STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

DEPARTMENT OF HEALTH, BOARD OF MEDICINE,	)	
Petitioner,	)	
vs.	)	Case No. 01-3030PL
DANIEL T. MCGUIRE, M.D.,	)	
Respondent.	)	

RECOMMENDED ORDER

Pursuant to notice, a formal hearing was conducted in this case on December 12, 2001, in Fort Myers, Florida, before Lawrence P. Stevenson, a duly-designated Administrative Law Judge of the Division of Administrative Hearings.

APPEARANCES

For Petitioner: Kim M. Kluck, Esquire
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For Respondent: Bruce M. Stanley, Esquire
Henderson, Franklin, Starnes & Holt, P.A.
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STATEMENT OF THE ISSUE

The issue presented for decision in this case is whether Respondent should be subjected to discipline for the violations of Chapter 458, Florida Statutes, alleged in the

Administrative Complaint issued by Petitioner on June 24, 2001.

PRELIMINARY STATEMENT

By Administrative Complaint dated June 24, 2001 (the "Complaint"), Petitioner alleged that Respondent, a licensed physician, violated provisions of Chapter 458, Florida Statutes, governing medical practice in Florida. The single count of the Complaint relates to the pre-operative and post-operative care of Patient M. S., on whom Respondent performed a complex open reduction and internal fixation of a left distal femur fracture.

The Complaint alleges that Respondent failed to practice medicine with that level of care, skill, and treatment which is recognized by a reasonably prudent similar physician as being acceptable under similar conditions and circumstances, in violation of Section 458.331(1)(t), Florida Statutes, in that Respondent failed to perform an irrigation and debridement of Patient M. S.’s left distal femur wound within the first 8-24 hours of his emergency admission; failed to obtain cultures of Patient M. S.'s left distal wound to identify organisms more specifically; and failed to timely obtain an infectious disease consultation to determine the cause and extent of Patient M. S.'s infection.

Respondent contested the allegations of the Complaint and timely requested a formal administrative hearing. Petitioner forwarded the Complaint to the Division of Administrative Hearings on July 27, 2001, requesting the assignment of an Administrative Law Judge and the conduct of a formal hearing pursuant to Sections 120.569 and 120.57, Florida Statutes. The matter was assigned to the undersigned, who set the case for final hearing on September 24 and 25, 2001. Two continuances were granted, the hearing ultimately being scheduled for and held on December 12, 2001.

At the final hearing, Petitioner presented the testimony of Steven J. Lancaster, M.D., by way of a deposition transcript. Petitioner's Composite Exhibit 1, the deposition and the curriculum vitae of Dr. Lancaster, was admitted into evidence.

Respondent testified on his own behalf and presented the testimony of Edward R. Sweetser, M.D., by way of a videotaped deposition and transcript. Respondent’s Exhibit 1, the curriculum vitae of Dr. Sweetser, and Composite Exhibit 2, the videotape and transcript of Dr. Sweetser's deposition, were admitted into evidence.

Joint Exhibit 1, the relevant medical records from Lee Memorial Hospital, was admitted into evidence.

A Transcript of the proceeding was filed on January 4, 2002. The parties timely filed Proposed Recommended Orders.

FINDINGS OF FACT

Based on the oral and documentary evidence adduced at the final hearing, and the entire record in this proceeding, the following findings of fact are made:

1. Petitioner is the state agency charged with regulating the practice of medicine in the State of Florida, pursuant to Section 20.43, Florida Statutes, and Chapters 456 and 458, Florida Statutes. Pursuant to Section 20.43(3), Florida Statutes, Petitioner has contracted with the Agency for Health Care Administration to provide consumer complaint, investigative, and prosecutorial services required by the Division of Medical Quality Assurance, councils, or boards.

2. At all times relevant to this proceeding, Respondent was a licensed physician in the State of Florida, having been issued license no. ME 0071241. At the time of Patient M. S.'s treatment, Respondent practiced orthopedic medicine in Florida. Respondent is currently employed as an orthopedic surgeon in Pennsylvania and as an assistant professor at the Medical Center of Penn State University. He no longer practices medicine in Florida.

3. On February 11, 1998, Patient M. S., a 41-year-old male, was involved in a motor vehicle accident. He was

transported by ambulance to Lee Memorial Hospital in Fort Myers, where he was evaluated by the emergency room physician. Respondent was consulted as the orthopedist on call for the emergency room that evening.

4. When Respondent arrived at the emergency room, Patient M. S. was lying on a stretcher with his lower left leg in provisional traction as applied by the emergency medical technicians at the scene of the accident. Patient M. S. spoke only Spanish, so Respondent had to rely on an interpreter to communicate with him. Respondent observed that the left lower leg was shortened and completely externally rotated, consistent with a comminuted distal femur fracture. A "comminuted" fracture is a fracture in which there are multiple breaks in the bone, with several fragments. Respondent testified that upon touch, Patient M. S.'s leg was like "a bag of marbles." The patient’s right leg was not fractured but had a six-centimeter deep laceration over the shin that went down to the bone.

5. There was a less than one-centimeter superficial wound over the left distal, anterior thigh, caused by a spike of bone fragment that had pierced the skin from within. This wound was leaking bloody, fatty material. Bones contain adipose, or fatty, tissue. A fracture of the bone can result in communication of that fatty tissue with the open wound,

meaning there is direct contact of the fracture site to the outside of the body.

6. X-rays confirmed Respondent's observation of a comminuted distal femur fracture. Respondent diagnosed Patient M. S. with a large wound to the right leg and "left complex intra-articular femur fracture, grade I open." A "grade I" open fracture, according to the Gustilo and Anderson system for grading open fractures, is a relatively clean wound with a skin fracture of less than one centimeter (cm).

7. Respondent described the femur fracture as one of the worst he had ever seen, with multiple bone fragments and a considerable degree of trauma to the muscle surrounding the fracture. Respondent and both expert witnesses agreed that a fracture of this nature is highly susceptible to infection.

8. Respondent irrigated the right lower leg wound with a Betadine and sterile saline solution, then debrided and closed the wound in the emergency room. "Betadine" is a trade name for povidone-iodine, a topical antiseptic microbicide. Intravenous antibiotics were administered to prevent infection of this deep wound.

9. Respondent then treated the fracture in Patient M. S.’s left lower leg by taking it out of the temporary traction applied by the EMTs, placing a skeletal traction pin in the proximal tibia and transferring the patient to a

hospital bed, where he was placed in balanced skeletal traction.

10. As to the small wound on the left leg, Respondent's contemporaneous notes indicate only that it was dressed with Betadine-soaked gauze. The discharge summary for Patient M. S. states that the left leg wound was "irrigated and dressed." Respondent testified that he cleaned and dressed the wound, but did not irrigate it on February 11. Respondent's testimony on this point is credited.

11. The complexity of the fracture to Patient M. S.'s left lower leg and the hospital's operating room schedule required that the surgery be done on February 14, 1998. Patient M. S. remained in traction in the hospital during this pre-operative period.

12. On February 14, 1998, Respondent conducted orthopedic reconstructive surgery to repair the complex fracture of Patient M. S.'s left lower leg. Respondent attached medial and lateral plates and screws and performed a bone graft. The surgery lasted approximately eight hours.

13. At the conclusion of the surgery, the incisions were dressed and Patient M. S.'s left leg was wrapped in a bulky sterile dressing. Deep drains were placed in the knee and thigh during wound closure to prevent the formation of a deep hematoma, which can be a medium for infection.

14. The nurse's assessment for February 16, 1998, notes a small amount of bloody drainage from the auto collection drainage device. Patient M. S. was running a temperature of 100.1°F.

15. The nurse's assessment for February 17, 1998, notes a large amount of bloody drainage from the auto collection device on two separate occasions. Subsequently, the assessment notes a "slight odor" from the dressing on Patient M. S.'s left leg surgical incision site.

16. On February 18, 1998, Patient M. S. had a temperature of 102°F, with an elevated white blood cell count. Respondent evaluated Patient M. S. and observed that the dressing on the left leg was "damp/green tinged" and had a "foul odor of Pseudomonas." Respondent lowered the dressing and found it to be "saturated and green." Respondent concluded that the dressing had been colonized from without by Pseudomonas bacteria, and ordered intravenous tobramycin as a precaution to prevent the bacteria from colonizing to the wound.

17. On both February 17 and 18, there was serosanguineous drainage from the surgical incision on Patient M. S.'s left leg.

18. On February 19, 1998, Patient M. S. ran a temperature of 102.1°F.

19. Respondent discharged Patient M. S. on February 20, 1998. At that time the patient fulfilled all appropriate discharge criteria. His fever had subsided to a normal temperature and his hemoglobin was stable. Patient M. S. was given discharge instructions by Respondent in writing as well as orally in Spanish. Respondent prescribed the oral antibiotics Keflex and Cipro for two weeks as a further precaution against infection. Patient M. S. was scheduled for a follow-up visit with Respondent on March 4, 1998.

20. Patient M. S. was instructed to call Respondent if he experienced increased pain, numbness or tingling, a fever of 101°F or higher, tenderness or pain in his calves, or excessive swelling, redness, or drainage.

21. On or about February 26, 1998, Patient M. S. presented to St. Joseph's Hospital in Tampa with apparent pain plus pus drainage from the surgical incision site on his left leg. He was diagnosed with methicillin resistant Staphylococcus aureus, Enterobacter, and Pseudomonas in his left leg.

22. On or about March 2, 1998, Patient M. S. underwent an above the knee amputation of his left leg due to complications from infection in the leg.

23. Subsequent to discharging Patient M. S. from Lee Memorial Hospital on February 20, 1998, Respondent received no

notice of further problems with Patient M. S.’s leg until receiving notice of this action against him. Patient M. S. did not contact Respondent after complications began to develop. St. Joseph's Hospital in Tampa did not contact or consult with Respondent after Patient M. S. presented there. Respondent's first knowledge of any complications from the surgery came when he received notice of this proceeding against his license.

24. Two issues are presented by the course of treatment described above. The first issue is whether Respondent acted within the standard of care by cleaning and dressing the less than one cm open fracture in the emergency room, or whether Respondent should have performed an irrigation and debridement of that wound in the operating room.

25. Respondent is a board certified orthopedic surgeon with a great deal of experience in trauma. This was one of the worst femur fractures he had ever seen. His priorities on the night of February 11 were to acutely address the severe cut on Patient M. S.'s right shin, and to pull the left leg to length prior to surgery. The small left leg wound was "very clean," and in hindsight Respondent questioned whether he should even have classified it as a Grade I open fracture. He cleaned the wound, placed a Betadine dressing on it, then

followed "routine procedure" by prescribing prophylactic antibiotics.

26. The agency's expert, Dr. Steven Lancaster, also is a Board-certified orthopedic surgeon who routinely undertakes trauma cases in his practice. Based on the testimony of Dr. Lancaster the standard of care requires urgent irrigation and debridement of all open fractures, and this standard is prescribed by both the American Board of Orthopedic Surgeons and the American Academy of Orthopedic Surgeons. Irrigation involves cleaning an area with saline solution. Debridement involves the trimming of contaminated or devitalized tissue, the removal of foreign material from wounds, and the cleaning of bone and muscle tissue.

27. Dr. Lancaster stated that, absent a life-threatening condition, it is necessary to perform the irrigation and debridement of an open fracture as soon as possible. Patient M. S. faced no life-threatening condition. According to Dr. Lancaster, the urgency is due to the fact that bacteria have already been introduced into the wound at the time of injury. If more than twelve hours pass, the bacteria have colonized, and the wound is more properly considered infected than merely contaminated. Dr. Lancaster testified that the small size of the wound did not change the urgency of performing the irrigation and debridement; microscopic

bacteria are as capable of entering a small wound as a large one.

28. Respondent's expert, Dr. Edward Sweetser, is also a board certified orthopedic surgeon with trauma experience, though the majority of his practice is in general orthopedics. Dr. Sweetser testified that he would not have debrided the small left leg wound in the emergency room, and that the standard of care would not require debridement. He noted that it was a very small laceration, that it appeared to be a puncture from within, and that it did not appear to be contaminated. Dr. Sweetser believed that cleaning and covering the wound with Betadine-soaked gauze was sufficient to keep bacteria out of the wound, and that the ordering of an intravenous antibiotic was entirely appropriate for treatment of any open wound.

29. It is found that the agency established by clear and convincing evidence that the standard of care required urgent irrigation and debridement of the small left leg wound. Dr. Lancaster persuasively testified that such observations as the small size of the wound or that the wound appeared "very clean" to the naked eye did not affect the potential for bacterial infection. Respondent offered no rebuttal to Dr. Lancaster's testimony that urgent irrigation and debridement of open fractures is the standard prescribed by

the American Board of Orthopedic Surgeons and the American Academy of Orthopedic Surgeons.

30. The agency failed to establish by clear and convincing evidence that Respondent's failure to perform the irrigation and debridement of the left leg wound was the cause of the subsequent infection. All of the testifying orthopedists agreed that an injury such as that suffered by Patient M. S. is highly susceptible to infection from multiple possible sources. Dr. Sweetser persuasively opined that the likely main cause of the infection was the severity of the injury, both to the bone and the soft tissue, and the extended length and extensive exposure of the surgical procedure.

31. The second issue is whether Respondent acted within the standard of care subsequent to the surgery by treating Patient M. S. with prophylactic antibiotics, or whether Respondent should have pursued the more aggressive course of reopening the left leg wound for purposes of taking a deep tissue culture to determine the presence of infection.

32. Respondent did not suspect an inside infection of Patient M. S.'s wound. He knew that an injury of this nature carries a high incidence of infection, and believed that prophylactic antibiotics sufficiently allayed that threat. When he changed the dressing on February 18, Respondent noted serous drainage, which he termed normal given the amount of

trauma and the extremely large exposure required to perform the surgery.

33. Respondent also noted the green tinge on the outside of the dressing. When the drainage soaks through to the outside of the dressing, it is not unusual for the outside of the dressing to become colonized by Pseudomonas bacteria, which are abundant in the hospital setting. He had no indication or suspicion that the infection was within the wound. The wound looked "very good," with no redness or purulence, intact with only serous drainage. Respondent put a clean dressing on the wound and, as a precaution due to the outside colonization, ordered tobramycin in addition to the intravenous antibiotics Patient M. S. was already receiving.

34. Respondent noted the fever and elevated white blood cell count, but also noted that Patient M. S. was afebrile with a stable hemoglobin when he was released from the hospital. Fever is common in post-surgical patients for reasons other than infection. The most common cause is the release of pyrogens by soft tissue trauma. Another common cause of fever is atelectasis, small areas of collapse in the lung resembling pneumonia. Patient M. S. received multiple transfusions, which can cause fever due to the body's immune response. In some instances, antibiotics themselves can cause a fever.

35. Respondent testified that, after spending eight hours in surgery, he would have "done anything" to save Patient M. S.'s leg. If he had suspected an inside infection, he would have taken the patient back into the operating room, reopened the wound, and obtained a deep culture.

36. Dr. Lancaster testified that Respondent fell below the standard of care by discharging Patient M. S. "with a febrile condition and, potentially, with an infected leg." Dr. Lancaster believed that the fever and elevated blood count required an explanation, and that Patient M. S. should not have been discharged until some effort was made to identify whether there was an infection. Dr. Lancaster's opinion is of questionable value because Patient M. S. was not running a fever and showed a stable hemoglobin on the date of discharge. Dr. Lancaster did not directly address how the patient's apparent stability on February 20 might affect his opinion. Dr. Lancaster acknowledged that post-surgery fever is common and not necessarily indicative of an infection.

37. Dr. Sweetser's credible testimony is that, "based on reasonable medical probability," Patient M. S.'s discharge on February 20 did not violate the standard of medical care. He based his opinion on the facts that the patient had no fever, no increasing swelling in the wound, no redness, no purulent drainage, and no increase in pain. Nothing in the medical

record provided a reasonable basis for Respondent to reopen the wound, and that reopening the wound delays healing and itself heightens the risk of infection.

38. It is found that the Agency failed to establish by clear and convincing evidence that the standard of care required reopening the left leg wound for purposes of taking a deep tissue culture to determine the presence of infection. The objective facts in the medical record make it reasonable that Respondent did not suspect infection in the wound on Patient M. S.'s left leg. Therefore, his failure to obtain a wound culture or to consult with an infectious disease specialist was not outside the standard of care required of him in this case.

39. Both experts agreed that the chances of saving Patient M. S.'s leg would have been better if Respondent had been consulted when the patient presented at St. Joseph's Hospital in Tampa. The Agency's expert, Dr. Lancaster, stated that when a patient has a complication, it is better practice for the operating surgeon to treat it. Dr. Sweetser testified that the operating surgeon possesses information for which the written notes and x-rays cannot substitute.

CONCLUSIONS OF LAW

40. The Division of Administrative Hearings has jurisdiction over the parties and subject matter of this

cause, pursuant to Sections 120.569, 120.57(1), and 456.073, Florida Statutes.

41. License revocation and discipline proceedings are penal in nature. The burden of proof on Petitioner in this proceeding was to demonstrate the truthfulness of the allegations in the Complaint by clear and convincing evidence. Section 458.331(3), Florida Statutes; Department of Banking and Finance v. Osborne Stern and Company, 670 So. 2d 932 (Fla. 1996); Ferris v. Turlington, 510 So. 2d 292 (Fla. 1987).

42. The "clear and convincing" standard requires:

> [T]hat the evidence must be found to be credible; the facts to which the witnesses testify must be distinctly remembered; the testimony must be precise and explicit and the witnesses must be lacking in confusion as to the facts in issue. The evidence must be of such weight that it produces in the mind of the trier of fact a firm belief or conviction, without hesitancy, as to the truth of the allegations sought to be established.

Slomowitz v. Walker, 429 So. 2d 797, 800 (Fla. 4th DCA 1983). The findings in this case were made based on the standard set forth in Osborne Stern and Ferris.

43. Pursuant to Section 458.331(2), Florida Statutes, the Board of Medicine is authorized to revoke, suspend, or otherwise discipline the license of a physician for violating the following relevant provision of Section 458.331, Florida Statutes:

> (1)(t) Gross or repeated malpractice or the failure to practice medicine with that level of care, skill, and treatment which is recognized by a reasonably prudent similar physician as being acceptable under similar conditions and circumstances . . . . As used in this paragraph, "gross malpractice" or "the failure to practice medicine with that level of care, skill, and treatment which is recognized by a reasonably prudent similar physician as being acceptable under similar conditions and circumstances," shall not be construed so as to require more than one instance, event, or act. Nothing in this paragraph shall be construed to require that a physician be incompetent to practice medicine in order to be disciplined pursuant to this paragraph.

44. Section 458.331(2), Florida Statutes, provides, in relevant part:

> The board may enter an order denying licensure or imposing any of the penalties in s. 456.072(2) against any applicant for licensure or licensee who is found guilty of violating any provision of subsection (1) of this section or who is found guilty of violating any provision of s. 456.072(1).

45. Section 456.072(2), Florida Statutes, sets forth the scope of discipline available to the Board of Medicine for violations of Section 458.331(1), Florida Statutes:

> (a) Refusal to certify, or to certify with restrictions, an application for a license.
>
> (b) Suspension or permanent revocation of a license.
>
> (c) Restriction of practice or license, including, but not limited to, restricting

the licensee from practicing in certain settings, restricting the licensee to work only under designated conditions or in certain settings, restricting the licensee from performing or providing designated clinical and administrative services, restricting the licensee from practicing more than a designated number of hours, or any other restriction found to be necessary for the protection of the public health, safety, and welfare.

(d) Imposition of an administrative fine not to exceed $10,000 for each count or separate offense. If the violation is for fraud or making a false or fraudulent representation, the board, or the department if there is no board, must impose a fine of $10,000 per count or offense.

(e) Issuance of a reprimand or letter of concern.

(f) Placement of the licensee on probation for a period of time and subject to such conditions as the board, or the department when there is no board, may specify. Those conditions may include, but are not limited to, requiring the licensee to undergo treatment, attend continuing education courses, submit to be reexamined, work under the supervision of another licensee, or satisfy any terms which are reasonably tailored to the violations found.

(g) Corrective action.

(h) Imposition of an administrative fine in accordance with s. 381.0261 for violations regarding patient rights.

(i) Refund of fees billed and collected from the patient or a third party on behalf of the patient.

> (j) Requirement that the practitioner undergo remedial education.
>
> In determining what action is appropriate, the board . . . must first consider what sanctions are necessary to protect the public or to compensate the patient. Only after those sanctions have been imposed may the disciplining authority consider and include in the order requirements designed to rehabilitate the practitioner. All costs associated with compliance with orders issued under this subsection are the obligation of the practitioner.

46. The Complaint alleged that Respondent practiced medicine below the standard of care by failing to perform an irrigation and debridement of Patient M. S.’s left distal femur wound within the first 8-24 hours of his emergency admission; failing to obtain cultures of Patient M. S.'s left distal wound to identify organisms more specifically; and failing to timely obtain an infectious disease consultation to determine the cause and extent of Patient M. S.'s infection.

47. Petitioner established that Respondent failed to practice Medicine with that level of care, skill, and treatment which is recognized as being acceptable under similar conditions and circumstances as set forth in the charge of failure to perform an irrigation and debridement of Patient M. S.’s left distal femur wound within the first 8-24 hours of his emergency admission. The evidence established that the standard of care requires urgent irrigation and

debridement of an open fracture, absent life-threatening circumstances, that there were no life-threatening conditions present in this case, and that Respondent cleaned and dressed the wound but did not irrigate and debride it within the first 8-24 hours of admission. However, the evidence also established that it was unlikely that Respondent's failure to irrigate and debride the left leg wound caused the subsequent infection.

48. Petitioner failed to establish that the standard of care required Respondent to obtain cultures of Patient M. S.'s left distal wound to identify organisms more specifically or to consult with an infectious disease specialist, under the facts as found above. Both experts agreed with Respondent's observation that Pseudomonas colonization on the outside of a saturated dressing is not uncommon and is not a necessary indication of infection within the wound. Rather, the colonization confirms the proximity of Pseudomonas and calls for the application of prophylactic antibiotics, the course pursued by Respondent.

49. The only other objective indicia of possible infection were fever and an elevated white blood cell count, both of which had stabilized on the date of discharge and neither of which necessarily indicated the need to reopen a healing wound to obtain a deep culture. In hindsight, it is

obvious that the more aggressive course advocated by Dr. Lancaster might have saved Patient M. S.'s leg. However, the fact that two physicians arrive at different determinations as to the course of treatment for a patient does not necessarily mean that either physician has deviated from the standard of care.

50. Rule 64B8-8.001(3), Florida Administrative Code, provides aggravating or mitigating factors to be considered in imposing a penalty upon a licensee. A possible aggravating factor in this case is "exposure of patient... to injury or potential injury." However, the weight of the evidence was that Respondent's failure to irrigate and debride the left leg wound was not the likely source of the infection. Another consideration is that Respondent was never consulted when Patient M. S. presented at St. Joseph's Hospital in Tampa. Both experts testified that the chances of saving a patient's leg are maximized when the orthopedic surgeon who performed the operation is consulted in a situation such as this. A mitigating factor relevant to this proceeding is Respondent's otherwise spotless disciplinary record in all jurisdictions in which he has practiced for approximately twelve years.

51. Based upon the totality of the circumstances, it is concluded that an appropriate penalty would be a reprimand, ten hours of Continuing Medical Education in orthopedic

medicine to be completed within 12 months of the final order, and payment of an administrative fine in the amount of $250.00.

RECOMMENDATION

Upon the foregoing Findings of Fact and Conclusions of Law, it is recommended that the Department of Health, Board of Medicine, enter a final order finding that Respondent violated Section 458.331(1)(t), Florida Statutes, and imposing the following penalty: a reprimand, 10 hours of Continuing Medical Education in orthopedic medicine to be completed within 12 months of the final order, and payment of an administrative fine in the amount of $250.00.

DONE AND ENTERED this 4th day of February, 2002, in Tallahassee, Leon County, Florida.

LAWRENCE P. STEVENSON
Administrative Law Judge
Division of Administrative Hearings
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Filed with the Clerk of the
Division of Administrative Hearings
this 4th day of February, 2002.

COPIES FURNISHED:

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NOTICE OF RIGHT TO SUBMIT EXCEPTIONS

All parties have the right to submit written exceptions within 15 days from the date of this recommended order. Any exceptions to this recommended order should be filed with the agency that will issue the final order in this case.