STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

DEPARTMENT OF HEALTH, BOARD OF MEDICINE,

Petitioner,

vs. Case No. 17-2565PL

MYRDALIS DIAZ-RAMIREZ, M.D.,

Respondent.
_____/

RECOMMENDED ORDER

The final hearing was held in this case on August 24 and 25, 2017. It was conducted using video teleconferencing between Sarasota and Tallahassee. Administrative Law Judge J. Lawrence Johnston conducted the hearing.

APPEARANCES

For Petitioner: Christopher R. Dierlam, Esquire
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For Respondent: Jon M. Pellett, Esquire
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STATEMENT OF THE ISSUES

The issues are whether the Respondent, a licensed physician, violated section 456.072(1)(bb), Florida Statutes (2013),[1/] by

mistakenly injecting a one-percent solution of Xylocaine® into an unintended site on a patient's left hip in advance of performing a right-side trochanteric bursa steroid injection; and, if so, the appropriate penalty.

PRELIMINARY STATEMENT

After the Petitioner filed a Second Amended Administrative Complaint against the Respondent in DOH case 2013-15828, charging the section 456.072(1)(bb) violation, the Respondent disputed the charges and requested a disputed fact hearing. The matter was referred to the Division of Administrative Hearings (DOAH) for assignment of an Administrative Law Judge on May 1, 2017.

After one continuance, the hearing was held on August 24 and 25. Several documents were officially recognized (including parts of the official records of other DOAH cases, and provisions of the relevant Florida Statutes and Florida Administrative Code), and a number of facts were stipulated in the parties' Joint Pre-hearing Stipulation. Joint Exhibit 1 and 2 were received in evidence. The Petitioner called Kevin Chaitoff, M.D., to testify as an expert, and the Petitioner's Exhibits 5, 7, and 8 were received in evidence. The Respondent testified, and called the patient, L.S., and two experts, Drs. Jean-Louis Horn and Albert Wu, to testify. The Respondent's Exhibits A, C through H, L, M, O, and P were received in evidence. Objections to the Respondent's Exhibits I, J, and K

were sustained, and those exhibits were proffered only and not received in evidence.

The Transcript of the hearing was filed on October 12. On October 23, the parties filed proposed recommended orders, and the Respondent filed a closing argument. The post-hearing submittals have been considered.

FINDINGS OF FACT

1. The Petitioner is the state agency charged with regulating the practice of medicine in Florida under section 20.43 and chapters 456 and 458, Florida Statutes (2017).

2. The Respondent is a board-certified anesthesiologist but no longer practices in that specialty, but instead practices pain management medicine in Sarasota. She has been licensed as a physician in Florida since August 15, 2006, and has not been disciplined by any state licensing board.

3. L.S. is one of the Respondent's pain management patients. In August 2013, she was 50 years old, stood 5'8" tall and weighed 310 pounds. She was considered morbidly obese and suffered from multiple medical issues, including recurring trochanter bursa pain in her right hip. The Respondent proposed a procedure involving the injection of steroidal fluid into the right trochanter bursa sac, guided by fluoroscopy, to reduce inflammation and alleviate the patient's pain. During this procedure, contrast dye is first injected into the site to enable

the physician to use fluoroscopy to visualize and guide the placement of the relatively large-gaged needle into the bursa sac within the hip joint and injection of steroidal fluid into the bursa sac.

4. The patient agreed to the proposed procedure but did not want to be awake while it was being performed. It was agreed and arranged that, instead of being performed at the Respondent's office, as it normally would have been done, the procedure would be done at the Intercoastal Medical Group Ambulatory Surgery Center under deep sedation administered by Intercoastal's staff (not by the Respondent). It also was decided and planned that the Respondent would administer a local numbing agent, using a smaller syringe and needle, to reduce post-operative pain from the bursa injection. When used for this purpose, particularly when the patient is going to be sedated for the procedure, the numbing agent can be administered either before or after the bursa injection. In this case, because the patient had a great fear of injections, it was decided to administer the numbing agent before the bursa injection.

5. The procedure was scheduled for August 16, 2013. That morning, the patient met the Respondent in the pre-operative holding area at Intercoastal. The patient's systems and medical history were reviewed again, and she consented to the right trochanter bursa steroid injection and the anesthesia. An

identification band was affixed to the patient, and the injection site was identified and marked by the Respondent. Intravenous (IV) saline was started and oxygen was provided by nasal cannula. Pre-bursa injection medications of Robinul and Versed were given through the IV as a push. The Intercoastal anesthesiologist evaluated the patient and pronounced her capable of safely undergoing the injection under monitored anesthesia care. The patient was then transported to the operating room on a stretcher.

6. The operating team included the Respondent, a certified registered nurse anesthetist (CRNA) who would administer the anesthesia under the supervision of the anesthesiologist, a circulating nurse, and a radiology technician. All but the Respondent were on staff at Intercoastal. Anesthesia monitors were placed, and the patient's identity, injection site, and consents were confirmed. An anesthesia safety check was completed, and the patient was assessed for a difficult airway or aspiration risk. The team reviewed the plan and determined they were ready to proceed. The patient rolled onto the operating table from the stretcher, so that she was in a prone (face-down) position. The Respondent was positioned to the patient's right side, where the equipment needed for the bursa injection was located. The patient's identity, consents, and injection site were re-verified. A "time-out" was performed before proceeding

with the administration of propofol. See Fla. Admin. Code R. 64B8-9.007(2)(b). The team verbally re-confirmed the patient's identity, the intended procedure, and the injection site.

7. After the "time-out," the CRNA administered the propofol. In very short order, it was noted that the patient's oxygen saturation had decreased, and she was having difficulty breathing. Immediate action was taken to resuscitate the patient. The propofol was discontinued, the stretcher was repositioned next to the operating table, the patient was rolled back over onto the stretcher in a supine (face-up) position, and oxygen was given. After a short time, the patient's breathing and oxygen saturation returned to normal. The Respondent explained to the patient what had happened, and it was decided by all, including the patient, to proceed. The team preferred to use the operating table because it would be easier to use the fluoroscope there than on the stretcher. However, because of the apneic event that resulted shortly after the patient was rolled onto the operating table into a prone position the first time, the team decided not to repeat that maneuver. Instead, the team attempted to slide the patient back onto the operating table while remaining in a supine position. Due to the still partially sedated patient's weight, the team decided it would be too difficult and unsafe to try to slide her onto the operating

table. Ultimately, the team decided to leave the patient on the stretcher in a supine position.

8. With the patient still on the stretcher in a supine position, the Respondent cleaned an unintended site on the patient's left hip, which was then facing her and the injection equipment, draped the unintended site, and began to inject it subcutaneously with Xylocaine® one-percent solution as a local numbing agent. Before more than 0.5 of the 5 milliliters of the intended dose in the syringe was injected, the Respondent realized her mistake and withdrew the needle. She told the patient what happened and asked if the patient wanted her to proceed with the intended right trochanter bursa injection. The patient said yes, and the Respondent moved to the intended right side, injected
5 milliliters of the numbing agent at the intended site, and proceeded with the intended bursa injection.

9. The Respondent documented the procedure accurately. Notwithstanding what happened, the patient still thinks very highly of the Respondent, continues to be the Respondent's patient, and does not want the Respondent to suffer any license discipline as a result. She does, however, want it noted in her patient records for future reference that she overreacts to propofol and that care should be taken not to overdose her if it ever is used on her again.

10. No license discipline against any of the Intercoastal staff has resulted from this incident. However, both the Respondent and Intercoastal have changed their operative procedures to require a second "time-out" if an emergency intervenes and interrupts an ongoing procedure, as happened in this case. This is the kind of safe practice improvements that can come from "near misses" and "close calls."

11. The Petitioner's expert witness, Dr. Kevin Chaitoff, testified that the incident resulted in a violation of section 456.072(1)(bb). The Respondent called two experts, Dr. Jean-Louis Horn and Albert Wu, who testified that it did not.

12. The Respondent and her experts contend that a trochanter bursa injection is not a surgery or the kind of procedure that must be reported if done, or attempted, on the wrong side or site. They also contend that the Respondent's injection of some numbing agent at the wrong side or site in this case was not a wrong side/site procedure, or attempted procedure, because all other preparation was done for the procedure planned for and ultimately done on the intended right hip. In their view, what happened in this case should be chalked up as a "close call" or "near miss" that does not have to be reported, and should not result in discipline, because it would have a chilling effect, discourage reporting, and hinder safety improvements.

13. The testimony of the Respondent and her experts also was based, in part, on their position that the subcutaneous injection of numbing agent was not preparation of the patient, but was something they called "pre-preparation." Their testimony seems to beg the question, if that were just "pre-preparation," what would qualify as preparation? Their testimony did not answer this question, but it does not have to be answered to resolve this case.

CONCLUSIONS OF LAW

14. Because the Petitioner seeks to impose license discipline, the Petitioner has the burden to prove its allegations by clear and convincing evidence. See Dep't of Banking & Fin. v. Osborne Stern & Co., Inc., 670 So. 2d 932 (Fla. 1996); Ferris v. Turlington, 510 So. 2d 292 (Fla. 1987). This "entails both a qualitative and quantitative standard. The evidence must be credible; the memories of the witnesses must be clear and without confusion; and the sum total of the evidence must be of sufficient weight to convince the trier of fact without hesitancy." In re Davey, 645 So. 2d 398, 404 (Fla. 1994). See also Slomowitz v. Walker, 429 So. 2d 797, 800 (Fla. 4th DCA 1983). "Although this standard of proof may be met where the evidence is in conflict, . . . it seems to preclude

evidence that is ambiguous." Westinghouse Elec. Corp. v. Shuler Bros., Inc., 590 So. 2d 986, 988 (Fla. 1st DCA 1991)(citations omitted).

15. Disciplinary statutes and rules "must be construed strictly, in favor of the one against whom the penalty would be imposed." Munch v. Dep't of Prof'l Reg., Div. of Real Estate, 592 So. 2d 1136, 1143 (Fla. 1st DCA 1992). See Camejo v. Dep't of Bus. & Prof'l Reg., 812 So. 2d 583, 583-84 (Fla. 3d DCA 2002); McClung v. Crim. Just. Stds. & Training Comm'n, 458 So. 2d 887, 888 (Fla. 5th DCA 1984)("[W]here a statute provides for revocation of a license the grounds must be strictly construed because the statute is penal in nature. No conduct is to be regarded as included within a penal statute that is not reasonably proscribed by it; if there are any ambiguities included, they must be construed in favor of the licensee." (citing State v. Pattishall, 126 So. 147 (Fla. 1930)).

16. The grounds proven in support of license discipline must be those specifically alleged in the administrative complaint. See, e.g., Trevisani v. Dep't of Health, 908 So. 2d 1108 (Fla. 1st DCA 2005); Cottrill v. Dep't of Ins., 685 So. 2d 1371 (Fla. 1st DCA 1996); Kinney v. Dep't of State, 501 So. 2d 129 (Fla. 5th DCA 1987); Hunter v. Dep't of Prof'l Reg., 458 So. 2d 842 (Fla. 2d DCA 1984). Due process prohibits the Petitioner from taking disciplinary action against a licensee

based on matters not specifically alleged in the charging instrument, unless those matters have been tried by consent. See Shore Vill. Prop. Owners' Ass'n, Inc. v. Dep't of Envtl. Prot., 824 So. 2d 208, 210 (Fla. 4th DCA 2002); Delk v. Dep't of Prof'l Reg., 595 So. 2d 966, 967 (Fla. 5th DCA 1992).

17. The Second Administrative Complaint in this case alleges that the Respondent subjected herself to license discipline by violating section 456.072(1)(bb) by "[p]erforming or attempting to perform health care services on the wrong patient, a wrong-site procedure, a wrong procedure, or an unauthorized procedure or a procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition." The statute continues: "For the purposes of this paragraph, performing or attempting to perform health care services includes the preparation of the patient."

18. Construing the statute in the light most favorable to the Respondent, as required by case law, it prohibits: performing or attempting to perform health care services on the wrong patient; performing or attempting to perform a wrong-site procedure; performing or attempting to perform a wrong procedure; or performing or attempting to perform an unauthorized procedure or a procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition."

19. Obviously, the Respondent injected numbing agent on the wrong site (side), where it was not authorized or medically necessary or related to the patient's diagnosis or medical condition. However, she did not inject the wrong patient. In addition, again construing the statute in the Respondent's favor, injecting the numbing agent subcutaneously was not a procedure, or an attempted procedure. The procedure was the bursa injection, which was only attempted (and performed) on the intended right side. This was a "close call," not a section 456.072(1)(bb) violation. It was not required to be reported as an adverse incident under either section 395.0197(5) or section 458.351, Florida Statutes, which address surgical procedures. See also Fla. Admin. Code R. 64B8-9.001(1)(a) (Mar. 9, 2000). Similarly, rule 64B8-9.007(2)(a) (Jan. 29, 2013) required a "time-out" or "pause" to help prevent wrong patient/wrong side/wrong site surgeries and certain other procedures, but did not require one for minor surgeries/procedures, such as a trochanter bursa injection, not requiring the administration of anesthesia or an anesthetic agent.

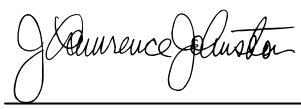
20. The Petitioner cites to Department of Health v. Robert Burns, M.D., DOAH Case 10-7289PL (Fla. DOAH Dec. 29, 2010; Fla. DOAH Feb. 16, 2011), in support of its argument that the Respondent violated section 456.072(1)(bb). However, the facts of that case were significantly different. There, an

anesthesiologist intended to perform a particular procedure--namely, a dorsal medial nerve block on the right side at the cervical level of the spine C5/C6/C7--but instead performed the procedure on the wrong (left) side. The Burns case would have applied had the Respondent performed a trochanter bursa sac steroid injection on the left side, which did not happen.

RECOMMENDATION

Based on the foregoing Findings of Fact and Conclusions of Law, it is RECOMMENDED that the Board of Medicine enter a final finding the Respondent not guilty of violating section 456.072(1)(bb) and dismissing the Second Amended Administrative Complaint.

DONE AND ENTERED this 17th day of November, 2017, in Tallahassee, Leon County, Florida.



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Filed with the Clerk of the
Division of Administrative Hearings
this 17th day of November, 2017.

ENDNOTE

[1/] Unless otherwise noted, statutory references are to the 2013 codification of the Florida Statutes, which was in effect at the time of the alleged offense.

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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.