Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:))
Wood Lake Nursing & Rehabilitation Center,)) Date: March 19, 2007)
Petitioner,) Docket No. C-04-83) Decision No. CR1577
v .)
Centers for Medicare & Medicaid Services.)))

DECISION

Petitioner, Wood Lake Nursing & Rehabilitation Center, violated 42 C.F.R. §§ $483.25(k)^1$ (Tag F 328)² and 483.75 (Tag F 490) on August 15, 2003. A total per instance civil money penalty (PICMP) of \$10,000 is reasonable in this case.

I. Background

Petitioner is a 120-bed facility located in West Palm Beach, Florida. Petitioner is certified for participation in the Medicare Program as a skilled nursing facility (SNF) and in the state Medicaid program as a nursing facility (NF). On August 15 and 16, 2003, the Florida Agency for Healthcare Administration (the state agency) conducted a complaint survey of Petitioner's facility and concluded that Petitioner was not in substantial compliance with five participation requirements. On August 25, 2003, the Centers for

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.

² This is a "Tag" designation that refers to the part of the State Operations Manual (SOM), Appendix PP, "Survey Protocol for Long Term Care Facilities," "Guidance to Surveyors" that pertains to the specific regulatory provision allegedly violated.

Medicare & Medicaid Services (CMS) notified Petitioner of the alleged noncompliance based on the survey completed on August 16, 2003, and that remedies including a PICMP of \$10,000,³ a denial of payment for new admissions (DPNA) effective November 16, 2003, and termination effective February 16, 2004, would be imposed. The state agency conducted a revisit survey of Petitioner's facility on September 23, 2003, and found Petitioner in substantial compliance with participation requirements effective that date. Thus, the DPNA and termination remedies were never effectuated. CMS notified Petitioner that the \$10,000 PICMP was due by letter dated November 4, 2003.

On November 21, 2003, Petitioner requested a hearing through counsel. The request for hearing was received at the Departmental Appeals Board (DAB), Civil Remedies Division (CRD) on December 2, 2003, and assigned to me for hearing and decision on December 17, 2003. On January 7, 2004, CMS moved to dismiss Petitioner's request for hearing pursuant to 42 C.F.R. § 498.70(c), on grounds that the request for hearing was not timely filed. Petitioner filed a response to the motion to dismiss on January 14, 2004. On February 9, 2004, I denied the CMS motion to dismiss finding that the 60-day period for filing an appeal ran from Petitioner's receipt of the CMS notice of November 4, 2003, and that the November 21, 2003 request for hearing was timely filed.

A hearing was conducted in this case on June 21 and 22, 2004, in West Palm Beach, Florida. CMS offered CMS exhibits (CMS Exs.) 1 through 44, which were admitted as evidence. CMS exhibits 45 through 48 were previously marked as evidence and exchanged but not offered at hearing by CMS. Transcript (Tr.) at 15-17. Petitioner offered Petitioner's exhibits (P. Exs.) 1 through 8, which were admitted as evidence.⁴ Petitioner's exhibit 9 was marked as evidence but not admitted. Tr. at 31-38. Posthearing, CMS moved that the February 20, 2004 deposition of Faith Thomas be admitted as evidence. Petitioner did not oppose the CMS motion and the February 20, 2004 deposition of Faith Thomas is admitted as P. Ex. 10.⁵

⁴ In its "Notice of Post Hearing Issues and Motion for Leave to Offer Exhibit" filed on July 26, 2004, CMS withdrew its continuing objection to the admissibility of P. Exs. 7 and 8, the deposition and testimony of Michael Ball, on grounds of prejudice and inability to cross-examine. CMS also waived the remedy I offered to subpoena Mr. Ball and elicit testimony at a supplemental hearing.

⁵ Petitioner called Faith Thomas as a witness at hearing and CMS objected because (continued...)

³ The PICMP in the amount of \$10,000 was divided between two tags such that \$5000 of the PICMP was for Tag F 328 and \$5000 of the PICMP was for Tag F 490. CMS Ex. 43.

At the hearing, CMS called as a witness Surveyor Sandra Pearce, RN (Registered Nurse), who participated in the survey of Petitioner's facility. Petitioner called the following witnesses: Billie Brock, RN; Steven Selznick, DO (Doctor of Osteopathy); Faith Thomas, LPN (Licensed Practical Nurse); and Reginald Eldridge, Petitioner's former Administrator.

CMS submitted its post-hearing brief (CMS Br.) on October 1, 2004 and its reply brief (CMS Reply) on November 8, 2004. Petitioner submitted its post-hearing brief (P. Br.) on October 7, 2004 and its reply brief (P. Reply) on November 10, 2004.

II. Discussion

A. Findings of Fact

The following Findings of Fact are based upon 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.

- 1. Petitioner's nursing procedure manual is consistent with the standard of care for tracheostomy care and suctioning.
- 2. Facts related to Tag F 328 concerning Resident 1:
 - a. Resident 1 had a tracheostomy.

⁵(...continued)

Petitioner had failed to produce Nurse Thomas' prior written statement as required by the Prehearing Order. Petitioner agreed to provide the deposition post-hearing for CMS to review and on June 24, 2004, Petitioner submitted the deposition marked as P. Ex. 10. On July 26, 2004, CMS moved that Nurse Thomas' deposition be admitted into evidence and marked as either CMS Ex. 47 or P. Ex. 10. I directed at hearing that if the deposition was offered as evidence it was to be marked and admitted as P. Ex. 10. Tr. at 238, 287. However, on August 2, 2004, a letter was issued by my office directing that if CMS chose to offer the deposition it should be marked as the next CMS exhibit. Thus, the cause for CMS's alternate suggestion for marking is my fault. I resolve the dilemma in favor of my original direction and the deposition is admitted in the record as P. Ex. 10.

b. On August 15, 2003, no obturator could be located in the resident's room.

c. Petitioner's care of Resident 1 was not consistent with the standard of care for tracheostomy care and suctioning.

3. Facts related to Tag F 328 concerning Resident 2:

a. Resident 2 had a tracheostomy.

b. No obturator could be located in Resident 2's room on August 15, 2003.

c. LPN Michael Ball failed to wash his hands prior to performing tracheostomy care and suctioning for Resident 2 on August 15, 2003.

d. On August 15, 2003, LPN Michael Ball failed to perform the following procedures prior to performing tracheal suctioning on Resident 2: instruct Resident 2 to cough and take several deep breaths; hyper-oxygenate Resident 2 by increasing oxygen saturation through the oxygen delivery device or manual resuscitator bag (ambu bag); open the suction kit using sterile technique; perform a respiratory assessment (heart rate, respiration rate, breath sound, cough effort, and sputum production) before initiation of tracheal suctioning; and auscultate (examine by listening with or without a stethoscope) the lungs.

e. On August 15, 2003, LPN Michael Ball failed to follow the standard of care when performing tracheal suctioning in that he: failed to hold the suction catheter in a hand that remained sterile; suctioned while inserting the catheter; and suctioned for 35 seconds.

f. Petitioner's care of Resident 2 was not consistent with the standard of care for tracheostomy care and suctioning.

4. Facts related to Tag F 328 concerning Resident 3:

a. Resident 3 had a tracheostomy.

b. No obturator could be located in Resident 3's room on August 15, 2003.

c. LPN Jeanette Bazile did not, prior to tracheostomy suctioning on August 15, 2003, perform a respiratory assessment on Resident 3, did not ask Resident 3 to cough or do deep breathing to oxygenate Resident 3, did not hyper-oxygenate Resident 3 by using an ambu bag, did not keep one hand sterile during tracheal care, and cross-contaminated items from one hand to another.

d. Petitioner's care of Resident 3 was not consistent with the standard of care for tracheostomy care and suctioning.

5. Facts related to Tag F 490:

a. A respiratory services company that had provided most tracheostomy care and suctioning at Petitioner's facility left the facility on August 12, 2003.

b. An in-service training conducted on August 12, 2003 was attended by only 16 members of Petitioner's staff and did not cover hands-on-training or demonstrations of proper tracheostomy care and suctioning. Tr. at 256, 269; CMS Ex. 12; CMS Ex. 44, at 11.

c. On August 13, 2003, the Omni Care Pharmacy provided a respiratory therapist who came to the facility to assess the tracheostomy patients, but not to train staff in proper tracheostomy care and suctioning.

d. On August 13, 2003, a durable medical equipment provider came to the facility to provide training on respiratory equipment, to inventory tracheostomy supplies, and to ensure that the needed supplies were on hand, but did not provide training in proper tracheostomy care and suctioning.

e. On August 14, 2003, Dr. Blake, a pulmonologist, visited the tracheostomy residents but he did not assess staff's ability to deliver proper tracheostomy care and suctioning.

f. Petitioner's Administrator did not ensure that his nursing staff received training necessary to ensure that they delivered tracheostomy care and suctioning consistent with the standard of care for such services, thereby depriving three residents of the quality of care they required.

g. Petitioner was not administered in a manner that enabled it to use its resources effectively and efficiently to attain or maintain the highest practicable physical, mental, and psychosocial well-being of each resident.

B. Conclusions of Law

- 1. Petitioner's request for hearing was timely and I have jurisdiction. Order, dated February 9, 2004.
- 2. Petitioner violated 42 C.F.R. § 483.25(k) (Tag F 328) on August 15, 2003.
- 3. Petitioner violated 42 C.F.R. § 483.75 (Tag F 490) on August 15, 2003.
- 4. The immediate jeopardy determination is not subject to my review in this case.
- 5. A total PICMP of \$10,000, \$5,000 for Tag F 328 and \$5,000 for Tag F 490, is reasonable.

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.

The State agency cited Petitioner with five deficiencies in the Statement of Deficiencies (SOD) dated August 16, 2003. However, the Parties agreed in their Joint Statement of Issues Presented, filed March 5, 2004, that only two deficiencies are at issue before me: the alleged violations of 42 C.F.R. § 483.25(k) (F Tag 328) and 42 C.F.R. § 483.75 (F Tag 490); and the PICMP related to those alleged deficiencies. *See also* Petitioner's Prehearing Brief at 1-2; CMS Prehearing Brief at 3.

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 Act and at 42 C.F.R. Part 483. Sections 1819 and 1919 of the Act vest the Secretary with the authority to impose remedies, including a DPNA and CMPs, against a long-term care facility for the 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. 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 CMP or a PICMP 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. 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). Further, "[s]ubstantial 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." Id. (emphasis in original).

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 CMPs, of 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 CMPs, 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). There is only a single range of \$1,000 to \$10,000 for a PICMP, which applies whether or not immediate jeopardy is present. 42 C.F.R. §§ 488.408(d)(1)(iv), 488.438(a)(2).

The Act and regulations make a hearing before an ALJ available to a long-term 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, et al*, DAB CR65 (1990), *aff*'d, 941 F.2d 678 (8th Cir. 1991). A facility has a right to appeal a "certification of noncompliance leading to an enforcement remedy." 42 C.F.R. § 488.408(g)(1); *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 aide training program. 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 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 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 (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. 1911 (2004); *Emerald Oaks*, DAB No. 1800 (2001); *Cross Creek Health Care Center*, DAB No. 1665 (1998).

E. Analysis

1. Petitioner violated 42 C.F.R. § 483.25(k).

The general quality of care standard established by 42 C.F.R. § 483.25, is that:

Each 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.

The regulation specifically requires that each resident receive proper treatment and care for special services, including tracheostomy care, tracheal suctioning, and respiratory care. 42 C.F.R. § 483.25(k). The surveyors found, and CMS alleges, that Petitioner failed in its duty to provide proper treatment and care of three residents referred to as Resident 1, Resident 2, and Resident 3 who required special services of tracheostomy care, tracheal suctioning, and respiratory care. CMS Ex. 2, at 9. There is no dispute that each of the three residents had a tracheostomy and none were ventilator dependent. I find that Petitioner was not in substantial compliance with 42 C.F.R. § 483.25 concerning Resident 1, Resident 2, and Resident 3.

a. The Standard of Care.

A tracheostomy or tracheotomy⁶ involves surgically opening a small hole at the throat and into the trachea or windpipe of an individual. The incision or small hole is a stoma. An endotracheal tube is inserted through the stoma and into the windpipe using a device know as an obturator, which fits inside the tube and has a rounded-end that is inserted into the stoma first, easing insertion of the endotracheal tube. Tracheostomies are necessary for individuals who cannot draw sufficient air through their mouth and nose, but does not prevent breathing through the mouth and nose. Endotracheal tubes come in different sizes in kits with an appropriate sized obturator. Endotracheal tubes do come out and reinsertion using the obturator is necessary to prevent oxygen deprivation and hypoxia, which can cause death. Tr. at 46, 73-75, 89-90, 96-99. Individuals with a tracheostomy require suctioning to remove mucus and maintain an open airway and failure to do so can cause serious harm or death. Tr. at 90.

On August 12, 2003, Petitioner had four residents with tracheostomies, none of whom required a ventilator to assist with their breathing. Tracheostomy care, tracheal suctioning, and respiratory care was provided to the four residents predominantly by a respiratory therapy company until about 3:00 p.m. on August 12, 2003, when the company pulled its staff from Petitioner's facility. Tr. at 253-54. Thereafter, Petitioner's staff undertook to provide tracheostomy care, tracheal suctioning, and respiratory care for the four residents.

Between about 9:45 a.m. and 10:00 a.m. on August 15, 2003, a surveyor from the state agency, Joe Narkier, arrived at Petitioner's facility to conduct a complaint survey. Tr. at 262. The complaint involved tracheostomy care at the facility. Tr. at 113. Surveyor Narkier requested assistance from Surveyor Sandra Pearce and she arrived at the facility about 6:30 p.m. on August 15 and stayed until about 1:30 a.m. on August 16, 2003, when the survey team left the facility. Tr. at 88-90. Surveyor Pearce is a RN with experience

with pulmonary, respiratory, and tracheostomy care. Tr. at 81-86. The surveyors documented their findings in the SOD dated August 16, 2003. CMS Ex. 2. Surveyor

⁶ Referred to by the surveyor and in staff testimony as a "trach" and construed to include the stoma and endotracheal tube in this case.

Pearce testified at the hearing but Surveyor Narkier did not.

The surveyors requested and the Director of Nursing (DON) provided them with a copy of the facility policy and procedure for tracheostomy suctioning. CMS Ex. 2, at 13. Surveyor Pearce identified the policy and procedure document she was provided as CMS Ex. 6.⁷ Tr. at 101. Surveyor Pearce testified that the document does reflect the standard of care for appropriate tracheostomy care. Tr. at 101. Two methods for tracheal suctioning are prescribed in CMS Ex. 6: "Open Method" and "Closed Method." The "closed-method" is for ventilator-dependent residents. CMS Ex. 6, at 10. None of the four residents involved in the survey were ventilator-dependent, thus, I need not review the "closed-method" text. The "open method" or "open' suction technique" is used for the non-ventilator resident. CMS Ex. 6, at 8. The policy sets out a 29-step procedure. The procedure requires, among other things, that the person doing suctioning should (not all the steps are listed here but the number of each step from the policy is used for ease of reference): (1) verify physician's order; (6) perform respiratory assessment to include evaluation of heart rate, respiration rate, breath sounds, cough effort, and sputum production; (7) instruct the resident to cough and take several deep breaths prior to suctioning; (8) hyper-oxygenate resident/patient by increasing the oxygen concentration through the oxygen delivery device or manual resuscitator bag if used; (10) open suction kit using sterile technique; (12) hold catheter in hand that will remain sterile and attach end of suction catheter to connecting tubing; (18) suction while withdrawing the catheter and limit suctioning to 15 seconds; (20) between suctioning instruct resident to take several slow deep breaths to relieve hypoxia and promote relaxation; (22) auscultate the resident's lungs; (24) assess for hypoxemia; and (29) document.

Petitioner argues that its policy and procedure exceeds the nursing home industry standard and that it should be held responsible to meet the minimum standard only. Tr. at 168; P. Br. at 13. Petitioner called Steven Selznick, D.O. and qualified him to offer expert opinions in the area of long-term care and as a medical director for long-term care facilities. Dr. Selznick opined that the error alleged by Surveyor Pearce regarding suctioning did not pose harm to the residents involved. Tr. at 54-60. Petitioner did not specifically elicit Dr. Selznick's opinion regarding the standard of care for tracheostomies in long-term care facilities. On cross-examination, Dr. Selznick agreed that tracheostomy care should be as ordered by the resident's physician (Tr. at 65); that a nurse should clean his or her hands before suctioning; and that sterile technique should be used while doing tracheostomy care (Tr. at 66-67). Dr. Selznick agreed that a resident with a tracheostomy is at increased risk for infection (Tr. at 65) and that improper suctioning can result in

⁷ The pages of CMS Ex. 6 are not numbered in the correct order. Tr. at 164. The document is more sensible when the pages are reordered as follows: 8, 1, 9, 10, 11, 12, 13, 14, 5, 2, 4, 6, 3, and 7.

harm (Tr. at 68-77).

Petitioner also called Billie H. Brock, a RN and Vice-President of Risk Management for the company that managed Petitioner. Petitioner qualified RN Brock as an expert in longterm patient nursing care. Tr. at 162. Despite my specific request (Tr. at 169-70), RN Brock never specifically articulated the long-term care standard for tracheostomy care and suctioning. RN Brock did offer opinions that there are several ways requirements from the facility policy might be satisfied by a nurse providing tracheostomy care (Tr. at 170-99, 215-19). I do not find RN Brock's testimony to be of any probative value regarding the standard of care for tracheostomy care and suctioning because she never specifically articulated the standard. She stated that the standard of care may be "somewhat flexible" (Tr. at 171); and on questioning by counsel for Petitioner, RN Brock responded:

- Q In your review of the allegations under Tag F-328, even assuming the allegations to be accurate, did you – is there, in your opinion, a failure to comply with nursing standards and a deficient practice?
- A No, not such that harm would come to residents.

Tr. at 199. The response, which garnered no objection, clearly is not responsive and is equivocal at best. RN Brock did testify that it is not necessarily the standard or practice to always have an obturator taped to the head of the resident's bed and that it is the standard of practice to have a universal obturator on the emergency cart. Tr. at 186. RN Brock did not explain what is the standard of practice for what to do with the obturator that came in the particular endotracheal kit that was used for a resident. Petitioner had admitted as P. Ex. 7, a deposition of LPN Michael Ball, one of the staff observed by Surveyor Pearce during the survey. LPN Ball testified that, while all facilities are different, the obturator for a resident is supposed to be over the bed or in a drawer by the bed. P. Ex. 7, at 28. He also testified that at the time Surveyor Pearce observed him during the survey, he knew that there was no obturator in the room of the resident he was suctioning but he believed that one could be found in the respiratory room or the supply room, and on the crash cart. P. Ex. 7, at 28-30. The February 20, 2004 deposition of LPN Faith Thomas was admitted as P. Ex. 10, post-hearing. In the February 20, 2004 deposition, after LPN Thomas' memory was refreshed as to what an obturator is, she testified that one is kept in the emergency box and usually there is one in the resident's room. At the hearing before me, LPN Thomas' testimony was different, she testified that obturators are usually on the emergency cart. LPN Thomas did not indicate

before me that there should also be an obturator in the room. Tr. at 223. Surveyor Pearce testified that the standard of care is to have an obturator in the resident's room, usually

taped to the head of the bed. Tr. at 97, 121.

Based upon the evidence presented, I conclude Petitioner's policy for tracheal suctioning, open method, specifically pages 8, 1, and 9 of CMS Ex. 6, in that order, does reflect the standard of care. I reject Petitioner's argument that the facility policy exceeds the standard of care and, thus, need not be followed. Surveyor Pearce's testimony in this regard was credible. Petitioner has failed to present evidence that is persuasive that there is some different standard of care. Rather, I observe as a general matter that Petitioner attempted to use its witnesses to rationalize the deviations from its own policy that were identified by Surveyor Pearce.

Based on the evidence, I also conclude that it is the standard of practice for the obturator that came with the endotracheal kit used for a particular resident to be either taped to the head of the bed or located somewhere in the room of the resident for emergency reinsertion of the endotracheal tube. My conclusion is based upon the testimony of Surveyor Pearce; the testimony of Dr. Selznick, and the deposition of LPN Ball. It is undisputed that each endotracheal kit comes with an appropriately sized obturator that is used to insert the endotracheal tube for a specific resident. Petitioner's policy entitled "Tracheostomy Tube Change," dated 8/03, items 22 and 23 specify that the obturator used is to be cleaned, dried, and placed in a plastic bag labeled with resident/patient's name, date, and room number, and it is to be stored in an area where it is readily accessible in the event of an emergency. CMS Ex. 6, at 6. Thus, Petitioner's own policy specifies that the obturator used to insert the endotracheal tube is to be retained and, thus, belies the assertion that it is sufficient to have a universal obturator on the crash cart. Petitioner's policy does not specify what location is considered to satisfy the requirement that the obturator be stored in an area readily accessible in the event of emergency, but it is more reasonable to conclude that the resident specific obturator should be in the resident's room where it might be needed, rather than located on a crash cart with the obturators of other residents.

The surveyors concluded that Petitioner did not ensure that three of four residents, Residents 1, 2, and 3, received the proper treatment for tracheostomy care, tracheal suctioning and respiratory care. CMS Ex. 2, at 9. The SOD under Tag F 328 includes many observations and allegations by Surveyor Pearce. However, CMS relies upon two primary allegations as the grounds for finding a regulatory violation. The CMS case focuses upon staff failure to follow the standard of care for tracheal suctioning related to Residents 2 and 3 (CMS Br. at 9-12; CMS Reply at 3-7); and failure of Petitioner to ensure that obturators were available in the rooms of Residents 1, 2, and 3 (CMS Br. at 13-16; CMS Reply at 7-10).

b. Residents 1, 2, and 3 did not receive proper treatment and care for

the special services of tracheostomy suctioning and care, a violation 42 C.F.R. 483.25(k).

(1) Resident 2.

The SOD alleges that Surveyor Pearce observed Resident 2 receive tracheostomy care on August 15, 2003. Prior to suctioning, Surveyor Pearce noted that the tracheostomy was plugged and the resident was in no respiratory distress. The SOD indicates that Surveyor Pearce interviewed a LPN on duty on August 15, 2003 at 7:35 p.m. There is no question that the LPN interviewed was LPN Ball. Surveyor Pearce noted in the SOD that LPN Ball told her that he had not done tracheostomy care for approximately a year and that he only put gauze under a trach since the respiratory service left the facility. The SOD records that Surveyor Pearce observed LPN Ball perform tracheostomy suctioning from 7:30 p.m. until 8:00 p.m. and 8:40 p.m. to 9:20 p.m., with the resident resting from 8:00 p.m. to 8:40 p.m. It is alleged in the SOD that LPN Ball did not wash his hands prior to the procedure; he donned two pair of sterile gloves; he inserted the suction catheter, suctioned as he inserted the catheter and suctioned continuously for 35 seconds; he did not instruct the resident to take three to five deep breaths before and after suctioning; he changed suction catheters three times, each time wrapping the used catheter in the outer pair of gloves and then discarding in the trash can. The surveyor notes in the SOD that LPN Ball did not clear the catheter tubing with water or normal saline; on each change of catheter the LPN obtained a new disposable care and cleaning kit, put on new sterile gloves over the first pair on his hands and continued with suctioning; secretions were noted by surveyor on the bed linen, the bed-side table, and suction equipment; and during the third attempt at suctioning the resident began coughing and indicated a need for a break before tracheostomy cleaning. The surveyor noted that LPN Ball shifted items from hand-to-hand not maintaining one hand for sterile items; the surveyor did not note an obturator taped to the head of the bed and LPN Ball could not locate one in the resident's room when requested to do so by the surveyor. The surveyor specifically alleged in the SOD that LPN Ball failed to perform a respiratory assessment, instruct Resident 2 to cough and take deep breaths prior to suctioning, failed to hyper-oxygenate the resident, and did not maintain a sterile hand to hold the suction catheter. CMS Ex. 2, at 9-13.

Surveyor Pearce testified about her observations of LPN Ball's tracheal care of Resident 2. Tr. at 90-103. Surveyor Pearce, testified that LPN Ball failed to wash his hands prior to performing tracheal care. Tr. at 91. Further, Surveyor Pearce specifically testified that LPN Ball failed to perform the following procedures prior to performing tracheal suctioning: instruct Resident 2 to cough and take several deep breaths; hyper-oxygenate Resident 2 by increasing oxygen saturation through the oxygen delivery device or manual resuscitator bag; open the suction kit using sterile technique; perform a respiratory

assessment (heart rate, respiration rate, breath sound, cough effort, and sputum production) before initiation of tracheal suctioning; and auscultate (examine by listening with or without a stethoscope) the lungs. Tr. at 92-96. Surveyor Pearce also testified to LPN Ball's failure to follow the standard of care when performing tracheal suctioning in that he: failed to hold the suction catheter in a hand that remained sterile; suctioned while inserting the catheter; and suctioned for 35 seconds. Tr. at 95-96.

In briefing, Petitioner refers to LPN Ball's testimony in the prior state administrative hearing where he testified that he did wash his hands prior to starting tracheostomy care and suctioning on Resident 2. P. Ex. 8, at 5. LPN Ball also asserted in prior testimony that he did not suction Resident 2 for as long as 35 seconds. P. Ex. 8, at 13. In its briefing, Petitioner also refers to LPN Ball's deposition made in preparation for the state administrative hearing where LPN Ball contends that he suctioned Resident 2 for only 15 to 20 seconds. P. Ex. 7, at 18-19. LPN Ball was not called as a witness at hearing by Petitioner even though his name was on Petitioner's witness list filed on January 29, 2004. CMS failed to subpoena LPN Ball to testify at the hearing.⁸ LPN Ball was not subject to cross-examination before me and I had no opportunity to examine LPN Ball or to view his demeanor.

I have examined P. Exs. 7 and 8, and I find that LPN Ball was not questioned in detail and he was not subject to very pointed questioning about his conduct on August 15, 2003. Rather, LPN Ball was permitted in his prior testimony and deposition to give general answers and evasive responses. Because LPN Ball's conduct was at issue, he had cause to be less than totally forthright in his responses. For example, when asked how LPN Ball could recall washing his hands prior to doing tracheal care on Resident 2, LPN Ball replied, "(i)t's just something I know." P. Ex. 8, at 21. When asked if he instructed Resident 2 to take deep breaths before starting tracheal care, LPN Ball responded, "I don't remember if I did or didn't." P. Ex. 8, at 27. During his deposition, LPN Ball testified it had been four years prior to August 2003 that he did tracheostomy care. P. Ex. 7, at 12. At the state administrative hearing, LPN Ball testified that prior to August 13, 2003, it had been three years and eights months, since January, 2000, when he had last suctioned a patient. LPN Ball also admitted that on August 13 and 14, 2003, he might have performed tracheal care that did not include suctioning. P. Ex. 8, at 14-15, 28-30.

⁸ At the hearing, CMS objected to both P. Exs. 7 and 8 on the basis of prejudice arising from its inability to cross-examine LPN Ball. I gave CMS the opportunity to subpoena LPN Ball to appear at a supplemental hearing if CMS decided that cross-examination was necessary. In its motion dated July 26, 2004, CMS waived further opportunity to subpoena LPN Ball because CMS argued that LPN Ball's state testimony and deposition were inaccurate and unpersuasive.

LPN Ball admitted that prior to August 13, 2003 when he began to do tracheostomy care on Resident 2, he had not reviewed any policies or procedures on tracheal care and that he had never received an orientation or in-service training on tracheal care while working at Petitioner's facility. P. Ex. 8, at 15-16, 18. LPN Ball never testified that he performed a respiratory assessment on Resident 2. P. Ex. 8, at 7-8. When asked if he listened to Resident 2's lung sounds or coughing, LPN Ball did not clearly respond and stated:

> Well, I went in before, as I mentioned, and he was clear, we had a good exchange. He didn't have any respiratory problems at the time. And he's very, again he was alert and oriented and he knows exactly, you know, when he needs suctioning.

P. Ex. 8, at 7-8. After admitting that it was typical to oxygenate a resident prior to tracheal care, LPN Ball was asked, "(d)id you oxygenate [Resident 2] prior to doing his trach care?" LPN Ball responded, "(h)e was on 4 liters [of oxygen] so he was breathing, you know, he was oxygenated." P. Ex. 8, at 24. I find LPN Ball's deposition and testimony from the state proceeding to be unclear, and evasive. Thus, I find LPN Ball's prior testimony and deposition to be of limited probative value and not particularly persuasive. In contrast, Surveyor Pearce was an eye-witness to what occurred between LPN Ball and Resident 2. Her testimony is clear, not evasive, and was subject to cross-examination by Petitioner. There is no indication that Surveyor Pearce had any cause to fabricate. I find Surveyor Pearce's testimony to be credible and highly probative.

The tracheal care of Resident 2 provided by LPN Ball did not meet the standard of care. LPN Ball did not wash his hands or clean them with alcohol solution prior to tracheal care. LPN Ball did not assess the resident prior to suctioning. LPN Ball did not hyperoxygenate the resident. LPN Ball suctioned while he inserted the suction catheter and he suctioned for an excessive amount of time. LPN Ball did not maintain sterile technique at all times. The tracheostomy suctioning did not comply with Petitioner's policy for such care and did not meet the standard of care.

Surveyor Pearce testified that she observed that Resident 2 experienced some respiratory distress and heavy coughing which required Resident 2 to rest before tracheostomy care could be completed.⁹ It is not subject to dispute that residents with tracheostomies are at

(continued...)

⁹ The totality of the evidence indicates to me that it is not uncommon for one undergoing tracheostomy suctioning to experience some distress due to the procedure. However, given LPN Ball's errors in conducting suctioning, I conclude that the distress Resident 2 suffered was greater than it would have been had suctioning been done

higher risk for infection than those who are not. It is also clear that a resident undergoing improper suctioning may experience hypoxia which can result in death.

Petitioner argues that a formal respiratory assessment and oxygenation of tracheal residents is not necessary because nurses are able to tell by observing the patient's skin color, breath sounds, and alertness whether a resident is stable enough to be suctioned. P. Br. at 6-7. The credible evidence does not show that LPN Ball did even a cursory assessment prior to beginning suctioning. Petitioner also argues that Resident 2 was not solely dependent on his tracheostomy tube for respiratory function and could breath without the tracheostomy tube. Tr. at 117, 118. I have no doubt that Resident 2 could breath through his mouth and/or nose when the tracheostomy tube was plugged as Surveyor Pearce observed it was prior to suctioning. However, Petitioner has presented no credible evidence that this makes a difference when the tracheostomy is open and being suctioned. Petitioner has also failed to explain how this fact warrants a deviation from its policy and the standard of care to hyper-oxygenate prior to suctioning. Petitioner's arguments that it was not necessary for LPN Ball to wash his hands or maintain sterile technique are equally meritless given the testimony of its own expert regarding the increased risk of infection for residents with tracheostomies and the need to maintain sterile technique.

Petitioner argues that tracheostomy patients are taught to provide their own care either while in a nursing home, or in preparation to return home from a nursing home. Tr. at 48, 115. Petitioner never clearly articulates why this is relevant. In this case Petitioner had a policy for tracheostomy suctioning and care that is consistent with the standard of care. LPN Ball failed to follow the policy.

(2) Resident 3.

It is alleged in the SOD that Surveyor Pearce observed tracheostomy suctioning and care on August 15, 2003, at 8:08 p.m. by LPN Jeanette Bazile. The surveyor alleges that LPN Bazile violated the facility policy because she: did not perform a respiratory assessment; failed to instruct the resident to cough and take several deep breaths prior to suctioning; failed to maintain a sterile hand for handling the suction catheter; was observed to crosscontaminate items from one hand to another; and did not clean the inner cannula of the endotracheal tube in the manner required by facility policy. The surveyor noted no obturator taped to the head of the bed and the LPN was unable to locate one in the

resident's room. The surveyor reports in the SOD that the nurse told her that she had

⁹(...continued) correctly.

been at the facility for 14 months and had no training in tracheostomy care. CMS Ex. 2 at 13-15.

Surveyor Pearce's testimony at hearing was not inconsistent with her observations as recorded in the SOD. The evidence shows that LPN Bazile did not assess Resident 3, did not ask Resident 3 to cough or take deep breaths, she did not hyper-oxygenate Resident 3, and she did not maintain sterile technique. Tr. at 103-04. No obturator was located in Resident 3's room. Tr. at 104. Surveyor Pearce testified that when LPN Bazile was asked about tracheal care experience and background that LPN Bazile replied that, "I have been here fourteen months and I've never had any trach care training." CMS Ex. 2, at 15; Tr. at 105. LPN Bazile did not appear at hearing and I have no prior testimony from her.

Petitioner does not dispute any of the surveyor's allegations concerning Resident 3. Rather, Petitioner argues that there was "no evidence that Ms. Bazile was observed touching anything unsterile in either hand and, if she had, she still did not create a risk of infection. Ms. Bazile did not touch the suction catheter in the area of the catheter that was doing the suctioning." P. Br. at 12. This argument is without merit particularly in the face of the testimony of Petitioner's expert that it is important to use sterile technique.

There is no dispute that staff could not locate an obturator for Resident 3 in the resident's room. I have already discussed that failure to maintain an obturator in the resident's room is a violation of the standard of care. The facility's nursing procedure manual does specify that after cleaning the inner cannula, the nurse should "verify that the inner cannula is clean and rinse for at least 10 seconds with sterile saline solution." CMS Ex. 6, at 5. The parties do not address this allegation and I have received insufficient evidence to determine the standard of care in this regard. However, the facility policy clearly calls for rinsing the inner cannula with saline before reinsertion. LPN Bazile failed to follow that policy and, thus, failed to deliver the quality of care that Petitioner was committed by its policy to deliver. Whether or not there is some risk of harm associated with residual hydrogen peroxide being introduced to the trachea is not established by the evidence. If supposition was permitted in adjudication, and it is not, one might suppose that hydrogen peroxide in the trachea would, at least, be unpleasant.

(3) Resident 1.

It is alleged in the SOD that Surveyor Pearce observed Resident 1 in his room at about 8:35 p.m. on August 15, 2003. Resident 1's tracheostomy was intact, he was receiving a nebulizer treatment, and he was not in respiratory distress. CMS Ex. 2, at 15-16.

Surveyor Pearce did not testify in any detail regarding this example of the alleged regulatory violation. With regard to Resident 1, during the hearing and in the parties' briefing, the parties focused upon whether an obturator could be located by either LPN Faith Thomas or the DON. Petitioner has never asserted that there was an obturator in the resident's room but, as already discussed, argued it sufficient for there to be an obturator on the crash cart. I conclude that the fact that there was no obturator in Resident 1's room violates the standard of care and that Petitioner was not providing the necessary care and services for this resident in violation of 42 C.F.R. § 483.25(k).

2. Petitioner violated 42 C.F.R. § 483.75.

The regulatory requirement is that a "facility must 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.

There is no dispute that on August 15, 2003, when the survey began, the facility had four residents with tracheostomies. Until August 12, 2003, tracheostomy care was provided by a respiratory therapy services company, Pulmonary Health Network, under contract with Petitioner. The respiratory therapy services company terminated its services because of a contract dispute at approximately 3:00 p.m. on August 12, 2003, leaving Petitioner to provide necessary tracheostomy services with its own nursing staff. CMS Ex. 11; Tr. at 253-56. Prior to the respiratory service company terminating its contract with Petitioner, Petitioner's staff did not regularly provide respiratory care to tracheostomy residents. Tr. at 227-28, 253-54, 278; CMS Ex. 44, at 10, 25; P. Ex. 7, at 9; P. Ex. 8, at 18.

The surveyors allege that Petitioner "was not administered in a manner that enabled it to use its resources effectively and efficiently to attain or maintain the highest practicable physical well being in rendering care to tracheostomy patients." CMS Ex. 2, at 19. My interpretation of the surveyor's allegation is that Petitioner did not effectively and efficiently use its resources in providing tracheostomy care in a manner to attain or maintain the highest practicable well being of its residents who required such care.

A narrow window of time is considered under this deficiency. The respiratory services contractor left the facility at 3:00 p.m. on August 12, 2003, the beginning of the second shift. The surveyors arrived on August 15, 2003 in the morning and made the observations related to Tag F 328 during the evening of August 15, 2003 to early morning hours of August 16, 2003. By mid-day on August 16, 2003, residents requiring tracheostomy care had been transferred to hospitals or other facilities. Thus, the focus of this deficiency citation is the three to four day period from August 12, 2003 to August 16, 2003. The issue is whether the Administrator and management took reasonable steps to ensure that,

despite the loss of the respiratory services company, the facility continued to deliver tracheostomy care to ensure residents with tracheostomies maintained the highest practicable state of physical well-being.

Petitioner argues that steps were taken by the administration so that its staff could provide competent tracheostomy care and suctioning. The DON conducted an emergency inservice training with the nursing staff at 3:30 p.m. on August 12, 2003. Tr. at 256-57; CMS Ex. 11; CMS Ex. 12. The August 12, 2003 in-service was used to announce that Petitioner's staff would now be providing tracheal care to residents since the respiratory service company was no longer providing services to residents. Tr. at 256; CMS Ex. 44, at 11. No hands-on-training with respiratory equipment or demonstrations on proper tracheostomy care were provided. Tr. at 268-69; CMS Ex. 44, at 11. No evidence was presented that any staff member at the in-service was observed by supervisors to determine if they were competent to perform tracheostomy care and suctioning. The sign-in sheet for the August 12, 2003 in-service showed that only 16 staff members attended. CMS Ex. 12.

Neither LPN Ball nor LPN Bazile attended the August 12, 2003 in-service. LPN Bazile had previously attended an in-service on November 23, 2002. P. Ex. 3. LPN Ball did not attend any in-service or review any policies or procedures prior to performing tracheostomy care. P. Ex. 1-7; P. Ex. 8, at 16, 18.

The Administrator, Reginald L. Eldridge, arranged for Omni Care Pharmacy to provide a respiratory therapist who came to the facility on August 13, 2003, to ensure all respiratory patients were stable. Tr. at 258-59; CMS Ex. 11. Also on August 13, 2003, a durable medical equipment (DME) provider came to the facility to provide training and to inventory tracheostomy supplies and make sure that the needed supplies were on hand. Administrator Eldridge thought that the DME provider would in-service staff on both care and equipment, however he later learned that only equipment was covered. Tr. at 257-58, 268; CMS Ex. 11; P. Reply at 4. On August 14, 2003, Dr. Blake, a pulmonologist, came to the facility on regular rounds to see all the tracheostomy residents. Tr. at 259-60, 267. The

Administrator Eldridge testified that Dr. Blake did not mention any issues with the residents that required respiratory care. Tr. at 259-60; CMS Ex. 11. Administrator Eldridge admitted on cross-examination that he did not know if Dr. Blake observed any staff providing tracheostomy care or suctioning. Tr. at 267.

Petitioner argues that the measures taken by Administrator Eldridge were sufficient to ensure that residents with tracheostomies received the required quality of care. P. Br. at 5, 14-15; P. Reply at 4-5. Although there is no dispute that Administrator Eldridge took immediate steps to attempt to ensure continued quality of care, those steps were

inadequate. Two residents did not receive quality care and those residents and another were placed at unnecessary risk for harm as no obturators were located in their rooms. Administrator Eldridge's errors or omissions that cause me to find that Petitioner violated 42 C.F.R. § 483.75 are: (1) he failed to ensure that all staff who would be required to deliver tracheostomy care and suctioning were knowledgeable and skilled in delivering those services; and (2) he failed to follow-up to ensure that the steps he immediately took actually led to staff being competent to perform tracheostomy care and suctioning. Administrator Eldridge admitted that he was aware of the possibility that the respiratory services company was going to leave. Tr. at 277. He also knew that his nursing staff had provided little or no tracheostomy care and suctioning on any shift during the time the respiratory services company was providing those services. Tr. at 253-54. While I do not find that Administrator Eldridge was deficient for not reacting before the respiratory services company left the building, he might have avoided the problems in this case by ensuring that his nurses received some supplemental training and were subjected to verification of their skills when he learned of the possibility that they were going to be providing the services if the company left. I do find Administrator Eldridge's management response deficient after the company left because he failed to follow-up after the DME representative visit and the pharmacy representative's visit to determine whether or not they provided any training on tracheostomy care and suctioning. He also failed to follow-up with his DON to determine whether the in-service training covered tracheostomy care and suctioning. Administrator Eldridge knew he had four residents that required tracheostomy care and suctioning but he did not follow-up or direct his DON to follow-up to ensure that his nurses were correctly doing tracheostomy care and suctioning. He just assumed his nurses were competent and failed to take the extra step to ensure they were. As already discussed in detail, at least two of the nursing staff failed to follow facility policy and provide tracheostomy care and suctioning in accordance with the standard of care.

Accordingly, I conclude that Petitioner violated 42 C.F.R. § 483.75.

3. The determination that the deficiencies posed immediate jeopardy is not subject to my review in this case.

The surveyors concluded that the violations of 42 C.F.R. §§ 483.25(k) and 483.75 posed immediate jeopardy for Petitioner's residents that required tracheostomy care and suctioning until they were removed from the facility on August 16, 2003. CMS does not indicate in its notice letter of August 25, 2003, whether or not it concurred with that finding or that it impacted the determination of the PICMP imposed. Counsel for CMS argues before me that there was immediate jeopardy and that it shows, for purposes of determining the appropriate remedy in this case, how serious the deficiencies were.

The regulations are clear that the scope and severity determination of immediate jeopardy, can be appealed but only if the range of CMP that can be imposed could change or if the facility's nurse's aide training program would be affected due to a finding of substandard quality of care. 42 C.F.R. §§ 498.3(b)(14)(i), (ii) and 498.3(d)(10)(i), (ii). The evidence does not show that Petitioner had a nurse aide training program. Further, there is but a single range for PICMPs and the amount of an PICMP is not affected by whether or not there is immediate jeopardy. 42 C.F.R. §§ 488.408; 488.438. As noted in Rosewood Living Center, DAB CR1293 (2005), at 17, "a determination of immediate jeopardy is irrelevant to the issue of what is reasonable in per-instance civil money penalties. A determination of immediate jeopardy is a necessary prerequisite to imposing a per-diem civil money penalty in excess of \$3,000, but is not a prerequisite to imposing a perinstance penalty in any amount up to \$10,000. See 42 C.F.R. § 488.438(a)(1)(i), (ii), (a)(2)." Thus, the immediate jeopardy finding is not subject to appeal or my review in this case. Nevertheless, I will consider whether or not the immediate jeopardy finding is an indication of the seriousness of the deficiency when deciding the reasonableness of the remedy.

4. A total PICMP of \$10,000, based upon \$5000 for each regulatory violation, is reasonable.

CMS determined to impose a PICMP of \$10,000, \$5,000 for each of the alleged deficiencies that posed immediate jeopardy. CMS Ex. 43. The regulation authorizes the imposition of a PICMP ranging from \$1,000 to \$10,000. 42 C.F.R. § 498.438(a)(2). I must assess *de novo* the reasonableness of the CMP proposed by CMS based on the factors set forth at 42 C.F.R. § 488.438(f). In determining the amount of the CMP, 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.

Neither party offered any evidence reflecting upon Petitioner's financial condition. Further, no evidence was presented to me concerning a history of similar deficiencies. Thus, the factors impacting my decision on reasonableness are the seriousness of the deficiencies and the culpability of Petitioner.

There is a potential for serious harm when tracheostomy care and suctioning is not performed competently in accordance with the standard of care. The evidence is persuasive that tracheostomy care and suctioning not performed in accordance with the standard of care could lead to infection, respiratory distress, obstruction of airways, and death. An extubation creates an emergency situation that requires that an obturator be readily available that can be used by competent staff for reinsertion. The evidence shows that for three residents an obturator was not present in their room where it would be readily available for reinsertion of the endotracheal tube if extubation occurred.Petitioner argues that none of its residents suffered respiratory distress or any other harm.P. Br at 15. Petitioner misunderstands the meaning of "immediate jeopardy." Very serious or even lethal harm could have resulted from the failure to provide quality tracheostomy care and suctioning and to have an obturator readily available for an emergency. This is a sufficient basis upon which to conclude that immediate jeopardy was posed in this case. Accordingly, I conclude that the deficiencies were extremely serious.

I also conclude that Petitioner was culpable in this case. The Administrator acknowledged that he was aware of the possibility that the respiratory services company would cease supplying services to Petitioner's residents. Nevertheless, the Administrator waited until the event occurred before taking action. When he did take action, he did so quickly, but he failed to follow-up to ensure that the four residents with tracheostomies received the quality of care required.

I conclude that a PICMP of \$10,000, \$5000 for each of two very serious deficiencies, is reasonable in light of the relevant factors.

III. Conclusion

For the foregoing reasons, I conclude that Petitioner failed to comply substantially with federal participation requirements and a PICMP of \$ 10,000 is reasonable.

/s/

Keith W. Sickendick Administrative Law Judge