STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

DEPARTMENT OF HEALTH, BOARD OF MEDICINE, Petitioner,	)	
vs.	)	Case No. 06-0598PL
RICHARD B. EDISON, M.D., Respondent.	)	

RECOMMENDED ORDER

Robert E. Meale, Administrative Law Judge of the Division of Administrative Hearings, conducted the final hearing in Fort Lauderdale, Florida, on July 25-26, 2006.

APPEARANCES

For Petitioner: John E. Terrell
Pamela Nelson
Assistant General Counsel
Department of Health
Prosecution Services Unit
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3267

For Respondent: George K. Brew
Lewis W. Harper
Brew & Harper
6817 Southpoint Parkway, Suite 1804
Jacksonville, Florida 32216

STATEMENT OF THE ISSUE

The issue is whether Respondent is guilty of failing to practice in accordance with the applicable standard of care or

failing to keep adequate medical records and, if so, what penalty should be imposed.

PRELIMINARY STATEMENT

By Administrative Complaint dated June 27, 2005, Petitioner alleged that Respondent performed a abdominoplasty and liposuction with Level II sedation on S. B. Based on his findings from a previous office visit, in which S. B. had displayed high blood pressure, Petitioner had allegedly referred her to her primary care physician, who cleared her for surgery after her blood pressure was less than 150/90. The Administrative Complaint alleges that S. B.'s blood pressure, immediately before surgery, was 162/96.

The Administrative Complaint alleges that earlier lab work had revealed that S. B. had abnormal prothrombin times, which are indicative of clotting problems due to liver dysfunction. The Administrative Complaint alleges that Respondent ordered S. B. to take vitamin K after examining her lab reports.

The Administrative Complaint alleges that Respondent performed the surgery with a registered nurse who was not a certified registered nurse anesthesiologist. Under Respondent's direction, the registered nurse allegedly administered Versed, lidocaine with epinephrine, Diprivan, and fentanyl, as well as nitrous oxide. Respondent allegedly ordered the registered nurse to administer the Diprivan by drip rather than controlled

infusion, and the medical records allegedly fail to indicate the length of the infusion, the details of the doses, and whether a pump was used, as well as whether S. B. could respond purposefully to verbal commands or tactile stimulation during surgery.

The Administrative Complaint alleges that S. B. spent the night at Respondent's surgical facility where she received medication to control blood pressure and relieve pain. At about 9:00 a.m. on January 16, 2004, S. B. was allegedly discharged to go home with her adult daughter. At about 1:00 p.m., the daughter allegedly checked her mother, found that she had no complaints, and left S. B. alone while the daughter ran errands.

The Administrative Complaint alleges that the daughter returned to her mother's home at about 6:00 p.m. and found S. B. on the floor in full cardiac arrest. Emergency management services technicians allegedly arrived at the home and found S. B. unresponsive and apneic, as she laid on the floor in a fetal position without a pulse. The technicians allegedly transported S. B. to the hospital, but she was dead.

On January 17, 2004, the medical examiner allegedly conducted an autopsy that revealed the cause of death to be combined drug overdose (heroin, temazepam, diazepam, methadone, meperidine (Demerol), and hydrocodone) with contributory causes of hypertension, abdominal wall hemorrhage, and liver cirrhosis.

The Administrative Complaint alleges that, based on the type and quantity of medication administered to S. B., the sedation was Level III, not Level II. The Administrative Complaint alleges that the standard of care precluded delegating to a registered nurse the administration of Diprivan and Versed and required the presence of a certified registered nurse anesthesiologist or a medical doctor anesthesiologist to administer and monitor the Diprivan and Versed. The Administrative Complaint alleges that Respondent violated the standard of care by performing this elective surgery before S. B.'s blood pressure had been brought under control.

Count One of the Administrative Complaint alleges that Respondent violated Section 458.331(1)(t), Florida Statutes, by failing to practice in accordance with the applicable standard of care in the following five ways:

> a. Ordering the administration of Diprivan by continuous drip, along with other anesthesia medications, without utilizing a C.R.N.A. or M.D. Anesthesiologist;
>
> b. Performing elective surgery on Patient S. B. before controlling her hypertension or waiting for her blood pressure reading to reach an acceptable level as opined by her general practitioner.
>
> c. Failing to perform further evaluations, tests or treatment prior to surgery after reviewing abnormal blood and/or prothrombin time (PT) test results;

d. Failing to obtain a consultation for the abnormal PT (prothrombin time) test results; and

e. Administering Lorcet and Tylenol to Patient S. B., since Tylenol is contraindicated for patients with liver problems.

Count Two of the Administrative Complaint alleges that Respondent violated Section 458.331(1)(m), Florida Statutes, by failing to keep legible medical records that justify the course of treatment of S. B. The Administrative Complaint alleges that Respondent failed to justify the course of S. B.'s treatment by failing to document three things: whether S. B. had reached the targeted blood pressure prior to the surgery, why Respondent had administered vitamin K before surgery, and appropriate plans concerning prior lab studies.

Count Three of the Administrative Complaint alleges that Respondent violated Section 458.331(1)(q), Florida Statutes, by prescribing or administering a legend drug other than in the course of his professional practice. The Administrative Complaint alleges that it is presumed that a physician prescribes or administers a legend drug other than in the course of his professional practice when he prescribes or administers the drug in excessive or inappropriate quantities, without regard to his intent. The Administrative Complaint alleges that Respondent prescribed or administered Diprivan excessively or

inappropriately by continuous drip, along with other anesthesia drugs, in the absence of a C.R.N.A. or M.D. Anesthesiologist.

Count Four of the Administrative Complaint alleges that Respondent violated Section 458.331(1)(w), Florida Statutes, by delegating professional duties to a person whom he knew or had reason to know was not qualified by training, experience, or licensure to perform them. In particular, Respondent allegedly delegated the administration of sedatives or anesthetic agents, including Diprivan, to a registered nurse, whom he knew or had reason to know was not licensed as a C.R.N.A.

At the hearing, Petitioner called six witnesses and offered into evidence 21 exhibits: Petitioner Exhibits 1-10, 14, 16-20, and 27-31. Respondent called three witnesses and offered into evidence seven exhibits: Respondent Exhibits 1-7. All exhibits were admitted except Petitioner Exhibit 18. Petitioner Exhibit 3 was admitted for penalty, not liability, purposes, and Petitioner Exhibit 19 and Respondent Exhibits 1 and 3 were not admitted for the truth of their contents.

The court reporter filed the transcript on August 11, 2006. The parties filed their proposed recommended orders on August 24, 2006.

FINDINGS OF FACT

1. At all material times, Respondent has been a licensed physician, holding license number ME 44240. He has been licensed in Florida since 1984. Respondent has practiced plastic surgery, particularly cosmetic plastic surgery, for the past 22 years. Respondent is certified by the American Board of Plastic Surgery in plastic surgery. He was also certified in Advanced Cardiac Life Support (ACLS) at the time of the surgery in question.

2. The Board of Medicine previously disciplined Respondent by Final Order filed September 1, 1995, pursuant to a Consent Agreement into which the parties had entered. The Consent Agreement arose from allegations that Respondent had failed to remove a sponge from a breast during breast augmentation surgery. Respondent did not admit the allegations, but agreed to pay a $2000 fine and attend ten hours of continuing medical education. The Administrative Law Judge admitted this evidence strictly for the purpose of penalty, not liability.

3. Respondent performs plastic surgery at the Cosmetic Surgery Center in Fort Lauderdale. The 5000 square-foot facility contains three examination rooms, two operating rooms, one recovery room, and an overnight hospital. Another physician also operates at the Cosmetic Surgery Center, which employs a wide range of staff, including a patient coordinator, nurse

practitioner, and a certified register nurse anesthesiologist (CRNA).

4. In the past, the Cosmetic Surgery Center retained a CRNA to assist in surgery on an as-needed basis. However, since mid-2005, the Cosmetic Surgery Center has regularly employed a CRNA after the Board of Medicine issued an Order of Emergency Restriction of License on June 8, 2005. Issued in response to the incident described below, the emergency order requires, among other things, that Respondent employ a CRNA or M.D. anesthesiologist to administer anesthesia at all surgeries, unless the surgery will involve Level I sedation. The emergency order also requires Respondent to obtain an unqualified surgical clearance from every patient's primary care physician.

5. Respondent has performed over 10,000 procedures using Level II sedation over 25 years. Level II sedation leaves the patient conscious, but tranquil, and responsive to painful stimulus or verbal command. Level III sedation leaves the patient unconscious.

6. This case involves a 50-year-old female, S. B., who presented to Respondent's office on July 9, 2003, to discuss the possibility of an abdominoplasty, breast augmentation, and arm lift. Respondent had previously performed an abdominoplasty, which is also known as a tummy tuck, on S. B.'s daughter, who wanted to make a present of cosmetic surgery for her mother.

After examining S. B., Respondent recommended against any work on the arms, as the surgical scars would outweigh the benefits of the surgery for S. B.

7. During this initial office visit, Respondent took a history from S. B., who had three children and was employed as a receptionist for a local roofing company. S. B. stated that her general health was good, and she had never had significant complications from any surgery. She reported that her only medical problem was hypertension and that she consequently took clonidine and Lasix. She stated that she had never reacted badly to general or local anesthesia, did not bruise easily, and did not bleed excessively from cuts. The form asked the patient to list intoxicating or mind-altering drugs, and S. B. did not list any. At no time during the July 9 visit did S. B. express an intent to proceed with the surgery, and, in fact, she was undecided at the time and remained so for several months.

8. Respondent next saw S. B. on December 11, 2003, when she presented at his office for a pre-operative examination. Respondent again discussed the surgical procedures. During this visit, S. B.'s blood pressure was 210/112, which was too high for Respondent to perform elective surgery. Instead, he discussed with S. B. the need to control her blood pressure and learned that she had quit taking her blood pressure medication. Respondent told S. B. to see her primary care physician to

control the blood pressure. Respondent's notes document S. B.'s blood pressure, the referral, and the purpose of the referral.

9. In anticipation of surgery on December 23, 2003, Respondent prescribed on December 11, 2003, fifteen 500-mg tablets of Duricef, fifteen 10-mg tablets of Lorcet, and fifteen 30-mg tablets of Restoril. Duricef is an antibiotic. An analgesic, Lorcet combines 10 mg of hydrocodone, an opioid, with acetaminophen. Restoril, or temazepam, is a sedative in the benzodiazepine family and is similar to Valium. Respondent typically prescribes these or similar medications, so that his patients can fill them prior to surgery and take them following surgery.

10. On December 11, 2003, Respondent also ordered pre-surgical lab work. The lab report, dated December 12, 2003, states that S. B.'s values were largely normal. However, S. B.'s prothrombin time (PT), which measures clotting time, was very slightly elevated. The normal range for this parameter for this laboratory is 11-13 seconds, and the PT for S. B. was 14.8 seconds. However, the International Normalization Ratio (INR), which normalizes results among labs and tissue samples, was 1.4, which is within the normal range, as was the partial thromboplastin time (PTT), which is another measure of clotting time.

11. S. B.'s red blood cell count was very slightly high (6.13 as compared to a range of 4.2-6.1 units per liter). Also very slightly low were S. B.'s M.C.V. (79.0 as compared to a range of 80.0-99.0 units), M.C.H. (26.3 as compared to a range of 27.0-31.0 units), and M.C.H.C (32.7 as compared to a range of 33.0-37.0 units per liter). Very slightly high was S. B.'s R.D.W. (15.4 as compared to a range of 11.5-15.0 percent). Except for the red blood cell count, the other parameters pertain to precursors of cells.

12. The next day, Respondent added to the pre-operative prescriptions two 5-mg tablets of Mephyton, which is vitamin K. The medical records contain no discussion of why Respondent added vitamin K the day after he had ordered the other pre-operative medications. Most likely, this information would have been contained in Respondent's notes, which are in a handwritten scrawl that is partly illegible. Clearly, though, Respondent's notes fail to disclose the purpose of ordering Respondent to take vitamin K. Respondent testified that he was responding to the PT value, explaining that he gives vitamin K to patients with borderline clotting studies, so that the patients will not experience as much bruising and swelling.

13. More important than the records' failure to contain an explanation for the ordering of vitamin K is their failure to address the high PT value in Respondent's plan of treatment for

S. B. Even if only borderline high and more suggestive of problems involving only bruising and swelling, the PT raised a clotting issue, which is of obvious importance given the nature of the contemplated surgery. Respondent's records must address this issue and the impact, if any, on the contemplated surgery.

14. In retrospect, the PT abnormality proved irrelevant. S. B. did not display any clotting problems or excessive bleeding during the surgery. At the hearing, Respondent explained the limitations of a PT value, especially when it is unaccompanied by an abnormal INR, although Respondent obviously thought enough of the PT test to order one for S. B. More cogent is Respondent's explanation at the hearing that the absence of any reported history of bleeding or bruising outweighed any concerns raised by a slightly elevated PT value, but this persuasive analysis is nowhere to be found in the medical records.

15. Petitioner argues alternatively, though, that the slightly elevated PT value should have alerted Respondent to cirrhosis, which is discussed in more detail below. At the pre-operative stage, at least, the history, findings, and complaints did not support a diagnosis of cirrhosis. In his pre-operative physical examination, Respondent found no evidence of jaundice or edema. S. B.'s anemia had resolved. Her history lacked any indication of liver disease, nor did S. B. complain of any

symptoms consistent with cirrhosis. These facts, as well as the information supplied by S. B.'s primary care physician, justified Respondent's failure to explore the possibility of liver disease prior to proceeding with surgery.

16. Nor did the circumstances impose a duty on Respondent to include in the medical records a plan of treatment that addressed the possibility of cirrhosis. The facts reasonably known to Respondent did not raise the possibility of cirrhosis, any more than they raised the possibility of heroin use by S. B. It is thus irrelevant to Respondent's documentation duties, although not necessarily to her death approximately 30 hours after the end of the surgery, that S. B. suffered from some degree of cirrhosis and used heroin.

17. On December 31, 2003, S. B.'s primary care physician completed a "Medical Clearance" form, even though Respondent had not requested a medical clearance, but had required only that the physician do what was necessary to get S. B.'s blood pressure under control. On the form, S. B.'s primary care physician noted that S. B.'s past history consisted of hypertension and, in June 2000, anemia. The addition of the date implied that S. B. no longer suffered from anemia--a fact borne out by her elevated red blood cell count. On the form, the primary care physician noted that her blood pressure was 160/98 and pulse was 80, changed one of S. B.'s blood pressure

medications, and cleared her for surgery under local and general anesthesia, "once BP < 150/90."

18. Two items on the Medical Clearance form support Respondent's decision not to investigate the possibility of liver disease before performing surgery. First, as noted above, the form indicates that S. B.'s anemia had resolved. It would be reasonable to assume that S. B.'s primary care physician was especially attentive to indicators of anemia or liver disease given this history. Second, the Medical Clearance indicates that S. B.'s primary care physician had ordered a comprehensive metabolic panel, which would include tests of liver function. The absence of any further contact from the primary care physician implies that the comprehensive metabolic panel revealed nothing of importance as to liver function, and the function of the liver is obviously important--not its post-mortem condition.

19. On January 15, 2004, S. B. presented at the Cosmetic Surgery Center for an abdominoplasty with liposuction to the waist area. Respondent's scrawled notes do not disclose why he or S. B. decided not to proceed with the breast augmentation.

20. In the pre-operative evaluation, which is initialed by Respondent, S. B.'s pulse was 95, and her blood pressure was 162/96, with the notation that she was nervous. Her rating on the American Society of Anesthesiologists (ASA) scale is I,

meaning that she has no disease. Respondent concedes that her hypertension warranted a II, which means some systemic disease, but not threatening. However, the mis-rating on the ASA scale is irrelevant because it did not impact her treatment or outcome.

21. The pre-operative evaluation contains two other notations of interest. First, Respondent planned for S. B. to remain overnight at the Cosmetic Surgery Center, rather than to discharge her to home on the day of the surgery or transfer her to a hospital. Thus, her remaining at the facility the night of the surgery did not suggest an unusually difficult surgery or recovery. Second, Respondent found S. B. fit for surgery under I.V. sedation in the office, rather than local or general anesthesia.

22. Obviously, the pre-operative evaluation reports a blood pressure in excess of the maximum listed in the medical clearance that Respondent had received from S. B.'s primary care physician. Respondent's medical records fail to address this discrepancy and the broader issue of S. B.'s blood pressure, which was about the same as it was when she visited her primary care physician, but considerably lower than when she last visited Respondent. Respondent could and did reasonably exercise his own medical judgment and proceed with surgery despite a blood pressure in excess of the maximum on the medical

clearance, but given this recommendation, S. B.'s extremely elevated blood pressure a month earlier, the challenges of maintaining reasonable blood pressure levels intra- and post-operatively, and S. B.'s hypertensive condition, Respondent was required to document his reasoning for proceeding with surgery despite the relatively high blood pressure.

23. At hearing, Respondent offered a persuasive explanation of why he proceeded to perform the surgery despite a blood pressure reading over 150/90. Attributing the elevated blood pressure (and pulse) to adrenalin-producing anxiety, not hypertension, Respondent decided that he would be able to control S. B.'s blood pressure adequately during surgery with sedatives and blood pressure medication. Considerable evidence indicates that S. B. was a very nervous patient. S. B.'s pulse was also quite rapid on both visits. As was the case with the PT value, it is easier to credit Respondent's reasoning given hindsight, as he successfully controlled S. B.'s blood pressure during surgery.

24. During surgery, Respondent's nurse practitioner, Michelle Huff, monitored heart function by an EKG, blood oxygenation and pulse by a disposable pulse oximeter, blood pressure, and respiration. During the surgery, Respondent was also assisted by Tiffany Archilla, a certified surgical technologist.

25. At Respondent's direction and under his supervision, Nurse Hoff, administered the following drugs immediately before and during surgery: Diprivan, which is an anesthetic whose specific effect depends on rate of administration; Versed, which is a sedative; Robinul, which controls nausea; Ancef, which is an antibiotic; fentanyl, which is an analgesic and anesthetic; and labetalol, which controls blood pressure. Nurse Huff also administered oxygen and nitrous oxide, which is an anesthetic.

26. Nurse Huff had been working at the Cosmetic Surgery Center for only two months at the time of S. B.'s surgery. Nurse Huff is not a CRNA, but is an advanced registered nurse practitioner and has been a registered nurse for 14 years. At the time of the hearing, she had been employed for three years at the Cosmetic Surgery Center, where she also had completed an internship. She estimates that she has participated in over 1000 surgical procedures involving Level II sedation.

27. At 8:40 a.m., Nurse Huff administered 2.5 mg of Versed, 0.2 mg of Robinul, and 1.0 g of Ancef. At 8:45 a.m., Nurse Huff started the oxygen, nitrous oxide, and Diprivan drip. The oxygen was in a two-liter bottle, and the nitrous oxide was in a four-liter bottle.

28. The Diprivan was 500 mg in a 500 cc solution. During the surgery, Nurse Huff administered all of this Diprivan, as well as all of another 200 mg of Diprivan in a 250 cc solution,

given S. B.'s resistance to sedation. In most cases, and probably in this one, Respondent uses a microchamber, which releases microdrips at the rate of 60 drops per minute. Respondent does not administer Diprivan by means of an infusion pump, which would offer more precise control of the rate of infusion. The records do not indicate the rate of administration of the Diprivan. However, Respondent rarely finds it necessary to discontinue Diprivan during surgery, and its clinical effect wears off after only about three minutes following its discontinuation, so the patient arouses quickly after Diprivan is stopped. Thus, the failure to record the rate of administration of the Diprivan is immaterial.

29. At 8:45 a.m., Nurse Huff also administered 100 mg of fentanyl, which was followed by 50 mg doses at 8:50 a.m., 8:55 a.m., 9:05 a.m., 9:35 a.m., 9:45 a.m., 10:05 a.m., and 10:10 a.m. S. B. thus received a total of 450 mg of fentanyl.

30. The surgery commenced at 9:30 a.m. At the start of surgery, Respondent administered subcutaneously at the surgical site 150 cc of one percent lidocaine, which is a local anesthetic, with epinephrine at 1/200,000. The epinephrine prevents the body from quickly absorbing the lidocaine.

31. S. B.'s blood pressure had varied between 8:40 a.m. and 9:30 a.m. It started at 164/97, but was 135/85 15 minutes later. Her blood pressure remained at 145/85 from 9:00 a.m. to

9:10 a.m. At the time of surgery, S. B.'s blood pressure was 162/88. In response to the start of surgery and reflective of S. B.'s level of anxiety, her blood pressure surged to 180/95 at 9:45 a.m., and Respondent directed Nurse Huff to administer 2.5 mg of labetalol at this time. S. B.'s blood pressure reached 190/80 at 10:00 a.m., five minutes after Nurse Huff had administered another 2.5 mg of labetalol. By 10:10 a.m., S. B.'s blood pressure was down to 125/75, where it remained for the remainder of the surgery.

32. S. B.'s other vitals remained good during the surgery. Oxygenation saturation remained over 96 percent, mostly 97 and 98 percent. Respiration remained around 18. Pulse ran in proportion to blood pressure, but settled within the range of 80-90 once S. B.'s blood pressure stabilized at 10:10 a.m.

33. Blood loss was minimal during the surgery. Typically, a patient may lose 200-300 cc of blood, but S. B. lost only 150 cc. Proceeding conservatively, Respondent did not try to tighten the muscle wall, as he found, once he had made the incisions, that S. B. did not require this procedure. The liposuction removed 200 cc, including 150 cc of fat.

34. Anesthesia ended at 11:05 a.m., and surgery ended at 11:10 a.m. During the surgery, S. B. had received 2000 cc of fluids. At all times, S. B. remained active and alert.

Evidencing S. B.'s level of alertness during surgery was her high oxygen levels at all times during surgery and the necessity of additional Diprivan.

35. At 11:20 a.m., S. B. was transported by stretcher from the operating room to the recovery room. At this time, her oxygen level was 98 percent, her blood pressure was 179/97, her pulse was 96, and her respiration was 16. At 11:30 a.m., S. B. received 2.5 mg of labetalol. At 11:35 a.m., S. B. was complaining of anxiety, so she received 2.5 mg of Valium.

36. At 11:40 a.m., a nurse emptied her Foley catheter of 1600 cc of clear yellow urine. At this time, S. B.'s blood pressure was 184/105, her pulse was 95, her respiration was 16, and her oxygen level was 96 percent. She received another 2.5 mg of labetalol. At 11:45 a.m., S. B. received another 2.5 mg of Valium.

37. At 12:15 p.m., S. B.'s blood pressure was 164/92, and she received clonidine 0.1 mg to reduce her blood pressure. Fifteen minutes later, S. B.'s blood pressure dropped to 143/88. She fell asleep at 1:00 p.m., but awoke an hour later, complaining of pain. She then received 75 mg of Demerol with 6.25 mg of Phenergan, which controls nausea.

38. At 2:30 p.m., S. B. complained again of pain. Her blood pressure had risen to 189/78, so she received another clonidine 0.1 mg. Fifteen minutes later, a nurse emptied

S. B.'s Foley catheter of 1400 cc of clear urine. S. B.'s blood pressure was 170/100, and the nurse notified Respondent of this reading. The nurse gave S. B. 10 mg of Procardia, which reduces high blood pressure. At 3:00 p.m., S. B. received 2.5 mg of labetalol and 2.5 mg of Versed.

39. Fifteen minutes later, S. B. was transferred by stretcher to the overnight room with a blood pressure of 141/60, pulse of 96, and respiration of 16. By 3:45 p.m., S. B.'s blood pressure was 125/59, and she was asleep. Thirty minutes later, S. B. was watching television, and her blood pressure was 141/78.

40. After complaining of pain, S. B. received 100 mg of Demerol with 12.5 mg of Phenergan at 4:50 p.m. At 5:10 p.m., S. B.'s blood pressure rose to 163/94, and her pulse was 108. She received another 10 mg of Procardia at this time. At 6:00 p.m., S. B.'s blood pressure was down to 142/88. Two hours later, after she complained of insomnia, S. B. received 30 mg of Restoril.

41. At 9:15 p.m., S. B. complained of abdominal pain. She received 100 mg of Demerol and 25 mg of Phenergan. At 11:30 p.m., S. B. received 30 mg of Restoril for insomnia and 10 mg of Lorcet for pain.

42. At 1:20 a.m. on January 16, S. B. was sleepy. Two hours later, her blood pressure was 148/70. At 5:30 a.m., after

an uneventful night, S. B. complained of abdominal pain and received another 10 mg of Lorcet. At 7:00 a.m., her intravenous line was discontinued. Alert and oriented, S. B. walked in the hall and received another clonidine 0.1 mg. A nurse emptied her Foley catheter of 400 cc of urine and removed the Foley catheter. At discharge at 8:00 a.m., Respondent examined the wound and found no evidence of bleeding, as he changed the dressing. At this time, S. B.'s blood pressure was 147/70 and pulse was 108. S. B. was transported by wheelchair to her daughter's car.

43. S. B. and her daughter arrived at S. B.'s home at about 9:00 a.m. on January 16, 2004. After spending the morning with her mother, the daughter left the home and returned at 1:00 p.m. Having forgotten the house key, the daughter knocked on the door, and S. B. had to crawl to the door due to her lack of strength. The daughter assisted her mother to bed. Mid-afternoon, the daughter left her mother to run some errands. When the daughter returned home shortly before 6:00 p.m., she found her mother unresponsive and curled into a fetal position on the floor with blood present on the bed sheets and nightshirt that she was wearing. The daughter immediately called 911 and requested an ambulance.

44. The emergency management technicians (EMTs) arrived at S. B.'s home at 6:23 p.m. and found her as her daughter had

found her. S. B. was in full cardiac arrest. The EMTs found S. B. cold to the touch with fixed and dilated pupils. They found a "small amount" of blood oozing from the staples in the lower stomach. The two surgical drains in the upper stomach contained no discharge. Blood had soaked the bandage and run down both legs to thigh level. The EMTs estimated blood loss at about 500 cc. The EMTs also found the Restoril and Lorcet in the doses that Respondent had prescribed pre-operatively. The EMTs attempted unsuccessfully to resuscitate S. B. and transported her to the hospital where she was pronounced dead on arrival at 6:35 p.m.

45. The medical examiner conducted an autopsy on January 17, 2004, at which time blood and urine samples were taken for toxicological analysis. The toxicology report notes that a gas chromatography/mass spectrometry procedure revealed the presence of 6-MAM, which is a metabolite of heroin and demonstrates conclusively that S. B. consumed heroin or, much less likely, 6-MAM; morphine, which is another indicator of heroin, at a concentration of 0.22mg/L; methadone at a concentration of less than 0.05 mg/L; meperidine, which is Demerol (a narcotic analgesic) at a near-toxic concentration of 0.98 mg/L; diazepam, which is Valium, at a concentration of less than 0.05 mg/L; nordiazepam, which is a metabolite of Valium, at a concentration of less than 0.05 mg/L; temazepam, which is, as

noted above, Restoril or another metabolite of diazepam, at a concentration of 0.29 mg/L; and hydrocodone, which is one of the two ingredients, as noted above, of Lorcet, at a concentration of 0.05 mg/L.

46. A drug's half-life is the amount of time for its potency to be reduced by half. Three to four half-lives are required for the complete elimination of a drug. Because various conditions can affect the half-lives of drugs, such as liver disease as to drugs eliminated substantially through metabolism by the liver, half-lives are stated as average ranges. Relevant half-lives are: Demerol--2-24 hours; diazepam--21-37 hours; hydrocodone--3.4-8.8 hours; and temazepam--3-13 hours. Diprivan and fentanyl have very short half-lives and were not detected by the toxicologist. The half-life of 6-MAM is also very short, about 6-25 minutes, leading the toxicologist who performed the report for the medical examiner to testify that S. B. had consumed heroin not more than two hours before her death.

47. The same toxicologist testified that the detected concentration of Demerol was six times the therapeutic level. (This testimony is credited over the testimony of the Deputy Chief Medical Examiner that the concentration of 0.98 mg/L is only twice the therapeutic level.) Given a half-life of 2-24 hours, all that can be said with certainty is that S. B.

suffered even greater concentrations of Demerol--possibly much greater--prior to the near-toxic concentration found by the toxicologist.

48. Undoubtedly, the heroin and methadone that S. B. consumed were not prescribed by Respondent. Undoubtedly, S. B. had access to Demerol that Respondent had not administered. Respondent could not have reasonably have anticipated, based on the circumstances, that S. B. would consume heroin, methadone, and toxic or near-toxic amounts of Demerol, in addition to her prescribed medications, within 12 hours of her release from the Cosmetic Surgery Center. Just as an illegal drug user has the right to treatment in accordance with the applicable standard of care, so a physician has a right to expect behavior on the part of his patient that is at least consistent with the instinct of self-preservation.

49. The autopsy determined that S. B. died of a combined drug overdose of heroin, temazepam, Valium, methadone, Demerol, and hydrocodone. Contributing causes of death were hypertension, abdominal wall hemorrhage, and cirrhosis. As to the hypertension, the autopsy report states that S. B. suffered from mild arteriosclerotic cardiovascular disease. As to the abdominal wall hemorrhage, the autopsy report states that S. B. was in status--post-tummy tuck and liposuction. As to the cirrhosis, the autopsy report states that S. B. suffered from

severe fatty metamorphosis of the liver. The autopsy report concludes that the manner of death was an accident.

50. Of the drugs that combined to kill S. B., Respondent clearly did not administer or prescribe the heroin or methadone. Although Respondent administered Demerol at the dosages of 75 mg at 2:00 p.m. 100 mg at 4:50 p.m., and 100 mg at 9:15 p.m., all on January 15, the near-toxic Demerol found in S. B. at the time of her death was not due to these doses, but due, at least in large part, to Demerol that S. B. obtained from other sources.

51. The hydrocodone and temazepam were probably derived, at least in part, from the Lorcet and Restoril that Respondent prescribed for post-operative use. Unfortunately, the record does not reveal how many pills of each that the EMTs found at the S. B.'s home, so it is impossible even to infer how much of each medication that S. B. took while at home during the afternoon of January 16 immediately preceding her death. Not much hydrocodone was found in S. B., and the 10 mg of Lorcet given at 11:30 p.m. on January 15 and 10 mg of Lorcet given at 5:30 a.m. on January 16 would have been nearly eliminated by the time of S. B.'s death, given the short half-life of hydrocodone. Considerably more temazepam was found in S. B., but the 30 mg of Restoril given at 8:00 p.m. and 30 mg of Restoril given at 11:30 p.m. would have been nearly eliminated by the time of S. B.'s death, given the short half-life of temazepam.

52. Clearly, in the two or three hours before she died, S. B. took heroin, methadone, and Demerol. Clearly, the fentanyl that she had last received at 10:10 a.m. on the prior day and the Diprivan that she had last received at 11:05 a.m. on the prior day had long cleared her system before she took the heroin, methadone, and Demerol. S. B. accidentally took her own life by taking these three drugs.

53. The record does not suggest that hemorrhaging from the surgical site was due to some failure on Respondent's part. Instead, it appears more likely that falling from the bed or possibly convulsing from the drug overdose, S. B. may have reopened the incision site.

54. The record does not suggest that cirrhosis materially extended the half-lives of any medications that Respondent administered. S. B. efficiently eliminated the Valium that Respondent administered. The record does not explain why she would not as efficiently eliminate other drugs metabolized primarily by the liver.

55. The record does not suggest that Respondent's management of S. B.'s hypertension intra- and post-operatively had any bearing on her demise. Her blood pressure stabilized late in the afternoon of January 15, and nothing in the record suggests that anything that transpired on that day concerning

S. B.'s hypertension caused an acute crisis that resulted in her death.

56. As to Count I, Respondent did not depart from the applicable standard of care. S. B. never fell below Level II sedation; she was always responsive to pain and attempts to communicate. S. B. proved difficult to sedate even to Level II. On these facts, it is impossible to find even that it was reasonably likely, at the outset of the procedure, that S. B. would reach Level III sedation.

57. Additionally, as to Count I, Respondent competently managed S. B.'s hypertension intra- and post-operatively. Based on the circumstances, Respondent correctly determined that the slight elevation of PT would not interfere with clotting or endanger the patient's safety and correctly determined that the other five slight abnormalities in the lab report were immaterial to patient safety in the contemplated surgical procedure. Respondent was thus not required to obtain additional tests or to obtain a consultation for the slight PT abnormality. Based on the physical examination and lab results, including those ordered by the primary care physician, insufficient evidence of liver abnormality existed to preclude the administration of the acetaminophen contained in Lorcet. Further, the standard of care does not preclude the prescription of acetaminophen to all patients with any kind of liver disease.

58. As to Count II, Respondent's medical records fail to document adequately why he proceeded to operate despite S. B.'s failure, pre-operatively, to reach a blood pressure of less than 150/90, why he administered vitamin K pre-operatively, and, most importantly, how he had assimilated the PT abnormality in his treatment plan for S. B. As noted above, at hearing, Respondent amply supplied all of this information--the problem is that he never bothered to do so in the medical records. Although these deficiencies in medical records did not contribute in any way to S. B.'s death, they are material failures to justify the course of treatment. In contrast to the detailed records of Nurse Huff intra-operatively and the post-operative records prepared by nurses, Respondent's notes, and thus the records themselves, do not approach the minimum level of detail necessary to justify the course of treatment in this case.

59. As to Count III, Respondent did not administer or cause to be administered excessive or inappropriate quantities of Diprivan.

60. As to Count IV, Respondent did not improperly delegate professional duties, with respect to the administration of Diprivan, to a registered nurse who was not a CRNA. At all times, Respondent adequately supervised and monitored the administration of this short-acting sedative.

61. The record does not support Respondent's claim of prejudice resulting from any delay in the prosecution of this case. Any claim of prejudice due to delay is undermined by Respondent's failure to demand an immediate hearing due to the imposition of an emergency restriction on his license.

CONCLUSIONS OF LAW

62. The Division of Administrative Hearings has jurisdiction over the subject matter. §§ 120.569 and 120.57(1), Fla. Stat. (2003).

63. Respondent's Motion for Recommended Order of Dismissal is denied because the Division of Administrative Hearings lacks the authority to dismiss the case for prosecutorial delay, and Respondent failed to prove any prejudice from any prosecutorial delay. Given the findings and conclusions that Respondent is guilty only of the charges concerning the inadequacy of his medical records, any claim of prejudice would necessarily fail, as the records are in the exact same condition as they were at the time of the incident, and no passage of time or testimony could alter this fact.

64. Section 458.331(1), Florida Statutes, authorizes the Board of Medicine to discipline Respondent for:

> (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.

* * *

(q) Prescribing, dispensing, administering, mixing, or otherwise preparing a legend drug, including any controlled substance, other than in the course of the physician's professional practice. For the purposes of this paragraph, it shall be legally presumed that prescribing, dispensing, administering, mixing, or otherwise preparing legend drugs, including all controlled substances, inappropriately or in excessive or inappropriate quantities is not in the best interest of the patient and is not in the course of the physician's professional practice, without regard to his or her intent.

* * *

(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.

* * *

(w) Delegating professional responsibilities to a person when the licensee delegating such responsibilities knows or has reason to know that such person is not qualified by training, experience, or licensure to perform them.

65. Florida Administrative Code Rule 64B8-9.009(4) and (5) provides:

(4) Level II Office Surgery.
(a) Scope.

* * *

2. Level II Office surgery includes any surgery in which the patient is placed in a state which allows the patient to tolerate unpleasant procedures while maintaining adequate cardiorespiratory

function and the ability to respond purposefully to verbal command and/or tactile stimulation. Patients whose only response is reflex withdrawal from a painful stimulus are sedated to a greater degree than encompassed by this definition.

(b) Standards for Level II Office Surgery.

1. Transfer Agreement Required. The physician must have a transfer agreement with a licensed hospital within reasonable proximity if the physician does not have staff privileges to perform the same procedure as that being performed in the out-patient setting at a licensed hospital within reasonable proximity. "Reasonable proximity" is defined as not to exceed thirty (30) minutes transport time to the hospital.

* * *

4. Assistance of Other Personnel Required. The surgeon must be assisted by a qualified anesthesia provider as follows: An Anesthesiologist, Certified Registered Nurse Anesthesist, or Physician Assistant qualified as set forth in subparagraph 64B8-30.012(2)(b)6., F.A.C., or a registered nurse may be utilized to assist with the anesthesia, if the surgeon is ACLS certified. . . .

* * *

(6) Level III Office Surgery.

(a) Scope.

1. Level III Office Surgery is that surgery which involves, or reasonably should require, the use of a general anesthesia or major conduction anesthesia and pre-operative sedation. This includes the use of:

a. Intravenous sedation beyond that defined for Level II office surgery;

b. General Anesthesia: loss of consciousness and loss of vital reflexes

with probable requirement of external support of pulmonary or cardiac functions; or

c. Major conduction anesthesia.

* * *

(b) Standards for Level III Office Surgery. In addition to the standards for Level II Office Surgery, the surgeon must comply with the following:

* * *

4. Assistance of Other Personnel Required. An Anesthesiologist, Certified Registered Nurse Anesthetist, or Physician Assistant qualified as set forth in subparagraph 64B8-30.012(2)(c)6., F.A.C., must administer the general or regional anesthesia and an M.D., D.O., Registered Nurse, Licensed Practical Nurse, Physician Assistant, or Operating Room Technician must assist with the surgery. The anesthesia provider cannot function in any other capacity during the procedure. . . .

66. Petitioner must prove the material allegations by clear and convincing evidence. Department of Banking and Finance v. Osborne Stern and Company, Inc., 670 So. 2d 932 (Fla. 1996) and Ferris v. Turlington, 510 So. 2d 292 (Fla. 1987).

67. Count I alleges that Respondent departed from the applicable standard of care. One basis for this allegation is that he administered or caused the administration of Diprivan without a CRNA. In this allegation, Petitioner relies on the Final Order in Department of Health v. Alton Earl Ingram, M.D., DOAH Case Nos. 04-0709PL and 04-0901PL. These cases are

distinguishable in one important respect: both patients in Ingram clearly slipped into Level III sedation during their operations, as they were not responsive to verbal and tactile stimuli during parts of their surgeries. In one case, the patient's oxygen saturation rate dropped to 78 percent, and, in the other case, the patient's oxygen saturation rate was not measurable, under circumstances that permit no inference but that the patient slipped into Level III sedation. Nor does the Ingram Final Order take issue to the following statement in the Recommended Order adopted by the Final Order: "Diprivan, when properly controlled, can be used to achieve Level II anesthesia." (Recommended Order, page 17.)

68. During her surgery, S. B. never slipped below Level II sedation. Respondent was ACLS certified, so he was permitted by rule to employ a registered nurse as his required assistant, rather than a CRNA. It is well-established that penal statutes are construed in favor of licensees. See, e.g., Djokic v. Department of Business and Professional Regulation, 875 So. 2d 693, 695 (Fla. 4th DCA 2004). The facts of this case do not support the effort by Petitioner to prohibit, by order rather than rule, the skilled use of Diprivan in office surgery using Level II sedation.

69. For the reasons set forth in the Findings of Fact, Petitioner likewise failed to prove the remaining bases for its

allegations that Respondent departed from the applicable standard of care.

70. Count II alleges that Respondent failed to keep medical records justifying the course of treatment. For the reasons set forth in the Findings of Fact, Petitioner proved these allegations.

71. Count III alleges that Respondent administered Diprivan excessively or inappropriately. Respondent effectively monitored the rate of administration of Diprivan, which generally was dripped without interruption during the entire procedure.

72. Count IV alleges that Respondent improperly delegated professional duties to a person unqualified to perform them. This allegation essentially restates the allegation that Respondent was required to use a CRNA, not a registered nurse, because he was proceeding with Level III sedation. However, as noted above, Petitioner failed to prove these allegations.

73. Section 458.331(2), Florida Statutes, provides that the Board of Medicine may impose such penalties as are authorized by Section 456.072, Florida Statutes. Section 456.072(2)(b), Florida Statutes, authorizes suspension or revocation. Section 456.072(2)(e), Florida Statutes, authorizes an administrative fine of up to $10,000 per offense or count. Section 456.072(2)(f), Florida Statutes, authorizes probation

for a period of time selected by the Board and upon such conditions, such as continuing education, as the Board may specify.

74. Florida Administrative Code Rule 64B8-8.001(2)(m) provides that, for a second offense, the penalty guidelines for failing to keep appropriate medical records range from probation to suspension and an administrative fine of $5000 to $10,000. In mitigation, Respondent's reasoning in support of his treatment plan was sound and all of his assumptions proved correct. Although maintaining S. B.'s blood pressure within reasonable limits demanded close attention and considerable effort, Respondent and his staff succeeded in meeting this challenge. Respondent's failures regarding medical records did not contribute to the death of S. B.; if they had, the recommendation would have exceeded the maximum penalties in the guidelines.

75. The disciplinary guidelines take into account the prior discipline by treating this violation as a second offense, so the prior discipline is not an aggravating circumstance. However, aggravating circumstances exist. Three separate bases support Petitioner's claim of inadequate medical records. As to these three matters, Respondent's records are silent, betraying either a dangerous ignorance of the purpose of medical records

or a casual disregard for the importance of the requirements concerning medical records.

RECOMMENDATION

It is

RECOMMENDED that the Board of Medicine enter a Final Order dismissing Counts I, III, and IV of the Administrative Complaint, finding Respondent guilty of a single violation of Section 458.331(1)(m), Florida Statutes, suspending his license for 30 days, placing his license on probation for two years, requiring him to complete successfully continuing medical education on medical records, and imposing an administrative fine of $10,000.

DONE AND ENTERED this 25th day of August, 2006, in Tallahassee, Leon County, Florida.

ROBERT E. MEALE
Administrative Law Judge
Division of Administrative Hearings
The DeSoto Building
1230 Apalachee Parkway
Tallahassee, Florida 32399-3060
(850) 488-9675 SUNCOM 278-9675
Fax Filing (850) 921-6847
www.doah.state.fl.us

Filed with the Clerk of the
Division of Administrative Hearings
this 25th day of August, 2006.

COPIES FURNISHED:

Larry McPherson, Executive Director
Board of Medicine
Department of Health
4052 Bald Cypress Way, BIN A02
Tallahassee, Florida 32399-1701

Timothy M. Cerio, General Counsel
Department of Health
4052 Bald Cypress Way, Bin AO2
Tallahassee, Florida 32399-1701

John E. Terrel
Department of Health
4052 Bald Cypress Way, Bin C-65
Tallahassee, Florida 32399-3265

Lewis W. Harper
Brew and Harper, PL
6817 Southpoint Parkway, Suite 1804
Jacksonville, Florida 32216

George Kellen Brew
Brew and Harper, P.L.
6817 Southpoint Parkway, Suite 1804
Jacksonville, Florida 32216

Patricia Nelson
Department of Health
4052 Bald Cypress Way, Bin C65
Tallahassee, Florida 32399

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 must be filed with the agency that will issue the final order in this case.