STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

DEPARTMENT OF HEALTH,)
BOARD OF MEDICINE,)
)
Petitioner,)
)
vs.) Case No. 05-3165PL
)
STEVEN WAYNE KINSEY, M.D.,)
)
Respondent.)
________________________________)

RECOMMENDED ORDER

Notice was provided and on December 15, 2005, a formal hearing was held in this case. Authority for conducting the hearing is set forth in Sections 120.569 and 120.57(1), Florida Statutes (2005). The hearing location was 2401 State Avenue, Suite 100, Panama City, Florida. The hearing commenced at 9:00 a.m. Central Time. The hearing was conducted by Charles C. Adams, Administrative Law Judge.

APPEARANCES

For Petitioner: William F. Miller
Ephraim D. Livingston
Assistants General Counsel
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For Respondent: Albert Peacock, Esquire
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Tallahassee, Florida 32312

STATEMENT OF THE ISSUE

Should the Board of Medicine (the Board) discipline Respondent's license to practice medicine in Florida, based upon allegations that he violated Sections 456.072(1)(bb), and 458.331(1)(t), Florida Statutes (2003), in the care and treatment of Patient H.J.?

PRELIMINARY STATEMENT

On March 7, 2005, in Case No. 2004-05727, the Department of Health (DOH) brought an Administrative Complaint against Respondent. It was alleged that:

> Respondent left a piece of peritoneal dialysis (catheter) and some length of plastic tubing in Patient H.J. during a surgery that took place on or about July 21, 2003.

Under those circumstances Respondent was accused of violating Section 456.072(1)(bb), Florida Statutes (2003). When served with the DOH Administrative Complaint calling for discipline to be imposed by the Board, Respondent made a written request for formal hearing consistent with Sections 120.569 and 120.57(1), Florida Statutes (2005).

On August 31, 2005, Robert S. Cohen, Director of the Division of Administrative Hearings (DOAH) received the Administrative Complaint and Respondent's request for formal hearing. The case became DOAH Case No. 05-3165PL and was assigned to this administrative law judge.

Following responses from the parties November 1 and 2, 2005, were selected as hearing dates. Upon Petitioner's motion those hearing dates were cancelled and the case was re-noticed to be heard on December 15 and 16, 2005.

Petitioner moved to relinquish jurisdiction in this case alleging that disputes of material fact no longer existed to be resolved at hearing. § 120.57(1)(i), Fla. Stat. (2005). On December 13, 2005, an order was entered denying the motion to relinquish jurisdiction.

Petitioner moved to amend the Administrative Complaint by adding an allegation of a violation of Section 458.331(1)(t), Florida Statutes (2003). On December 13, 2005, an order was entered granting the motion to amend. By virtue of the amendment the Administrative Complaint became a two-count Administrative Complaint.

Official recognition was made of Sections 456.072, 456.073(5), and 458.331, Florida Statutes (2003), and 456.073(5), Florida Statutes (2005), as well as Florida Administrative Code Rule 64B8-8.001.

Petitioner presented the Respondent as its witness, together with Stanley P. Kococki, M.D. Petitioner's Exhibits numbered 1 through 5 were admitted. Respondent testified in his own behalf and presented the testimony of Ahmad Oussama Refai, M.D.;

Patient H.J.; and Thomas R. Gadacz, M.D. Respondent's Exhibits numbered 1 and 2 were admitted.

The parties responded to a prehearing order requiring among other things that they offer a statement of facts stipulated by the parties. Those facts agreed to are set out in the fact-finding to this Recommended Order.

A hearing transcript was prepared and filed on January 4, 2006. The parties filed proposed recommended orders which have been considered in preparing the Recommended Order.

FINDINGS OF FACT

Stipulated Facts

1. Respondent is and has been at all times material hereto a licensed physician in the State of Florida, having been issued license number ME: 65565.

2. Petitioner is the state agency charged with regulating the practice of medicine pursuant to Section 20.42, Florida Statutes.

3. On or about July 21, 2003, the Respondent performed peritoneal dialysis catheter removal on Patient H.J. at Bay Medical Center (Bay Medical).

4. Peritoneal dialysis is a technique that uses the patient's own body tissues inside of the abdominal cavity to act as a filter.

5. On or about August 25, 2003, Patient H.J. presented with erythema (a redness of the skin resulting from inflammation) and induration (localized hardening of soft tissue of the body) in the area where the peritoneal dialysis catheter had been removed.

6. On or about December 3, 2003, the Respondent performed exploratory surgery of Patient H.J.'s wound.

Additional Facts

7. Patient H.J. suffers from end-stage kidney failure, diabetes and heart disease. Dr. Ahmad Oussama Refai treated Patient H.J. for his kidney failure. Dr. Refai is a board-certified Nephrologist.

8. Dr. Refai referred Patient H.J. for placement of a peritoneal dialysis catheter (catheter) to address the end-stage kidney failure. The catheter, as Dr. Refai describes it, was intended to remove the poisonous material in the blood of Patient H.J. By using the catheter clean fluid is introduced into the abdomen where it remains for a period of about four hours. The fluid introduced contains electrolytes put in the patient's blood stream. After the residence time for the fluid expires, the fluid is withdrawn through the catheter removing the harmful material. The patient, once instructed, is capable of performing the procedures described. The other option in performing this method of dialysis is to use a device that is employed at nighttime called a cycler, used while the patient is asleep and

without the need for the patient to conduct the process. The patient's use of the catheter for dialysis is referred to as "home dialysis."

9. Before Dr. Refai referred the patient to Respondent to place the catheter, the patient had been treated for his end-stage renal disease through a forearm AV graph to provide hemodialysis. That technique allows access to the patient's blood through a shunt, with the blood being run through a machine and cleansed and returned back to the patient. This procedure is done several times a week at out-patient centers, whereas the peritoneal dialysis is done daily by the patient or at night.

10. On June 30, 2000, Respondent saw Patient H.J. and determined that the patient was a good candidate for the surgery necessary to place the catheter to perform peritoneal dialysis. On July 19, 2000, Respondent placed the catheter and peritoneal dialysis treatment was commenced.

11. Following the placement the catheter was used by the patient as overseen by the Dr. Refai.

12. As Dr. Refai describes it, the catheter is a silestic tube that has two cuffs. The cuff at the lower level sits on the fascia where it is secured and the other cuff is just under the skin or in the subcutaneous tissue. Dr. Refai describes the cuffs as fuzzy. The cuffs are expected to induce an inflammatory process promoting scarring so that the body forms tissue to hold

the catheter in place. Dr. Refai calls this a bond. Dr. Refai explains that the other parts of the catheter are "slippery." It is the fuzzy part that holds the catheter in place.

13. Petitioner's Exhibit No. 5 is an unused catheter similar in design to that placed in Patient H.J.

14. On July 7, 2003, Respondent, Dr. Refai, and a Dr. Dean discussed Patient H.J. and the plan to remove the catheter that was no longer adequately performing the dialysis. On July 21, 2003, Respondent did surgery to remove the catheter from Patient H.J.

15. On July 17, 2003, before Respondent did the surgery to remove the catheter, an explanation was made to Patient H.J. of the risks associated with the surgery as to bleeding, infection, MI stroke, death, and allergic reaction following removal of the catheter.

16. Following the surgery Dr. Refai as the treating physician was aware that the wound associated with the surgery was not healing well and Dr. Refai sent Patient H.J. back to Respondent. Dr. Refai is familiar with the course of antibiotics prescribed for Patient H.J. to respond to the condition and the surgical exploration done by Respondent where a piece of cuff, as Dr. Refai describes it, was removed and the wound healed. December 3, 2003, was the date of the exploratory surgery. At that time, Patient H.J. was on hemo-dialysis and was being seen

by Dr. Refai once a week. In Dr. Refai's opinion Patient H.J. was doing remarkably well, making allowances for his underlying condition (illnesses). At present Dr. Refai is aware that the patient is on the list to receive a kidney transplant.

17. On August 1, 2003, Respondent saw Patient H.J. In his notes Respondent stated:

> His wounds look good. There is no evidence of infection. No fever or chills. He looks well. He is not taking any pain medicine. I am going to see him back in a month for a final visit.

18. On August 25, 2003, Respondent saw Patient H.J. again. The Respondent's notes stated:

> His p.d. catheter removal site which was removed 4 weeks ago has some erythema and induration around it. I ultrasounded it here in the office and it looked like there was a little fluid. I anesthetized the area and opened it. There was no gross pus. I am going ahead and treat [sic] him with some Keflex and have him see Dr. Beaver on Friday as I am going to be out of town. This may come to a head and become an abscess. It may just be some cellulitis. I am not real sure why he would have cellulites as it certainly did not look like a hernia. I am going to have him see Dr. Beaver on Friday and make sure it is improving.

19. On August 29, 2003, a note was made by Dr. Beaver concerning his visit with Patient H.J. In that note Dr. Beaver said:

> Patient of Dr. Kinsey. He was seen back for re-check. Apparently he was having some questionable cellulites around his p.d. cath

> today. He states that he is feeling much better. On examination, I see no redness at all and per the office assistance it has much improved. There is really not tender [sic]. It looks to me like it is improving. We will plan for him to see Dr. Kinsey back next week.

20. On September 12, 2003, Respondent saw Patient H.J. and in the office note stated:

> The area in his left lower quadrant is completely healed. He is doing well. I am going to see him back in one month for a final visit.

21. On September 16, 2003, Respondent saw Patient H.J. again and in the office note stated:

> He had some drainage from his previous p.d. catheter site. It does not appear to be infected. I am going to follow this area and see him in the office in a month.

22. On September 30, 2003, Respondent saw Patient H.J. again and in the office note it states:

> He still has some drainage from the p.d. catheter exit site [sic] it was done about eight weeks ago. I told him that I would like to leave that along [sic] for at least three months and follow that. If it does not improve after three to four months then we may need to explore the wound but it may be a piece of suture that it [sic] trying to spit. We will see him back in the office in about 6 to 8 weeks.

23. On November 11, 2003, Respondent saw Patient H.J. and noted:

> He is still draining from his p.d. catheter exit site. This has been 5 months. It is time to explore the wound. We will proceed to the operating room for exploration in the sinus tract. I suspect that there will be a piece of the catheter in the bottom of the wound.

24. On December 1, 2003 Respondent saw Patient H.J. for the pre-operative visit. At that time he noted:

> He is here for a pre-op for a wound exploration for his p.d. catheter removal site. He still has some granulation tissue there. I am going to plan to probe the area and evaluate where the sinus goes.

25. On December 3, 2003, the surgery was conducted on Patient H.J. and Respondent noted:

> He underwent a left lower quadrant wound exploration. The p.d. catheter cuff was within the subcutaneous tissue and that is why his wound [sic] not close. This was removed and then the would [sic] was closed. He tolerated the procedure well.

26. The various surgeries that have been discussed which were performed by Respondent took place at Bay Medical in Panama City, Florida. In the operative procedure report at the hospital related to the December 3, 2003 exploratory operation Respondent described a pre-operative diagnosis as:

> Non-healing wound, left lower quadrant of the abdomen.
>
> The post-operative diagnosis stated:
>
> 1. Non-healing wound, left lower quadrant of the abdomen.

> 2. Foreign body (peritoneal dialysis catheter cuff), left lower quadrant abdominal wound.

The procedure performed was described as:

> Wound exploration and foreign body removal.

The intra-operative findings related to the operation were:

> He was found to have a cuff of the catheter within the tissue. He had a small piece of p.d. catheter attached to it. The cuff had obviously broken. The catheter was broken with a cuff remaining in the subcu tissue. There was no intra-abdominal portion.

27. In comparison, on July 21, 2003, in the operative/procedure report at Bay Medical through the description of the procedure to remove the catheter Respondent stated:

> . . . The previous incision in the left hypogastric area was anesthetized with local anesthetic and sharply incised. This was carried into the subcutaneous tissue and p.d.-catheter dissected and divided. The catheter was then pulled from the subcutaneous tissue at the exit site. The catheter was then delivered into the wound and abdominal wall cuff sharply incised and the catheter removed. The fascial edges were then reapproximated with 2 figure-of-eight0-vicryl sutures.

28. On July 21, 2003, when Respondent removed the catheter from Patient H.J. no pathology was ordered. On December 3, 2003, following the exploratory surgery and retrieval of the catheter pathology was ordered.

29. Daniel G. Dena was the pathologist at Bay Medical who addressed the specimen which was described by the pathologist as: "Tissue-p.d. catheter cuff" The anatomic diagnosis referred stated: "p.d. catheter cuff: plastic catheter, with attached fibro-fatty tissue at one end, showing acute and chronic inflammation." The macroscopic examination in the pathology report stated: "The specimen is labeled 'pd catheter cuff'. Received is a portion of plastic tubing measuring approximately 5 cm in length and up to 0.5 cm in diameter, with a cuff of soft tissue at one end measuring 2.5 cm in length and 1.2 cm in diameter."

30. On July 26, 2004, in responding to the investigation that led to this prosecution Respondent stated in writing in relation to Patient H.J.:

> The original peritoneal dialysis catheter removal had gone uneventfully and I felt that both cuffs of the catheter had been removed in their entirety. But this was found not to be the case. I have placed a number of these catheters and removed a number as well and have not had this type of problem before. Visual inspection of the catheter on removal is routinely undertaken to ensure that the cuffs are removed and I felt that this had been completely removed but I was obviously mistaken. I am not sure if this was a defect in the catheter. Evaluation of the catheter and assurance of complete cuff removal would have probably prevented this process. I am certainly more cognizant of this being a problem in subsequent catheters that I have removed. At the original time of catheter

removal the operative site appeared
appropriate.

31. At hearing Respondent offered additional explanation concerning the July 21, 2003 operation to remove the catheter from Patient H.J. and the exploratory surgery on December 3, 2003.

32. As Respondent explained, in the July 21, 2003 surgery Respondent made a 3-to-4 cm incision about the belly button towards the middle of the abdomen through the skin, subcutaneous tissue, the fascial layer and muscle and peritoneal layer. The peritoneal layer is a semi-permeable membrane that waste products removed in the dialysis will cross. The catheter is placed into the abdomen. The catheter is 12 to 14 inches in length with a curlicue tail and holes in the end of the catheter that allows the fluids to be introduced and withdrawn from the abdomen. As Respondent explained the catheter has two cuffs, the smaller of which is designed for placement in the rectus muscle located along the inset part of the abdomen. The smaller cuff sits inside that muscle. Tissue attaches to that cuff to keep fluid from leaking out, to keep the catheter in place and to prevent bacteria from going down the outside of the catheter. There is a segment of the catheter between that cuff and a larger cuff which sits underneath the skin in the subcutaneous tissue. The tissue

in that area attaches to the cuff and serves to hold the catheter in place.

33. When removing the catheter on July 21, 2003, Respondent used an incision of about 3 cm and encountered the mid-portion of the catheter located between the two cuffs which was dissected down through the fascia and taken out with the portion in the abdomen being removed first. Before making the incision to remove the catheter, Respondent cut the portion of the catheter outside the body of Patient H.J. off, including the metal and plastic valves and other paraphernalia hanging out of the patient. The purpose of removing the catheter outside the patient's body was in the interest of protecting the surgical field from contamination to avoid wound infection.

34. The part removed inside the patient initially was the intra-abdominal portion. The intra-abdominal portion of the catheter, including the cuff in that area was sharply removed. The cuff was 2 or 3 times the size that it would have been when first placed and the part around the cuff was cut to allow the catheter to be extracted. The area of the fascia was closed.

35. Next Respondent addressed the subcutaneous portion of the catheter by following it out and sharply cutting the tissue around the catheter and the subcutaneous cuff with scissors to remove that portion which also had an ingrowth of scar and fibroblastic tissue.

36. Once the portions of the catheter with the cuffs, had been removed Respondent looked to determine if he had both cuffs which appeared at that time as a wad of scar and tissue.

37. Respondent then closed the wound. Respondent believed that he had removed the whole catheter, to include the cuffs. In fact the subcutaneous cuff was not entirely removed and another portion of the catheter remained in the patient following the July 21, 2003 surgery.

38. Respondent's estimate of what had been left in the patient and removed on December 3, 2003, was about 2 cm of the subcutaneous cuff and then a portion of the balance of the catheter.

39. In commenting on the difference between the pathology report and his visual assessment on December 3, 2003, Respondent remarked about "all the stuff" grown onto the cuff and catheter. He also said it had a lot of specimen, taken to mean the "stuff" attached to the cuff and catheter.

40. Although in the operative notes from December 3, 2003, Respondent says the catheter broke, at hearing he stated that he did not know whether the catheter had been cut or broke during the July 21, 2003 procedure to remove the catheter.

41. No independent tests were conducted to determine whether the catheter broke during the July 21, 2003 surgery or was cut by Respondent.

42. Respondent does not precisely remember the appearance of the catheter, to include the cuffs, when examining it on July 21, 2003. But he believed that he had successfully removed the entire catheter.

43. In his testimony Respondent describes the office visits subsequent to the July 21, 2003 surgery. When he saw Patient H.J. he observed cellulitis around the area of the incision which was treated with oral antibiotics and resolved. Respondent used ultrasound to determine whether fluid had collected in the area where he observed the cellulitis. No fluid collection was seen. Drainage was noticed around the exit site where the catheter came out of the skin, which ordinarily takes a month to six weeks to heal.

44. Concerning the drainage around this exit site, Respondent expected the drainage to resolve within around five weeks unless there were a piece of suture or other kind of event keeping the site opened and draining.

45. The wound site where the incision was made healed without incident. The exit site continued to drain. After a time Respondent concluded that the reason for the drainage was either an epithelilized sinus tract, a piece of suture, a piece of catheter, a piece of cuff, or a piece of dressing for the wound. Respondent waited a time before doing the exploratory surgery in view of the use of an absorbable suture in the

July 21, 2003 surgery which would have dissolved over time, precluding the need to do the exploration.

46. Respondent, given the problem with the drainage from Patient H.J. following the July 21, 2003 surgery to remove the catheter, does not believe that the failure to remove this fragment would have killed the patient or have caused a lot of problems, but it was bothersome enough that it was worth the effort to try and find it and get the patient healed.

47. Respondent in dictating his post-operative note on December 3, 2003, thinks that the catheter had broken and continues to hold to that belief, although he recognizes that it may have been cut in the prior surgery.

48. Concerning his practice at Bay Medical, Respondent did not routinely have an X-ray done for patients undergoing surgery without a more specific reason for ordering it. Nor did he order a pathology examination following surgery absent the need for specific information.

49. Patient H.J. in his testimony described the level of pain following the July 21, 2003 surgery to remove the catheter as "a little pain."

Expert Opinion

50. Dr. Stanley P. Kococki is a general surgeon licensed in Florida. He is board-certified in general surgery. He has had experience placing and removing peritoneal dialysis catheters.

He was qualified to offer expert opinion testimony concerning Respondent's treatment of Patient H.J., in particular, the surgery performed July 21, 2003.

51. Dr. Kococki expressed the opinion that the Respondent fell below the standard of care in treating Patient H.J., in that Respondent failed to recognize that he had left a portion of the catheter in the patient, which Dr. Kococki describes as a retained foreign body and that this caused the patient to undergo a second unnecessary procedure, meaning that the second procedure would not have been necessary if the catheter had been removed completely in the first surgery. The failure to remove could possibly have caused serious problems for the patient, to include septicemia and death, according to Dr. Kococki. Dr. Kococki refers to the Respondent's obligation in removing the catheter, to make certain that the whole catheter was removed and that the wound properly healed beyond that point so that the patient would not experience problems.

52. While recognizing that there are different techniques for removing the catheter from Patient H.J., Dr. Kococki took issue with the method employed by the Respondent. Dr. Kococki believes that there are other methods for avoiding the problem with infection than to cut the catheter outside the body. There was no description of the use of a hemostat or clamps to hold the retained part of the catheter once the outside segment had been

cut, so that the remaining portion of the catheter would not be lost under the skin. In addition, by cutting the catheter in two places there was a chance of leaving a piece of the catheter in the patient. Dr. Kococki expressed the opinion that when you cut the catheter in several places you have to remember where the pieces of the catheter are left in the patient. Given other circumstances during the surgery that occupy the surgeon's mind, it can lead to leaving a piece of catheter behind.

53. Dr. Kococki expressed the opinion that leaving the catheter behind was not in the best interest of the patient because it led to subsequent surgery and had the sinus tract closed over the foreign body would have caused a localized infection and abscess formation around that area and possibly allowed for the bacteria from the abscess to enter the patient's bloodstream causing sepsis, and abscess formation in other organs, possibly the abdominal cavity, with a possible rupture intra-abdominally causing the patient to have generalized peritonitis. That can be life threatening and ultimately lethal. It is more of a problem with the person that has end-stage renal failure, in that the patient has a weakened immune system and lessened prospects to fight off infection.

54. Dr. Kococki relied upon the pathology report made after the December 3, 2003 surgery to accurately describe the size of the segment that was left in the patient.

55. In order to ascertain what actually happened with the catheter Dr. Kococki believes that the company or an independent examining body would have to determine if the catheter was defective. Even in the instance where the catheter may have broken in the initial surgery to remove it on July 21, 2003, the onus is still on the surgeon removing the catheter to examine it to make certain it was removed intact.

56. Dr. Kococki characterizes the catheter as commonly present and utilized in surgical procedures to place and remove peritoneal dialysis catheters. Dr. Kococki describes the catheter as a medical device, unlike a sponge, forceps, clamp or surgical needle. Dr. Kococki recognizes that the purpose of the catheter is to perform dialysis but the retained portion left after the initial surgery to remove the catheter does not have a medical purpose, in his judgment.

57. Dr. Kococki describes the cuff in the field related to the abdominal wall as providing a seal to avoid bacteria. The cuff as he understands it has an antibiotic coating that will help fight off infection. The cuff reacts with the patient's body tissue to act as a sealant.

58. To have avoided the problem of failing to account for a portion of the catheter during the initial surgery to remove it from Patient H.J., Dr. Kococki believes that the easiest thing to have done was while the patient was in the operating room send

the catheter to a pathologist and have it measured for comparison against the known size of the catheter when first placed. A second safe-guard would be to use a portable X-ray of the abdominal cavity to make sure that there was no radiopaque material in the abdomen or subcutaneous tissue. The catheter has radiopaque material allowing this identification in Dr. Kococki's understanding.

59. Dr. Kococki was not familiar with the procedures at Bay Medical where the catheter removal from Patient H.J. was performed. The bylaws of the institution do not require that the catheter be sent to pathology following removal.

60. Dr. Thomas A. Gadacz testified in the interest of Respondent. He is licensed in several states. He is not licensed in Florida. He is an expert in the field of general surgery. He has placed and removed peritoneal dialysis catheters.

61. Dr. Gadacz describes the catheter as a medical device. It has nothing in common with a sponge, forceps, clamp or surgical needle, in his opinion.

62. As a surgeon Dr. Gadacz refers to sponges, forceps, clamps and surgical needles as items whose sole purpose is to assist during an operation, not intended to be left in the body. They are to facilitate an operation to provide exposure, to conduct the operation but they are not a therapeutic modality.

By contrast the peritoneal dialysis catheter is used primarily for therapy by remaining in the patient for specified periods of time to treat the patient.

63. Other aids in performing an operation are cotton balls called kitners, metal retractors and cannulas.

64. Dr. Gadacz explains that the purpose of the cuffs related to the catheter is to react to the body so that tissue grows around them. The other part of the catheter made of Teflon is designed to be non-reactive.

65. Dr. Gadacz is aware that catheters of the type under discussion have fractured or broken. Dr. Gadacz explained that the fracture of a cuff is not common. In his experience, in the instance where a segment broke in a catheter, Dr. Gadacz removed it. On the other hand the failure to remove the piece is not necessarily below the standard of care as Dr. Gadacz explains, "because some times this happens, and its, you don't know that that has happened." The possibility of knowing that the segment broke off is difficult. As Dr. Gadacz describes, it was impossible given the tract involved with the surgery here. The gross inspection of the catheter once removed from the patient is a process in which it is difficult to make certain that both cuffs are there because of the encrusting fibrous tissue found after removing the cuffs, causing the cuffs to no longer have the same appearance as when first placed. The visual inspection made

of the catheter after removal would not necessarily reveal whether it was removed in its entirety, according to Dr. Gadacz.

66. Dr. Gadacz is unfamiliar with surgeons who would use an X-ray after removal of the catheter to confirm that the entire catheter had been removed. Instead he defers to Respondent's operative note on December 3, 2003, where the Respondent says that the catheter had obviously broken to explain the failure to retrieve the catheter.

67. Dr. Gadacz does not believe sending the catheter to pathology after it was removed on July 21, 2003, would necessarily have been useful because it would take familiarity on the part of the pathologist with that form of catheter to recognize that a part was missing.

68. Dr. Gadacz recognizes that the fragment from the catheter left in Patient H.J. at the end of the initial surgery to remove the catheter is medically considered a foreign body because it was not part of the human body.

69. Dr. Gadacz found nothing in the care provided by Respondent by to Patient H.J. after the July 21, 2003 surgery that was questionable.

70. Dr. Gadacz did not find the technique Respondent used in removing the catheter on July 21, 2003, from the Patient H.J. to be below the standard of care.

71. Generally Dr. Gadacz did not express the opinion that Respondent practiced below the standard of care.

72. Dr. Gadacz explained that had the segment continued to be present in the patient there would have been a major risk of continuing infection and ultimately the patient could have developed a serious abscess in the subcutaneous tissue that could become life-threatening or nothing may have happened, and the segment may have been walled off by the patient's body.

73. In determining the comparability of what is described in Section 456.072(1)(bb), Florida Statutes (2003), as "other paraphernalia," to those items listed within that section, "such as a sponge, clamp, forceps, surgical needle," that are "used in surgical examination, or other diagnostic procedures," reliance is made upon testimony from Dr. Gadacz. As a surgeon, the opinion by Dr. Kococki is rejected for reasons that will be explained in the conclusions of law.

74. When considering whether Respondent failed to practice medicine with that level of care, skill and treatment which is recognized by a reasonable prudent similar physician as being acceptable under similar conditions and circumstances, as envisioned by Section 458.331(1)(t), Florida Statutes (2003), with the specificity called for in that provision, Dr. Kococki is more compelling in his opinion that the fragment left in Patient H.J. should have been removed in the earlier operation

whether it broke or was cut by Respondent. The notion that there are times when some portion of the catheter may have been left in the patient, as was the case here, with no consequences to the practitioner, as expressed by Dr. Gadacz is not persuasive.

Disciplinary History

75. The Respondent has no prior disciplinary history.

CONCLUSIONS OF LAW

76. The Division of Administrative Hearings has jurisdiction over the subject matter and the parties to this proceeding pursuant to Sections 120.569, 120.57(1), and 456.073(5), Florida Statutes (2005).

77. The Amended Administrative Complaint left open the possibility that discipline might be imposed that led to the revocation or suspension of Respondent's license to practice medicine. For that reason, clear and convincing evidence must be shown to prove the allegations in the Amended Administrative Complaint. § 458.331(3), Fla. Stat. (2003). See also Department of Banking and Finance Division of Securities and Investor Protection v. Osborne Stern and Co., 670 So. 2d 932 (Fla. 1996) and Ferris v. Turlington, 510 So. 2d 292 (Fla. 1987).

78. The meaning of clear and convincing is explained in the case In re: Davey, 645 So. 2d 398 (Fla. 1994), quoting, with approval from Slomowitz v. Walker, 429 So. 2d 797 (Fla. 4th DCA 1983).

79. Respondent allegedly left a piece of the catheter in Patient H.J. after the July 21, 2003 surgery to remove the catheter, and is accused of two separate violations of law for the oversight.

80. Count 1 to the Amended Administrative Complaint refers to Section 456.072(1)(bb) Florida Statutes (2003), which would allow the imposition of discipline for:

> (1) . . . as specified in s. 456.072(2):
>
> (bb) Leaving a foreign body in a patient, such as a sponge, clamp, forceps, surgical needle, or other paraphernalia commonly used in surgical, examination or other diagnostic procedures. For the purposes of this paragraph, it shall be legally presumed that retention of a foreign body is not in the best interest of the patient and is not within the standard of care of the profession, regardless of the intent of the professional.

81. In relation to Count 2 Respondent is said to have violated Section 458.331(1)(t), Florida Statutes (2003), which would allow the imposition of discipline for:

> (1) . . . as specified in s. 456.072(2):
>
> (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. The board shall give great weight to the provisions of s. 766.102 when enforcing this paragraph. As used in this paragraph, 'repeated malpractice' includes, but is not limited to, three or more claims for medical malpractice

within the previous 5-year period resulting in indemnities being paid in excess of $50,000 each to the claimant in a judgment or settlement and which incidents involved negligent conduct by the physician. 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. A recommended order by an administrative law judge or a final order of the board finding a violation under this paragraph shall specify whether the licensee was found to have committed 'gross malpractice,' 'repeated malpractice,' or 'failure to practice medicine with that level of care, skill, and treatment which is recognized as being acceptable under similar conditions and circumstances,' or any combination thereof, and any publication by the board must so specify.

82. As alluded to, in the event that Respondent was shown to have violated either statute he would be subject to discipline in accordance with Section 456.072(2), Florida Statutes (2003), which details the discipline as:

* * *

(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, or department when there is no 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.

83. Section 456.079, Florida Statutes (2003) required that the Board of Medicine adopt rules setting out disciplinary guidelines applicable to each Count in the Amended Administrative Complaint. Florida Administrative Code Rule 64B8-8.001 addresses the requirement as to the range of punishment taking into account aggravating and mitigating circumstances.

84. The allegations in the Amended Administrative Complaint are considered based upon penal statutes, in their respective Counts. As such, they are strictly construed, with ambiguities construed to favor the Respondent. See Lester v. Department of Professional and Occupational Regulation, 348 So. 2d 923 (Fla. 1st DCA 1977).

85. Pertaining to Section 456.072(1)(bb), Florida Statutes (2003), the rule of ejusdem generis is applied. See Smith v. Nussman, 156 So. 2d 680 (Fla. 3rd DCA 1963); Green v. State, 604 So. 2d 471 (Fla. 1992) and Suncoast International, Inc. v. Dept of Business Regulation, Division of Florida Land Sales, condominiums and Mobile Homes, 596 So. 2d 1118, (Fla. 1st DCA 1992). Under this rule of construction where there is an

enumeration of things with particular specific meanings, followed by a general reference, the general words or reference would not be constructed in the broader sense but would be construed as applying to things in the same class as the specific words. Here the terms sponge, clamp, forceps, surgical needle, followed by the reference to "other paraphernalia" in the statute at issue, leads to the conclusion that the "other paraphernalia" must be of a similar nature to the enumerated items. Further, the foreign body that is being described must have commonly been used in surgical, examination, or other diagnostic procedures. Based upon the testimony by Dr. Gadacz, the catheter is not an item in that category used in surgery, examination or diagnosis. The catheter is part of a therapeutic modality to provide peritoneal dialysis. Nor is a fragment of the catheter left within the patient considered within that category. That the catheter was fragmented does not change its character as being outside the items listed in the statute. The piece of the catheter is a foreign body, but it is not of the class of foreign bodies described in the statute. Therefore, even though it was not in the best interest of the patient to retain it, there can be no violation of the standard of care envisioned by this statute.

86. Respondent did fail to practice "with the level of care, skill, and treatment which is recognized by a reason by a reasonably prudent similar physician as being acceptable under

similar conditions and circumstances." When Respondent left the fragment in place following the July 21, 2003 surgery he violated the standard of care, this according to Dr. Kococki. As a consequence he violated Section 458.331(1)(t), Florida Statutes (2003). Whether the catheter was excised and left by Respondent or broke without regard for Respondent's intervention in the case, he had a duty to remove the catheter and all its segments and to make certain that he had accomplished that outcome. A reasonably prudent similar physician under similar conditions and circumstances would have recognized a significant portion of the catheter was left in the patient. Respondent failed in that respect. Nothing else in his conduct that has been described fell below the standard of care, in particular the care provided after the July 21, 2003 surgery and the performance of the December 3, 2003 exploratory surgery to locate and remove the piece left behind.

RECOMMENDATION

Based upon the findings of fact, and conclusions of law, and the guidance set forth in Florida Administrative Code Rule 64B8-8.001, it is

RECOMMENDED:

That a final order be entered finding that Respondent did not violate Section 456.072(1)(bb), Florida Statutes (2003); that Respondent did violate Section 458.331(1)(t), Florida Statutes

(2003); placing Respondent on probation for two years; imposing an administrative fine in the amount of $2,500.00; requiring Respondent to perform 50 hours of community service; requiring the completion of 5 hours of continuing medical education on "risk management" and requiring him to present a one-hour lecture to a group of peers discussing retention of foreign bodies in surgeries and techniques to avoid the retention.

DONE AND ENTERED this 14th day of February, 2006, in Tallahassee, Leon County, Florida.

CHARLES C. ADAMS
Administrative Law Judge
Division of Administrative Hearings
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Filed with the Clerk of the
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this 14th day of February, 2006.

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.