STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

DEPARTMENT OF HEALTH,	)	
	)	
Petitioner,	)	
	)	
vs.	)	Case No. 06-3707PL
	)	
RICHARD B. EDISON, M.D.,	)	
	)	
Respondent.	)	
_____	)	

AMENDED RECOMMENDED ORDER ON REMAND

Pursuant to notice, a formal hearing was held in this case on December 5 through 7, 2006, in Fort Lauderdale, Florida, before Patricia M. Hart, a duly-designated Administrative Law Judge of the Division of Administrative Hearings.

The Board of Medicine having remanded this case to the Division of Administrative Hearings and the remand having been accepted, the Recommended Order entered on May 1, 2007, is hereby amended as follows:

Preliminary Statement: On Remand, page 9.

Findings of Fact: Paragraphs 59, 68a, and 68b.

Conclusions of Law: Paragraphs 82a, 85, 85a, 85b, 88a, and 90.

Recommendation: Paragraphs 1 through 4.

APPEARANCES

For Petitioner: Patricia Nelson, Esquire
John E. Terrell, Esquire
Department of Health
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For Respondent: George K. Brew, Esquire
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STATEMENT OF THE ISSUE

Whether the Respondent committed the violations alleged in the Administrative Complaint filed July 7, 2006, and, if so, the penalty that should be imposed.

PRELIMINARY STATEMENT

In a four-count Administrative Complaint filed July 7, 2006, the Department of Health ("Department") charged Richard B. Edison, M.D., with the following violations arising out of Dr. Edison's care and treatment of patient P.L. on July 7, 2005, as he began to perform breast augmentation surgery:

(1) Section 458.331(1)(t), Florida Statutes (2005),[1] committing medical malpractice by failing "to practice medicine in accordance with the level of care, skill, and treatment recognized in general law related to" licensure to practice medicine, § 456.50(1)(g), Florida Statutes;

(2) Section 458.331(1)(m), Florida Statutes, "failing to keep legible, . . . medical records . . . 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";

(3) Section 458.331(1)(q), Florida Statutes, "[p[rescribing, dispensing, administering, mixing, or otherwise preparing a legend drug, including any controlled substance, other than in the course of the physician's professional practice"; and

(4) Section 458.331(1)(w), Florida Statutes, which prohibits "[d]elegating 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."

Dr. Edison timely requested an administrative hearing to resolve disputed issues of material fact, and the Department forwarded the matter to the Division of Administrative Hearings for assignment of an administrative law judge. The case was originally assigned to Administrative Law Judge Larry J. Sartin but was transferred to Administrative Law Judge Hart for hearing. Pursuant to notice, the final hearing was held on December 5 through 7, 2006.

On November 30, 2006, Dr. Edison filed Respondent's Motion for a Determination that Petitioner Participated in the

Proceeding for an Improper Purpose and Determine the Award of Attorney's Fees and Costs Pursuant to Section 120.595, Florida Statutes. After discussion during the final hearing, a telephone conference was held on December 13, 2006, during which the undersigned requested that the Department file a written response to the motion and that Dr. Edison file a reply to the Department's response; the parties filed the requested submittals on December 19, 2006, and January 6, 2007, respectively. On February 2, 2007, Dr. Edison filed Respondent's Motion for Attorney's Fees and Costs Pursuant to Section 57.105, Florida Statutes, and the Department filed its response in opposition to the motion on February 12, 2007. Finally, on March 9, 2007, Dr. Edison filed a statement of attorneys' fees and costs incurred by Dr. Edison to date. The motions for attorneys' fees and costs will be addressed in a separate order issued contemporaneously with this Recommended Order.

The parties filed a Joint Pre-Hearing Statement on November 21, 2006. At the hearing, the Department presented the testimony of patient P.L. and her husband, A.A.; Michelle Hoff, A.R.N.P., Dr. Edison's nurse; Franklin Segal, M.D., the Department's anesthesiology expert; Shana Pender, paramedic; Holly Schmorr, paramedic; Katherine Rosenblatt, an employee of the Department; Todd Gardner, M.D., emergency room physician;

Robert Alterbaum, M.D., intensive care physician; and Marguerite P. Barnett, M.D., the Department's plastic surgery expert. Petitioner's Exhibits 1 through 10, 12 through 18, and 20 through 23 were offered and received into evidence. Dr. Edison testified in his own behalf and presented the testimony of Samuel Rosenthal, M.D., Dr. Edison's expert in plastic surgery; Liliana Gabor, a surgical technician employed by Dr. Edison; and Jay Raja, M.D., Dr. Edison's expert in anesthesiology. Respondent's Exhibits 1 through 5 were offered and received into evidence.

Official recognition was granted, at Dr. Edison's request and without objection by the Department, to Florida Administrative Code Rules 64B8-9.003 and 9.009, 64B9-4.002 and 4.003, and 28-105.001; to Sections 120.565, 120.54, 464.001, .002, and .003, 456.073, and 458.331, Florida Statutes; to the Final Order in Department of Health v. Alton Earl Ingram, M.D., DOAH Case No. 04-0709PL (DOH December 16, 2004)(FO No. DOH-04-1585-FOF-MQA); and copies of written opinions issued by various Florida appellate courts.

Official recognition was granted, at the Department's request, of the Final Order entered pursuant to a Consent Agreement in Agency for Health Care Administration, Board of Medicine v. Richard B. Edison, M.D., AHCA Case No. 92-13004 (AHCA August 30, 1995)(FO No. AHCA-95-1210); the Recommended

Order in Department of Health, Board of Medicine v. Richard B. Edison M.D., DOAH Case No. 05-0598PL (DOAH August 25, 2006); the Final Order in Department of Health, Board of Medicine v. Richard B. Edison M.D., DOAH Case No. 05-0598PL (DOH January 4, 2007)(FO No. DOH-07-0026-FOF-MQA), together with a copy of the Recommended Order, the exceptions to the Recommended Order filed by the Department and Dr. Edison, Dr. Edison's response to the Department's exceptions, and the Administrative Complaint[2]; Florida Administrative Code Rules 64B8-8.001 and 9.009; the Recommended Order in Department of Health v. Alton Earl Ingram, M.D., DOAH Case No. 04-0709PL (DOAH September 24, 2004); and the Final Order in Department of Health v. Alton Earl Ingram, M.D., DOAH Case No. 04-0709PL (DOH December 16, 2004)(FO No. DOH-04-1585-FOF-MQA).

At the conclusion of the final hearing, the Department was given leave to file an additional motion for official recognition, which the Department filed December 18, 2006. Dr. Edison objected to the request on the grounds of relevance and lack of notice and was given the opportunity to file his objections in writing no later than seven days after the motion was filed. Dr. Edison did not file written objections, and it is, therefore, assumed that he waived the objections raised at the hearing. Accordingly, as requested by the Department, official recognition was taken of the Department's Final Order

of Emergency Restriction of License, DOH Case No. 04-4940 (DOH June 8, 2005)(FO No. DOH 05-0864-ERO-MQA); the Order of the First District Court of Appeal in Case No. 1D05-2853 (June 20, 2005), granting a stay of the Order of Emergency Restriction of License; and Edison v. Department of Health, Case No. 1D05-2853 (August 30, 2005), in which the court affirmed, per curiam, the Order of Emergency Restriction of License.

The Department also requested, in the second Petitioner's Motion for Official Recognition filed December 4, 2006, that official recognition be taken of the Final Order entered February 20, 2002, by the Board of Nursing on the Petition for Declaratory Statement of Brenda Sammy, R.N., Final Order No. DOH-02-0365-DS-MQA. The motion was addressed at the beginning of the final hearing, which convened on December 5, 2006, and the undersigned withheld ruling on this portion of the Department's motion and requested that the parties file written arguments. Dr. Edison objected to the Department's request that official recognition be taken of this order on the grounds that it was not relevant to any issue in these proceedings, first, on the ground that declaratory statements, by statute, rule, and case law, do not bind anyone but the person submitting the petition for a declaratory statement and, second, on the ground that the declaratory statement was issued by the Board of Nursing, which has no jurisdiction over Dr. Edison. The

Department responded that its purpose in requesting official recognition of the declaratory statement was not to establish a basis for disciplining Dr. Edison but to establish that Dr. Edison had notice about the dangers of the administration of Diprivan by registered nurses during office surgery and the concern in the medical community over this practice.

The Department has the burden of proving that Dr. Edison's conduct violated the standard of care applicable to physicians. The declaratory statement at issue does not tend to prove any fact material to a determination of the standard of care applicable to Dr. Edison's use of Diprivan in office surgery.[3] Having carefully considered the arguments of counsel, the Department's request for official recognition of the Final Order entered February 20, 2002, by the Board of Nursing on the Petition for Declaratory Statement of Brenda Sammy, R.N., Final Order No. DOH-02-0365-DS-MQA, is denied.

The four-volume transcript of the proceedings was filed with the Division of Administrative Hearings on December 18, 2006. The parties timely filed proposed findings of fact and conclusions of law, and Dr. Edison also filed Respondent's Closing Argument and Memorandum of Law, all of which have been considered in the preparation of the Recommended Order.

On Remand

In an Order dated June 27, 2007, the Board of Medicine ("Board") remanded this case to the Division of Administrative Hearings for "findings as to whether Lidocaine is a legend drug and, if so, whether the Respondent is in violation of Section 458.331(1)(q), Florida Statutes, and whether Respondent violated Section 458.331(1)[(m)], Florida Statutes, by failing to document any reason for administering 70 cc or 700 mg of Lidocaine to patient P.L." The remand was accepted in an Order entered July 24, 2007, and the parties timely filed proposed findings of fact and conclusions of law on the issues presented on remand, which have been considered in the preparation of this Amended Recommended Order on Remand.

(It is noted that the Board misstated the reference in its Order to "Section 458.331(1)(q), Florida Statutes," in the context of its statement of the issue of whether Dr. Edison committed a statutory violation "by failing to document any reason for administering 70 cc or 700 mg of Lidocaine to patient P.L." It is clear from the charges recited in paragraph 2 of the Board's Order and from the charges included in the Administrative Complaint in this case that the correct reference is to Section 458.331(1)(m), Florida Statutes, and the quotation above has been altered to reflect the correct statutory reference.)

FINDINGS OF FACT

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

1. The Department is the state agency responsible for the investigation and prosecution of complaints involving physicians licensed to practice medicine in Florida. See § 455.225, Fla. Stat. (2006). The Board is the entity responsible for regulating the practice of medicine in Florida and for imposing penalties on physicians found to have violated the provisions of Section 458.331(1), Florida Statutes. See § 458.331(2), Fla. Stat. (2006).

2. Dr. Edison is, and was at the times material to this matter, a physician licensed to practice medicine in Florida, having been issued license number ME 44240.

3. Dr. Edison received his medical degree from the University of Massachusetts; did his residency in general surgery at the Kaiser Foundation in Los Angeles, California; and did a residency in plastic surgery, with specialties in reconstructive surgery and cosmetic surgery.

4. Dr. Edison is certified in plastic surgery by the American Board of Plastic Surgery and is a lifetime diplomate of that Board. Dr. Edison was also certified in Advanced Cardiac Life Support ("ACLS") at the times material to this proceeding.

5. Dr. Edison has been practicing plastic surgery in Florida for 22 years.

6. Prior to the time material to this proceeding, Dr. Edison performed approximately 150-to-200 breast augmentation surgeries each year and approximately 100-to-150 liposuction procedures each year.

7. Dr. Edison practices at the Cosmetic Surgery Center, which is an office that contains two operating rooms, a recovery room, and an overnight recovery facility that is staffed by an ACLS-certified nurse for patients who undergo procedures such as stomach tucks or facelifts.

8. Dr. Edison's surgical practice is limited to Level II office surgery, which is defined in Florida Administrative Code Rule 64B8-9.009, Standard of Care for Office Surgery, in pertinent part as follows:

> (4) Level II Office Surgery.
>
> (a) Scope
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> 1. Level II Office Surgery is that in which peri-operative medication and sedation are used intravenously, intramuscularly, or rectally, this making intra and post-operative monitoring necessary. . . .
>
> 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.
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> * * *
>
> 4. Assistance of Other Personnel Required. The surgeon must be assisted by a qualified anesthesia provider as follows: An Anesthesiologist, Certified Registered Nurse Anesthetist, 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. An assisting anesthesia provider cannot function in any other capacity during the procedure. If additional assistance is required by the specific procedure or patient circumstances, such assistance must be provided by a physician, osteopathic physician, registered nurse, licensed practical nurse, or operating room technician. . . .

The level of pain and anxiety management achieved under Level II sedation is determined by the type of drugs administered and the dosages in which they are administered.

9. Dr. Edison was ACLS certified and was, therefore, authorized to use the services of a registered nurse to administer the drugs that bring patients to Level II sedation. He does not use the services of an anesthesiologist or of a Certified Registered Nurse Anesthetist in his surgical facility.

Patient P.L.

10. P.L. first consulted with Dr. Edison on July 5, 2005. P.L. filled out a portion of a Patient Information form, and Dr. Edison took a general medical history from P.L., but he did not weigh P.L. during this initial visit, and the Patient Information form does not include her blood pressure, height, or weight. Dr. Edison found P.L. to be a healthy 29-year-old female, the mother of three children, who had no known allergy or adverse reaction to any medication.

11. P.L. wanted breast implants, and, upon examination, Dr. Edison found that P.L. would be a good candidate, anatomically, for the surgery. Dr. Edison spent the majority of time during this initial consultation talking with P.L. and her husband, A.A., about the various breast implant options. He also discussed with them the risks and possible complications of the surgery.

12. After her visit to Dr. Edison's office on July 5, 2005, P.L. notified Dr. Edison's office that she had decided to have the surgery. Dr. Edison had a cancellation on July 7, 2005, and P.L. was scheduled for surgery for 8:00 a.m. on that date.

13. P.L. returned to Dr. Edison's office on July 6, 2005, for a pre-operative examination. At that time, Dr. Edison did an examination during which he checked P.L.'s heart, lungs, blood pressure, and pulse rate, and he noted the results in his examination notes dated July 6, 2005. He found nothing abnormal and concluded that P.L. was a 29-year-old patient in perfect

health, with no known allergy or adverse reaction to any medication.

14. Dr. Edison also had blood drawn during the July 6, 2005, office visit, which was sent to a laboratory for testing. The laboratory report was completed at 8:21 a.m. on July 7, 2005, and showed nothing abnormal.

15. P.L. presented herself at Dr. Edison's office on July 7, 2005, at approximately 8:00 a.m. She was examined by Dr. Edison at 8:10 a.m., and he stated in his office notes that she had decided on the 300 cubic centimeter implant. There were no notations of her vital signs in his office notes.

16. Dr. Edison intended for P.L.'s breast augmentation surgery to be Level II office surgery, and he noted this on P.L.'s Immediate Pre-Op Evaluation, which he completed on July 7, 2005. He also decided to use the transaxillary technique, making incisions under the arms through which to insert the implants under the muscle in P.L.'s chest.

17. Dr. Edison was assisted during surgery by Michelle Hoff, an Advanced Registered Nurse Practitioner, who administered the sedatives and other drugs to P.L. under Dr. Edison's direction. Dr. Edison was also assisted by Liliana Gabor, a surgical technician.

18. Ms. Hoff is not a Certified Registered Nurse Anesthetist, nor has she received any formal training in administering sedative drugs or anesthesia. She has a significant amount of experience administering drugs for pain and

anxiety management. Her experience administering drugs to achieve Level II sedation consists of an externship with Dr. Edison while working on her master's degree in nursing and extensive on-the-job training while working in the operating room with Dr. Edison, which she has done every day since beginning to work with Dr. Edison full-time in November 2003.

19. At some point immediately prior to surgery, Dr. Edison asked P.L. her weight, which she reported as 95 pounds, or 43 kilograms, on the morning of surgery. Dr. Edison needed to know P.L.'s weight in order to calculate the correct dosage of the drugs she would be given, and he wrote "95 lbs" on the outside of P.L.'s folder. Dr. Edison noted P.L.'s weight on the outside of the folder so it would be plainly visible to Ms. Hoff when she had the chart on the anesthesia stand.[4]

20. Dr. Edison did not enter P.L.'s weight in his examination notes, and the only other mention of P.L.'s weight in the medical records maintained by Dr. Edison is the notation "<100 lbs" on a sheet containing the contact numbers for P.L. and for her husband, who would be picking her up after surgery.

21. At approximately 8:20 a.m. on July 7, 2005, P.L. walked to the operating room. Working under Dr. Edison's direction, Ms. Hoff hooked P.L. up to various monitoring devices, so that her heart, blood pressure, and oxygen saturation level could be monitored during surgery. Her vital signs were noted on the anesthesia chart by Ms. Hoff; at 8:20 a.m., P.L.'s heart rate was approximately 104.

22. At 8:20 a.m., Ms. Hoff began to administer drugs to P.L. to achieve Level II sedation in accordance with directions from Dr. Edison; she documented the name of the drugs she administered, together with the time and dosage administered; she monitored and documented P.L.'s vital signs, including heart rate, blood pressure, and oxygen saturation level; and she maintained anesthesia notes.

23. At 8:20 a.m., Ms. Hoff administered two milligrams of Valium; one gram of Ancef, and 0.2 milligrams of Robinol at Dr. Edison's direction.

24. At 8:25 a.m., she administered 10 milligrams of Ketamine and 10 milligrams of Talwin and started the administration of Diprivan by microdrip at the rate of approximately 25 micrograms per kilogram of weight per minute. Ms. Hoff's notes do not indicate the manner in which she administered the Diprivan, nor the dosage or rate of administration. Ms. Hoff also administered nitrous oxide and oxygen at 8:25 a.m., and she noted that Dr. Edison also began administering local anesthetic by injection at 8:25 a.m. Ms. Hoff noted that P.L. was responding to verbal stimuli.

25. Ms. Hoff was not involved with the preparation or administration of local anesthetic to P.L. Dr. Edison prepared a dilute solution of 70 cubic centimeters of 1% Lidocaine with epinephrine with 350 cubic centimeters of saline solution and 10 cubic centimeters of 1/2% marcaine. At approximately 8:25 a.m., Dr. Edison began injecting the Lidocaine solution, which totaled approximately 700 milligrams or approximately

14 milligrams of Lidocaine per kilogram of P.L.'s body weight and 50 milligrams of marcaine, into the tissue surrounding P.L.'s breasts.

26. At 8:30 a.m., Ms. Hoff, at Dr. Edison's direction, administered another 10 milligrams of Talwin.

27. At 8:35 a.m., P.L.'s heart rate was 112 beats per minute and her blood pressure was 142/102. At Dr. Edison's direction, Ms. Hoff administered 1/4 cubic centimeter of Labetalol to help control P.L.'s blood pressure. Ms. Hoff noted that P.L. tolerated the Labetalol well and was responsive to verbal stimuli.

28. At 8:45 a.m., Ms. Hoff noticed a brief facial twitch on P.L.'s face, which is an indication of a possible seizure. At Dr. Edison's direction, she immediately stopped administering all sedatives, and the surgery was cancelled. At Dr. Edison's direction, Ms. Hoff administered 2.5 milligrams of Valium to keep P.L. sedated and to help control the seizure, together with three liters of oxygen by mask.

29. At 8:55 a.m., Ms. Hoff administered another 2.5 milligrams of Valium at Dr. Edison's direction,[5] and she noted that P.L.'s status was unchanged, by which Ms. Hoff meant that P.L.'s airway, breathing, and circulation were maintained, that her vital signs were stable, and that she remained responsive to verbal stimuli.

30. Between 8:55 a.m. and 9:15 a.m., P.L.'s status was unchanged. According to Ms. Hoff's notes, P.L.'s airway, breathing, circulation, and vital signs were maintained at normal

levels, and she responded well to the Valium and oxygen. Ms. Hoff observed during this time that P.L. was lethargic and appeared to be a little more deeply sedated than typical Level II sedation. P.L. continued breathing on her own and responding to verbal stimuli.

31. During this interval, Dr. Edison was waiting for P.L. to come out of sedation, and he intended to send her home and recommend that she see her doctor about the twitch.

32. Ms. Hoff noticed a second facial twitch between 9:15 a.m. and 9:20 a.m., and Dr. Edison directed Ms. Hoff to call Emergency Medical Services to transport P.L. to the hospital. Ms. Hoff continued to monitor P.L.'s airway, breathing, circulation and vital signs until the Emergency Medical Services team arrived at 9:30 a.m. During this time, Ms. Hoff noted that P.L. responded to verbal stimuli by moving her head a little bit and attempting to open her eyes.

33. P.L.'s oxygen saturation rate was consistently maintained at 99% to 100% between 8:20 a.m. and 9:30 a.m., when Emergency Medical Services arrived. During this time, P.L. was breathing independently and did not need any assistance with her airway.

34. Emergency Medical Services received the call from Dr. Edison's office at 9:21 a.m. and arrived at 9:26 a.m. At that time, P.L. was receiving oxygen, her airway was normal, and her perfusion was good. Her blood pressure was 102/68, her pulse was strong and regular at 120 beats per minute, her respiratory rate was 20, her respiratory effort was normal, and her breath

sounds were clear. She was, however, non-responsive: She was not able to open her eyes, she had no motor response, and she was not able to give a verbal response. She appeared to be having seizure activity in the form of twitching on both sides of the jaw line.

35. P.L. was transported to Memorial Regional Hospital at 9:31 a.m., and she arrived at the hospital at 9:36 a.m. A notation on the EMS Report for the incident states that a "[l]ist of sedation medication [was] given to ER staff."

36. Dr. Todd Gardner was the emergency room physician who treated P.L. on her arrival at Memorial Regional Hospital. His diagnosis on admission was status epilepticus and hypoxia. Status epilepticus is seizures that are unrelenting to normal therapeutic intervention, and hypoxia is low oxygen level. Dr. Gardner did not attribute a cause to the status epilepticus.

37. Dr. Gardner's intake notes reflect that, prior to presenting at the emergency room, P.L. had received Ketamine, Labetalol to lower her blood pressure, and Valium to relieve the seizures. Nothing on the intake sheet indicates that P.L. had received Lidocaine, and there is no list of the medications given by Dr. Edison in the hospital file.

38. Dr. Gardner intubated P.L. at 10:02 a.m. and placed her on a ventilator in the emergency room because she was unable to breathe on her own. He also treated her with Valium, Dilantin, and Diprivan, which is used to sedate patients in the intensive care unit.

39. Dr. Robert Alterbaum, an internist specializing in pulmonary medicine and critical care, provided care to P.L. in the intensive care unit of Memorial Regional Hospital.

40. P.L.'s chest X-ray was abnormal and showed pneumonitis, or an inflammation of the lungs, caused by fluid being aspirated into the lungs.

41. Based on the emergency room chart, Dr. Alterbaum diagnosed P.L. with status epilepticus, or seizures, related to the administration of Ketamine during the pre-operative procedure for breast augmentation surgery. There was no objective medical evidence to support Dr. Alterbaum's conclusion that Ketamine was the cause of the seizures; he reached this conclusion because Ketamine was the only medication noted on the chart as having been administered to P.L. Dr. Alterbaum was not aware that P.L. had also received Lidocaine; had he been aware of this, it might have been information he would have considered in reaching his conclusion regarding the cause of P.L.'s seizures.[6]

42. P.L. was discharged from Memorial Regional Hospital on July 12, 2005. She had difficulty walking at first, but has fully recovered except that she sometimes experiences a little memory loss.

Drugs administered to P.L.

Valium

43. Valium is a benzodiazopene used to control anxiety, and the standard dosage ranges from two to 20 milligrams for conscious sedation. Valium is a controlled substance.

Ancef

44. Ancef is an antibiotic.

Ketamine

45. Ketamine is a disassociative non-barbiturate analgesic used for sedation and general anesthesia; the maximum dosage is 4.5 milligrams per kilogram of body weight. Ketamine causes a large amount of secretions, and its effects last only five to 10 minutes. Ketamine is a controlled substance.

Robinol

46. Robinol is an anticholinergic medication used to prevent bradycardia, a heart rate of less than 60 beats per minute, and to help dry out secretions in mucous membranes. Robinol is contraindicated for a patient with tachycardia, or a heart rate of more than 100 beats per minute, however, because it could make the patient's heart rate increase. In a healthy 29 year-old patient such as P.L., however, it was not a violation of the standard of care to administer 0.2 milligrams of Robinol to P.L. even though her heart rate was 104 beats per minute at the time it was administered; a healthy 29-year-old patient could easily sustain a heart rate of 140 beats per minute without ill effects.

47. Dr. Edison administered Robinol to P.L. as a drying agent, to control secretions brought on by the use of Ketamine. Although other drugs can be used to control these secretions, Robinol is the best drug for this purpose and the one most commonly used.

48. Dr. Edison had ample justification for using Robinol under the circumstances, and he did not violate the standard of

care by ordering Ms. Hoff to administer the drug even though P.L.'s heart rate slightly exceeded 100 beats per minute.

Talwin

49. Talwin is an opiate analgesic that is used to control pain, and the standard dosage is 30 milligrams. Talwin is a controlled substance.

Nitrous oxide

50. Nitrous oxide is an anesthetic gas that is used for analgesia and sedation; it was administered to P.L. by nasal cannula, which delivers a relatively small amount of gas.

Diprivan

51. Diprivan is a sedative hypnotic medication used both for intravenous sedation and for general anesthesia; the package insert recommends a dosage from 100 to 150 micrograms per kilogram of body weight per minute. Diprivan's clinical effects wear off approximately three minutes after its administration is discontinued.

52. The total dose of Diprivan administered to P.L., 25 milligrams, was included in Dr. Edison's medical records, but the manner of administering the Diprivan and the rate of infusion are not recorded.

53. Diprivan, together with other sedative drugs, may be administered in Florida by a registered nurse at the direction and under the supervision of a surgeon during Level II office surgery.[7] Dr. Edison did not deviate from the standard of care in Florida by delegating responsibility to Ms. Hoff, an Advanced Registered Nurse Practitioner, for administering the various

drugs to P.L., under his direction and supervision. Based on her training and experience, Ms. Hoff was qualified to administer these drugs to P.L. to achieve Level II sedation under Dr. Edison's direction and supervision.

54. The combination of sedative drugs Dr. Edison ordered administered to P.L., specifically Diprivan, Ketamine, Talwin, Valium, and nitrous oxide, was appropriate to induce Level II sedation in P.L., and the dosage of each of the drugs administered to P.L. was well below the maximum dosage recommended for each of the drugs. These drugs work synergistically, however, and, depending on the patient and the circumstances, the same combination of sedative drugs could induce Level III sedation.

55. Florida Administrative Code Rule 64B8-9.009 defines Level III office surgery and sets forth the standards that must be met, in pertinent part, as follows:

> (6) Level III Office Surgery.
>
> (a) Scope.
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> 1. Level III Office Surgery is that surgery which involves, or reasonable should require, the use of a general anesthesia or major conduction anesthesia and pre-operative sedation. This includes the use of:
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> a. Intravenous sedation beyond that defined for Level II Office Surgery;
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> 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.
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> * * *
>
> (b) Standards for Level III Office Surgery. In addition to the standards for Level II Office Surgery, the surgeon must comply with the following:
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> * * *
>
> 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)(b)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. . . .

56. One difference between Level II and Level III sedation is the degree of alertness of the patient. At Level II sedation, the patient must be able to respond to verbal and/or tactile stimuli. If a patient's only response is a reflexive withdrawal from a pain stimulus, the patient is sedated beyond Level II. A primary indication that a patient has slipped from Level II to Level III sedation is the loss of the ability to breathe without assistance, and the patient's airway must be partially or totally managed. In Level II sedation, the need for management of the airway is minimal compared to that required at Level III sedation.

57. P.L.'s blood pressure, pulse rate, oxygenation, and mental state were consistent with Level II sedation until P.L.

had her first seizure and all medications, except for the one-half therapeutic dose of Valium, were discontinued. She remained responsive to verbal stimuli after the second 2.5 milligram dose of Valium was given to control the seizure activity, even though she was more lethargic than normal under Level II sedation. P.L. was non-responsive when examined by Emergency Medical Services personnel, but she was breathing independently and was not at Level III sedation. Her lack of response was more likely than not the result of the seizures, after which a patient can go into a postictal state, or a trance of sleepiness.[8]

58. Dr. Edison did not violate the standard of care for office surgery in ordering the amounts and combination of drugs used to sedate P.L. because P.L. did not reach Level III sedation. In accordance with the standard of care for Level II office surgery, Ms. Hoff, as a registered nurse, was qualified to administer anesthesia to P.L., including Diprivan, Ketamine, and the other sedative drugs used in P.L.'s surgery, at the direction and under the supervision of Dr. Edison.

Dosage of Lidocaine

59. As stated above, Dr. Edison injected a dilute solution of Lidocaine with epinephrine and marcaine into the tissue around P.L.'s breasts between 8:25 a.m. and 8:45 a.m., before P.L. had her first seizure at 8:45 a.m. Lidocaine is a legend drug used as a local anesthetic used to numb nerves and tissue. In breast augmentation surgery Dr. Edison always uses Lidocaine with epinephrine because epinephrine is a vasoconstrictor that causes intense vasoconstriction, or closing of the small blood vessels,

which slows the rate of absorption of the Lidocaine and virtually eliminates bleeding at the site of surgery. Marcaine is also a local anesthetic similar to Lidocaine, but it is slow to take effect and lasts four to six hours and helps control pain after surgery is completed. Marcaine is commonly used with Lidocaine.

60. It is Dr. Edison's practice to perform breast augmentation surgery using the tumescent infiltration technique to infuse a relatively large volume of dilute Lidocaine solution into the breast area as a local anesthetic. Dr. Edison uses this tumescent infiltration technique in breast augmentation surgery because he can deliver a large volume of Lidocaine that is evenly distributed throughout the breast area, which results in more effective pain reduction.

61. The injection technique Dr. Edison uses for tumescent infiltration in the breast area is very specific, and it takes between 20 and 30 minutes to complete the injections. The needle cannot penetrate close to the pectoral muscle, especially in a woman as small as P.L., because of the danger of puncturing a lung. Dr. Edison injects the solution under pressure into the subcutaneous tissue between the breast and the pectoral muscle.

62. Lidocaine is absorbed faster in areas that are highly vascular. The tissue in the aerolar space between the breast and the pectoral muscle does not contain many blood vessels, so Lidocaine injected in this tissue is absorbed more slowly than it would be if injected into highly vascular tissue. In Dr. Edison's experience, because the epinephrine in the Lidocaine solution causes intense vasoconstriction in the tissue

surrounding the injection sites, the Lidocaine stays in place and numbs the area in which the surgery is to be performed. The Lidocaine solution is absorbed slowly over approximately 24 hours, and the peak serum concentration of Lidocaine occurs approximately 10 to 12 hours after it is administered.

63. In this case, Dr. Edison prepared approximately 400 cubic centimeters of solution, which contained 700 milligrams of Lidocaine and 50 milligrams of marcaine, together with a small, non-therapeutic dose of epinephrine. According to his surgical notes, Dr. Edison began the injections of Lidocaine at 8:25 a.m. and had completed the injections by the time P.L. had the first seizure at 8:45 a.m., although it is his recollection that he had not used all of the Lidocaine solution he had prepared. Dr. Edison did not, however, record in the medical records the amount of Lidocaine solution he injected, and any remaining solution was discarded without being measured, so he does not know the dosage of Lidocaine P.L. actually received. Had he injected all of the solution, P.L. would have received approximately 14 milligrams of Lidocaine per kilogram of body weight.

64. According to the package insert that accompanies a bottle of Lidocaine, the maximum dosage of Lidocaine without epinephrine is five milligrams per kilogram of body weight, and the maximum dosage of Lidocaine with epinephrine is seven milligrams per kilogram of body weight. There is nothing in Dr. Edison's medical records to indicate that the Lidocaine he used in P.L.'s surgery included epinephrine or that he calculated

the amount of Lidocaine to administer to P.L. based on her body weight.

65. Using the maximum dosage specified on the package insert, the maximum dosage of Lidocaine without epinephrine for P.L. would have been 215 milligrams, and the maximum dosage of Lidocaine with epinephrine would have been 301 milligrams, using the traditional method of administering the drug. Based on the standard established by the package insert, Dr. Edison exceeded the maximum dosage of Lidocaine with epinephrine injected into P.L. by approximately 400 milligrams, which constituted a toxic dose of Lidocaine when measured by the maximum dosage stated on the package insert.

66. The maximum dosage of Lidocaine with epinephrine stated on the package insert is routinely exceeded by surgeons performing liposuction, which involves suctioning fatty tissue. The tumescent infiltration technique using Lidocaine with epinephrine in a dilute solution is commonly used with liposuction, and Florida Administrative Code Rule 64B8-9.009(2)(d), which sets out the standards of care for office surgery, specifically provides that a "maximum of fifty (50) mg/kg of Lidocaine can be injected for tumescent liposuction in the office setting." Large dosages of Lidocaine can be safely used in liposuction because Lidocaine is metabolized more slowly by fatty tissue than by muscle or skin, and approximately 20% of the Lidocaine solution is suctioned out of the body with the fat that is aspirated during liposuction. As a result, it is possible to administer what would otherwise be toxic doses of

Lidocaine under the maximum dosages specified in the package insert.

67. Dr. Edison has used the tumescent infiltration technique many times in performing breast augmentations without his patients' suffering any ill effects. There is, however, no rule in Florida equivalent to that relating to liposuction that permits the use of high dosages of Lidocaine as local anesthetic in breast augmentation surgery. Furthermore, Dr. Edison has failed to submit persuasive evidence of a standard of care in Florida among plastic surgeons that would permit the use of dosages of Lidocaine with epinephrine in excess of the seven milligrams per kilogram specified on the package insert for breast augmentation surgery.[9]

68. Dr. Edison violated the standard of care by injecting approximately of 700 milligrams of Lidocaine with epinephrine into the tissue surrounding P.L.'s breasts when the maximum allowable dosage, according to the insert packaged with the drug and based on P.L.'s weight, was approximately 300 milligrams.

68a. Dr. Edison also administered Lidocaine, a legend drug, in an excessive and inappropriate quantity when he exceeded the maximum allowable dosage identified on the insert packaged with the drug. It is, therefore, presumed that Dr. Edison administered the 700 milligrams of Lidocaine other than in the course of his professional practice.

68b. Dr. Edison failed to document in his medical records his course of treatment of P.L., specifically, the basis on which

he calculated the dosage of 700 milligrams of Lidocaine to be administered to P.L.

Dr. Edison's previous discipline[10]

69. Dr. Edison was charged in an Administrative Complaint dated February 21, 1995, with having committed medical malpractice in violation of Section 458.331(1)(t), Florida Statutes. He executed a Consent Agreement in which he neither admitted nor denied the factual allegations in the complaint but agreed that, if proven, the facts would constitute a violation of Section 458.331(1)(t), Florida Statutes. The Agency for Health Care Administration entered a Final Order dated August 20, 1995, adopting the Consent Agreement in relevant part. This Final Order does not establish that Dr. Edison committed a violation of Section 458.331(1)(t), Florida Statutes.

70. In a Final Order entered January 4, 2007, the Board adopted the recommended disposition in the Recommended Order in Department of Health, Board of Medicine v. Richard B. Edison, M.D., DOAH Case No. 06-0598PL (Recommended Order August 25, 2006), that Dr. Edison be found guilty of a single violation of Section 458.331(1)(m), Florida Statutes.

CONCLUSIONS OF LAW

71. The Division of Administrative Hearings has jurisdiction over the subject matter of this proceeding and of

the parties thereto pursuant to Sections 120.569, 120.57(1), and 456.073(5), Florida Statutes (2006).

72. Section 458.331(1), Florida Statutes, authorizes the Board to impose penalties ranging from the issuance of a letter of concern to revocation of a physician's license to practice medicine in Florida if a physician commits one or more acts specified therein. In its Administrative Complaint, the Department has alleged that Dr. Edison violated Sections 458.331(1)(m), (q), (t), and (w), Florida Statutes, which provide that the following acts constitute grounds for disciplinary action by the Board:

> (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) Notwithstanding s.456.072(2) but as specified in s. 456.50(2):

1. Committing medical malpractice as defined in s. 456.50. The board shall give great weight to the provisions of s. 766.102 when enforcing this paragraph. Medical malpractice shall not be construed to require more than one instance, event, or act.

2. Committing gross medical malpractice.

3. Committing repeated medical malpractice as defined in s. 456.50. A person found by the board to have committed repeated medical malpractice based on s. 456.50 may not be licensed or continue to be licensed by this state to provide health care services as a medical doctor in this state.

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 medical malpractice," "repeated medical malpractice," or "medical malpractice," 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.

73. Section 456.50(1), Florida Statutes, defines "medical malpractice" as follows:

> g) "Medical malpractice" means the failure to practice medicine in accordance with the level of care, skill, and treatment recognized in general law related to health care licensure. Only for the purpose of finding repeated medical malpractice pursuant to this section, any similar wrongful act, neglect, or default committed in another state or country which, if committed in this state, would have been considered medical malpractice as defined in this paragraph, shall be considered medical malpractice if the standard of care and burden of proof applied in the other state or country equaled or exceeded that used in this state.

Burden and Standard of Proof

74. The Department seeks to impose penalties against Dr. Edison that include suspension or revocation of his license and/or the imposition of an administrative fine. Therefore, the Department has the burden of proving the violations alleged in the Administrative Complaint by clear and convincing evidence. Department of Banking and Finance, Division of Securities and Investor Protection v. Osborne Stern and Co., 670 So. 2d 932 (Fla. 1996); Ferris v. Turlington, 510 So. 2d 292 (Fla. 1987); Pou v. Department of Insurance and Treasurer, 707 So. 2d 941 (Fla. 3d DCA 1998); and Section 120.57(1)(h), Florida Statutes ("Findings of fact shall be based on a preponderance of the

evidence, except in penal or licensure disciplinary proceedings or except as otherwise provided by statute.").

75. "Clear and convincing" evidence was described by the court in Evans Packing Co. v. Department of Agriculture and Consumer Services, 550 So. 2d 112, 116, n. 5 (Fla. 1st DCA 1989), as follows:

> . . . [C]lear and convincing evidence requires that the evidence must be found to be credible; the facts to which the witnesses testify must be distinctly remembered; the evidence must be precise and explicit and the witnesses must be lacking in confusion as to the facts in issue. The evidence must be of such weight that it produces in the mind of the trier of fact the firm belief or conviction, without hesitancy, as to the truth of the allegations sought to be established. Slomowitz v. Walker, 429 So. 2d 797, 800 (Fla. 4th DCA 1983).

See also In re Graziano, 696 So. 2d 744 (Fla. 1997); In re Davey, 645 So. 2d 398 (Fla. 1994); and Walker v. Florida Department of Business and Professional Regulation, 705 So. 2d 652 (Fla. 5th DCA 1998)(Sharp, J., dissenting).

Count One: Section 458.331(1)(t), Florida Statutes; The Standard of Care.

76. The Administrative Complaint alleges that Dr. Edison violated the standard of care in his treatment of P.L. by:

> a. ordering a dose of Lidocaine for Patient P.L. that was not measured based on the patient's weight;
>
> b. ordering a toxic dose of Lidocaine for Patient P.L.;
>
> c. ordering anesthesia for, and performing surgery on, Patient P.L. without performing an appropriate history and physical examination;

> d. ordering Ms. Hoff [a registered nurse] to administer Diprivan, Ketamine and other anesthesia agents when that was outside the scope of her practice;
>
> e. performing surgery while utilizing Diprivan, Ketamine and other anesthesia agents without having a Certified Registered Nurse Anesthetist or M.D. Anesthesiologist monitoring the administration of the Diprivan, Ketamine and other anesthesia agents;
>
> f. ordering an amount and type of anesthetic drugs that produced a Level III office surgery;
>
> g. ordering Robinol when Patient P.L.'s heart rate was already above normal.

77. Based on the findings of fact herein, the Department has failed to prove the violations alleged in paragraphs c., d., e., f., and g. by clear and convincing evidence.

78. Specifically with respect to paragraphs d. and e., the Board has rejected the position of the Department that the delegation of responsibility to administer sedative drugs, including Diprivan, to put a patient in Level II sedation to a registered nurse working under the direction and supervision of a surgeon constitutes a per se violation of the standard of care for office surgery as contrary to Florida Administrative Code Rule 64B8-9.004(4)(b)4. and the ruling in Ortiz v. Department of Health, Board of Medicine, 882 So. 2d 402, 405-06 (Fla. 1st DCA 2004). See Final Order in Department of Health, Board of

Medicine v. Richard B. Edison M.D., DOAH Case No. 05-0598PL (DOH January 4, 2007)(FO No. DOH-07-0026-FOF-MQA) at paragraphs 1 and 4 and Petitioner's Exceptions to the Recommended Order in Department of Health, Board of Medicine v. Richard B. Edison M.D., DOAH Case No. 05-0598PL (DOAH August 25, 2006) at paragraphs 4 through 8 and 14 through 18.

79. With respect to paragraphs c., f., and g., based on the findings of fact herein, the Department did not prove by clear and convincing evidence that Dr. Edison failed to note P.L.'s weight in his medical record; the Department did not prove by clear and convincing evidence that P.L. slipped into Level III sedation at any time, either before or after the sedative drugs were discontinued; and the Department did not prove by clear and convincing evidence that administering a small dose of Robinol to P.L. as a drying agent when her heart rate was four beats per minute above "normal" violated a standard of care under the circumstances.

80. Based on the findings of fact herein, the Department did prove by clear and convincing evidence that Dr. Edison violated the applicable standard of care by failing to calculate the dose of Lidocaine to be administered to P.L. based on her weight and by administering a toxic dose of Lidocaine to P.L. The Department has, therefore, proven that Dr. Edison committed medical malpractice as defined in Section 456.50(1)(g), Florida

Statutes, in violation of Section 458.331(1)(t)1., Florida Statutes.

Count Two: Section 458.331(1)(m), Florida Statutes; Medical Records

81. The Administrative Complaint alleges that Dr. Edison's medical records were inadequate in violation of Section 458.331(1)(m), Florida Statutes, with regard to his treatment of P.L. In particular, the Department alleged that Dr. Edison violated Section 458.331(1)(m) by:

> a. failing to document Patient P.L.'s weight in the record;
>
> b. failing to document any reason for administering 70 cc or 700 mg of Lidocaine;
>
> c. failing to document the dosing amounts of the infusion of the Diprivan or whether any type of pump was used.

82. Based on the findings of fact herein, the Department did not prove by clear and convincing evidence that Dr. Edison failed to document P.L.'s body weight in his medical records. P.L.'s body weight was recorded on the outside cover of her folder, and this was sufficient documentation for the purposes of calculating the dosages of drugs that were to be administered to P.L. under the circumstances of this case.

82a. Based on the findings of fact herein, the Department proved by clear and convincing evidence that Dr. Edison did not justify in his medical records the course of P.L.'s treatment because he failed to document the basis for his calculation that

he should administer 700 milligrams of Lidocaine to P.L. during breast augmentation surgery.

83. Based on the findings of fact herein, the Department did prove by clear and convincing evidence that Dr. Edison failed to document the rate of infusion of Diprivan or the method of infusion of the Diprivan. The only information in the medical records relating to the dose of Diprivan given to P.L. was the notation that 25 milligrams of Diprivan were administered. This information is insufficient to satisfy the requirements of Section 458.331(1)(m), Florida Statutes, that the medical records document the course of treatment.

Count Three: Section 458.331(1)(q), Florida Statutes; Legend Drugs.

84. The Administrative Complaint alleges that Dr. Edison violated Section 458.331(1)(q), Florida Statutes, with regard to his treatment of P.L. by

> a. ordering the excessive or inappropriate administration of Diprivan by continuous drip, along with other anesthesia drugs, without having a C.R.N.A. or Anesthesiologist present;
>
> b. ordering an excessive amount of Lidocaine for Patient P.L.;
>
> c. ordering Robinol when Patient P.L.'s heart rate was already above normal.

85. Based on the findings of fact herein, the Department did not prove the allegations related to the administration of Diprivan or of Robinal by clear and convincing evidence. There

is no evidence that the amount of Diprivan administered to P.L. was excessive, and there is no evidence that Robinol is a legend drug.

85a. Based on the findings of fact herein, the Department has proven by clear and convincing evidence that Dr. Edison violated Section 458.331(1)(q), Florida Statutes, by administering Lidocaine, a legend drug, to P.L. in an excessive and inappropriate quantity. The gravamen of the offense described in Section 458.331(1)(q), Florida Statutes, is, relevant to this case, "administering . . . a legend drug . . . other than in the course of the physician's professional practice." The Legislature included in Section 458.331(1)(q), Florida Statutes, the legal presumption that, relevant to this case, "administering . . . legend drugs . . . 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."

85b. Dr. Edison was, unquestionably, operating in the course of his professional practice when performing breast augmentation surgery on P.L., and it would, therefore, seem that his administration of Lidocaine to P.L. would not fall within the prohibition of Section 458.331(1)(q), Florida Statutes. Nonetheless, because the Department proved by clear and convincing evidence that the quantity of Lidocaine Dr. Edison administered to P.L. was excessive and inappropriate, it must be concluded that, applying the legal presumption included in

Section 458.331(1)(q), Florida Statutes, Dr. Edison was acting outside the course of his professional practice when he administered 700 milligrams of Lidocaine to P.L. His intent to perform breast augmentation surgery on P.L. using the tumescent infiltration technique is not relevant to this conclusion.

Count Four: Section 458.331(1)(w), Florida Statutes; Improper Delegation of Authority.

86. The Administrative Complaint alleges that Dr. Edison

> delegated professional responsibilities to a person when he knew or had reason to know that such person was not qualified by training, experience, or licensure to perform them, in that the Respondent delegated the administration of sedatives and/or anesthetic agents, including Diprivan, during Patient P.L.'s procedure to a registered nurse, whom he knew or had reason to know was not licensed as a Certified Registered Nurse Anesthetist or M.D. Anesthesiologist.

This charge duplicates the charges set forth in paragraphs d. and e. of Count One. The Department has failed to prove this violation by clear and convincing evidence for the same reasons set forth above in paragraph 78.

Penalty

87. The Board's disciplinary guidelines are found in Florida Administrative Code Rule 64B8-8.001.

88. Florida Administrative Code Rule 64B8-8.001(2)(m) provides that the permissible penalties for a violation of Section 458.331(1)(m), Florida Statutes, range from a reprimand

to two years' suspension followed by probation and an administrative fine ranging from $1,000.00 to $10,000.00. The permissible penalties for a second violation of Section 458.331(1)(m), Florida Statutes, range from probation to suspension followed by probation and an administrative fine ranging from $5,000.00 to $10,000.00.

88a. Florida Administrative Code Rule 64B8-8.001(2)(q) provides that the permissible penalties for a violation of Section 458.331(1)(q), Florida Statutes, range from one year's probation to revocation and an administrative fine from $1,000.00 to $10,000.00.

89. Florida Administrative Code Rule 64B8-8.001(2)(t) provides that the permissible penalties for a violation of Section 458.331(1)(t)1., Florida Statutes, range from one year's probation to revocation and an administrative fine ranging from $1,000.00 to $10,000.00.

90. Florida Administrative Code Rule 64B8-8.001(3) permits consideration of aggravating and mitigating factors in determining the appropriate penalty. In this case, there are several aggravating factors that must be considered. First, Dr. Edison's violation of the standard of care relating to the maximum dosage of Lidocaine with epinephrine exposed P.L. to potential injury even though there was not sufficient persuasive evidence to establish that P.L.'s seizures resulted from the

administration of 700 milligrams of Lidocaine with epinephrine. Second, the Department has established that Dr. Edison committed three statutory violations in his treatment of P.L. Third, Dr. Edison has previously been disciplined for the failure to maintain adequate medical records. It is also noted that Dr. Edison has practiced plastic surgery in Florida for 22 years and has had two disciplinary actions filed against him.[11]

Dr. Edison's Motion for Attorneys' Fees and Costs pursuant to Section 120.595(1), Florida Statutes.

91. On November 30, 2006, Dr. Edison filed Respondent's Motion for a Determination that Petitioner Participated in the Proceeding for an Improper Purpose and Determine the Award of Costs and Attorney's Fees Pursuant to Section 120.595, Florida Statutes. In the motion, Dr. Edison argues that the Department participated in this proceeding for an improper purpose by filing and prosecuting an Administrative Complaint against Dr. Edison which included charges that the Department knew or should have known had been rejected by the Board.

92. Section 120.595, Florida Statutes, provides in pertinent part:

> 1) CHALLENGES TO AGENCY ACTION PURSUANT TO SECTION 120.57(1).--
>
> (a) The provisions of this subsection are supplemental to, and do not abrogate, other provisions allowing the award of fees or costs in administrative proceedings.

(b) The final order in a proceeding pursuant to s. 120.57(1) shall award reasonable costs and a reasonable attorney's fee to the prevailing party only where the nonprevailing adverse party has been determined by the administrative law judge to have participated in the proceeding for an improper purpose.

(c) In proceedings pursuant to s. 120.57(1), and upon motion, the administrative law judge shall determine whether any party participated in the proceeding for an improper purpose as defined by this subsection. In making such determination, the administrative law judge shall consider whether the nonprevailing adverse party has participated in two or more other such proceedings involving the same prevailing party and the same project as an adverse party and in which such two or more proceedings the nonprevailing adverse party did not establish either the factual or legal merits of its position, and shall consider whether the factual or legal position asserted in the instant proceeding would have been cognizable in the previous proceedings. In such event, it shall be rebuttably presumed that the nonprevailing adverse party participated in the pending proceeding for an improper purpose.

(d) In any proceeding in which the administrative law judge determines that a party participated in the proceeding for an improper purpose, the recommended order shall so designate and shall determine the award of costs and attorney's fees.

(e) For the purpose of this subsection:

1. "Improper purpose" means participation in a proceeding pursuant to s. 120.57(1) primarily to harass or to cause unnecessary delay or for frivolous purpose or to needlessly increase the cost of litigation,

> licensing, or securing the approval of an activity.
>
> 2. "Costs" has the same meaning as the costs allowed in civil actions in this state as provided in chapter 57.
>
> 3. "Nonprevailing adverse party" means a party that has failed to have substantially changed the outcome of the proposed or final agency action which is the subject of a proceeding. In the event that a proceeding results in any substantial modification or condition intended to resolve the matters raised in a party's petition, it shall be determined that the party having raised the issue addressed is not a nonprevailing adverse party. The recommended order shall state whether the change is substantial for purposes of this subsection. In no event shall the term "nonprevailing party" or "prevailing party" be deemed to include any party that has intervened in a previously existing proceeding to support the position of an agency.

93. This statutory provision is, on its face, not applicable in the instant case to support an award of attorneys' fees and costs to Dr. Edison against the Department even if the Board rejects the recommended disposition and finds in its final order that Dr. Edison is the prevailing party.

94. Section 120.595(1)(b), Florida Statutes, authorizes the award of fees and costs to the prevailing party when the "nonprevailing adverse party" is found to have "participated in the proceeding for an improper purpose." "Nonprevailing adverse party" is defined in Section 120.595(1)(e)3., Florida Statutes, as "a party that has failed to have substantially changed the

outcome of the proposed or final agency action which is the subject of a proceeding."

95. The "proposed agency action" that is the subject of this proceeding is the Department's attempt to discipline Dr. Edison's license to practice medicine for the violations alleged in the Administrative Complaint. The Department does not seek to substantially change the outcome of its proposed agency action, and it is, therefore, not possible for the Department to be a "nonprevailing adverse party" against which an award of attorneys' fees and costs may be assessed in this case.

96. Even though Section 120.57(1)(d), Florida Statutes, provides that "a party" can be found to have participated in the proceeding for an improper purpose, the fact remains that, under the statute, the award of fees and costs can only be made against a "nonprevailing adverse party." It is, therefore, unnecessary under the circumstances for the undersigned to make a determination of whether the Department participated in this proceeding for an improper purpose.

97. For these reasons, the Respondent's Motion for a Determination that Petitioner Participated in the Proceeding for an Improper Purpose and Determine the Award of Costs and Attorney's Fees Pursuant to Section 120.595, Florida Statutes, is denied.

RECOMMENDATION

Based on the foregoing Findings of Fact and Conclusions of Law, it is RECOMMENDED that the Board of Medicine enter a final order

1. Dismissing Count Four of the Administrative Complaint;

2. Finding Dr. Edison guilty of violating Section 458.331(1)(t)1., Florida Statutes, as alleged in paragraphs a. and b. of Count One of the Administrative Complaint; of violating Section 458.331(1)(m), Florida Statutes, as alleged in paragraphs b. and c. of Count Two of the Administrative Complaint; and of violating Section 458.331(1)(q), Florida Statutes, as alleged in paragraph b of Count Three of the Administrative Complaint;

3. Suspending Dr. Edison's license for a period of 180 days, followed by four years' probation under such terms as shall be imposed by the Board; and

4. Imposing an administrative fine in the amount of $20,000.00.

DONE AND ENTERED this 7th day of January, 2008, in Tallahassee, Leon County, Florida.

PATRICIA M. HART
Administrative Law Judge
Division of Administrative Hearings
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Filed with the Clerk of the
Division of Administrative Hearings
this 7th day of January, 2008.

ENDNOTES

[1]/ All references to the Florida Statutes shall be to the 2005 edition, except where noted otherwise.

[2]/ Official recognition was granted at the hearing even though the Final Order was not entered until after the hearing had been closed; the hearing before the Board of Medicine occurred December 1, 2006.

[3]/ See Ehrhardt, C.W., Florida Evidence, § 201.1; Wilson v. State, 666 So. 2d 979, 980 (Fla. 1st DCA 1996).

[4]/ The Department argues that Dr. Edison's testimony that he entered P.L.'s weight on the outside of the folder containing her chart is not credible because he did not provide a copy of the outside of the folder with the medical records he produced during the investigation of the charges against him and because he did not mention the entry or provide a copy of the outside of the folder until his deposition. Having considered the evidence and the argument of the Department, it is concluded that Dr. Edison's testimony is persuasive, and the inference suggested by the Department is rejected.

[5]/ The normal dosage of Valium for controlling seizures is five milligrams, but Dr. Edison decided to administer this dosage in two increments.

[6]/ Dr. Franklin Segal, the Department's expert anesthesiologist, testified that he would attribute P.L.'s seizures to a toxic dose of Lidocaine. According to Dr. Segal, using an amount of Lidocaine with epinephrine in excess of the maximum dosage increases the risk that the patient will suffer neurotoxicity, which is the most common response to a toxic dose of Lidocaine. The symptoms of neurotoxicity are progressive and begin with numbness around the face and mouth and progress to light-headedness, ringing in the ears, twitching, convulsions, and seizures, with the patient eventually becoming unconscious and going into respiratory arrest. P.L.'s symptoms included twitching and losing consciousness. The evidence is not, however, sufficient to establish that P.L. experienced respiratory failure as a result of a neurotoxic response to an overdose of Lidocaine. As previously noted, the records of the emergency treatment P.L. received at Memorial Regional Hospital indicated that P.L. was intubated in the emergency room because she had aspirated fluid into her lungs. In addition, Dr. Alterbaum attributed the cause of the seizures to a reaction to Ketamine, and, although his conclusion might have changed had he known at the time about the dosage of Lidocaine administered to P.L., the cause of the seizures cannot now be established with any acceptable degree of certainty. In any event, the cause of P.L.'s seizures is not relevant to the charges in the Administrative Complaint.

[7]/ See Final Order in Department of Health, Board of Medicine v. Richard B. Edison M.D., DOAH Case No. 05-0598PL (DOH January 4, 2007)(FO No. DOH-07-0026-FOF-MQA) at paragraphs 1 and 4 and Petitioner's Exceptions to the Recommended Order in Department of Health, Board of Medicine v. Richard B. Edison M.D., DOAH Case No. 05-0598PL (DOAH August 25, 2006) at paragraphs 4 through 8 and 14 through 18. It is also noted that the Final Order in Department of Health v. Alton Earl Ingram, M.D., DOAH Case No. 04-0709PL (DOH December 16, 2004)(FO No. DOH-04-1585-FOF-MQA) accepted Dr. Ingram's voluntary relinquishment of his license to practice medicine in lieu of consideration of the Recommended Order entered in that case. Even though the Recommended Order was attached to and made a part of the Final Order, it was not adopted by the Board and, therefore, has no force or effect with respect to the facts found therein or the conclusions of law. See § 120.52(7), Fla. Stat. (2006)("Final

order" means a written final decision which results from a proceeding under . . . s. 120.57 . . . and includes final agency actions which are affirmative, negative, injunctive, or declaratory in form. A final order includes all materials explicitly adopted in it. . . ."")(Emphasis supplied.)

[8]/ Dr. Franklin Segal, the Department's anesthesiology expert, testified that P.L. never reached Level III sedation. Transcript of the proceedings, volume 2, pages 200-01. Dr. Segal also testified that P.L. was at Level III sedation when Emergency Medical Services arrived. Id. at pages 240-41. Careful consideration was given to this testimony and to the testimony and questions on pages 237-40 of the transcript, which preceded Dr. Segal's statement that P.L. was at Level III sedation. Dr. Segal, on page 238, attributed P.L.'s greater degree of sedation, as described by Ms. Hoff, to her seizure. In addition, the hypothetical question that prompted Dr. Segal's response was premised on facts not in evidence, specifically, it was not established in the record that, at the time the Emergency Medical Services personnel recorded that P.L. was unresponsive, her lack of response was "due to the medications and the Lidocaine that triggered the seizure." Accordingly, Dr. Segal's statement that P.L. was at Level III sedation is found to be not credible in light of all of the evidence.

[9]/ Through the testimony of its expert witness in plastic surgery, Dr. Marguerite Barnett, the Department established that the approved maximum dosage of Lidocaine with epinephrine, as specified in the insert included with the product, is seven milligrams per kilogram of body weight and that deviation from this maximum dosage violated the standard of care in Florida for plastic surgeons performing breast augmentation surgery. Dr. Samuel Rosenthal, Dr. Edison's expert witness in plastic surgery, testified about his own practice, in which he uses a dilute solution of Lidocaine with epinephrine at a dosage of approximately 20 milligrams per kilogram of body weight when performing breast augmentation surgery; he does not, however, use the tumescent infiltration technique used by Dr. Edison because he believes that it is not possible to use this technique in breast augmentation surgery because of the relatively small area in which the solution can be infiltrated.

Dr. Rosenthal testified that he was familiar with the practice of other plastic surgeons performing breast augmentation surgery and that Dr. Edison's use of Lidocaine was consistent with the standard of care. He did not, however,

define in his testimony the standard of care in Florida regarding the maximum dosage of Lidocaine with epinephrine that is used in breast augmentation surgery. His only reference was to a 1999 journal article reporting on a Norwegian study of 10 women who received dosages of Lidocaine with epinephrine of up to 20 milligrams per kilogram of body weight. The observation is made in the article that 20 milligrams per kilogram of body weight of Lidocaine with epinephrine had routinely been used for over 20 years in Norway for breast augmentation surgery and that clinical experience had shown that it was a safe dosage. The authors of the article concluded that, based on the scientific evidence collected in their study, this dosage was safe and produced no toxicity when administered as described in the study. The results of this study do not, however, establish the standard of care among plastic surgeons performing breast augmentation surgery in Florida.

[10]/ Previous discipline is not considered for purposes of determining liability but only for purposes of determining penalty.

[11]/ The Order of Emergency Restriction of Dr. Edison's license filed on June 8, 2005, in the context of the Administrative Complaint filed against Dr. Edison that was resolved by the Board's Final Order in DOAH Case No. 06-0598PL, has not been considered disciplinary action for the purpose of aggravating and mitigating factors.

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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.