncompliance – which includes its immediate jeopardy finding – must be upheld unless it is "clearly erroneous." 42 C.F.R. § 498.60(c). The Board has observed repeatedly that the "clearly erroneous" standard imposes on facilities a "heavy burden" to show no immediate jeopardy, and has sustained determinations of immediate jeopardy where CMS presented evidence "from which '[o]ne could reasonably conclude' that immediate jeopardy exists." *Barbourville Nursing Home*, DAB No. 1962, at 11 (2005); *Florence Park Care Center*, DAB No. 1931, at 27-28 (2004), *citing Koester Pavilion*, DAB No. 1750 (2000). Here, the facility has not satisfied its burden.

The facts related to Resident 1's injury, and the facility's response are a sufficient basis for the immediate jeopardy finding. The significant delay in initiating necessary treatment of the displaced and open femur fracture is unquestionably likely to cause serious injury including pain, harm, or death, and justifies the immediate jeopardy determination. The open fracture posed a high risk for infection of the wound or the bone. Tr. 288-89. Further, while facility staff did not recognize signs of pain from Resident 1, Dr. Mason did. P. Ex. 15, at 2.

Petitioner failed to consult with Resident 1's physician and to inform Resident 1's family timely of the accident, so that they could participate knowingly in her care. Petitioner then failed to obtain prompt and appropriate emergency treatment for Resident 1. Nursing staff should have recognized that bone had broken the skin, that any protrusion of a bone through the skin should be considered an emergency situation, and that any fracture of a bone for that matter is an emergency, particularly in a resident such as Resident 1. Petitioner's staff was, nevertheless, unable to initiate the appropriate response to Resident 1's condition. Staff may have been more concerned with a shift change than with ensuring Resident 1 was appropriately diagnosed and treated. Even after learning on July 26, 2005 at 2:00 p.m. that x-rays confirmed a fracture of the femur, Petitioner still took no action to treat Resident 1's situation as an emergency. The failure to consult and to respond with appropriate care placed the resident at risk of serious harm. The fact that Petitioner's staff failed to act appropriately in Resident 1's case, permits the inference that staff would similarly fail to address emergencies involving other residents. The gist of Petitioner's

¹⁴ The surveyors note that, while immediate jeopardy was removed on October 20, 2005, Petitioner continued out of compliance at a lower scope and severity of D (no actual harm but the potential for more than minimal harm) until the ability to maintain compliance with certain corrections was demonstrated. CMS Ex. 3, at 2, 30.

argument is that the CMS finding of immediate jeopardy was clearly erroneous because no deficiencies were shown by CMS, there was no risk for infection, and Petitioner did not cause amputation of Resident 1's right leg.¹⁵ P. Reply at 1-5. I have already discussed in detail that deficiencies did exist. Petitioner's own staff recognized that an open wound did pose the risk for infection.

I conclude that Petitioner has not shown that the CMS determination that the facility's deficiencies posed immediate jeopardy to resident health and safety was clearly erroneous.

f. Petitioner has failed to show that immediate jeopardy was abated before October 20, 2005, or that it returned to substantial compliance before November 12, 2005.

Petitioner's principal defense is that no violations occurred and Petitioner presented no credible evidence that either the immediate jeopardy was abated before October 20, 2005 or that it returned to substantial compliance before November 12, 2005.

Until the state surveyors came into the facility for its survey on October 17, 2005 and informed the Administrator concerning the significant failures with respect to Petitioner's care of Resident 1, Petitioner's staff was completely unaware that it was deficient with respect to Resident 1. Only after Petitioner was notified of the immediate jeopardy situation on October 18, 2005 by the surveyors, and Petitioner's development and institution on October 20, 2005 of a plan of correction that would ensure proper consultation with physicians and proper institution of policies with respect to acute episodes requiring emergency hospitalization, was the immediate jeopardy abated.

Moreover, substantial compliance means not only that the specific cited instances of substandard care are corrected and that no other instances occur, but also, that the facility has implemented a plan of correction designed to assure that no such incidents occur in the future. The burden is on the *facility* to prove that it has resumed complying with program requirements, not on CMS to prove that deficiencies continued to exist after they were discovered. *Asbury Center at Johnson City*, DAB No. 1815, at 19-20 (2002). Petitioner has not made a showing that it returned to substantial compliance prior to November 13, 2005.

¹⁵ I do not attribute the amputation to action or inaction of Petitioner. I do not consider the amputation in assessing the reasonableness of the CMP.

2. A \$3050 per day CMP for the period of immediate jeopardy from July 25 through October 19, 2005 and a \$50 per day CMP for the period of October 20 through November 12, 2005, are reasonable.

If a facility is not in substantial compliance with program requirements, CMS has the authority to impose one or more of the enforcement remedies listed in 42 C.F.R. § 488.406, including a CMP. CMS may impose a CMP for the number of days that the facility is not in compliance or for each instance that a facility is not in substantial compliance. 42 C.F.R. § 488.430(a). There are two ranges for per day CMPs. 42 C.F.R. § 488.408, 488.438. The upper range of CMP, \$3050 per day to \$10,000 per day, is reserved for deficiencies that constitute 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). The lower range of CMP, \$50 per day to \$3000 per day, is reserved for deficiencies that on a 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)(i).

In this case, CMS proposes a CMP of \$3050 per day based upon the deficiencies that posed immediate jeopardy for the period immediate jeopardy existed, and a \$50 per day CMP for the period after the immediate jeopardy was abated but until Petitioner returned to substantial compliance effective November 13, 2005. I have already discussed my conclusion that Petitioner failed to show clearly erroneous the CMS determination that immediate jeopardy was present from July 25 through October 19, 2005. I have also concluded that Petitioner failed to show it returned to substantial compliance prior to November 13, 2005.

Pursuant to 42 C.F.R. § 488.438(e), because I have found there is a basis for imposition of a CMP, my authority on review of the reasonableness of the CMP is limited: (1) I may not set the penalty at or reduce it to zero; (2) I may not review the CMS or state decision to use a CMP as an enforcement remedy; and (3) I may only consider the factors specified at 42 C.F.R. § 488.438(f). In determining whether the amount of the CMP is reasonable, the following factors specified at 42 C.F.R. § 488.438(f) must be considered: (1) the facility's history of non-compliance, including repeated deficiencies; (2) the facility's financial condition; (3) the seriousness of the deficiencies as set forth at 42 C.F.R. § 488.404; and (4) the facility's degree of culpability.

CMS proposes a CMP of \$3050 per day for the period during which the three deficiencies posed immediate jeopardy, July 25 through October 19, 2005. The \$3050 is the lowest end of the range of per day CMPs that may be imposed by CMS for a deficiency that poses immediate jeopardy. CMS proposes a CMP of \$50 per day for the period that began after immediate jeopardy was abated and continued until Petitioner returned to substantial compliance with program participation requirements, October 20 through November 12, 2005. The \$50 per day CMP is the lowest end of the range for deficiencies that do not

pose immediate jeopardy. I have no evidence of a prior history of noncompliance to consider. Petitioner argues that the proposed CMP would have "a significant negative impact on the facility and limit funds available for patient care." P. Brief at 24. Petitioner presented financial data for my consideration. P. Ex. 34. Petitioner does not assert and I do not find upon review of the financial data submitted that Petitioner is unable to pay the proposed total CMP of \$266,550.¹⁶ I do recognize that large CMPs may impact a facility's financial stability, but presumably both Congress and the Secretary also recognized this fact when authorizing the imposition of large CMPs to encourage facilities such as Petitioner to deliver quality care to long-term care facility residents. The deficiencies in this case are certainly serious and Petitioner was culpable, based upon the facts already discussed in detail.

I conclude that the proposed remedies are reasonable.

III. Conclusion

For the foregoing reasons, I conclude that Petitioner was not in substantial compliance with program participation requirements and that three deficiencies posed immediate jeopardy to its residents. The CMPs of \$3050 per day during the period July 25 through October 19, 2005 and \$50 per day for the period October 20 through November 12, 2005 are reasonable.

/s/

Keith W. Sickendick Administrative Law Judge

¹⁶ There are 87 days of immediate jeopardy from July 25 through October 19, 2005, and 24 days of noncompliance without immediate jeopardy from October 20 through November 12, 2005. My calculation of the total amount of the CMP is: (3050×87) + (50×24) = 266,550.