STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

DEPARTMENT OF HEALTH, BOARD OF MEDICINE,	)	
Petitioner,	)	
vs.	)	Case No. 07-1852PL
EDWARD ST. MARY, M.D.,	)	
Respondent.	)	

RECOMMENDED ORDER

On June 28, 2007, a formal administrative hearing in this case was held in Viera, Florida, before William F. Quattlebaum, Administrative Law Judge, Division of Administrative Hearings.

APPEARANCES

For Petitioner: Jennifer Forshey, Esquire
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For Respondent: Michael R. D'Lugo, Esquire
Richard J. Brooderson, Esquire
Wicker, Smith, O'Hara, McCoy,
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STATEMENT OF THE ISSUES

The issues in this case are whether the allegations of the Administrative Complaint are correct, and, if so, what penalty should be imposed.

PRELIMINARY STATEMENT

By Amended Administrative Complaint dated December 11, 2006, the Department of Health (Petitioner) alleged that Edward St. Mary, M.D., (Respondent) violated various Florida Statutes related to the practice of medicine. The Respondent disputed the allegations and requested a formal administrative hearing. By letter dated April 24, 2007, the Petitioner forwarded the matter to the Division of Administrative Hearings, which scheduled and conducted the hearing.

At the hearing, the parties had Joint Exhibit A admitted into evidence. The Petitioner presented no live testimony and had Exhibits numbered A and C through E admitted into evidence. The Respondent presented the testimony of five witnesses, testified on his own behalf, and had Exhibits numbered A through L and N through MM admitted into evidence.

The hearing Transcript was filed on July 27, 2007. Both parties filed Proposed Recommended Orders that have been considered in the preparation of this Recommended Order.

FINDINGS OF FACT

1. At all times material to this case, the Respondent, a board-certified orthopedic surgeon, was a medical doctor holding Florida license number ME53713, with an address of record of 300 Michigan Avenue, Melbourne, Florida 32901.

2. Since the mid 1990’s, the Respondent provided medical care and treatment to Patient D.P. for orthopedic problems, including pain in both of the patient's great toes.

3. Towards the end of November 2001, the patient and the Respondent decided to treat the continued toe pain through surgical removal of spurs from the metatarsophalgeal joints in both great toes, a procedure identified as a "dorsal cheilectomy."

4. Rather than leave the patient immobilized by performing surgery on both feet at the same time, two separate surgeries were planned separated by several weeks, with the repair being done to one toe at a time. There was some discussion between the Respondent and the patient as to which toe surgery should be performed first. A decision was made to perform surgery on December 6, 2001, to the left toe, with the right toe surgery occurring at some later date, most likely before the end of the year.

5. The consent documentation executed by the patient stated that the December 6, 2001, surgery would be to the great left toe. Various insurance authorizations were obtained to assure coverage for the December 6 procedure to the patient's great left toe.

6. On the date of surgery, the patient arrived at Melbourne Same Day Surgery, and for reasons that are unclear,

had her great right toe prepared and draped for surgery by a nurse.

7. The Respondent thereafter performed surgery on the great right toe of Patient D.P. He realized that he was operating on the wrong toe when the nurse advised the Respondent that the wrong foot had been prepped. Approximately 75 percent of the procedure was completed at the time the error was discovered.

8. The Respondent completed the procedure, and while the patient remained in the operating room, the Respondent went to the waiting room and spoke to the patient's husband, who was her health care surrogate. The Respondent advised the husband of the surgical error, and recommended that the patient's great left toe be injected with medication (“depomedrol") to address the pain for which the surgery had been planned. The husband consented to the injection.

9. On the date of the surgery, the patient had a burn injury on the great left toe. Had the extent of the injury been observed when the patient was being prepped for surgery, the surgery on the left toe would not likely have occurred.

10. There was some question as to when the injury was first observed, but there was no evidence that the extent of the injury was observed prior to surgery being performed on the wrong toe, or that the erroneous surgery to the right toe was

the result of a conscious decision based with consideration of the injury to the left toe.

11. There is no credible evidence that the patient or the surrogate consented to having the dorsal cheilectomy performed on December 6, 2001, to the patient's great right toe.

12. After the Respondent completed the patient’s surgery and injection, he reported the wrong site surgery to the facility’s risk managers. He also documented the procedure performed in an operative note, which is part of the patient’s medical records.

13. Although the operative note appears to adequately identify the procedures that were actually performed on the patient, the operative note does not indicate that a wrong site surgery occurred. Neither the operative note nor any other document in the patient's medical records affirmatively indicate that the right toe surgery was not the procedure to which the patient consented.

14. The medical records, including the executed consent forms, document the course of treatment to include surgery on December 6, 2001, to the patient's great left toe. The medical records include no explanation or rationale as to why surgery was performed on the patient’s great right toe on December 6, 2001, rather than to the left toe.

15. The Respondent testified that the risk managers at the facilities where he practices have instructed him not to document wrong-site surgical procedures in patient records and referred to such documentation as "editorializing." He indicated that the practice was of long-standing.

16. The Respondent asserts that appropriate documentation of the wrong-site surgery was made though the "Form 15" filed with the Florida Agency for Health Care Administration; however, that document is a confidential report to a state regulator and is not part of the patient's medical records.

17. The Petitioner presented the expert testimony of Dr. Jack S. Cooper by deposition. Dr. Cooper is a Florida-licensed and board-certified orthopedic surgeon, who opined that the patient's medical records should have stated not only what happened with the patient, but should have included the reasons the wrong site surgery occurred, and how the error was resolved by the Respondent during the procedure.

18. In response, the Respondent presented the testimony of two persons employed by the facility where the surgery was performed (the administrative director and the risk manager) and the testimony of a licensed Health Care Risk Manager, all of whom testified that they believed the patient's medical records were appropriate.

19. Dr. Cooper's testimony was persuasive and has been fully credited in this Recommended Order. The testimony of the Respondent's witnesses on this point was not persuasive and has been disregarded.

20. The patient testified at the hearing that at the time of the surgery, she was receiving psychiatric treatment related to injuries sustained in an automobile accident in 1999 and viewed the erroneous surgery as "a significant psychological setback," but acknowledged that she trusted, and was still receiving care from, the Respondent. The patient's husband also testified at the hearing and stated that the emotional difficulties resulting from the erroneous surgery were more an issue related to the surgical facility than to the Respondent.

CONCLUSIONS OF LAW

21. The Division of Administrative Hearings has jurisdiction over the parties to and the subject matter of this proceeding. §§ 120.569 and 120.57, Fla. Stat. (2006).

22. The Respondent is the state agency charged with regulating the practice of medicine. § 20.43 and Chapters 456 and 458, Fla. Stat. (2006).

23. The Amended Administrative Complaint charges the Respondent with a violation of Subsection 456.072(1)(aa), Florida Statutes (2001), which provides in relevant part as follows:

> (1) The following acts shall constitute grounds for which the disciplinary actions specified in subsection (2) may be taken:
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> * * *
>
> (aa) Performing or attempting to perform health care services on the wrong patient, a wrong-site procedure, a wrong procedure, or an unauthorized procedure or a procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition. For the purposes of this paragraph, performing or attempting to perform health care services includes the preparation of the patient.

24. The Amended Administrative Complaint further charges that the Respondent violated Subsection 458.331(1), Florida Statutes (2001), which provides in relevant part as follows:

> (1) The following acts constitute grounds for denial of a license or disciplinary action, as specified in s. 456.072(2):
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> * * *
>
> (m) Failing to keep legible, as defined by department rule in consultation with the board, medical records that identify the licensed physician or the physician extender and supervising physician by name and professional title who is or are responsible for rendering, ordering, supervising, or billing for each diagnostic or treatment procedure and that justify the course of treatment of the patient, including, but not limited to, patient histories; examination results; test results; records of drugs prescribed, dispensed, or administered; and reports of consultations and hospitalizations.
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> * * *

> (p) Performing professional services which have not been duly authorized by the patient or client, or his or her legal representative, except as provided in s. 743.064, s. 766.103, or s. 768.13.

25. The Petitioner has the burden of proving by clear and convincing evidence the allegations set forth in the Administrative Complaint against the Respondent. Department of Banking and Finance v. Osborne Stern and Company, 670 So. 2d 932, 935 (Fla. 1996); Ferris v. Turlington, 510 So. 2d 292 (Fla. 1987).

26. Clear and convincing evidence is that which is credible, precise, explicit, and lacking 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 the firm belief of conviction, without hesitancy, as to the truth of the allegations. Slomowitz v. Walker, 429 So. 2d 797, 800 (Fla. 4th DCA 1983). In this case, the burden has been met.

27. The evidence establishes that the treatment plan developed between the Respondent and the patient included surgery first on the great left toe, followed by surgery on the great right toe within a few weeks time. The surgery scheduled for December 6, 2001, was for D.P.'s great left toe.

28. There is no credible evidence that the patient consented to have the dorsal cheilectomy performed on

December 6, 2001, to her great right toe. On the date of surgery, the Respondent erroneously performed surgery on the great right toe of Patient D.P. and thereby violated Subsection 456.072(1)(aa), Florida Statutes (2001).

29. The patient’s medical records include her consent to the December 6, 2001, surgery on the great left toe. The operative notes indicate that the surgery was performed on the great right toe.

30. Although there is no evidence that the Respondent made any attempt to conceal the erroneous surgery from the patient, the facility or regulatory agencies, the patient's medical records provide no explanation as to why the Respondent performed surgery on December 6, 2001, to the patient's great right toe rather than to the left. Another medical professional reviewing the patient’s records would be have no information as to why the December 6, 2001, surgery was performed on the patient’s great right toe.

31. The failure to properly document the surgical error in the patient’s medical records constitutes a violation of Subsection 458.331(1)(m), Florida Statutes (2001), because the records fail to justify the course of treatment actually provided to the patient on the date of surgery.

32. There is no credible evidence that the patient or the patient’s surrogate consented to permit the Respondent to

perform surgery on December 6, 2001, on the patient's great right toe, and, accordingly, the Respondent also violated Subsection 458.331(1)(p), Florida Statutes (2001).

33. Florida Administrative Code Rule 64B8-8.001 sets forth the disciplinary guidelines applicable to the statutory violations relevant to this proceeding.

34. Florida Administrative Code Rule 64B8-8.001(2)(qq) provides that the penalty for a first violation of wrong site surgery ranges from a $1,000.00 fine, a letter of concern, a minimum of five hours of risk management education, and an one hour lecture on wrong-site surgery, to a $10,000.00 fine, a letter of concern, a minimum of five hours of risk management education, a minimum of 50 hours of community service, a risk management assessment, an one hour lecture on wrong-site surgery, and license suspension to be followed by a term of probation.

35. Florida Administrative Code Rule 64B8-8.001(2)(m) provides that the penalty for a first violation of Subsection 458.331(1)(m), Florida Statutes (2001), ranges from a reprimand to license denial or two years' suspension followed by probation, and an administrative fine from $1,000.00 to $10,000.00.

36. Florida Administrative Code Rule 64B8-8.001(2)(p) provides that the penalty for a first violation of Subsection

458.331(1)(p), Florida Statutes (2001), ranges from a reprimand or license denial to two years' suspension, and an administrative fine from $1,000.00 to $10,000.00.

37. Florida Administrative Code Rule 64B8-8.001(3) provides as follows:

> Aggravating and Mitigating Circumstances. Based upon consideration of aggravating and mitigating factors present in an individual case, the Board may deviate from the penalties recommended above. The Board shall consider as aggravating or mitigating factors the following:
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> (a) Exposure of patient or public to injury or potential injury, physical or otherwise: none, slight, severe, or death;
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> (b) Legal status at the time of the offense: no restraints, or legal constraints;
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> (c) The number of counts or separate offenses established;
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> (d) The number of times the same offense or offenses have previously been committed by the licensee or applicant;
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> (e) The disciplinary history of the applicant or licensee in any jurisdiction and the length of practice;
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> (f) Pecuniary benefit or self-gain inuring to the applicant or licensee;
>
> (g) The involvement in any violation of Section 458.331, F.S., of the provision of controlled substances for trade, barter or sale, by a licensee. In such cases, the Board will deviate from the penalties recommended above and impose suspension or revocation of licensure.

> (h) Where a licensee has been charged with violating the standard of care pursuant to Section 458.331(1)(t), F.S., but the licensee, who is also the records owner pursuant to Section 456.057(1), F.S., fails to keep and/or produce the medical records.
>
> (i) Any other relevant mitigating factors.

38. The Respondent has had no prior disciplinary action taken against his license.

39. Although the patient experienced an emotional setback related to the wrong site surgery, the evidence establishes that there was no physical injury to the patient by the December 6, 2001, surgery to the right toe, because the treatment plan was to surgically address both toes prior to the end of 2001.

40. There was no evidence of pecuniary gain related to the wrong site surgery, although the decision to omit an affirmative acknowledgment of, and specific explanation for, the wrong site surgery from the patient's medical records based on risk management concerns negates any consideration of this factor as mitigation in favor of the Respondent. The fact that the failure to disclose was allegedly based on instructions from the risk management staff at the facility where the wrong site surgery occurred does not excuse the Respondent from his obligation to comply with the requirements of law.

41. The Petitioner's Proposed Recommended Order suggests a penalty of a $10,000.00 administrative fine, completion of

100 hours of community service, completion of not less than five hours of continuing medical education courses in risk management, requiring the Respondent to present a one hour lecture on wrong site surgery to the medical staff at an approved medical facility, and issuance of a reprimand from the Board of Medicine.

42. The Respondent's Proposed Recommended Order suggests a penalty of a $5,000.00 administrative fine, completion of 50 hours of community service, completion of four hours of continuing medical education courses in risk management, requiring the Respondent to present a one hour lecture on wrong site surgery to the medical staff at an approved medical facility, a letter of concern from the Board of Medicine, and reimbursement to the Department of Health of all costs associated with the investigation and prosecution of the case.

43. As support for the Respondent's suggested penalty, the Respondent cited the penalties in numerous disciplinary cases against medical practitioners where Final Orders were entered based on Consent Agreements entered into between the parties.

44. Review of the cited Final Orders reveals that although the Consent Agreements indicate that each practitioner acknowledged that the factual allegations "if proven" would constitute violation of the various cited statutes, the Consent Agreements were executed in order to terminate litigation. None

of the factual allegations set forth in any of the Administrative Complaints were admitted in the Consent Agreements. Each of the cited disciplinary cases was resolved without an evidentiary hearing, and there was no final determination as to whether the allegations of the Administrative Complaints were accurate or were supported by evidence.

45. In all but one of the cited cases, the allegations involved wrong site surgical procedures and lack of consent. In the one case, which included an alleged failure to keep medical records justifying the course of treatment (Department of Health v. Shanahan, Department of Health Case 2003-30327), a patient was scheduled to undergo an upper endoscopy with biopsy, but the physician erroneously performed a colonoscopy, and then performed the endoscopy after realizing the error. The charge of improper medical records was based on an allegation that the physician's operative notes incorrectly stated that the scheduled endoscopy was performed prior to the colonoscopy. Because the case was resolved through a Consent Agreement, no final determination as to the accuracy of the allegations was made.

46. In the instant case, the allegations of the Administrative Complaint have been established by clear and convincing evidence. The Respondent performed a wrong site

surgical procedure to which the patient had not consented and then purposefully failed to enter any information that would directly and specifically disclose that a wrong site surgery had occurred. Accordingly, the following disposition is recommended.

RECOMMENDATION

Based on the foregoing Findings of Fact and Conclusions of Law, it is RECOMMENDED that the Department of Health enter a final order finding Edward St. Mary, M.D., in violation of Subsections 456.072(1)(aa) and 458.331(1)(m) and (p), Florida Statutes (2001), and imposing a penalty as follows: a $15,000.00 administrative fine; a reprimand from the Board of Medicine; completion of 75 hours of community service as approved by the Petitioner; completion of not less than eight hours of continuing medical education courses related to risk management; requiring the Respondent to present a one hour lecture on wrong site surgery to the medical staff at a facility approved by the Petitioner; and requiring reimbursement to the Department of Health of all costs associated with the investigation and prosecution of the case.

DONE AND ENTERED this 2nd day of October, 2007, in Tallahassee, Leon County, Florida.

WILLIAM F. QUATTLEBAUM
Administrative Law Judge
Division of Administrative Hearings
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Filed with the Clerk of the
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this 2nd day of October, 2007.

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.