MODEL EXPERT OPINION #5

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Date

Investigator/Medical Consultant (requesting review)
Medical Board of California
Street
City, CA Zip

Re: Jill A. Smith, M.D. Case #17-2008-000000 Patients: Multiple (3)

Materials Reviewed:

Binder #1:

- 1. Draft Investigation Report
- 2. Memoranda of District Medical Consultant
- 3. Dr. Smith's C.V., CME
- 4. Letters (6) written on behalf of Dr. Smith
- 5. Tape recordings of Dr. Smith's Interviews
 - > February 22, 2006
 - > July 21, 2006
- 6. Taped deposition of Dr. Smith

Binder #2:

- 7. Copy of the Certified Medical Records on patient Ann Doe.
- 8. Copy of the additional documentation provided by Dr. Smith in regards to Ann Doe during an interview about this patient on July 21, 2006.

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- 9. Copy of the certified medical record for Patient Abby Milton.
- 10. Copy of the additional documentation provided by Dr. Smith in regards to Abby Milton during an interview about this patient on July 21, 2006.

Binder #3

11. Copy of the certified medical records for patient Jack Brown.

Background Information:

Dr. Smith had Pulmonary and Critical Care privileges at University Hospital up until October of 2005. The Medical Board of California received an 805 Health Care Facility Report from University Hospital on 10-28-2005 restricting her interventional pulmonary and critical care privileges. The report stated that this was "based on multiple concerns regarding Dr. Smith's case selection and judgment." Dr. Smith had no prior investigations by the Medical Board or known malpractice cases. She denies any prior hospital inquiry or restriction of her privileges.

PATIENT: ANN DOE

Summary of Case:

Ms. Ann Doe (5' 7", 68.5 kg, BMI = 23.5) is a 62 year-old female who was admitted to University Hospital on 9-17-2004. Her initial complaint was chest pain. She had a history of a skin cancer removal from her cheek two years prior to admission. A chest radiograph in the Emergency Room revealed a left upper lung mass (5.3 cm x 3.4 cm). Cardiac work-up was negative. She was a non-smoker.

Dr. Smith performed a Pulmonary Consultation on Saturday, September 18, 2004. The hand written assessment is "Pt (patient) with LUL (left upper lobe) mass. Plan: Plan for FOB (fiber optic bronchoscopy) if...illegible... No evidence or constitutional symptoms for infection." There was no detailed discussion of the malignant possible etiologies of this mass in this non-smoker, or the relative benefits or risks of various approaches to work up the mass, either in the hand written note, or the dictated consultation.

There is also no indication why this procedure would be performed the following day (Sunday), rather than waiting for the regular bronchoscopy staff day. The work up was not emergent, therefore, if the patient was ready to be discharged from the point of view of the cardiologist and primary care physician, the bronchoscopy could have been done later as an outpatient or as a CT guided biopsy.

An elective bronchoscopy (with endobronchial biopsy and brushing) to elucidate the cause of this lung mass was performed by Dr. Smith on September 19, 2004 (Sunday). During the procedure, a 5 cm section of the cotton swab apparently broke off in her nares, and was subsequently swallowed by the patient. This broken wooden Q-tip required endoscopic (EGD)

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removal later that day (~1600). An addendum to the handwritten bronchoscopy note states that the patient swallowed a Q-tip. There were otherwise no other complications from the bronchoscopy and the patient was discharged Monday, September 20, 2004. The bronchoscopic dictation by Dr. Smith was performed one month after the procedure was performed (i.e. October 18, 2004). The EGD report was dictated on the same day as the procedure by Dr. Smith.

Respiratory cultures revealed a normal upper-airway bacterial flora and were negative from fungi, Legionella, viral, or AFB (tuberculosis) organisms. The pathologic reports from the bronchoscopy (washings and endobronchial biopsy, and brush) were non diagnostic, i.e. no malignant cells were identified.

During Dr. Smith's taped interview, she stated that the patient eventually was diagnosed with metastatic melanoma from her prior face lesion, however, this is not noted in the written documentation given to me to review. The subsequent diagnostic work up of the patient is not included in the records provided.

Medical Issues:

1. Medical record documentation.

♦ Standard of Care:

The standard of medical practice in California is to keep timely, accurate, and legible medical records.

♦ Analysis:

The handwritten consultation (9-18-2004), including the assessment and plan is very difficult to read due to handwriting illegibility. The consultation was not dictated for one month after the incident (10-18-2004 at 2020 hours), therefore, it was not available to the other providers taking care of this patient. The bronchoscopic procedure note was also not dictated until one month after the procedure and the handwritten bronchoscopic note is very difficult to read (10-18-2004 at 2023 hours). The necessity for legible and timely documentation of the bronchoscopic procedure is even more important in this case since a complication occurred (retained Q-tip) during the procedure requiring another procedure (EGD) to retrieve it. It is not clear from the case why the dictations were performed almost one month after the patient care was provided. The dictation system was clearly working as Dr. Smith was able to dictate his procedure note that same day (9-19-2004 at 1606 hours).

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♦ Conclusion:

There was a simple departure from the standard of care for failure to provide timely and legible documentation.

2. Were most appropriate strategies to work up this patient's chest mass considered in the pulmonary consult?

♦ Standard of Care:

The standard of medical practice in California is to identify the optimal test to obtain a diagnosis in the patient (i.e., the test that is the one most likely to obtain a diagnosis, while resulting in the least likelihood of potential harm to the patient). This may include a common pulmonary procedure, like bronchoscopy, but it also may include a procedure performed by other physicians, for example a CT guided percutaneous biopsy performed by the radiology department. This diagnostic evaluation should then lead to specific therapy.

♦ Analysis:

The bronchoscopy performed had a high likelihood of being non-diagnostic (as it was), since the greatest probability in this patient was a malignancy from some other site in the body, with metastasis to the lungs. This case would have been better approached by CT guided biopsy. Bronchoscopy was a more appropriate test, only if the patient had a long history of smoking increasing the probability that this was bronchogenic carcinoma. This type of peripheral solitary pulmonary nodule (no adenopathy, no pleural effusion) observed in this case is not well suited to bronchoscopy. There was no documentation of a discussion with the patient regarding other alternatives that might have been of higher diagnostic yield (including CT guided biopsy). During the interview the subject physician said she did not consider any other tests.

♦ Conclusion:

There was a lack of knowledge for failure to document and consider more appropriate strategies for diagnostic work-up of this patient's chest mass.

3. Performing a bronchoscopy procedure on a Sunday

♦ Standard of Care:

The standard of medical practice in California is to perform non-urgent or non-emergent procedures in the optimal setting for the patient. This includes minimizing the risk of a complication, maximizing safety, minimizing the risk of an additional procedure, and

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using the optimal staff to perform a procedure.

♦ Analysis:

This bronchoscopic procedure had very few indications, and certainly was not urgent or emergently required. There was no indication for this procedure to be done emergently on a Sunday with staffing that likely was sub-optimal for the procedure. The staffing of hospitals on a Sunday is always reduced compared to a regular business day, and the staff may have been pulled between other duties. There was no documentation of a discussion with the patient of performing this procedure, or a CT guided biopsy as an outpatient. Proceeding with a routine bronchoscopy on a Sunday could have increased the likelihood of complications. The patient also required an additional procedure (EGD), additional sedation, additional risk, and additional monitoring to remove a foreign body, and did not leave the hospital until the following morning (Monday, 9-20-2004).

♦ Conclusion:

There was a simple departure from the standard of care in proceeding to perform a non-urgent bronchoscopy on a Sunday, exposing the patient to potential greater risk.

PATIENT: ABBY MILTON

Summary of Case:

Ms. Abby Milton was a 35 year-old female (5' 8", 68.9 kg, BMI =23) who was admitted to University Hospital on 2-19-2005 for new-onset diabetes and hyperglycemia. She had no history of diabetes and was on no therapy to lower her blood sugar. Her blood sugar upon presentation was very high, 1172 mg/dl, the Sodium was 135, the osmolarity was 342, the bicarbonate was 31, the anion gap was 21 (electrolytes as of 2020 hours on 2-19-2005). She was given normal saline (approximately 2 liters) in the Emergency Department as well as insulin, 5 units IV push and a 5 unit/hour drip of regular insulin. Dr. Smith was called as the admitting physician by the Emergency Room Physician who comments on her blood sugar response to insulin, stating that "...we did recheck blood sugar an hour or two later and it was in the high 400 range. It was clear she was responding rather quickly..."

Dr. Smith saw the patient and wrote her handwritten admission note with a date of 2-19-2005 (no time). The admission laboratories are not filled in on her note. There is a recommendation to give additional insulin IV in her dictated note, and to continue with 6 units of insulin per hour, even though her blood sugar was already down from 1172 to ~ 400 in just 4 hours, an average drop of ~ 200 mg/dl/hour. The beta-HCG was negative.

Admitting orders that were written at 01:00 am on 2-20-2005, are very confusing. Dr. Smith

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wrote "Insulin Drip CT Surgery Protocol" in her admission orders (item #3) and then "(continue) Insulin Drip protocol aggressive protocol" as item #11 of the same order set, dated and timed at the same time. The "Intensive Insulin Infusion Protocol" was signed by Dr. Smith at 0100 hours on 2-20-2005. At this time, an additional set of blood chemistries had returned, approximately 4 hours after presentation (0045 hours on 2-20-2005), and the patient's glucose was 398. The anion gap had resolved. The drop in blood sugar was ~ 200 mg/dl/hour over that period. An order clarification at 0200 hours on 2-20-2005 states "Follow CT Surgery Insulin Protocol." Nursing states that they advised Dr. Smith that the protocol was not designated for diabetic ketoacidosis because the blood sugar would fall too quickly. Further blood sugars throughout the night and following day of 2-21-2005 were 206 (03:25 am), 209 (11:15 am), 207 (1815 hours or 6:15 pm), and 168 (05:18 am on 2-22-2005). Potassium fell to as low as 2.8 mmol/L, magnesium fell as low as 0.9 mg/dl, and phosphate apparently wasn't measured. No episodes of a blood sugar less than 100 mg/dl were recorded. The patient's insulin drip was discontinued the following morning, and she was placed upon a subcutaneous regiment of insulin (70/30), and discharged after Diabetes Education on 2-22-2005. The dictated discharge summary was performed on 2-22-2005 at 1548 hours.

Dr. Smith noted in her second interview with the Medical Board on 7-21-2006 that she was more familiar with the CT Surgery protocol as she had worked on it for the hospital. She did not appear to understand the issue of the rapidity of the blood sugar fall over such a short period of time. She seemed more focused on getting the blood sugar "normal" even if the rate of fall was very abrupt during her questioning at the Medical Board interview.

Medical Issues:

1. Medical Record Documentation

♦ Standard of Care:

The standard of medical practice in California is to keep timely, accurate, and legible medical records.

♦ Analysis:

The handwritten admission history and physical examination is very difficult to read and does not have critical information, including current electrolyte results and a treatment plan.

♦ Conclusion:

There was a simple departure from the standard of care for failure to provide timely, legible and important written documentation into the medical records.

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2. Use of the correct insulin therapy and treatment of DKA

♦ Standard of Care:

The standard of medical practice in California is to diagnose and appropriately treat illnesses in a safe, effective, and thoughtful way and to understand the common complications of treating DKA, including aggressive insulin therapy, and appropriately monitor, and treat electrolyte imbalance and prevent other complications. Moreover, the standard of medical practice in California is to confer and address the concerns of other health care providers when patient care issues arise, like use of the correct insulin order set and over aggressive correction of the blood sugar.

♦ Analysis:

Failure to utilize the correct insulin therapy for the patient could have resulted in serious complications. The drop in blood sugar was ~ 200 mg/dl/hour over the initial 4 hours of therapy. The recommended fall in blood sugar per hour is about one half that, or approximately 90 to 100 mg/dl/hour. Continuous, low-dose intravenous (IV) insulin infusion is generally felt to be the safest and most effective method of insulin delivery for treating DKA. Low-dose IV insulin infusion is simple, provides more physiological serum levels of insulin, allows gradual correction of hyperglycemia, and reduces the likelihood of sudden hypoglycemia and hypokalemia. The usual dose per drip is 0.1 U/kg/hr, but a lower dose of 0.05 U/kg/hr is enough to prevent gluconeogenesis and results in a slower reduction of blood glucose levels. Once this patient's blood sugar had fallen rapidly with hydration and higher dose insulin therapy, the dosage should have been cut down to approximately 3 units per hour.

Cerebral edema is the most serious complication of DKA. Its causes are not known, but associated factors include duration and severity of DKA before treatment, over aggressive fluid replacement, use of sodium bicarbonate to treat the acidosis, too aggressive correction of blood sugar levels, and the level of hyperglycemia. Cerebral edema is the most important cause of mortality and long-term morbidity with DKA.

There was a failure to adequately consider and monitor (every 1-2 hours) for important electrolyte complications of intensive insulin therapy, including hypokalemia, hypomagnesia, and hypophosphatemia. Levels of potassium, magnesium and phosphate should have been routinely measured and supplemented. Levels as low as in this patient can increase the risk of cardiac arrhythmia.

There was a lack of familiarity with the various insulin protocols existing in the hospital and failure to consider the well-meaning nursing advice regarding the various insulin protocols and the rapidity of blood sugar correction.

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♦ Conclusion:

There was an extreme departure from the standard of care and a demonstrated lack of knowledge in the management of this patient's DKA, and electrolyte imbalance. There was a lack of knowledge of the hospital's insulin protocols and the appropriate insulin dosing in this patient and a failure to address concerns raised by nurses regarding the insulin protocol being used.

PATIENT: JACK BROWN

Summary of Case:

Mr. Jack Brown is a 70 year old male (5' 2", 75.4 Kg, BMI = 23.8) with advanced, metastatic lung cancer and peptic ulcer disease/bleeding who was admitted to University Hospital on 10-10-2004. The paramedic report states that "Pt. (Patient) per family has been unable to recognize his family today and has not been answering appropriately. Pt. with mumbled speech and unable to answer questions(s)...Pt. also had one episode of clear emesis earlier." Mr. Brown had undergone his second cycle of chemotherapy ~ 6 days prior to his admission. He had also received radiation therapy to his hip. He was apparently extremely confused, combative, and uncooperative according to the Emergency Room note. Mr. Brown's blood pressure was also labile (as low as 50/30 mmHg) and he was tachycardic (~130 bpm). He was given Type Onegative blood and due to his continued altered mental status and unstable clinical state, he was intubated in the Emergency Room. His initial hemoglobin/hematocrit was 4.3 and 13. A right groin femoral line was placed to deliver blood and vasopressor therapy. Octreotide was started, IV Protonix was given for an active GI bleed, and Dr. Smith was contacted to admit the patient to the ICU. NG tube placement was attempted in the Emergency Room, but was unsuccessful. The patient was initially sedated with Propofol in the ED, but this was discontinued in the ICU and Fentanyl and Ativan drips were begun.

Dr. Smith performed a critical care consultation/history and physical on October 10, 2004 at 1740 hours. She wrote orders at 2150 hours. An EGD on 10-10-2004 revealed a Mallory Weiss Tear and severe Duodenitis. Levofed, NeoSynephrine, and Dopamine were used to support the low and labile blood pressure (goal for mean arterial pressure, MAP > 60 mmHg). Octreotide was discontinued.

Mr. Brown was transfused and stabilized. His platelet count remained low ~ 30 K. His mental status remained altered. No head CT scan was obtained until 10-13-2004 (3 days after admission) when the Hematologist/Oncologist consultant suggested it in his note dated 10-12-2004. The CT scan of the head (10-12-2004) did not reveal any evidence of CNS metastasis or bleeding.

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There were two bronchoscopies performed by Dr. Smith on this patient. The first was on 10-12-2004 at 1600 hours, the second was 10-15-2004 at 1300 hours. The indication for the first bronchoscopy appears to be thick, copious secretions. Dr. Smith was apparently interested in identifying an organism responsible for the ventilator associated pneumonia (VAP) and right sided infiltrate on the CXR (according to the note dated 10-12-2004), and clearing secretions from that side of the lung. The dictation lists the indication for the procedure as "#1) Respiratory Failure, status post self extubation, #2) Hemodynamic compromise, and #3) Obtundation to protect the airway". The patient was apparently re-intubated over a bronchoscope. Cultures were sent, although it is unclear if a bronchoscopy wash or BAL was performed from the dictated note. No bronchoscopic findings were dictated in the original procedure note (10-12-2004 at 1711 hours), however, 11 minutes later (10-12-2004 at 1722 hours), Dr. Smith dictated an addendum that lists the findings of "copious amounts of foul-smelling secretions in the right middle lobe and right lower lobe." There was no mention of the altered mental status, or the possibility of a metastasis or intracranial bleed resulting in the increased intracranial pressure, possibly increasing the risk of the bronchoscopic procedure. The bronchoscopic wash culture from 10-12-2004 revealed "Few Pseudomonas, Moderate Alpha Streptococcus and Neisseria species consistent with Normal Respiratory Flora."

A second bronchoscopy was performed on 10-15-2004 at 1300 hours. The dictation was performed on 10-15-2004 at 1839 hours. The indications listed on the dictated procedure note are "Bilateral worsening infiltrates on chest x-ray. Copious secretions since yesterday. Consent obtained by the family." BAL and bronchoscopy wash was performed on the right side. The respiratory culture from the bronchoscopy grew Pseudomonas again.

The patient was on Versed (24 mg over 12 hours from 0600 hours to 1800 hours on 10-15-2004), and Fentanyl drips (104 mcg over 12 hours from 0600 hours to 1800 hours on 10-15-2004) for sedation. Mr. Brown continued on Neosynephrine and Levophed drips. During the bronchoscopy procedure on 10-15-2004, Dr. Smith ordered 10 mg of Versed at 1310 hours and 10 more mg of Versed at 1335 hours. The patient was given 50 mcg of Fentanyl at 1300 hours. The dictated procedure note only lists 6 mg of Versed and 30 mcg of Fentanyl for sedation. The nursing documentation also states "Due to large amounts of Versed given, nurse wished to confirm meds given. MD (Dr. Smith) refused to write out order." Nursing and medication sheets indicate that more than 6 mg of Versed and more than 30 mcg of Fentanyl were given during the bronchoscopy. The patient developed tachycardia (HR 135), PVCs, and then elevated systolic blood pressure (Systolic BP ~ 180 mmHg) during/after the procedure.

Dr. Smith attempted three arterial lines (R Radial, L Femoral, R Femoral). On the dictated note (10-13-2004 at 1501 hours), the indication for "...A (arterial) line is hypotension, requiring Levophed, lost other arterial line, and needing serial ABGs." All three sites had pulses identified prior to attempting the arterial lines according to the dictation. All three sites attempted were unsuccessful by Dr. Smith on 10-13-2004. According to the handwritten and dictated note the femoral sites were aborted due to "Bilateral artery stenosis secondary to possible radiation therapy." A successful left femoral arterial line was placed by another physician on the same day

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at 1600 hours. The Medical Board interview on 4-6-2006 stated that the proctor was not at bedside during these procedures.

There were also significant behavioral issues raised by the peer review from University Hospital on this case. Specifically, that Dr. Smith was inappropriate with staff, patients and family members, and displayed unethical and dishonest behavior. The family requested to have a different physician than Dr. Smith as of 10-15-2004. The stated reasons were "lack of communication, questioned judgment." They stated that she was "madly ordering tests and thinking out loud." Further, they felt she was abrupt and always in a hurry, thus not addressing their concerns and questions. Dr. X covered the patient over the weekend of 10-16-2004 to 10-18-2004 as a "second opinion", and Dr. X was the new physician in charge as of 10-18-2004. According to the peer review documentation, on 10-18-2004, Dr. Smith angrily confronted the family and wanted to know why they wanted her removed from the case. It also stated that Dr. Smith told the family that the "problems were caused by the inexperience of ICU nurses." During her interview with the Medical Board on 2-22-2006, Dr. Smith stated that she had not been argumentative with the family. The family simply stated that "it was not a popularity contest and they wanted a second opinion." Dr. Smith arranged for a second opinion with Dr. X, and eventually the care was transferred to Dr. X. Mrs. Brown wrote a letter to University Hospital (received by the medical staff office on October 27, 2004) expressing her dismay with Dr. Smith's performance in the care of her husband, her dismay that Dr. Smith is being "assigned to critically ill patients," and requesting that Dr. Smith's "place at University (be) reviewed.", i.e. her role in the ER panel.

The patient was eventually stabilized and extubated, his mental status improved, and he was discharged on 10-30-2004. Mr. Browm was apparently going to move with his family to Dallas for follow-up care.

Medical Issues:

1. Medical Record Documentation

♦ Standard of Care:

The standard of medical practice in California is to keep timely, accurate, and legible medical records.

The standard of medical practice in California for a Critical Care Physician is to identify, comment upon, and appropriately manage all aspects of critical care illness.

♦ Analysis:

There was a failure to provide timely, legible, and accurate documentation. The handwritten consultation admission note to the ICU is incomplete (platelet count not

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filled in) and very disorganized. The note fails to document and address several important features of this patient's presentation, including his altered mental status and severe thrombocytopenia (11K). The handwritten assessment and plan is very difficult to read due to handwriting illegibility and is poorly organized and incomplete. The dictated note was performed in a timely fashion (10-10-2004 at 1821 hours), but it is poorly organized and also fails to address important problems including thrombocytopenia and altered mental status and has an inadequate neurological assessment.

♦ Conclusion:

There was an extreme departure from the standard of care in failure to maintain adequate records with failure to provide legible and organized assessment and treatment plans, including daily progress notes (e.g. 10-15-04) and failure to note the marked thrombocytopenia with an altered mental state.

2. Indication for bronchoscopies

♦ Standard of Care:

The standard of medical practice in California is to perform only clinical indicated procedures such as a bronchoscopy when the patient is stable enough to perform the intervention, and when the procedure will not contribute to additional morbidity and mortality. The standard of medical practice in California is to understand the complications of sedation and to utilize the minimum amounts required to perform the procedure and to accurately order and record the quantity of sedative medication administered.

♦ Analysis:

The bronchoscopic procedures performed in this patient appeared to have minimal indications, despite being high risk, i.e. performed in a very ill patient with altered mental status who was requiring an enormous amount of sedation.

Dr. Smith apparently refused to provide a written order for the verbal orders she gave for use of 10 mg Versed x 2 on 10-15-04. The quantity of Versed given to this patient was excessive, given the patient had a Versed drip in place.

♦ Conclusion:

There were two simple departures from the standard of care in performing two bronchoscopies without clear cut clinical indication and simple departure from the standard of care for excessive prescribing of Versed during a bronchoscopy on 10-15-04.

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3. Placement of arterial line

♦ Standard of care:

The standard of medical practice in California is to have the appropriate procedural skills to perform the indicated procedure such as placement of an arterial line, or to consult someone else who does.

♦ Analysis:

There was a failure to obtain assistance with the arterial lines in a timely fashion, despite attempting placement in three different locations. Dr. Smith appears to have great difficulty with arterial line placement. Indeed, she dictated that the patient had "Bilateral artery stenosis secondary to possible radiation therapy" despite the fact that she was able to palpate pulses at each site prior to starting the procedures and another operator was able to place a left femoral arterial line later that same day without difficulty.

♦ Conclusion:

There was demonstrated lack of knowledge in attempting to place an arterial line.

4. Dr. Smith's response to the patient's family and hospital staff

♦ Standard of Care:

The standard of medical practice in California is to be considerate, reassuring, and comforting with the patient's family. The physician should communicate regularly and effectively regarding the constantly changing clinical status of a patient in the Intensive Care Unit.

The standard of medical practice in California is to confer and address the concerns of other health care providers, including nursing staff when patient care issues, like over sedation and an unstable state are raised.

♦ Analysis:

It is alleged by University Hospital staff that Dr. Smith was confrontational with the patient's family and nursing staff especially when her judgment was called into question. This resulted in both verbal and written complaints from the patient's family.

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♦ Conclusion:

If the allegations made by the patient's family and hospital staff are true, this would represent a simple departure from the standard of care, for failure to effectively communicate with the patient's family to allow them to change physicians, and for failure to effectively communicate with hospital nursing staff so as not to impair the quality of care provided.

(Signature) Michael Murray, M. D. (Date) 1/2/13 Michael Murray, M.D., FACP, FCCP