Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

Troy Health & Rehabilitation Center
(CCN: 01-5213),

Petitioner

v.

Centers for Medicare and Medicaid Services.

Docket No. C-08-615

Decision No. CR2209

Date: August 11, 2010

DECISION

I conclude that Petitioner, Troy Health & Rehabilitation Center, substantially complied with the Medicare participation requirement governing quality of care under 42 C.F.R. § 483.25. Petitioner did not manifest any immediate jeopardy level failures to comply with this participation requirement. Therefore, the Centers for Medicare and Medicaid Services (CMS) had no basis for imposing a per instance civil money penalty (CMP) of $6,000 against Petitioner.

I. Background

Petitioner is a long-term care facility located in Troy, Alabama. Petitioner is authorized to participate in the federal Medicare program as a skilled nursing facility (SNF) and in the Medicaid program as a nursing facility (NF). Transcript (Tr.) at 101. From April 30, 2008 to May 3, 2008, the Alabama Department of Public Health, Division of Health Care Facilities (state survey agency) conducted a complaint survey of the facility. The state survey agency determined that Petitioner was not in substantial compliance with the Medicare participation requirement found at 42 C.F.R. § 483.25 (Tag F309) and cited the alleged deficiency at the immediate jeopardy scope and severity level.

By letter dated May 14, 2008, the state survey agency notified Petitioner of the survey results. P. Exhibit (Ex.) 2. The state survey agency informed Petitioner that it was found not in substantial compliance with participation requirements and that past noncompliance immediate jeopardy was found to exist. The state survey agency advised Petitioner that it was recommending that CMS impose a per instance CMP of $5,000.

In a notice letter dated May 21, 2008, CMS advised Petitioner that, based on the findings of the May 3, 2008 complaint survey, it was imposing a per instance CMP of $6,000 for Tag F309, and loss of approval of a nurse aide training and competency evaluation program. P. Ex. 3. CMS noted that Petitioner was currently in substantial compliance.

In a letter dated July 15, 2008, Petitioner timely requested a hearing.

I conducted an in-person hearing in Montgomery, Alabama, on September 29-30, 2009. CMS offered exhibits (CMS Exs.) 1 through 19, and Petitioner offered P. Exs. 1 through 42. I admitted all of the exhibits into evidence. Tr. at 8, 9. CMS elicited testimony from Sammy Bean, a state agency surveyor. Petitioner elicited testimony from: James Warren Kelly, Petitioner's Administrator; Patty Herndon, Petitioner's Director of Nursing; Margarette Calhoun, RN supervisor at Petitioner's facility; Catherine Ward, a licensed practical nurse (LPN) at Petitioner's facility; Luvonne Jones, a certified nurse aide (CNA) at Petitioner's facility; Wanda Mote, an LPN at Petitioner's facility; Richard Duszak, Jr., M.D.; and Satinderjit Rick Gill, M.D.

Each party submitted a post-hearing brief (CMS Brief and P. Brief, respectively). Petitioner submitted a post-hearing reply brief. By letter dated March 26, 2010, CMS advised that it opted not to file a post-hearing reply brief. Each party received a copy of the hearing transcript.

II. Issues

The issues before me are:

(1) whether the facility was in substantial compliance with 42 C.F.R. § 483.25 at the time of the May 3, 2008 survey; and

(2) if the facility was not in substantial compliance, whether the penalty imposed, a $6,000 per instance CMP, was reasonable.

III. Applicable Law and Regulations

Petitioner is considered a long-term care facility under the Social Security Act (Act) and regulations promulgated by the Secretary of Health and Human Services (Secretary). The statutory requirements for a long-term care facility's participation are found at sections 1819 and 1919 of the Act and at 42 C.F.R. Part 483. Sections 1819 and 1919 of the Act vest the Secretary with authority to impose CMPs, and other remedies, against a long-term care facility for failure to comply substantially with participation requirements.

Pursuant to the Act, the Secretary has delegated to CMS the authority to impose various remedies against a long-term care facility that is not complying substantially with federal participation requirements. Facilities that participate in Medicare may be surveyed on behalf of CMS by State survey agencies to ascertain whether the facilities are complying with participation requirements. 42 C.F.R. §§ 488.10-488.28; 42 C.F.R. §§ 488.300-488.335. Under Part 488, CMS may impose a per instance or per day CMP against a long-term care facility when a State survey agency ascertains that the facility is not complying substantially with 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.

Pursuant to 42 C.F.R. Part 488, CMS may terminate a long-term care facility's provider agreement when a survey agency concludes that the facility is not complying substantially with federal participation requirements. CMS may also impose a number of alternative enforcement remedies in lieu of or in addition to termination. 42 C.F.R. §§ 488.406, 488.408, 488.430. In addition to termination and the alternative remedies CMS is authorized to impose, pursuant to section 1819(h)(2)(D) of the Act and 42 C.F.R. § 488.417(b), CMS must impose the "mandatory" or "statutory" denial of payment for new admissions (DPNA). Section 1819(h)(2)(D) requires the Secretary to deny Medicare payments for all new admissions to a SNF, beginning 3 months after the date on which such facility is determined not to be in substantial compliance with program participation requirements. The Secretary has codified this requirement at 42 C.F.R. § 488.417(b).

The regulations specify that a CMP imposed against a facility can be either a per day CMP for each day the facility is not in substantial compliance or a per instance CMP for each instance that a facility is not in substantial compliance. 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 broad ranges of penalties. 42 C.F.R. §§ 488.408, 488.438. The upper range of CMP, from $3,050 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 $3,000 per day, is reserved for deficiencies that do not constitute

immediate jeopardy, but either cause actual harm to residents or cause no actual harm, but have the potential for causing more than minimal harm. 42 C.F.R. § 488.438(a)(1)(ii). Only a single range of $1,000 to $10,000 exists for a per instance CMP, which applies whether or not immediate jeopardy is present. 42 C.F.R. §§ 488.408(d)(1)(iv), 488.438(a)(2).

The regulations define the term "substantial compliance" to mean "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. Noncompliance that is immediate jeopardy is defined as "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." *Id.* The Act and regulations make a hearing before an administrative law judge (ALJ) available to a long-term care facility against whom 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*, 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." *See* 42 C.F.R. § 488.408(g)(1); *see also* 42 C.F.R. §§ 488.330(e), 498.3. However, CMS's choice of remedies, or the factors CMS considered when choosing remedies, are not subject to review. 42 C.F.R. § 488.408(g)(2). A facility may only challenge the scope and severity level of noncompliance that CMS found, if a successful challenge would affect the amount of the CMP that CMS could collect or impact upon the facility's nurse aide training program. 42 C.F.R. § 498.3(b)(14)(i), (ii). 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 Ctr.*, DAB No. 1726, at 9, 38 (2000), *aff'd, Woodstock Care Ctr. v. U.S. Dep't. of Health & Human Servs.*, 363 F.3d 583 (6th Cir. 2003). The Departmental Appeals Board (the Board or DAB) 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 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).

In a CMP case, CMS must make a prima facie case that the facility has failed to comply substantially with participation requirements. To prevail, a long-term care facility must overcome CMS's showing by a preponderance of the evidence. *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 Discussion

I make one finding of fact and conclusion of law to support this decision. I set it forth below as a separate heading in bold type and then discuss it in detail.

The preponderance of the evidence establishes that Petitioner was complying substantially with the requirements of 42 C.F.R. § 483.25 (Quality of Care, Tag F309).

The regulation at 42 C.F.R. § 483.25 requires that "[e]ach resident must receive and the facility must provide the necessary care and services to attain or maintain the highest practicable physical, mental, and psychosocial well-being, in accordance with the comprehensive assessment and plan of care."

CMS's allegations of noncompliance with 42 C.F.R. § 483.25 pertain to the care provided to Resident 1 (R1). With respect to this citation, the Statement of Deficiencies (SOD) alleges that, based on interviews, medical record reviews, and the facility's policy and procedure for "Gastric Tube Insertion" dated June 1, 2004, Petitioner's nurse identified as RN #1 "failed to verify correct placement of a Gastrostomy tube (G-tube) after re-inserting the G-tube on [R1] on the morning of 2/9/08. Also, RN #1 failed to document the procedure (G-tube re-insertion) in [R1's] medical [sic] according to the facility's policy." The SOD alleges also that "the Staff Development Coordinator failed to provide RNs employed by the facility educational training on proper G-Tube re-insertions with demonstrated skill competency prior to allowing the RNs to re-insert G-Tubes in the facility." CMS Ex. 1, at 1-2; P. Ex. 1, at 1-2. Additionally, besides alleging that Petitioner failed to properly insert R1's G-tube and verify its placement, as well as failed to document this, CMS alleges in its post-hearing brief that Petitioner's noncompliance necessitated surgical intervention to remove dead tissue (referred to as necrotizing fasciitis) that developed as a result of the improper tube placement, placing R1 in immediate jeopardy of physical harm.[1] CMS Brief at 9, 11.

With respect to the incident that occurred on February 9, 2008, the SOD states that "[a]ccording to the facility, the off-going shift [certified nursing assistant (CNA)] #2 observed [that R1's] G-tube [was] in place around 5:00 a.m. on 2/9/08." Around 7:15 a.m., CNA #1 found R1's G-tube dislodged and lying in her bed. Following this discovery, RN #1 re-inserted R1's G-tube. The SOD alleges that RN #1 admitted that she failed to verify the correct placement of the G-tube, after she re-inserted it, and failed to document the re-insertion of the G-tube. CMS Ex. 1, at 2; P Ex. 1, at 2.

According to the SOD, three days later, on February 12, 2008, R1 complained of abdominal pain and was transferred to a local hospital emergency room. The SOD alleges that x-rays of her abdomen confirmed that the G-tube was in the subcutaneous tissue of the abdomen and was not correctly placed in her stomach. CMS Ex. 1, at 2; P. Ex. 1, at 2. The SOD alleges that Petitioner's deficient practice posed an immediate threat to the health and safety of R1. CMS Ex. 1, at 2; P. Ex. 1, at 2.

[1] According to Dr. Duszak, necrotizing fasciitis is a severe infection of the tissue. Tr. at 214-15.

R1, an 87-year old female at the time of the survey, was first admitted to Petitioner's facility on October 14, 2003, and was readmitted on November 8, 2007. P. Ex. 5, at 1; CMS Ex. 9, at 1, 26, 28. As stated in the SOD, R1's diagnoses included: pyelonephritis; dehydration; renal and urethral disorder; nonpsychotic disorder; peripheral vascular disease; bilateral amputation; arthropathy; and abnormal blood chemistry. CMS Ex. 1, at 3; P. Ex. 1, at 3. I note that R1's minimum data set (MDS) assessment dated October 21, 2003, and other records, show that R1 was also diagnosed with anemia, dementia, Alzheimer's disease, hypertension, hypoalbuminemia, hypokalemia, and colon cancer. P. Ex. 5, at 4.

The SOD states that R1's MDS assessment, dated January 8, 2008, shows that R1 had short and long term memory problems, as well as severely impaired cognitive skills for daily decision making. CMS Ex. 1, at 3; P. Ex. 1, at 3; *see* CMS Ex. 9, at 28. R1 was totally dependent on staff for all activities of daily living, and R1's bowel and bladder was incontinent. In the "Nutritional Approaches" section of the MDS, staff noted that R1 had a feeding tube for nutritional support. CMS Ex. 1, at 3; P. Ex. 1, at 3.

According to the SOD, R1's care plan, dated November 8, 2007, documented that she had a G-tube related to dysphasia and poor oral intake. The care plan listed as a goal that R1 would have no risk of complications related to the G-tube. Among the care plan interventions were: "[c]heck placement of G-tube before giving medications, water, or feedings; . . . [l]isten to lung sounds as needed; . . . [c]hange tube per MD orders; . . . [c]heck residual per MD order; . . . [m]onitor/report irritation, redness of G-tube site; . . . [f]lush tube with water as ordered. 60 cc after feedings; [f]lush tube with water post medicine; . . . [c]heck residual Q [every] shift – if > 100 cc, hold feeding x 1 hr & recheck after feeding." CMS Ex. 1, at 3-4; P. Ex. 1, at 3-4; *see* CMS Ex. 9, at 31.

The SOD states that R1's G-tube was found dislodged around 7:00 a.m. on February 9, 2008, which R1 re-inserted around 7:15 a.m. It is alleged that no documentation existed in the nurse's notes. The SOD states that the "[t]he only nurse entry for this date [2/9/08]" indicated that R1's G-tube was patent and intact, placement was verified, with no residual noted, and that R1 was tolerating her bolus feedings well. CMS Ex. 1, at 4; P. Ex. 1, at 4.

According to the SOD, a nurse's note dated February 11, 2008 (shift 10-6), shows that R1 was "[r]esting in bed yelling out complaining [with] G tube site hurting & stomach hurting." The nurse's note stated also that the placement of R1's G-tube was checked, and no residual was noted. R1 was medicated with Tylenol, and no nausea, vomiting, or diarrhea was noted. CMS Ex. 1, at 4; P. Ex. 1, at 4.

A nurse's note dated February 12, 2008, at 10:15 a.m., shows that staff was notified to check R1's G-tube site. The note states "[r]eport pulled out tube on Sat. Replaced. In to see. Noted site large gaping. Foul smelling thin brownish drainage from site. Mod.

amt." The note states that the nurse notified R1's physician and received orders to send R1 to the emergency room for evaluation. CMS Ex. 1, at 10; P. Ex. 1, at 10; *see* CMS Ex. 9, at 65; P. Ex. 26, at 32; P. Ex. 28, at 2.

The SOD refers to R1's hospital records from Troy Regional Medical Center, where R1 was transferred on February 12, 2008. The SOD notes that R1's "History and Physical" stated:

> [R1] . . . presented to the ER on 2/12/08 secondary to nursing home personnel noting that the tube feedings were exuding from the abdominal wall and apparently she had the PEG tube replaced on Saturday, 2/9/08, and since than [sic] time she has been getting the usual tube feedings. In the ER it is evident that the tube feedings have been placed subcutaneously. Dr. Gill was consulted to see the patient in the ER and after evaluation determine [sic] that she needed immediate abdominal wall debridement and surgery.

CMS Ex. 1, at 10; P. Ex. 1, at 10; *see* CMS Ex. 9, at 100.

The SOD also refers to the hospital consultation report for R1 (dictated by Dr. Gill, Tr. at 276) dated February 12, 2008, and notes that it states the following in the "History" section:

> I am being consulted in the ER for evaluation of cellulitis, subcutaneous emphysema and leukocytosis and abdominal pain in the ER. . . . Per the record she had a PEG tube placed in the past and they changed out the tube on Saturday and since that time she has been getting feedings but today they noticed the tube feedings were coming out of the abdominal wall so she was sent to the ER. In the ER they evaluated it and found that she had the tube completely dislodged. They ordered multiple studies . . . that showed the tubes to be in the subcutaneous tissues and she also had a CT scan of abdomen and pelvis done and this showed no intraabdominal free air or fluid but a large collection of material in the subcutaneous tissues . . . she does state that she hurts every time I press on her abdominal cavity.

CMS Ex. 1, at 11; P. Ex. 1, at 11; *see* CMS Ex. 9, at 103.

The SOD also reflects that Surveyor Bean conducted interviews with Petitioner's employees CNA #1, LPN #1, and RN #1, and with the surgeon, Dr. Gill. CMS Ex. 1, at 6-9, 11-12; P. Ex. 1, at 6-9, 11-12. According to the record, CNA #1 is Luvonne Jones

(Tr. at 17, 41, 85, 175), LPN #1 is Catherine Ward (Tr. at 17, 154), and RN #1 is Margarette Calhoun (Tr. at 48). As stated above, Ms. Jones, Ms. Ward, Ms. Calhoun, and Dr. Gill were among the witnesses who testified at the hearing.

Petitioner argues that the evidence demonstrates that its nursing staff appropriately reinserted and monitored R1's G-tube. Petitioner argues that its staff had received appropriate training and education regarding the reinsertion of G-tubes and verification of its placement and is experienced in providing care to residents requiring G-tube feedings. Further, Petitioner contends that no evidence exists that the necrotizing fasciitis, which R1 developed, was caused by any action or inaction by its staff.

I find that, based on its fact contentions, CMS has made a prima facie case as to the alleged deficiency cited under Tag F309 – but just barely. Petitioner, however, has offered evidence to rebut CMS's prima facie case that proves that it complied substantially with participation requirements. Consequently, I do not sustain CMS's allegations of noncompliance.

There is no dispute that, between 7:00 and 7:30 a.m. on Saturday, February 9, 2008, R1 pulled out her G-tube, and CNA Jones discovered that it was out of her stomach. Tr. at 173. (Apparently, R1 had been combative while receiving a bath during her morning care and had pulled out her G-tube. *See* P. Exs. 35, 36). CNA Jones saw LPN Ward in the hall passing out medications and told LPN Ward that R1 had pulled out her G-tube. Tr. at 149, 173, 177. LPN Ward then called her RN supervisor, RN Calhoun. Tr. at 141, 149. RN Calhoun reinserted R1's G-tube in the presence of LPN Ward and CNA Jones. Tr. at 137-38, 141, 149-50. RN Calhoun did not verify the placement of the G-tube herself, apparently because she did not have a stethoscope with her. Tr. at 142, 164-65. She told LPN Ward to verify the placement of the G-tube. Tr. at 138. RN Calhoun did not document in the nurse's notes that she reinserted the G-tube, because she believed that LPN Ward would do this task. Tr. at 139. LPN Ward checked the placement of the G-tube by injecting air into the tube as she listened with the stethoscope, a method called auscultation.[2] Tr. at 150-51; *see* Tr. at 220-23. It appears that verification of placement took place somewhere between 10 and 30 minutes after the reinsertion of the G-tube. Tr. at 142-43, 153. LPN Ward did not document in the nurse's notes that RN Calhoun

[2] In explaining how she checked the placement of R1's G-tube, LPN Ward stated, "I had a 60 cc feeding syringe and a stethoscope. I injected 30 ccs of air into the feeding tube as I listened over the stomach, listening for the swishing sound, and then at that moment, I pulled back on the syringe and checked for residual." Tr. at 150-51. According to Dr. Duszak, Petitioner's expert witness, clinical providers routinely use auscultation to verify placement of a G-tube. Tr. at 220. Dr. Duszak explained that the sound made when air is injected into the stomach is "very, very distinctive" and stated that, if a G-tube was improperly placed into the soft tissues, you would not be able to inject air easily because of resistance, and you would not really hear any sound. Tr. at 220-23. Surveyor Bean described the auscultation method as well in his testimony. Tr. at 45.

replaced R1's G-tube, but she did document with her initials on R1's Medication Administration Record (MAR) that she verified placement of the G-tube. Tr. at 139, 152, 161-63; *see* P. Ex. 29; CMS Ex. 9, at 113, 114. On February 10 and 11, 2008, Petitioner's staff indicated in the nurse's notes that the placement of R1's G-tube was checked, noted to be patent, and no residual was noted. P. Ex. 28. On February 12, 2008, at 10:15 a.m., a nurse noted that there was foul-smelling, thin brownish drainage from the G-tube site. The nurse notified R1's physician, who ordered R1 to be sent to the emergency room for evaluation. P. Ex. 28, at 2. At the Troy Regional Medical Center ER, it was observed that her G-tube had become dislodged. P. Ex. 30, at 1. R1 received evaluations and various tests. Dr. Gill diagnosed, among other things, possible necrotizing fasciitis of her left upper quadrant and performed surgery on R1, which consisted of "debridement of skin, subcutaneous tissues, muscles and fascia." P. Ex. 30, at 2; P. Ex. 31, at 1.

Although CMS would have me find from the evidence it presented that Petitioner's staff improperly reinserted R1's G-tube on February 9, 2008, I am unable to reach this conclusion based on the record before me, especially in light of the testimony of Drs. Duszak and Gill, which I discuss below. Moreover, I find no basis to conclude that RN Calhoun and LPN Ward did not have the proper training regarding G-tubes to carry out their respective RN and LPN duties.

The only witness CMS presented in support of its case was Surveyor Bean, who conducted the survey of Petitioner's facility. Surveyor Bean testified that he drafted the allegations under Tag F309 in the SOD. Tr. at 94. He testified about his interviews with CNA Jones, LPN Ward, RN Calhoun, and Dr. Gill.

According to Surveyor Bean, Petitioner's staff failed "to ensure that [R1's] gastrostomy tube was properly placed and was checked for placement for verification so that she could safely receive her nutritional support via the G-tube." Tr. 77. Surveyor Bean stated, moreover, that Petitioner failed "to ensure that the RN that was on staff had competency skills" with respect to G-tubes. Tr. 77. When asked how R1's life was placed in immediate jeopardy, Surveyor Bean stated that the improper placement of the G-tube "could cause complications" and "could cause what they actually found in the ER, which was dead tissue, which could cause her to become septic, and she could go into septic shock and die." Tr. at 77-78.

Surveyor Bean testified that no documentation existed in the nurse's notes that R1's G-tube had come out and was replaced on February 9, 2008. Tr. at 29, 35-36, 76. He testified that RN Calhoun, who reinserted the G-tube, told him in their interview that she did not document this information, because she thought LPN Ward would do it. Tr. at 53-54. Surveyor Bean noted that it is usually an RN who replaces the G-tube and that an LPN can verify the insertion. Tr. at 46, 52. Surveyor Bean testified that LPN Ward told him in an interview that she had verified placement of the G-tube and documented this on the MAR. Tr. at 48, 52, 79-80.

Surveyor Bean also testified concerning two internal policies that were in effect in February 2008 at Petitioner's facility: one policy, entitled "Gastric Tube Insertion" (CMS Ex. 9, at 81); and another policy, entitled "Documentation Guidelines for Skilled Care -- Enteral Feeding: Nasogastric – Gastrostomy – Jejunostomy" (CMS Ex. 9, at 90). According to Surveyor Bean, the first policy sets forth the steps to follow when inserting a G-tube. Tr. at 70-71. With respect to the second policy, Surveyor Bean testified that it sets forth documentation expectations for residents having G-tubes. Tr. at 73-74. Surveyor Bean noted that documentation was required when, among other things: the tube position was checked; verification of placement was done; and the tube was replaced (noting reason, type of tube/size). Tr. at 74-75. According to Surveyor Bean, Petitioner's staff did not follow its own policies. Tr. at 71-72, 76.

When questioned about his interview with the surgeon, Dr. Gill, Surveyor Bean testified, among other things, that Dr. Gill had opined that "the tube was probably forced into the fascia." Tr. at 67. Surveyor Bean acknowledged that, following their interview on May 1, 2008, a letter written by Dr. Gill dated May 2, 2008, came into his office while he was writing the SOD and that it was inconsistent with his interview with Dr. Gill. Tr. at 68, 69, 94; *see* CMS Ex. 9, at 13.[3] Surveyor Bean stated, "on the statement here, he's saying that he don't know how the tube was displaced, but during the interview, he told me that it was improperly done, that it was improperly forced in by the nurse." Tr. at 69; *see* Tr. at 86. Surveyor Bean said that Dr. Gill did not contact him to clarify his interview statements, nor did he contact Dr. Gill regarding his letter. Tr. 69-70, 89. Despite being confronted by Petitioner's counsel with other alleged instances where he misquoted or misrepresented what Dr. Gill said in their interview, Surveyor Bean stated that he stood by all his statements in the SOD. Tr. at 89.

Petitioner attempted to show that Surveyor Bean was biased on the grounds that his aunt is a resident at Petitioner's facility and that his mother and R1 were "longtime neighbors in Troy." Tr. at 90. Surveyor Bean did not deny that his aunt resides at Petitioner's facility, nor did he deny that his mother and R1 were longtime neighbors. Tr. at 90-92. Surveyor Bean stated that he went to the same high school as two of R1's children. When asked whether he had disclosed his family's relationship to Petitioner's facility at the time of the survey, Surveyor Bean said he had not. Tr. at 91. Surveyor Bean stated that his family "did not have a relationship" with R1 and took issue with Petitioner's counsel's characterization. Tr. at 92. According to Surveyor Bean, "[his] mother knows [R1]; I know her children, but I'm not friends, per se, that we go out and we hang out together." *Id*. He stated that, prior to the survey, he had disclosed the information concerning his aunt and his mother to his superiors at the state survey agency and had asked whether another surveyor could perform the survey; however, his superiors determined that no conflict of interest existed and approved him to conduct the survey. Tr. at 91-93, 95. Surveyor Bean stated that it was not his first time surveying Petitioner's facility, and he had provided a written statement advising his office of the conflict of

[3] Dr. Gill addressed his letter to Dr. Peter DiChiara, Petitioner's Medical Director.

interest. According to Surveyor Bean, although concerns had been raised in the past, he was still sent out to survey Petitioner's facility. Tr. at 92, 96.[4] Surveyor Bean stated, "if they [i.e. the state survey agency] deem that you can go do your job without being biased, then you would be given that assignment. But they still like to know all facilities that you have a conflict of interests with." Tr. at 98.

In examining Surveyor Bean's testimony, I do not find that Petitioner was able to show that he was biased. I find that, in accordance with his office policy, Surveyor Bean appropriately disclosed to his superiors any potential conflicts of interest arising from any family ties to the facility, and, when they sent him to the facility to conduct the May 3, 2008 survey, he acted in a professional manner. While I ultimately conclude that Surveyor Bean's testimony was unpersuasive and not entitled to much weight, I do not base that conclusion on any finding of bias on his part.

To rebut CMS's arguments, Petitioner offered the expert medical testimony of Dr. Richard Duszak, Jr., via telephone. Dr. Duszak is a dual board-certified radiologist with a primary certification in diagnostic radiology and a subspecialty certification in vascular and interventional radiology. Tr. at 199. Dr. Duszak is employed by Mid-South Imaging and Therapeutics in Memphis, Tennessee. Tr. at 202. He testified that he routinely sees patients in long-term care facilities and estimated that, over the course of a year, he provides care to approximately 100 patients with G-tubes. Tr. at 202. I qualified Dr. Duszak as an expert "in the areas of radiology and the areas of long-term care and treatment of residents with G-tubes." Tr. at 204.

Dr. Duszak testified that a G-tube goes through the anterior abdominal wall, through the peritoneal cavity, directly into the stomach, and is "usually for long-term enteral . . . feedings." Tr. at 204, 206. He testified that "every patient with a gastrostomy tube is at risk of complications related to the tube" and that this is why placement of a G-tube is done after a discussion with the patient and family. Tr. at 210. Dr. Duszak stated that the tube, by its very presence, puts a patient at risk for bleeding, malposition, bowel injury, and infection. Dr. Duszak stated that these "are acceptable risks of complications if maintained appropriately." Tr. at 210-11.

Dr. Duszak opined that, based on his review of R1's records and to a reasonable degree of medical certainty, there was "no way that [he], as a practicing physician with experience in this area, could ever in any way reasonably draw" the conclusion that, based on R1's condition when she went to the hospital, her G-tube was improperly reinserted on February 9, 2008. Tr. at 217. As support for his opinion, Dr. Duszak testified as follows:

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[4] Surveyor Bean testified that, prior to conducting the May 2008 survey of Petitioner's facility, he had surveyed the facility twice before. Tr. at 22. He stated that if a surveyor had previously been employed at a long-term care facility or had family members who were residents at a facility, he or she is required to disclose the facility's name "and put it on the list and give it to your supervisor." Tr. at 98.

> [I]t's my opinion that the evidence is quite strong to the contrary. There are numerous instances between the time that the gastrostomy tube was replaced on the 9th until the time of hospital admission on the 12th where nurses documented several times verification of the tube position. And in addition, there is an overwhelming amount of evidence based upon a several year period . . . in which this patient has frequently pulled her tube out, and in fact, on another occasion, had an infection -- fortunately at that time less severe -- related to her displacing her tube. So it's my opinion that the overwhelming evidence is not that the tube was misplaced, but that the tube was in fact displaced by the resident herself probably a couple of days after it was appropriately replaced, again, after she pulled it out at the time of a bath or some other care the morning of the 9th.

Tr. at 217-18.[5] Dr. Duszak testified further that, in his professional opinion and to a reasonable degree of medical certainty, R1's necrotizing fasciitis was not caused by an improper placement of the G-tube by the RN on February 9, 2008. Tr. at 234.

On cross-examination, despite CMS counsel's attempts to cast doubt on his opinions, Dr. Duszak reiterated his earlier testimony:

> [I]f you want a specific, you know, hour and second on the clock as to when the nursing home resident dislodged her tube, I can't give you a specific time. But what I can state with as much reasonable medical certainty as I possibly can put forth is that the tube was replaced appropriately on the 9th. There's documentation for the subsequent days that it was confirmed to be in good position. Tube feeds were administered through the tube for some period of time without any untoward consequences, and then at some point on the 12th, things went bad. And the only explanation I have

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[5] Dr. Duszak testified that R1's chart indicated "at least five documentations over the course of several years going back to 2003" where R1, because of her dementia, pulled at her tube and, in fact, pulled it out. Tr. at 212. Dr. Duszak noted that, in 2005, R1 was admitted to the hospital with a cellulitis infection around her G-tube after she had displaced it and was treated with antibiotics. He stated that cellulitis is a less severe infection than fasciitis. Tr. at 212-13.

> for that is what I've already said, which is at some point, the tube was dislodged, almost certainly as a result of what this unfortunate patient has done numerous times in the past to herself, which is dislodged it.

Tr. at 253-54.

Further, Dr. Duszak testified that there was no evidence that R1 was harmed as a result of the RN's delegating the task of checking placement of the tube to the LPN after the RN had replaced it. Tr. at 230. Dr. Duszak testified that waiting 10 minutes or 30 minutes after the RN reinserted R1's G-tube for the LPN to check the placement did not put R1 at any risk of harm, because the tube was documented to be in the correct position, and no tube feedings were administered during the interval. Tr. at 232-33. Dr. Duszak stated that "one could conceivably conjecture harm" if the tube were in the wrong position (Tr. at 233); however, he opined also that, even if the tube were in the wrong position, there would have been no harm to R1 as long as nothing was administered through it that would have created an infection risk. Tr. at 232. Dr. Duszak noted that his review of the records showed that nothing was administered at all through R1's G-tube. Tr. at 232.

With respect to documentation, Dr. Duszak stated that RN Calhoun's failure to document that she had replaced R1's G-tube in the nurse's notes did not harm R1 or put her at risk of harm. Tr. at 258. He noted that the information was available that the treating physician in the ER on February 12, 2008, knew that R1's tube had been replaced, and, as such, there was no impact upon R1's clinical care. Tr. at 258-59.

As further support for its contention that R1's G-tube was not improperly reinserted by RN Calhoun, Petitioner also offered the testimony of Dr. Satinderjit Rick Gill, who performed R1's surgery. Dr. Gill is a general surgeon who practices primarily at Troy Regional Medical Center. Tr. at 261.

Dr. Gill testified that, as stated in the SOD, he had an interview with Surveyor Bean on May 1, 2008. Tr. at 262-63. Dr. Gill testified that certain quotes in the SOD that are attributed to him by Surveyor Bean are not accurate. According to Dr. Gill, he did not tell Surveyor Bean in the interview that R1 "had a G-Tube, PEG tube, stomach tube that was improperly placed." *See* Tr. at 263; *see also* CMS Ex. 1, at 11; P. Ex. 1, at 11; P. Ex. 40. Referring to his affidavit, Dr. Gill testified that the statement he gave in that affidavit – "the tube was dislodged and in the subcutaneous tissues instead of the stomach" – is correct. Tr. at 263; P. Ex. 40. Dr. Gill testified that he did not express any opinion or conclusion regarding how or when the G-tube migrated to the subcutaneous tissue of R1's abdomen when he spoke to Surveyor Bean. Tr. at 263-64; P. Ex. 40.

Dr. Gill testified that the SOD misquotes him again where it states that he said that R1 "had been receiving her tube feeding for a number of days. This lead [sic] to the necrotizing of the abdominal wall." Tr. at 264; P. Ex. 40; *see* CMS Ex. 1. Dr. Gill

testified that "the tube feeding system is not a high pressure system and therefore, . . . the tube feeds would not have ran [sic] for two days. So with that in mind, . . . I could not determine how long the tube had actually been in the subcutaneous tissue." Tr. at 265. Dr. Gill testified, moreover, that he did not know what caused the necrotizing fasciitis. Tr. at 265, 281-82; *see* P. Exs. 33, 40.

Another instance where he was inaccurately quoted by Surveyor Bean, according to Dr. Gill, is where the SOD quotes him as having stated, "[w]hen the tube was replaced by the nurse at the nursing home, that was improperly done. In my opinion, the tube was probably forced into the fascia. As a surgeon that is my opinion." Tr. at 268-69; CMS Ex. 1, at 12; P .Ex. 1, at 12; P. Ex. 40. Dr. Gill testified that he could not conclude whether or not R1's G-tube was reinserted correctly by the nurse based on his assessment. Tr. at 269; P. Ex. 40. Dr. Gill noted that, by the time he examined R1, the ER physician had removed her G-tube. Tr. at 268.

As stated above, on May 2, 2008, the day after his interview with Surveyor Bean, Dr. Gill wrote a letter to Dr. Peter DiChiara, Petitioner's Medical Director, stating his opinion with respect to R1's medical status.[6] Tr. at 264-65, 278-79; P. Ex. 33. In his letter, Dr. Gill stated, among other things, "I can in no way determine the length of time that the G-Tube had come out nor can I determine the exact etiology of the necrotizing fasciitis that she had." P. Ex. 33. Dr. Gill's letter also stated that the tube feedings could not have run for two days if the G-tube had been in the subcutaneous tissues, and that, when he performed surgery, "there was not two to three liters of tube feeds in there, there was purulent material and necrotic muscle and debris." P. Ex. 33.

Dr. Gill stated that he did not contact Surveyor Bean to discuss his letter. Tr. at 279; *see* Tr. at 69-70. As previously stated, Surveyor Bean did not contact Dr. Gill either, after he received the letter.

With respect to the subject of tube feedings, I note that both Dr. Duszak and Dr. Gill testified along similar lines. As previously stated, Dr. Duszak testified that his review of the records showed that nothing had been administered at all through R1's G-tube. Tr. at 232. Dr. Duszak testified that, based upon his personal review of R1's abdominal and pelvic CT scan (Tr. at 227, 246-47), he saw air in the soft tissues (called "subcutaneous emphysema" (Tr. at 227, 247)) and x-ray dye from the diagnostic study, but "there was no non-x-ray dye liquid to in any way indicate that there was any feed at all within the anterior abdominal wall or within the subcutaneous tissues." Tr. at 228, 232-33, 247-48. Dr. Duszak's testimony is consistent with that of Dr. Gill, for Dr. Gill testified that, when he performed surgery on R1, he did not find "copious amounts of tube feeds" in the subcutaneous tissue or in the abdominal abscess; instead, when he opened the abscess,

[6] Dr. Gill was uncertain as to how his letter was provided to the state survey agency. Tr. at 264-65. Dr. Gill stated that he gave the letter to Dr. DiChiara, and sent a copy to the hospital. Tr. at 264-65. He said that he "didn't personally mail it in the mail" himself. Tr. at 265.

"there was more so abscessed material, which was necrotic muscle and debris." Tr. at 266, 280-81. Dr. Gill testified that, based on a reasonable degree of medical certainty, R1 would not have been able to have received two or three days of tube feedings in the subcutaneous tissue, because "you couldn't put that much tube feeds into a subcutaneous space. It just couldn't happen." Tr. at 266.

I find that both Dr. Duszak and Dr. Gill were credible witnesses and gave convincing reasons for their medical opinions. Although counsel for CMS cross-examined both Dr. Duszak and Dr. Gill, cross-examination was ineffective and did not undermine their credibility. I note, moreover, that CMS did not offer any physician expert testimony to rebut the expert opinion of Dr. Duszak, or the informed medical opinion of Dr. Gill, nor did CMS address their testimony in its post-hearing brief. I thus give greater weight to Dr. Duszak's and Dr. Gill's testimony than that of CMS's only witness, Surveyor Bean. Although Surveyor Bean is a registered nurse and has had experience with G-tubes and providing care to patients with G-tubes (Tr. at 20-22), I find his opinions and conclusions regarding R1's medical status to be unpersuasive in light of the record before me.

As Dr. Duszak opined, there is "overwhelming evidence" that R1, as she had done several times in the past, most likely dislodged the G-tube herself a couple of days after it had been appropriately reinserted on February 9, 2008, after R1 had displaced it that morning. No dispute exists that the record shows that R1 had a history of pulling out her G-tube, due to her altered mental status caused by Alzheimer's disease and dementia. In October 2005, she displaced her G-tube and went to the hospital, where she was diagnosed with cellulitis at the PEG site and treated with IV antibiotics. P. Exs. 19, 20. A hospital consultation report dated October 19, 2006, indicates that R1, who had apparently been admitted the day before for altered mental status and dehydration, again pulled out her G-tube, and a physician was called to replace it. P. Ex. 22; *see* P. Ex. 23. In November 2007, R1's G-tube was found to be out, and it was replaced. P. Ex. 26, at 27; CMS Ex. 9, at 62; *see* Tr. at 50, 75.

Thus, I cannot conclude that RN Calhoun failed to appropriately reinsert R1's G-tube on February 9, 2008, as CMS has alleged. In her testimony, RN Calhoun stated that she did not meet any resistance when she reinserted the G-tube and that R1 did not display any signs or symptoms of discomfort during the reinsertion. Tr. at 14. LPN Ward and CNA Jones also testified that R1 did not display any discomfort or signs of pain when Nurse Calhoun reinserted the G-tube. Tr. 150, 173-74. Although RN Calhoun did not herself verify placement of the G-tube, LPN Ward testified that she verified placement of the G-tube through a method called auscultation and documented that she performed this task on R1's MAR. P. Ex. 29; CMS Ex. 9, at 113, 114. Also, no question exists that the nurse's notes contain documentation that Petitioner's staff checked the placement of R1's G-tube on February 10 and 11, 2008, and indicated that R1's G-tube was checked, noted to be patent, and no residual was noted. P. Ex. 28. What the record also indicates, based on the testimony of Dr. Duszak and Dr. Gill, is that R1 had "necrotic debris and dead tissue" but did not have "copious amounts of tube feeds" within the subcutaneous tissue

or in her abdominal abscess at the time of her surgery. Tr. at 266, 281. This is further proof that undermines CMS's argument that R1 received tube feedings "via the ill placed tube for three days" before she was admitted to the hospital. CMS Brief at 18.

I find that CMS misrepresents the facts when it states in its post-hearing brief that "[R1] had to endure a life threatening surgery to remove the improperly placed G-tube, as well as to remove the dead skin tissue caused by the improper placement." CMS Brief at 18. R1 did undergo emergency surgery; however, its purpose was not "to remove the improperly placed G-tube." As discussed above, Dr. Gill testified that the G-tube had already been removed by the ER physician by the time he examined R1.

Moreover, CMS has produced no evidence to support its claim that improper G-tube placement caused R1's necrotizing fasciitis. Dr. Duszak testified that, in his professional opinion and to a reasonable degree of medical certainty, R1's necrotizing fasciitis was not caused by an improper placement of the G-tube by the RN on February 9, 2008. Dr. Duszak stated that R1's diagnoses of peripheral vascular disease and diabetes predisposed her to a much higher risk of infection than the general population. According to Dr. Duszak, patients with these diagnoses have immune systems that are "dramatically compromised," and, with them, "one will not uncommonly see infections, number one; more commonly, and number two, when they progress, those infections will often progress in what is really almost a fulminant course . . . than somebody who has an intact immune system." Tr. at 211. Dr. Duszak also testified that, "at some point on the 12th [of February], things went bad." Dr. Duszak went on to state that R1 most likely dislodged her G-tube herself and that a "small amount of tube feeds probably got administered into the anterior abdominal wall, contributed to the fulminant fasciitis," probably "just hours" before she went to the ER. Tr. at 254. R1's surgeon, Dr. Gill, testified that there was "no way" for him to determine what caused R1's necrotizing fasciitis. Dr. Gill testified that an abscess can develop anywhere, it can be "caused by a multitude of things," and that an infection can travel to a different place in the body. Tr. at 281-82.

It is clear that R1 was much more susceptible to infections due to her highly compromised immune system and that, once an infection appeared anywhere in her body, there was a high probability that it would rapidly develop and worsen. Based on Dr. Duszak's and Dr. Gill's credible testimony, I find that, whatever the cause of R1's necrotizing fasciitis, CMS has not shown that it resulted from any deficient care on the part of Petitioner's staff.

On the issue of staff training, CMS argues that Petitioner failed to provide proper training to its nurses on the reinsertion of G-tubes. CMS Ex. 1, at 2; P. Ex. 1, at 2. In its post-hearing brief, Petitioner asserts that 42 C.F.R. § 483.25 "makes no mention of how or where the nursing staff should receive their training. The regulation only requires that the nurses are trained and that they perform their duties appropriately." P. Brief at 12. I

agree with Petitioner. The thrust of 42 C.F.R. § 483.25 is on whether a resident received the necessary care and services from facility staff. It does not set forth any explicit requirements regarding how or where nursing staff receive training.

I find that Petitioner has demonstrated that its nursing staff had the proper education and training in G-tubes. At the hearing, RN Calhoun testified that, before becoming an RN, she had been an LPN for 14 years. She testified that both her LPN and RN nursing education included training on reinsertion of G-tubes. Tr. at 135-36. According to RN Calhoun, as part of her LPN training, she had to perform the procedure for reinsertion of a G-tube before a clinical instructor. Tr. at 135-36. RN Calhoun stated that, during her RN training, she studied the anatomy and physiology of the stomach and learned about G-tubes. She also demonstrated reinsertion of a G-tube before a clinical instructor. Tr. at 136. RN Calhoun stated that she received additional training regarding reinsertion of a G-tube when she previously worked at another long-term facility. She again demonstrated the skill in a clinical setting. Tr. at 136-37; P. Ex. 38. Further, RN Calhoun testified that she has cared for residents with tube feedings on a regular basis, and, during her RN career, she has inserted G-tubes on a regular basis. Tr. at 137.

I have no reason to doubt RN Calhoun's training on the reinsertion of G-tubes. It is evident that RN Calhoun has taken coursework and received clinical training in the reinsertion of G-tubes and had experience performing this procedure in the long-term care setting. While Petitioner may not have provided any "competency courses" on G-tube insertion to its nurses, as the SOD alleged, I do not consider this to be a relevant issue. I note that the record contains a document titled "Gastric Tube Insertion Certification," dated September 27, 2006, which indicates that RN Calhoun had successfully demonstrated competence in the procedure of G-tube insertion. As such, she was fully certified to perform this procedure at the Cullman Health and Rehab facility (her former employer).[7] P. Ex. 38; *see* Tr. at 136. RN Calhoun and her supervisor at the time signed the document. P. Ex. 38. Furthermore, given the fact that I have concluded that the evidence does not support a finding that RN Calhoun improperly reinserted R1's G-tube on February 9, 2008, this only reinforces a finding that RN Calhoun was qualified to perform this procedure.

There is also little evidence in the record to suggest that LPNs Ward and Mote did not have proper training on the verification of the placement of G-tubes. LPN Ward testified that, at LPN school, she received training on verifying G-tube placement, which consisted of academic studying and performing it in front of a clinical supervisor. Tr. at 151. She stated that she checks the placement of G-tubes on residents approximately 25 to 30 times a week and uses the auscultation method. Tr. at 150-52, 220-21. LPN Mote testified that she had received training on the verification of G-tube placement "over the

[7] The certification document lists the following three areas in which competency is required: "Demonstrates understanding of G-tube placement . . . Demonstrates skill in checking G-tube for correct placement . . . Demonstrates knowledge of correct calculation of diet and fluids." P. Ex. 38.

years" and that, in LPN school, her training consisted of "[w]atching films and watching one being put in and being watched" by a nursing instructor when she performed this skill. Tr. 184. LPN Mote testified that she uses the auscultation technique and checks the placement of G-tubes on residents at least 20 times a week. Tr. at 185.

As discussed above, on February 9, 2008, LPN Ward verified the placement of R1's G-tube using the auscultation method after RN Calhoun reinserted it and documented the verification on R1's MAR. In the days following the reinsertion, there is documentation that Petitioner's staff verified the placement of the G-tube. On February 10, 2008, in a nurse's note, LPN Mote stated that R1's G-tube was "patent & intact. [No] residual noted." P. Ex. 26, at 31; P. Ex 28. In another nurse's note dated February 11, 2008, LPN Mote wrote that R1 was "complaining [with] G tube site hurting & stomach hurting. Placement of G tube checked. [No] residual noted." P. Ex. 26, at 32; P. Ex. 28, at 2. LPN Mote testified that she verified placement using auscultation and documented this on the MAR with her initials. Tr. at 188; P. Ex. 29; CMS Ex. 9, at 113, 114. I note that CMS does not dispute that Ms. Ward and Ms. Mote initialed the MAR to indicate that they had checked R1's G-tube placement. Tr. at 161, 162, 189. Based on their education and experience, it is reasonable to infer that both LPNs Ward and Mote were properly trained to check the placement of R1's G-tube.

V. Conclusion

For the reasons discussed above, I conclude that Petitioner established by a preponderance of the evidence that it complied substantially with 42 C.F.R. § 483.25. Further, Petitioner did not manifest any immediate jeopardy level failures to comply with this participation requirement. CMS therefore had no basis for imposing a per instance CMP of $6,000 against Petitioner.

/s/
Alfonso J. Montaño
Administrative Law Judge