STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

DEPARTMENT OF HEALTH, BOARD OF MEDICINE,

Petitioner,

Case No. 19-5173PL

vs.

ANTHONY GLENN ROGERS, M.D.,

Respondent.
_____/

RECOMMENDED ORDER

On July 16 and 17, 2020, Robert E. Meale, Administrative Law Judge of the Division of Administrative Hearings (DOAH), conducted the final hearing by Zoom.

APPEARANCES

For Petitioner: Michael J. Williams, Esquire
Geoffrey M. Christian, Esquire
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For Respondent: Sharon Bidka Urbanek, Esquire
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STATEMENT OF THE ISSUES

The issues are: 1) whether Respondent committed medical malpractice, in violation of section 458.331(1)(t)1.; 2) whether Respondent failed to keep or maintain medical records, in violation of section 458.331(1)(m); 3) whether

Respondent performed a wrong procedure or wrong-site procedure, in violation of section 456.072(1)(bb); and 4) if so, the determination of the penalty, pursuant to Florida Administrative Code Rule 64B8-8.001. (All references to statutes and rules are to the Florida Statutes and rules in effect in 2012, as cited in the Amended Administrative Complaint.)

PRELIMINARY STATEMENT

On June 30, 2017, Petitioner filed an Amended Administrative Complaint alleging that, on September 28, 2012, Respondent performed a lumbar transforaminal epidural steroid injection with catheter and fluoroscopy on M.S. The Amended Administrative Complaint alleges that, during the procedure, Respondent inserted the tip of the catheter through the epidural space and into the intrathecal space and injected contrast and injectate into the intrathecal space instead of the epidural space.

The Amended Administrative Complaint alleges that Respondent "did not create or keep documentation of obtaining" intra- and post-injection lateral view epidurograms to confirm the location of the catheter tip or the dispersal pattern of the contrast and injectate. The Amended Administrative Complaint alleges that Respondent did not recognize, or did not create or keep documentation of recognizing, that he had performed an intrathecal administration instead of an epidural injection.

The Amended Administrative Complaint alleges that, after the procedure, M.S. complained of bilateral hip and leg pain, numbness, and paralysis. She was transferred to Bethesda Memorial Hospital where she was diagnosed with conus medullaris syndrome.

Count I alleges that Respondent violated section 458.331(1)(t)1. because he failed to practice within the minimum standard of care required by

sections 456.50(1)(g) and 766.102(1) by failing to obtain an intra-injection lateral view epidurogram to confirm the location of the catheter tip and dispersal pattern of the contrast and injectate, failing to obtain a post-injection lateral view epidurogram to confirm the location of the catheter tip and dispersal pattern of the contrast and injectate, and failing to recognize that he had performed an intrathecal injection instead of an epidural injection.

Count II alleges that Respondent violated section 458.331(1)(m) and (nn) and rule 64B8-9.003(1), (2), and (3) because he failed to obtain an intra-injection lateral view epidurogram to confirm the location of the catheter tip and dispersal pattern of the contrast and injectate, failed to obtain a post-injection lateral view epidurogram to confirm the location of the catheter tip and dispersal pattern of the contrast and injectate, and failed to recognize that he had performed an intrathecal injection instead of an epidural injection.

Count III alleges that Respondent violated section 456.072(1)(bb) because he performed or attempted to perform a wrong-site procedure or a wrong procedure by injecting contrast and injectate into a patient's intrathecal space instead of epidural space.

The Amended Administrative Complaint seeks relief in the form of revocation, suspension, restriction of practice, imposition of an administrative fine, imposition of probation, corrective action, refund of fees, and remedial education.

Petitioner requested a formal hearing.

Respondent transmitted the file to DOAH on September 27, 2019. The hearing was set for December 2 and 3, 2019, but continued at the request of Respondent due to a death of a member of the family of Respondent's counsel. After continuing the hearing to January 13 and 14, 2020, the administrative law judge abated the case through January 21, 2020. Following that date, the administrative law judge reset the hearing for April 6 and 7, 2020. This hearing was continued at the request of Petitioner due to incomplete discovery and reset for June 15 and 16, 2020. This hearing was continued at the joint request of the parties due to Covid-19 and reset for July 16 and 17, 2020.

At the hearing, Petitioner called two witnesses and offered into evidence 13 exhibits: Petitioner Exhibits 1 through 10, 13, 15, and 18. Respondent called one witness and offered into evidence eight exhibits: Respondent Exhibits 1 through 3, 7 through 10, and 12. All exhibits were admitted for all purposes except Petitioner Exhibit 13 (penalty only) and Respondent Exhibits 7 (hearsay; basis for expert witness's testimony only) and 8 through 10 (hearsay; impeachment only).

The court reporter filed the transcript by July 31, 2020. The parties filed proposed recommended orders on August 31, 2020.

FINDINGS OF FACT

1. Respondent is a medical physician, holding license number ME 0062034. He is certified as a pain management specialist by the American Board of Anaesthesia and American Academy of Pain Management. Licensed for nearly 40 years, Respondent practiced in 2012 in Lake Worth at the Palm Beach Pain Management Center, where he was the chief executive officer. Respondent has performed the specific procedures involved in this case at least 500 times and many thousands of epidural injections.

2. Respondent's expert witness was Dr. Brett Schlifka, who is an osteopathic physician licensed in Florida and practicing in Wellington. Dr. Schlifka is certified by the Board of Neurosurgeons of the American College of Osteopathic Surgeons. As a neurosurgeon, Dr. Schlifka performs epidural injections, but never of hypertonic saline, so he was unable to address in any detail the epidural injection of hypertonic saline, nor does he use a catheter in performing epidural steroid injections (ESIs), so he was unable to address in any detail the specifics of the processes of threading a catheter through epidural space and inadvertently into intrathecal space and administering injectates through a catheter. Dr. Schlifka and Respondent are friends and refer patients to each other.

3. Petitioner's expert witness was Dr. Harold Cordner, who is a medical physician licensed in Florida and practicing in Sebastian. Dr. Corner is certified by the American Board of Anesthesiology with an added qualification in Pain Management. For ten years, he has served as a clinical assistant professor at the Florida State University School of Medicine, where he teaches procedures such as those involved in this case--procedures that he himself has performed many times.

4. This case involves procedures performed by Respondent on M.S.'s back on September 28, 2012. From bottom to top, relevant vertebra are sacral 1 (S1), lumbar 5 (L5), L4, L3, L2, and L1. Above the lumbar vertebra are thoracic vertebra, which are not directly pertinent to this case. The spinal cord extends no lower than L1/L2; the tapered end of the spinal cord is known as the conus.

5. Relevant anatomical features in the area of the lumbar vertebrae, from the exterior to the interior, are ligaments, the epidural space, the dura, the subdural space, the arachnoid, the subarachnoid space, and the spinal cord. The subdural space is potential, presumably responding to changes in posture or movement, or even theoretical, because the epidural and subarachnoid spaces may be separated by less than one mm. Cerebral spinal

fluid (CSF) is present in the subarachnoid space, but not the epidural space. The subarachnoid space is also known as the intrathecal space, so an intrathecal injection is an injection into the subarachnoid space. Intrathecal injections may be intentional or inadvertent, although this case does not involve any intentional intrathecal injections.

6. "Bilateral" refers to the left and right sides of the vertebrae on the left and right sides of a patient's body. "Transforaminal" is across the space, within the epidural space, occupied by the foramen, which is a bony structure at each vertebral level through which spinal nerves pass. This case involves epidural injections of various injectates, including steroids--i.e., ESIs--although an ESI routinely includes the epidural injection of contrast and an anaesthetic in addition to a steroid. The ESIs in this case all involve lumbar transforaminal ESIs, so any reference to an "ESI" is to a lumbar transforaminal ESI. The alternative to a transforaminal ESI is an interlaminar ESI, which is an ESI within the space between vertebrae. At the time in question, at least, an interlaminar ESI was a safer procedure than a transforaminal ESI, if, for no other reason, than the proximity of an artery to the nerve passing through a foramen and the possibility of causing an infarction of the spinal cord by an inadvertent injection into the artery.

7. M.S. was a patient of Respondent at the Palm Beach Pain Management Center from 2006 through September 28, 2012. On the latter date, Respondent performed procedures on M.S., immediately after which she has been left paralyzed in her lower extremities and incontinent of bladder and bowel.

8. Born in 1951, M.S. presented to Respondent in 2006 with complaints of low back pain for many years. She had undergone failed back surgeries in 1989, 1993, and 2003. In the course of these surgeries, surgeons had performed spinal fusions of L3/L4 and L4/L5 and implanted hardware at L3/L4. M.S. was five feet, two inches tall and weighed 160 pounds.

9. At the time of M.S.'s initial office visit on February 7, 2006, M.S. described the pain in her low back as ranging from 5 to 10 on a scale of 0-10 and stated that she had not had "injection therapy" recently. Respondent's impressions included lumbar failed back surgery syndrome and lumbar radiculopathy, which is a condition in which a compressed spinal nerve causes pain along the nerve. Respondent recommended a bilateral ESI. Imaging conducted shortly after the initial office visit revealed the above-mentioned hardware, postoperative changes in the disc at L4/L5, a mild disc bulge at L1/L2, a "very minimal" posterior disc bulge at the postoperative site of L3/L4, and a small central protrusion at L2/L3 causing a mild compression along the central aspect of the thecal sac, which is within the subarachnoid space.

10. Besides the initial office visit and some imaging reports from late 2010, the evidentiary record contains Respondent's medical records only from December 2011 through September 28, 2012. In late 2010, imaging disclosed disc degeneration at L1/L2 and L2/L3 with mild thecal sac impingement, the surgical fusion of L3/L4 and L4/L5, and disc desiccation at L5/S1. There was also thickening or clumping of nerve roots through the surgical levels that could be regarded as arachnoiditis, which is inflammation of the arachnoid membrane.

11. However, the evidentiary record contains billing records from late 2006 through September 28, 2012. These records indicate that Respondent performed 21 epidural injection procedures on M.S. from December 6, 2006, through September 28, 2012. The last ten such procedures, from April 19, 2010, were billed as ESIs using Code of Procedural Terminology (CPT) code 64483, although one procedure was billed as CPT code 64473. Respondent also billed ESIs under CPT code 64483 or 62311 on February 6, 2008, May 15, 2009, May 29, 2009, and February 22, 2010. The remaining procedures were billed on December 6, 2006, March 20, 2007, June 13, 2007, November 8, 2007, February 21, 2008, September 5, 2008, January 9, 2009,

and October 30, 2009, under CPT code 62264 as "Racz" procedures, which are described below. Among other things, these records establish that Respondent performed ESIs on M.S. on 90-day intervals from late 2010 until September 28, 2012.

12. Obviously, the billing records also establish that the lumbar region of M.S. was the site of numerous procedures over the six years leading up to September 28, 2012. Although the experts agree that M.S.'s lumbar epidural space was challenging due to myriad deformities following years of disease and multiple surgeries, Respondent had navigated this space over 20 times, so Respondent at least knew that he would encounter, if not where he would encounter, lesions, narrowed openings, and other pathological changes.

13. For many years, Respondent had prescribed Percocet to control pain. The medical records for the nine months preceding the September 28 procedures indicate that Respondent consistently administered drug screens, which appropriately revealed only oxycodone. However, on at least a half dozen office visits during 2012, M.S. admitted that she was not abiding by the Narcotic Treatment Agreement, but, each time, Respondent's notes misstate that she was in compliance, so as to indicate no inquiry into the details of the noncompliance or its significance, if any, and recordkeeping by rote.

14. Respondent likewise displayed inattention to detail as to the informed consents that he obtained from M.S. during this nine month timeframe. Each informed consent contains a handwritten description of the procedure to which M.S. was consenting by signing the form. For each procedure, the procedure is "lumbar transforaminal epidural steroid injections with fluoroscopy and catheter"; the June 25 informed consent rephrases the last four words as "with catheter with fluoroscopy," and the September 28 informed consent adds "left" to the typical description of the procedure. Respondent never obtained M.S.'s informed consent for the injection of hypertonic saline, even though Respondent injected hypertonic saline, with

the amounts shown parenthetically, during the procedures of December 23 (5 cc), June 25 (5 cc), and September 28 (8 cc).

15. For the December 23 procedures, Respondent took 12 minutes from "start" to "end" for the actual procedures and 18 minutes from "in" to "out" of the operating room. Coincidentally, the December 23 procedures' start and end and in and out times are identical to these times for the September 28 procedures. The start to end times of other two procedures were 11 minutes. This brisk pace betrays Respondent's experience as a pain specialist, but belies M.S.'s challenge as a patient.

16. During each set of procedures from December 2011 through September 28, 2012, Respondent injected the same injectates, except for the March 23 procedure that omits hypertonic saline, but at different dosages, which is discussed below. Respondent used a form that allowed him to document his surgical plan by circling levels--L1/L2, L2/L3, L3/L4, and L5/S1--and sides--left, right, and bilateral. For December 2011, Respondent circled nothing; for March and June 2012, Respondent circled levels L3/L4, L4/L5, and L5/S1 and the right side; and for September 28, 2012, Respondent circled the same levels, but the left side.

17. The efficacy of the epidural procedures is revealed in the notes from postsurgical office visits during which M.S. described her pain. On January 2, 2012, M.S. reported that her pain ranged from 6-10 all day and all night, the pain ranged from her back down her legs, everything made her pain worse, and the injections helped, although, after several injections, she reported that she had experienced "floppiness" in one leg--side unspecified. M.S. concluded that the pain relief from the injections made a difference in her life and restored functionality.

18. On January 10, 2012, M.S. returned to Respondent's office complaining of pain ranging from 8-10 without medications and 6-10 with medications. The pain was radiating from her low back down her legs, mostly her right leg. The pain was continuous and "sharp, burning, shooting,

achy, knife-like, stabbing, deep, heavy, and gnawing." On February 7, 2012, M.S. returned to Respondent's office with the same complaints. Interestingly, on March 6, 2012, M.S. returned to Respondent's office describing her pain as improved--5-10 without medications and 3-6 with medications. This time the note specifies that "transforaminal epidurals" gave her the greatest relief. The note for this office visit mentions a treatment plan of another ESI of a steroid and anaesthetic, but does not specify the side.

19. On April 3, 2012, M.S. returned to Respondent's office for her first visit after the March 23 ESI. Again, the pain was worse immediately after the procedure--9-10 without medications and 5-8 with medications, although the note adds, "the transforaminal epidural with catheter has also helped her tremendously." The notes contain no analysis of the worsened pain 11 days after the ESI compared to 17 days before the ESI, but leg floppiness does not recur in this or any subsequent note.

20. On May 5, 2012, M.S. returned to Respondent's office describing her pain as 8-10 without medications and 5-9 with medications. M.S. stated that the medications and "transforaminal epidurals with catheter" were the only treatments that helped with the pain. On May 15, 2012, M.S. returned to Respondent's office describing her pain as 6-10 without medications and 4-6 with medications. On June 22, 2012, M.S. returned to Respondent's office following a trip to North Carolina, where she had been unable to obtain her oxycodone and had been in considerable pain. On the day of the visit, though, M.S. reported her pain to be an 8 without medications and 6 with medications. The treatment plan contained in the note includes a right ESI, which Respondent described to M.S. as the injection of Cortisone and Marcaine or lidocaine with no mention of hypertonic saline.

21. On July 20, 2012, M.S. returned to Respondent's office for her first visit after the June 25 ESI. M.S. described the pain as 8-10 without medications and 5-8 with medications. The recent "right lumbar

transforaminal with catheter [helped] about 50% to 60%." On August 17, 2012, M.S. returned to Respondent's office describing her pain as 7-10 without medications and 1-7 with medications. The note adds, "She states no real change in her status, just looking forward to another injection." The treatment plan was for a left ESI with Cortisone and Marcaine or lidocaine, but, again, with no mention of hypertonic saline.

22. On September 28, 2012, Respondent performed three procedures--first, a caudal lumbar epidurogram with interpretation; second, an ESI; and, third, a distinct procedure involving the injection of hypertonic saline. In all three procedures, Respondent relied on live or real-time fluoroscopy to guide the spinal needle and catheter, which are described below. M.S. was positioned on a table, which, as relevant to these procedures, accommodates the 90-degree rotation of a fluoroscope, which is also called a C-arm due to the ability of the device to project onto a monitor anterior-posterior (AP), lateral, and oblique views of the spine and related structures. The AP view is a head-on (or back-on) view, and the lateral view is a side view at 90 degrees from the AP view. At the direction of Respondent, a technician not only rotated the C-arm, but also captured a still image from the radiographic output, which otherwise ran live or in real time or was switched off entirely when unneeded, to avoid over-exposing the patient to radiation.

23. The caudal lumbar epidurogram is a relatively simple diagnostic procedure. Respondent passed a spinal needle through the sacral hiatus, which is a hole in the bony structure at the base of the spine below S1, and into the caudal epidural space. By lightly pushing the syringe plunger, Respondent employed the loss-of-resistance technique to sense the lack of resistance characteristic of the epidural space; by lightly pulling the syringe plunger, Respondent aspirated the needle and line to rule out the presence of any CSF, which would reveal an intrathecal penetration, or blood, which would reveal a vascular penetration. M.S., who remained conscious during the procedures, also did not indicate any paresthesia, which is numbness or

tingling. Respondent withdrew the hollow core of the spinal needle in preparation for threading the catheter through the now-hollow needle and up through the epidural space. Respondent has maintained five AP views and one lateral view from the fluoroscopic imagery that he conducted on September 28. The lone lateral view, which is of the sacrum, was taken and preserved as part of the epidurogram.

24. During the entirety of the September 28 procedures, including the epidurogram, Respondent injected 6 cc of contrast in the form of Omnipaque 300. As with all injectates, Respondent's records refer only to divided doses, so it is impossible to know how much of any injectate, including the contrast, that he administered at what level. The ESIs in March and June 2012 may have involved fewer levels than the ESIs in December 2011 and September 2012, because the former involved 3 cc each of Omnipaque and the latter involved 5 cc each of Omnipaque.

25. Returning to the epidurogram, as the contrast flowed up the epidural space, the radiography revealed lesions at S1 on the right and L5 on the left. The dispersal pattern of the contrast indicated that the contrast was within the epidural space. Without incident, Respondent completed the epidurogram about two minutes after starting the procedure.

26. For the ESI and hypertonic saline procedures, Respondent passed the catheter up through the epidural space to the level or levels that he was targeting for treatment. At each level, Respondent injected, in order, the above-described contrast, an anaesthetic, a steroid known as Depo Medrol, and hypertonic saline solution. For all four procedures from December 2011 through September 28, 2012, Respondent used Marcaine 0.25% and lidocaine 1%, but his records did not indicate the location at which he administered each anaesthetic. It appears that the anaesthetic used in the greater dose was used in the epidural space, and the other anaesthetic was used elsewhere, likely at the site of the initial injection. If so, for the September 28 procedures, Respondent used 5 cc of lidocaine in the epidural

space--or what he intended to be the epidural space--and 1 cc of Marcaine elsewhere. In March 2012, Respondent used 3 cc of Marcaine and no lidocaine; in December 2011, Respondent used 5 cc of each anaesthetic; and, in June 2012, Respondent used 2 cc of Marcaine and 3 cc of lidocaine.

27. Respondent's use of Depo Medrol was more consistent. He administered 80 mg during the September 28 ESI, but had used 120 mg during each of the three preceding ESIs.

28. The greatest variability occurred with the hypertonic saline, which, as already noted, was omitted from the March 2012 ESI. Respondent administered 8 cc of hypertonic saline during the September 28 procedures and only 5 cc--nearly 40% less--during the December 11 and June 2012 procedures. The record contains no indication of why he failed to inject hypertonic saline during the March 12 procedure, but the sole reference to leg floppiness, as noted above, was after the preceding procedures in December 2011.

29. There is some dispute in this case as to what may be injected as part of an ESI. Obviously, the ESI contemplates the injection of a steroid, as well as contrast and an anaesthetic, which support the injection of the steroid by heightening the safety of the ESI and the comfort of the patient during the ESI. Also, these injectates are amenable to grouping because this record does not suggest that an inadvertent intrathecal injection of these injectates, even at the doses intended for the epidural space, affects patient safety nearly as much as an inadvertent intrathecal injection of hypertonic saline. An intrathecal injection of a very high dose of anaesthetic could proceed up the spinal canal and cause respiratory and cardiovascular collapse, but the record does not indicate that such dangers exist for the dosages involved in the September 28 procedures. For the same reason, an ESI may include an injection of normal saline, which is harmless in the subarachnoid space.

30. The epidural injection of hypertonic saline is the distinguishing feature of a Racz procedure, which also involves an epidural injection.

Named after its physician-developer, Gabor Racz, the Racz procedure is intended to break up, or lyse, epidural lesions or adhesions that may be the source of part or all of a patient's pain when a nerve is trapped by an adhesion. In the Racz procedure, a physician injects hypertonic saline near the lesion. The salinity of hypertonic saline solution is ten times greater than the salinity of ambient conditions in the body, so the hypertonic saline solution, by osmosis, causes the body to compensate for the sudden appearance of hypersaline conditions by delivering fluid that expands the space and may thus lyse any nearby adhesions. Although the catheter is typically not stiff enough to break up lesions mechanically, such mechanical lysis may also occur incidentally while performing a Racz procedure.

31. Other distinguishing features of an ESI and Racz procedure involve the sources of pain and the term of pain relief. The lysis of an adhesion permanently eliminates one potential source of pain--a nerve trapped by an adhesion. An ESI reduces inflammation wherever it may be present, so it treats a wider range of conditions, but offers only temporary relief. The pain relief from the steroid may extend weeks or months. The pain relief from the anesthetics--one hour for lidocaine and four hours for Marcaine--is not intended to persist past the intra-operative and recovery stages of the procedures.

32. There may also be a locational difference between the ESI and Racz procedures. As noted above, in the ESI, the catheter traverses the foramen within the epidural space, and, in the Racz procedure, the catheter is threaded to lesions anywhere within the epidural space. Dr. Cordner opined that Respondent failed to perform an ESI due to the lack of proximity of the injection sites to the various foramina. Labels notwithstanding, the procedures performed by Respondent on September 28 substantially conformed to an ESI and, because an ESI does not include the epidural injection of hypertonic saline, a Racz procedure.

33. Determining that Respondent performed two distinct procedures in addition to the epidurogram does not answer several relevant questions. First, which injectate, once introduced into the subarachnoid space, injured M.S.? If introduced to the subarachnoid space, the hypertonic saline is a known cause of the paralysis and incontinence that M.S. suffered, such as myopathic injury resulting in paralysis. Because safe practices, as described by Dr. Cordner below, include the provisional injections of contrast and anaesthetic to confirm that a catheter tip is safely in the epidural space, the only other injectate that might injure the patient is the steroid, but, again, the record is silent on the consequence of the introduction of the Depo Medrol, at the dosages used by Respondent, into the subarachnoid space.

34. Second, when did Respondent decide to inject the hypertonic saline? The record provides no basis to answer this question. As noted above, Respondent did not administer hypertonic saline in the March 2012 procedure, but administered hypertonic saline in the December 2011 and June 2012 procedures, as well as the September 28 procedure, in which he increased the dose by 60%. For none of the three procedures in which Respondent injected hypertonic saline did his treatment plans or informed consents mention hypertonic saline. Respondent may have decided, prior to the day of surgery, to use hypertonic saline and merely failed to document this decision in advance, or he may have decided, during surgery, to use hypertonic saline and documented the use of hypertonic saline as noted above.

35. Third, why did Respondent inject hypertonic saline and why did he administer the dosages that he used? The record provides no basis to answer these questions, although, as noted above, the omission of hypertonic saline from the March 2012 procedure corresponds to leg floppiness after the December 2011 procedure and the increased dose of hypertonic saline in the September 28 procedures corresponds to a lower dose of the Depo Medrol. The medical records indicate that M.S. believed that the ESIs relieved her

pain, but she could not have had a preference about hypertonic saline because she evidently never knew that Respondent was using this injectate. On the other hand, M.S.'s rating of her pain after the March 2012 procedure, without hypertonic saline, was not much different from her rating of her pain after the December 2011 and June 2012 procedures. The likely inference is, if Respondent's use of hypertonic saline were not arbitrary or capricious, he injected hypertonic saline, at least when M.S. had not mentioned leg floppiness after the last injection of hypertonic saline, because he believed it worked and used considerably more of it on September 28 because he believed that more would work better.

36. Returning to the remaining September 28 procedures, Respondent injected the four injectates described above on M.S.'s left side at three levels: S1/L5, L4/L5, and L3/L4. At each level, Respondent waited three or four seconds after injecting the contrast, while he watched the radiographic output, before injecting the anaesthetic, after which he waited 30 to 40 seconds to allow the anaesthetic to numb the area. Then, Respondent injected the steroid, waited five seconds, and lastly he injected the hypertonic saline. Assisted directly by the epidurogram, Respondent properly located the catheter tip in the epidural space at S1/L5. The evidence is mixed as to the location of the catheter tip at L4/L5, but the catheter tip was in the subarachnoid space at L3/L4.

37. As Dr. Cordner testified, an inadvertent penetration of the subarachnoid space by a catheter tip is not evidence of negligence; the negligence arises in what a physician does or fails to do after such an intrathecal penetration. Here, the reasons why Respondent failed to realize that the catheter tip was in the subarachnoid space at L3/L4 relate to the reasonable precautions that Respondent failed to take--and thus establish Respondent's negligence. Respondent failed to realize that the catheter tip had entered the subarachnoid space at L3/L4 because, after injecting the contrast, he misread the AP real time view from the fluoroscope that showed

a dispersal pattern suggesting that the contrast was not within the epidural space; because, after injecting the contrast, he did not direct the technician to obtain a lateral real time view, which would have provided another dimension, so as to confirm that the contrast was not in the epidural space; because he did not perform the loss-of-reduction technique, which would have confirmed that the catheter tip was not in the epidural space; because he did not aspirate the catheter and line, which would have revealed CSF; and because, after injecting the anaesthetic, he did not wait at least 15 minutes to rule out a gross motor block of the lower extremities, which would have indicated that the catheter tip was in the subarachnoid space.

38. Unreasonably unaware that the catheter tip was in the subarachnoid space, Respondent injected the steroid and hypertonic saline, withdrew the catheter, and completed the ESI and Racz procedures within ten minutes from the end of the epidurogram procedure and turned over responsibility for M.S. to Respondent's nurse.

39. One minute after the completion of the procedure, at 9:38 a.m., M.S. complained of pain in her hips and legs, and Respondent administered 60 mg of Toradol. Ten minutes later, M.S. stated that both of her legs were numb, although by 10:15 a.m. she was moving both legs. By 11:30 a.m., she could move both legs, but had no feeling from the top of her thighs down. By 1:00 p.m., M.S. reported feeling to her mid-calf, but, three hours later, she could not move her legs. Although Respondent justifiably had not been concerned about transient numbness, the deterioration in the ability to move the legs concerned him, and Respondent insisted that M.S. be admitted to a nearby hospital. Respondent thus discharged M.S. at 5:25 p.m. for transfer by ambulance to Bethesda Memorial Hospital (Bethesda), where other physicians assumed responsibility for her care.

40. Imaging conducted at Bethesda upon the admission of M.S. revealed no epidural hematomas, but evidence of arachnoiditis, which is inflammation of the arachnoid membrane. Most significantly, a lumbar CT

scan revealed a small amount of air in the subarachnoid space, which was consistent with Respondent's recent intrathecal injections. Also, M.S.'s thecal sac displayed enhancement of disc disease at S1 through L4 suggestive of a recent subarachnoid injury.

41. About six weeks after the procedures, an MRI at the JFK Medical Center (JFK) revealed conus medullaris syndrome posteriorly within the thecal sac at L1/L2 through L3/L4. This syndrome results from injury to the conus, such as from trauma, and is consistent with Respondent's intrathecal injection of hypertonic saline. This hospitalization followed a finding from an outpatient MRI of a large hematoma in the lumbar spine. Respondent and Dr. Schlifka contend that the Bethesda physicians missed the hematoma, but it is as likely that the hematoma formed after M.S.'s discharge from Bethesda. M.S. underwent a resection of a mass, which was found to be an arachnoid cyst. Post-operatively, M.S. still was unable to move her lower extremities, but started to regain sensation in her great toes.

42. Respondent relies on a succinct affidavit from Dr. Racz himself, which, as noted in the Conclusions of Law, is available only to impeach Dr. Cordner's testimony. Dr. Racz's affidavit states that he has examined Respondent's medical records, including the six fluoroscopic images retained by Respondent; all of the images available in connection with the Bethesda and JFK hospitalizations; and some earlier images. From these materials, without more, Dr. Racz's affidavit concludes that Respondent's care was "appropriate and that he met or exceeded the standard of care throughout the lumbar transforaminal epidural steroid injection with catheter and fluoroscopy on September 28, 2012. Further, the complications suffered by [M.S.] are known risks and complications of the procedure that are not indicative of negligence."

43. The most obvious difference between the opinions of Dr. Cordner and Dr. Racz is not the amount of work; each physician has examined all of the available medical records. But Dr. Cordner has painstakingly analyzed the

September 28 procedures and Respondent's negligent actions and omissions, and Dr. Racz has declared by fiat that Respondent was not negligent.

44. Undoubtedly, Dr. Racz learned from his examination of the medical records that Respondent injected hypertonic saline on September 28, yet Dr. Racz describes the procedure as an ESI and makes no mention of hypertonic saline. Perhaps Dr. Racz is sensitive to the greater potential for injury introduced by hypertonic saline, which is the prominent injectate of his procedure. Perhaps, the procedure followed by Respondent on September 28 failed to follow strictly the requirements of the Racz procedure. Dr. Cordner, who co-teaches the Racz procedure with Dr. Racz, testified that the procedure requires a physician to wait 15 to 30 minutes after injecting anaesthetic to confirm the injection is in the epidural space. Regardless, an informed opinion as to Respondent's negligence must take into account the injectate that, on this record, bears the clear potential for patient injury, and Dr. Racz's opinion fails to do so.

45. Perhaps, Dr. Racz's affidavit is an expression of agreement with Dr. Cordner's concession that, in itself, an inadvertent intrathecal penetration is not evidence of negligence. But Dr. Racz's affidavit needs to account for the acts and omissions, set forth above, that simultaneously explain why Respondent failed to realize that the catheter tip was in the subarachnoid space at L3/L4 and constitute his failure to take these simple precautions against patient injury.

46. The last sentence of Dr. Racz's affidavit dismisses M.S.'s "complications"--a veiled reference verging on a euphemism when describing permanent paralysis and incontinence--as known risks of the ESI and not indicative of negligence. Obviously, a bad result does not prove medical malpractice, although, as explained in the Conclusions of Law, the risk of a bad result and the impact on a patient of a bad result drive the precautions that a physician must take to avoid a finding of medical malpractice. On the other hand, the known risk of permanent paralysis and incontinence from a

Racz procedure or an ESI with the injection of hypertonic saline does not obviate the necessity of analysis of the adequacy of the precautions taken by Respondent to avoid such a result; to the contrary, these grave consequences underscore the importance of such analysis.

47. Notwithstanding Dr. Racz's status in the field of pain management, his affidavit is entitled to no weight whatsoever and fails to impeach the testimony of Dr. Cordner.

48. Dr. Schlifka's testimony is better than Dr. Racz's affidavit in one respect: he clearly acknowledged that injectate had entered the subarachnoid space. It is impossible to dispute this fact based on M.S.'s dramatic response, the dispersal pattern of contrast depicted in one saved AP view, air found in the subarachnoid space shortly after the September 28 procedures, the injury to the thecal sac, and the conus injury.

49. On the other hand, Dr. Schlifka's testimony shared the failure of Dr. Racz's affidavit in addressing the particulars of the September 28 procedures performed by Respondent. As Dr. Racz failed to focus on anything but a theoretical ESI, Dr. Schlifka failed to focus on anything but the fragile anatomy of the dura--never addressing, for instance, the likelihood that a catheter during an ESI could tear the dura--something that the experienced Dr. Cordner has never encountered; whether a tear would introduce air into the subarachnoid space; or whether the injectate entering through a tear could possibly injure the thecal sac and conus. Obviously, Dr. Schlifka lacks the experience to opine as to whether a catheter may tear the dura and, if so, the probability of this complication. On the other hand, Dr. Schlifka failed to explain why a dural tear would admit injectates into the subarachnoid space, but not allow injectates and CSF to escape from the subarachnoid space into the epidural space. Nor did he address the behavior of injectates--the most important one of which he has never worked with--if injected through the dura and into the subarachnoid space or if entering the subarachnoid space through a tear in the dura. Although qualified to advise

that the dura may tear, and, as he testified, the dura may be more prone to tearing after numerous surgeries and procedures in the affected area, Dr. Schlifka clearly lacked the means to address, on these facts, the probability that M. S.'s injuries were caused by a dural tear or an intrathecal injection.

50. Compared to Dr. Cordner's detailed analysis and superior relevant experience, Dr. Schlifka's opinions are speculative and perhaps reflective of an understandable desire to help a beleaguered friend. However, Dr. Schlifka's explanation for the intrathecal penetration of the injectate by a dural tear is rejected as unsupported by the evidence.

51. For Count I, Petitioner proved that, based on the standard of care in effect in 2012, Respondent committed medical malpractice by failing to recognize that he was performing intrathecal injections of steroid and hypertonic saline at L3/L4. Petitioner failed to prove that any injections at L4/L5 and L5/S1 were intrathecal. The evidence of intrathecal injections at L3/L4 is set forth in paragraph 48, and Respondent's negligent acts and omissions are set forth in paragraph 37.

52. The intrathecal injections of the contrast and anaesthetic at L3/L4 were wrongful solely because Respondent failed to use the information obtainable from these injections to discover that the catheter tip was in the subarachnoid space. In other words, Respondent would not have committed medical malpractice (or a wrong-site procedure or wrong procedure) if he had injected intrathecally contrast and an anaesthetic as part of what is intended to be epidural injections, as long as he learned from these injections that the catheter tip was in the subarachnoid space and moved the tip into the epidural space or terminated the procedure: the epidural injection of these injectates performs both a therapeutic and diagnostic function.

53. For Count II, Petitioner failed to prove that, in 2012, Respondent was required to obtain and retain a permanent image of any lateral view of

L3/L4 or any other location as part of the procedures after the epidurogram or that Respondent's failure to realize that the catheter tip was in the subarachnoid space violated his recordkeeping obligation. The latter point finds no support in the record. As for the images, Dr. Cordner's testimony on this "requirement" of medical recordkeeping was vague, conditional, and never tethered to the requirements in effect in 2012. Although his practice is different, Dr. Schlifka does not keep permanent views from his epidural steroid injections by needles. Petitioner itself seems to have missed the point that a permanent image of an AP view helped prove that the catheter tip was in the subarachnoid space at L3/L4.

54. It is one thing to hold Respondent responsible for failing to interpret a real time AP view of L3/L4 and failing to obtain a real time lateral view of L3/L4, as discussed in connection with Count I, but it is another thing to hold Respondent responsible for failing to maintain permanent images of any views for the procedures following the epidurogram. Among myriad shortcomings in Petitioner's case for Count II is the failure to address whether, for reasons of cost or radiation exposure, a physician in 2012 could still perform a blind ESI and, if so, the ramifications of more elaborate and expensive recordkeeping requirements imposed on the physician who performed image-guided ESIs--or otherwise would do so, but for this expensive recordkeeping requirement.

55. For Count III, Petitioner proved that Respondent performed a wrong procedure or a wrong-site procedure by injecting "injectate," but not contrast, into the intrathecal space when he intended to inject injectates into the epidural space. As noted above, an inadvertent intrathecal administration is not evidence of carelessness, and the timely detection of such a mishap--before the intrathecal injections of a steroid or hypertonic saline--may involve interpreting the dispersal of contrast or the effect of the anaesthetic and determining that either or both injectates have been accidentally injected into the subarachnoid space. For this reason, the

inadvertent intrathecal injections of contrast or anaesthetic into the subarachnoid space is not a wrong procedure or wrong-site procedure because of the secondary diagnostic value of this otherwise-therapeutic procedure. The wrong procedure or wrong-site procedure occurred when Respondent then injected the steroid and hypertonic saline into the subarachnoid space at L3/L4; the intrathecal injections of these injectates lacked any diagnostic purpose and were thus wrong procedures or wrong-site procedures.

56. In its proposed recommended order, Petitioner has proposed a reprimand, probation for two years, and a $30,000 fine. Despite the passage of seven years from the September 28 procedures and the transmittal of the file to DOAH, Petitioner failed to identify important features of this complicated case. Although not charged with these matters, Respondent was guilty of serious failures to obtain informed consent for the use of injectate that caused M.S.'s catastrophic injuries--hypertonic saline--and to keep medical records documenting his plans for an ESI or an ESI with hypertonic saline and the locations and dosages of each injectate during the procedures, as well as analysis of the efficacy of each set of procedures. These aggravating factors necessitate the imposition of a suspension.

57. On the other hand, past discipline is not an aggravating factor. By final order entered April 20, 2006, the Board of Medicine fined Respondent for a failure to keep adequate medical records 20 years ago, but the failure was in performing adequate physical examinations, which is not an issue here. Given the age and nature of the offense, past discipline is irrelevant in this case.

CONCLUSIONS OF LAW

58. DOAH has jurisdiction. §§ 120.569, 120.57(1), and 456.073(5), Fla. Stats.

59. Petitioner must prove the material allegations by clear and convincing evidence. § 120.57(1)(j); *Dep't of Banking & Fin. v. Osborne Stern & Co.*, 670 So. 2d 932 (Fla. 1996). Clear and convincing evidence is evidence that is "'precise, explicit, lacking in confusion, and of such weight that it produces a firm belief or conviction, without hesitation, about the matter in issue.'" *Robles-Martinez v. Diaz, Reus & Targ, LLP*, 88 So. 3d 177, 179 n.3 (Fla. 3d DCA 2011) (citing Fla. Std. Jury Instr. (Civ) 405.4).

60. A charging document must allege facts that support an alleged violation of law, because disciplinary action against a licensee based on unalleged facts would violate the licensee's right to a hearing under chapter 120. *Cottrill v. Dep't of Ins.*, 685 So. 2d 1371, 1372 (Fla. 1st DCA 1996). *See also Trevisani v. Dep't of Health*, 908 So. 2d 1108 (Fla. 1st DCA 2005).

61. The affidavit of Dr. Racz was available for use in the cross-examination of Dr. Cordner, so as to impeach his testimony, but not to establish the truth of the contents of the affidavit. *Cf. Kirkpatrick v. Wolford*, 704 So. 2d 708 (Fla. 5th DCA 1998) (use of medical treatise).

62. Pursuant to sections 456.072(2) and 458.331(1), the Board of Medicine is authorized to discipline Respondent's license for the following:

> (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. [Count I]

* * *

> (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. [Count II]
>
> * * *
>
> (bb) Performing or attempting to perform health care services on the wrong patient, a wrong-site procedure, a wrong procedure, or an unauthorized procedure or a procedure that is medically unnecessary or otherwise unrelated to the patient's diagnosis or medical condition. For the purposes of this paragraph, performing or attempting to perform health care services includes the preparation of the patient. [Count III]

63. Petitioner failed to prove the material allegations of Count II. The Findings of Fact adequately address the alleged failure to keep images of fluoroscopic views after the epidurogram was completed. The cryptic allegation in Count II based on Respondent's failure to recognize that the catheter tip was in the subarachnoid space fails to meet the due process standards recognized in *Trevisani*. Ultimately unable to understand this allegation as a recordkeeping issue, the administrative law judge doubts that Respondent understood it any better.

64. Petitioner proved the material allegations of Count III. This is a straightforward case of a wrong-site procedure or wrong procedure with the intrathecal injection of the steroid and hypertonic saline, regardless of whether Respondent did so negligently or completely innocently. Perhaps

wisely, Petitioner did not allege merely that the intrathecal penetration of the catheter tip constituted the wrong-site procedure or wrong procedure, although, under the terms of the statute, it does.

65. Petitioner proved the material allegations of Count I. Two statutes apply to this count. First, section 458.331(1)(t) requires the administrative law judge, as well as the Board of Medicine, to specify whether the licensee has committed "medical malpractice," "gross medical malpractice," or "repeated medical malpractice": the administrative law judge specifies "medical malpractice."

66. Second, section 456.073(5) provides that "a determination of the reasonable standard of care … is a conclusion of law to be determined by the board … and is not a finding of fact to be determined by an administrative law judge." Conclusions of law retain a precatory quality in any recommended order, but especially so here. In any event, section 456.50(1)(g) provides: "'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." Section 766.102(1) adds:

> the claimant shall have the burden of proving … that the alleged actions of the health care provider represented a breach of the prevailing professional standard of care for that health care provider. The prevailing professional standard of care for a given health care provider shall be that level of care, skill, and treatment which, in light of all relevant surrounding circumstances, is recognized as acceptable and appropriate by reasonably prudent similar health care providers.

Section 766.103(3)(b) cautions: "The existence of a medical injury does not create any inference or presumption of negligence against a health care provider, and the claimant must maintain the burden of proving that an injury was proximately caused by a breach of the prevailing professional standard of care by the health care provider."

67. Petitioner contends that Dr. Schlifka fails to meet the requirements of section 766.102(5)(a)1. for failing to specialize in the same specialty as Respondent. However, section 766.102(14) authorizes the trial court to qualify an expert on grounds other than those stated in section 766.102, and, in the end, Dr. Schlifka's testimony was discredited on its merits so as to moot this issue.

68. An informed formulation of a standard of care or identification of the acts or omissions that constitute medical malpractice, as defined above, must balance the risk of an adverse outcome and the gravity of an adverse outcome against the burden of the precautions to avoid an adverse outcome. *U. S. v. Carroll Towing Co.*, 159 F.2d 169, 173 (2d Cir.1947). *See also Restatement (Third) of Torts: General Principles,* § 4 "Negligent" (Oct. 2020 update).

69. Even assuming that the risk of an inadvertent intrathecal injection was low, the gravity of an intrathecal injection of hypertonic saline was very high, so as to require Respondent to undertake more extensive precautions while performing the ESI and Racz procedures and, certainly, perform the unburdensome tasks set forth in paragraph 37. On these facts, Respondent's failure to perform these tasks and ensuing failure to recognize that the catheter tip was in the subarachnoid space prior to injecting the steroid and hypertonic saline at L3/L4 constituted medical malpractice.

70. As effective May 28, 2012, rule 64B8-8.001(2)(t) provides a penalty range of one year's probation to revocation and a fine of $1000 to $10,000 for a first violation of section 458.331(1)(t). Rule 64B8-8.001(2)(ss) provides a $1000 fine, letter of concern, and education to a $10,000 fine, suspension followed by probation, and education for a first violation of section 456.072(1)(bb). Rule 64B8-8.001(3) identifies as aggravating or mitigating factors the severity of injury to the patient and the licensee's disciplinary history and length of practice.

RECOMMENDATION

It is

RECOMMENDED that the Board of Medicine enter a final order finding Respondent not guilty of the alleged violation of section 458.331(1)(n) in Count II, but guilty of the alleged violations of sections 458.331(1)(t)1. and 456.072(1)(bb) in Counts I and III, respectively, and imposing a reprimand, six months' suspension, two years' probation following the end of the suspension, and a fine of $20,000.

DONE AND ENTERED this 18th day of November, 2020, in Tallahassee, Leon County, Florida.

ROBERT E. MEALE
Administrative Law Judge
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Filed with the Clerk of the
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this 18th day of November, 2020.

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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.