

**STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS**

DEPARTMENT OF HEALTH, BOARD OF
MEDICINE,

Petitioner,

vs.

Case No. 20-5447PL

STEPHANIE STOVER, M.D.,

Respondent.

RECOMMENDED ORDER

On January 28, 2021, Robert E. Meale, Administrative Law Judge (“ALJ”) of the Division of Administrative Hearings (“DOAH”), conducted the final hearing by Zoom teleconference. Due to Judge Meale’s unexpected (at the time of hearing) retirement, the undersigned ALJ was assigned to review the record and issue this Recommended Order.

APPEARANCES

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STATEMENT OF THE ISSUES

The issues are whether Respondent injected fat into or below G.R.'s gluteal muscles in violation of section 458.331(1)(t) and/or 458.331(1)(nn), Florida Statutes (2020); and, if so, what penalty should be imposed.

PRELIMINARY STATEMENT

Petitioner, Department of Health, Board of Medicine ("Department" or "Petitioner"), filed a two-count Administrative Complaint ("AC") against Respondent, Stephanie Stover, M.D. ("Dr. Stover" or "Respondent"), charging her with violating Florida Administrative Code Rule 64B8-9.009(2)(f) "in one or more of the following ways": (1) "By inserting fat into Patient G.R.'s gluteal muscles during her gluteal fat grafting procedure"; (2) "By inserting fat under Patient G.R.'s gluteal muscles during her gluteal fat grafting procedure"; and/or (3) "By crossing the gluteal fascia to inject fat during Patient G.R.'s gluteal fat grafting procedure." The Department asserts that precisely the same conduct and alleged violation of rule 64B8-9.009(2)(f) constitutes a violation both section 458.331(1)(t) (Count One) and section 458.331(1)(nn) (Count Two).

Dr. Stover responded and requested a disputed-fact hearing. The matter was referred to DOAH on December 18, 2020. The disputed-fact hearing was held on January 28, 2021, via Zoom teleconference.

Prior to hearing, Dr. Stover filed a Motion to Dismiss Count I or Count II of the Administrative Complaint as Multiplicitous, a Violation of the Prohibition against Double Jeopardy and Dr. Stover's Right to Due Process, arguing that one of the counts must be dismissed because the two were based on precisely the same conduct, and precisely the same alleged rule violation. The Department filed a response to Dr. Stover's motion to dismiss, and

conceded the Department “charged Respondent with two statutory violation[s] that arose from the same conduct.” To the extent necessary in writing this Recommended Order, the undersigned will address the arguments made in this regard.

At the hearing, Petitioner called Onelio Garcia, M.D., an expert in gluteal fat transfers, and Amelia Nakanishi, M.D., a pathologist, and offered into evidence Petitioner’s Exhibits 1 through 11, without objection. Respondent testified on her own behalf. Respondent’s Exhibit 1 was admitted into evidence without objection, and Respondent’s Exhibits 2 and 3 were admitted over objection.

A Transcript of the final hearing was filed on February 8, 2021, and the parties each filed a Proposed Recommended Order (“PRO”). The timely PROs filed by the parties have been considered in the preparation of this Recommended Order. Citations to the Florida Statutes or Florida Administrative Code refer to the versions in effect during the time that the violation was allegedly committed.

FINDINGS OF FACT

1. The Department is the state agency charged with regulating the practice of medicine in the state of Florida, pursuant to section 20.43 and chapters 456 and 458, Florida Statutes.

2. Dr. Stover is a licensed physician in the state of Florida, having been issued license number ME82217. Dr. Stover has been licensed to practice in the state of Florida since April 2001 and has never been disciplined in Florida or elsewhere. She has an impressive academic record. After earning her doctor of medicine degree from the University of Florida College of Medicine in 1996, where she was on the President’s List (GPA greater than 3.9), Dr. Stover completed her residency in general surgery at the Mount Sinai

Medical Center of Greater Miami, during which she served as Administrative Chief Resident of Trauma and Vascular Surgery and as Administrative Chief Resident of General Surgery.

3. After graduating from medical school and completing her five-year general surgery residency, Dr. Stover spent five years completing additional fellowships and residencies in plastic and reconstructive surgery. Dr. Stover completed a one-year Reconstructive Craniofacial and Aesthetic Fellowship at the University of Mississippi Medical Center, a two-year Plastic and Reconstructive Surgery Residency at the University of Mississippi Medical Center, a one-year Breast Reconstruction and Microsurgery Fellowship at the Memorial Sloan-Kettering Cancer Center in New York City, and a one-year Breast and Aesthetic Surgery Fellowship with G. Patrick Maxwell, M.D., at the Baptist Hospital in Nashville, Tennessee.

4. Over her career, Dr. Stover has regularly served as a speaker, panel member, and teacher, sharing her knowledge, insights, and experience with other physicians, medical students, residents in surgical rotations, and the community. Dr. Stover regularly engages in continuing medical education and attends professional courses and meetings. She is a member of the International Society of Aesthetic Plastic Surgery, the American Society of Plastic Surgeons, and the American College of Surgeons, among other professional organizations and societies.

5. Respondent is certified by the American Board of Plastic and Reconstructive Surgery, and has previously been certified by the American Board of General Surgery.

6. During the course of her professional practice, Dr. Stover has successfully completed thousands of plastic and reconstructive surgeries, including between 800 and 1,000 gluteal fat transfer procedures, also known as a “Brazilian Butt Lift” (“BBL”).

7. Prior to this occasion, Dr. Stover never experienced anything other than minor complications in the 800 to 1,000 successful BBL procedures she performed.

8. Of the 800 to 1,000 successful BBL procedures Dr. Stover has performed in her career, between 100 and several hundred were performed on genetic males, either males or transgender females.

9. While performing BBLs, Dr. Stover always follows a “subcutaneous only” approach, and employs all current recommendations and best practices to avoid injecting into the muscle or below the fascia.

10. Based upon her testimony at hearing, Dr. Stover has had a distinguished career as an effective and caring practitioner, with vast experience in plastic and reconstructive surgery, in general, tremendous experience in performing BBLs, in particular, and something of a specialty in performing BBLs on genetic males. As noted, throughout her more than 20 years as a physician she has an unblemished record.

The Department’s Expert, Onelio Garcia, Jr., M.D.

11. The Department presented the testimony of Onelio Garcia, Jr., M.D. Dr. Garcia is a plastic surgeon in private practice in Miami-Dade County. Dr. Garcia earned his medical degree at the Autonomous University of Guadalajara, Mexico. Like Dr. Stover, Dr. Garcia is board certified in plastic surgery. Unlike Dr. Stover, Dr. Garcia has never been board certified in general surgery.

12. The BBL is among the procedures Dr. Garcia performs in Miami-Dade County. It is found that Dr. Garcia is in economic competition with Dr. Stover as a plastic surgeon performing the same types of procedures as she in close geographic proximity.

13. Dr. Garcia has performed far fewer BBL procedures than Dr. Stover. Dr. Garcia testified that he has performed “an average of 60 [BBLs] a year”

for the past “several years.” He testified he has performed fewer than 500 BBLs over his career and “maybe” fewer than 400.

14. Dr. Garcia has “never” performed a BBL on a transgender individual, and testified that he has performed “very few” BBLs on anatomical males.

15. A dispute arose at hearing regarding the mortality rate for individuals undergoing a BBL. First, a statistic suggesting that one out of 3,000 BBL procedures result in death came from testimony at a public hearing given by Respondent in 2019 at which she said that number of deaths referred to those occurring over all BBLs, not just subcutaneous procedures. She was in favor at that time of recommending a ban on non-subcutaneous or intramuscular procedures. However, one year later, in 2020, research data showed the mortality rate to be only one in 18,000 for those undergoing subcutaneous BBL procedures, a far more acceptable mortality rate for a plastic surgery procedure. These data were from the Aesthetic Surgery Education and Research Foundation’s (“ASERF”) Task Force to study the mortality rate associated with BBLs. The undersigned finds that, based upon the entirety of the testimony, the lower mortality rate of one in 18,000 is credited for those receiving subcutaneous-only BBLs.

16. In June 2019, in light of the findings from the studies, the Board of Medicine enacted Emergency Florida Administrative Code Rule 64B8-ER19-1 (“Emergency Rule”), which states:

Standard of Care for Gluteal Fat Grafting. When performing gluteal fat grafting procedures, fat may only be injected into the subcutaneous space and must never cross the gluteal fascia. Intramuscular or submuscular fat injections are prohibited.

17. The Emergency Rule was codified in rule 64B8-9.009(2)(f). This rule defined the standard of care in Florida relating to gluteal fat grafting and explicitly prohibited intramuscular and submuscular fat injections. The Emergency Rule was superseded by rule 64B8-9.009(2)(f), effective March 2, 2020, which adopted the same standard of care.

The Procedure Generally

18. The “BBL” involves harvesting fat from the patient, i.e., “remov[ing] fat from the different parts of the body, typically around the trunk.” “The fat is processed in a sterile container and it is injected into the soft tissues of the buttock area in order to enlarge it.”

19. In “the most common method” of the procedure, the processed fat is injected by hand from a syringe attached to a cannula, described as “a long metal rod” with a blunt tip and a small hole near the tip. “[I]t is a blind procedure,” in that the injecting surgeon is unable to see the location of the tip of the cannula.

20. The “pertinent layers” of the gluteal area, proceeding from the outermost in, are: the skin, the outermost layer; “[t]hen the subcutaneous layer, which is the fatty layer”; then “the fascia which is covering the muscle”; then “the gluteal musculature.” “[T]here is no anterior fascia,” meaning that the gluteus muscle has no fascia underneath the muscle; “the muscle layer only has one covering on the outside.” If fat gets below the fascia, which “is relatively thin,” “[i]t has nowhere to go but down.”

21. This is a serious problem because BBLs have been associated with serious risk of pulmonary embolisms, often fatal, when injected fat enters the bloodstream through the large blood vessels under the gluteal muscle and ultimately impede blood flow to the lungs. The largest blood vessels, including the gluteal veins are beneath the gluteal muscle, and the vessels get smaller and smaller as they progress toward, and penetrate the fascia.

22. The evidence presented at hearing establishes that BBLs have become significantly more popular in the United States over the past five to ten years. “Gluteal fat grafting has historically been a relatively unpopular procedure in the United States, with little awareness of serious side effects until 2015” is a statement from one of Dr. Stover’s exhibits.

23. Further, as both Dr. Stover and Dr. Garcia testified, the medical community, in general, and the plastic surgery community, in particular, are

aware of the dangers associated with BBLs and have made progress identifying ameliorative techniques and instrumentation. Despite this, research is still developing as to the precise mechanisms and causes of pulmonary fat embolisms associated with BBLs.

24. In 2017, the ASERF Task Force published a study indicating that gluteal fat grafting carries a mortality risk of one out of 2,351 to one out of 4,000, “possibly 10-20 times greater than the average mortality rate for aesthetic surgery procedures in AAAASF facilities ... and it [the mortality risk from BBLs] is possibly three to five times higher than the risk from abdominoplasty, which until this paper [in 2016-17] was thought to have the highest risk of any aesthetic procedure.”

25. The ASERF Task Force indicated that the risks associated with BBLs may be unavoidable even using the proper instruments, “constant vigilance,” and the best practices and procedures, stating:

It is not known whether with proper positioning and constant vigilance a specific plane can be reliably maintained or whether there will inevitably be a rate of unintended deeper passes of the cannula into the deep muscle. It is also not understood whether superficial injection might possibly cause distraction injuries to the larger and deeper veins or whether superficially injected fat can travel along a tissue plane towards that disrupted vessel. There are many hundreds or even thousands of cannula passes during a typical case, so even the very slightest rate of accidental deeper passes could present a significant risk. It is impossible to ascertain whether with ideal instrumentation, positioning, and constant vigilance unintended deeper injections can be eliminated or whether they will always occur with some finite frequency.

26. In May 2019, leading BBL surgeons published a study attempting to explore “the potential for fat placed in the subcutaneous space,” i.e., the fatty tissue under the skin and above the fascia and muscle, to migrate into the

deep submuscular space,” and whether “fat could potentially enter and migrate into the deep submuscular space” through “perforations in the fascia” caused by “occasional unintended passes into the muscle.” The study attempted to shed light on “whether fat placed in the subcutaneous space under a variety of pressures and fascial integrity scenarios can indeed migrate into the deep submuscular space.”

27. Dr. Garcia and Dr. Stover both testified that studies are continuing to investigate the causes of complications and adverse outcomes associated with BBLs and to provide guidance and recommendations for practitioners.

28. Despite all the uncertainties regarding BBL complications, and the “blind” nature of the procedure, the plastic surgery community has coalesced around a set of recommendations and best practices to perform BBLs safely and avoid serious complications. These include: (1) to “use a stiff cannula, at least four millimeters”; (2) with only a single hole; (3) to “create angles” for inserting the cannula; (4) to angle the tip of the cannula up while injecting; (5) to palpate with the non-injecting hand to create three-dimensional awareness of where the tip of the cannula is at all times; (6) to keep the cannula moving continuously; (7) to inject only in retrograde, that is, while withdrawing or moving the cannula away from the deeper tissue; and (8) to “stay in the subcutaneous plane” with the cannula during injections.

29. The rule discussed above establishing the standard of care for gluteal fat grafting, 64B8-9.009(2)(f), was based upon concern from the plastic surgery community, the Board of Medicine, and the public, that the recent popularity of BBLs brings with it the recognition of serious side effects, chief among them the potential for pulmonary fat embolism.

30. The pulmonary fat embolisms associated with BBLs are caused by damage to the large vessels under the gluteal muscle, including the superior and inferior gluteal veins, that allow fat to enter the blood stream, and eventually block blood flow to the lungs.

31. Damage to the large vessels can be caused either by a direct injury from a cannula or by fat that has migrated deep into the muscle “expanding the submuscular space” and stretching the “rich and cavernous venous plexus [that] may result in tears [in the vessels] that allow migrated fat to be siphoned into the low-pressure venous system.” Dr. Garcia testified that “[t]he injury can be direct or it can be caused by simple stretching of the vessel.”

The Procedure on Patient G.R.

32. In September 2020, Respondent performed plastic surgery procedures as an independent contractor at Xiluet Plastic Surgery in Miami, Florida. On September 15, 2020, G.R., a 46-year-old transgender woman who was HIV positive, presented to Xiluet to undergo several cosmetic procedures with Respondent, including a BBL. G.R. was being treated with medication and her HIV was under “very good control” at the time of the surgery scheduled in this case.

33. Prior to surgery, Dr. Stover conducted a pre-operative medical clearance, during which Dr. Stover reviewed G.R.’s lab work, EKG, chest x-ray, and surgical history. Dr. Stover also conducted a “medical interview,” performed a “physical exam,” and had discussions with the patient prior to the day of surgery.

34. Dr. Stover advised G.R. of the risks of the BBL procedure prior to the surgery on two occasions, first, as part of the pre-operative clearance and consultation the day before the surgery, and, second, on the day of the procedure. G.R. signed an informed consent form—Dr. Stover uses the forms provided by the American Society of Plastic Surgery—indicating she was aware of the surgical risks and consented to them.

35. G.R. had been dieting prior to her surgeries, including the BBL procedure, and had lost significant weight and, as a result, “she was extremely thin and especially [in] the layer of the subcutaneous tissue in the

area of the buttocks.” In some areas of G.R.’s gluteal region, the subcutaneous layer was “even less than a centimeter.”

36. Because G.R. was born an anatomical male, she had a “very [androgynous] shape,” and due to the “inherent nature of [G.R.’s] tissues,” the tissues were “denser,” “thicker,” “more fibrous,” and, because of her “thin subcutaneous plane, even less than a centimeter.” During the pre-injection portion of the procedure Dr. Stover performed on G.R., Dr. Stover used a 4 mm cannula to “go in gently, but bluntly, to separate those tissues.” The one to two dozen “passes with the cannula,” made by Dr. Stover during the pre-injection, “pre-tunneling,” or “blunt dissection,” portion of the procedure are the same kinds of cannula passes made during the injection portion, but without any injection of fat. The pre-injection cannula passes are also “a tactile procedure,” made blind, and could cause “some trauma ... to those tissues.”

37. Dr. Garcia acknowledged “anatomical or genetic males and females have ... quantifiable differences in either the anatomy or the structural anatomy of the gluteal area that is pertinent to BBL.” He testified: “The male pelvis is obviously narrower and the fatty layer is significantly thinner. ... In a male patient sometimes even running the cannula parallel to the skin will have you within the muscle, because the buttocks is a spare dome. It peaks at the center and simply running your cannula parallel will not give you any subcutaneous tissue.” He testified that “obviously those patients,” anatomical males, “were more at risk because it is a blind procedure. You have less of a layer to work with.”

38. Dr. Garcia testified that during a “model for the study of BBLs” he worked on, “we had to discard all male specimens and only use females of a certain [body mass index] because the angles were completely different. ... We wanted to create a situation of reasonably large fatty layer to inject to.”

39. Dr. Garcia, who testified he has very little experience performing BBLs on genetic males, provided no testimony regarding pre-tunneling or

blunt dissection. There was no evidence presented at hearing that Dr. Garcia has ever performed pre-tunneling or blunt dissection to create space prior to injecting during a BBL, or has any expertise or knowledge about this technique.

40. Dr. Stover performed the pre-tunneling or blunt dissection on G.R., as she had hundreds of times in other procedures, because G.R. had a “significantly thinner fatty layer” with very little subcutaneous tissue.

41. Dr. Stover used a 4 mm, rigid, single-hole cannula with a blunt tip for both the pre-injection dissection, where she separated the skin and subcutaneous tissue from the underlying structure, and for injecting fat during the injection portion of the procedure. The instruments Dr. Stover used during this procedure comply with the recommendations of the ASERF Task Force.

42. Dr. Stover had previously done pre-tunneling or blunt dissection thousands of times during surgery and approximately 300 times during gluteal fat transfer procedures, most often on genetic males.

43. Dr. Stover also performed the fat injection portion of the procedure on G.R. in accordance with ASERF Task Force recommendations. She employed a strategy to avoid injecting into the muscle. She positioned the patient on her side and avoided the prone position. Dr. Stover kept her cannula tip “angled up,” and she used her free hand to palpate Patient G.R.’s gluteal region in order to stay aware “from a 3D spa[t]ial dimension” where the tip of her cannula was. Dr. Stover made sure that the paralytics (given as anesthesia to G.R.) had worn off so that she would be able to detect any muscle twitches in the patient that might indicate the cannula was close to entering the muscle. Dr. Stover avoided plunging the plunger on the syringe—thus avoided injecting fat—while entering the cannula, and instead only injected “in a [retrograde] fashion so you are going away from the structure,” in other words, while the cannula was moving in an outward direction. Dr. Stover only injected small amounts of fat at a time under steady

pressure, and always while her cannula was in motion, to avoid injecting “a bolus high amount at one time.”

44. The technique used by Dr. Stover is the surgical approach and procedural practice she employs in all the gluteal fat transfers she performs, and is the surgical technique she employed in the September 15, 2020, gluteal transfer procedure she performed on G.R.

45. At the conclusion of the BBL procedure, within two to three minutes of the final injection, G.R. began to show signs of distress. Dr. Stover immediately followed advanced cardiac life support (“ACLS”) protocols and took all possible actions to save G.R.’s life, including initiating ACLS, which comprises properly positioning the patient and confirming the tube is properly placed to avoid blocking the airway, then performing CPR, immediately calling 911, and going to Kendall Regional Medical Center with G.R. to provide any information or assistance in life-saving efforts.

46. All life-saving efforts failed and G.R. died. Her body was transferred to the Miami-Dade Medical Examiner’s Office, where Amelia Nakanishi, M.D., performed an autopsy.

Post-Mortem Findings

47. During the autopsy, Dr. Nakanishi dissected G.R.’s lungs and opened the veins returning to the lungs. Dr. Nakanishi observed numerous globules of yellow fat inside the veins entering G.R.’s lungs.

48. Dr. Nakanishi certified that G.R. died from pulmonary embolism—an obstruction of blood flow to the lungs.

49. Because emboli are not naturally occurring, Dr. Nakanishi continued the autopsy to determine the source of the fat emboli.

50. Dr. Nakanishi dissected G.R.’s hips and buttocks. First, Dr. Nakanishi removed the skin covering G.R.’s buttocks to expose the subcutaneous layer. The subcutaneous layer was full of “yellow grafted fat” and “red-peach fat.”

51. Dr. Nakanishi then dissected the subcutaneous layer, exposing G.R.'s muscles, followed by her dissecting G.R.'s gluteal muscles. The dissection revealed gratuitous amounts of grafted fat in G.R.'s musculature, including "strands" of fat clearly injected by a cannula into the muscle.

52. Dr. Nakanishi observed damaged vessels in G.R.'s gluteal muscles. Based on her clinical observations, Dr. Nakanishi determined that the fat in G.R.'s muscles was deposited, and she specifically observed a rope-like structure of fatty tissue protruding between G.R.'s muscle fibers that indicated it had been injected there.

53. Dr. Nakanishi determined that the gluteal fat transfer caused G.R.'s pulmonary embolism. In the course of her examination, Dr. Nakanishi found no disruption to the large vessels of G.R.'s gluteal muscle, but did find evidence of disrupted small vessels. Dr. Stover explained this by testifying that smaller vessels proceed up to and through the fascia into the subcutaneous layer. She testified: "it is actually here where they [the smaller vessels] pierce the fascia where the fascia has its weaknesses." Dr. Garcia acknowledged there is "a tiny network [of vessels] that continues upward into the subcutaneous tissue."

54. The medical examiner, not an expert in BBLs, did not specifically testify the "deposited fat" found in G.R. was deposited into her muscle; she testified only that she "believed" the fat in G.R.'s gluteal muscle was "deposited fat," as opposed to native fat. Dr. Nakanishi provided no testimony explaining how the fat in G.R.'s muscle entered that muscle. Further, neither the medical examiner nor Dr. Garcia, the Department's expert in BBLs, testified there was any damage to G.R.'s gluteal muscles or gluteal fascia. The Department presented no evidence of traumatized muscle fiber or muscle damage. The Department presented no testimony or evidence of cannula tracks in or through the muscle. The Department presented no direct proof, either physical evidence or testimony, that G.R.'s gluteal fascia was damaged. However, Dr. Garcia testified there was no reasonable explanation for the

deposited fat in G.R.'s gluteal muscles other than Dr. Stover having directly injected it there. Dr. Garcia's testimony is credited.

55. Despite acknowledging the presence of grafted fat in and under G.R.'s gluteal muscles, Dr. Stover denied performing intramuscular fat injections and claimed to only inject fat subcutaneously.

How Did Fat Enter G.R.'s Gluteal Muscle?

56. As framed by Respondent in her PRO, the central issue in this case is whether the fat in and/or under the central region of G.R.'s gluteal muscle was injected there directly by Dr. Stover, or got there some other way, such as by migrating from another region, such as from the subcutaneous plane after "tissue trauma."

57. As noted at hearing, this is an issue that medical researchers are trying to determine more generally. Medical and scientific research introduced into evidence in this case sheds some light on the possibilities, but fails to conclusively resolve the issue as a general matter, and, unfortunately, provides no direct evidence with regard to the specific case of G.R.

58. In this case, the evidence indicates "grafted fat"—that is, fat that was "harvested" from G.R.'s body—was found in and under G.R.'s muscle during the postmortem examination. There is no dispute that some of that "grafted fat" ended up in G.R.'s lungs and caused a fatal pulmonary embolism.

59. In short, there is no serious dispute as to whether "grafted fat" ended up in G.R.'s muscle. The determinative question here is: How did that fat get there? The evidence on this point is conflicting and contradictory. Two highly qualified experts in the BBL procedure weighed in on the mystery.

60. Dr. Stover testified that, with respect to the subject BBL procedure, she employed a strategy to avoid injecting into the muscle that included (1) using a "rigid four [millimeter] single hole blunt tipped cannula"; (2) positioning the patient laterally to allow her trajectory to be "in a more superficial plane" and to avoid dilation of the vessels; (3) palpating with her

free hand to maintain three-dimensional “3D special dimension” of the location of the tip of her cannula; (4) injecting only a small amount of fat at a time under steady pressure; (5) injecting only while the cannula was moving toward the superficial layers; and (6) by waiting for the paralytics to have worn off, so she could watch for muscle twitches.

61. Dr. Stover further testified that she did not “insert fat into patient G.R.’s gluteal muscles,” she “did not insert fat under patient G.R.’s muscles,” and she did not “cross the gluteal fascia to inject fat during patient G.R.’s gluteal fat grafting procedure.”

62. Dr. Stover did acknowledge that it was possible that she inadvertently injected fat into the gluteal muscles due to the fact that the muscles in the area she was working in were thin, and it was possible they did not twitch or she did not see them twitch when she was injecting small amounts of fat in the area.

63. Dr. Stover testified that, “while anything is possible,” she did not believe she accidentally or inadvertently injected fat into the gluteal muscles because her preparatory work had already created the space and pocket to receive the fat without it being injected into the muscles.

64. The blood vessels in the subcutaneous layer of the gluteal muscles are very small, even as small as a “couple of milliliters,” so a small puncture was possible. She testified that, even if a puncture was made before the fat injection, there was time for the puncture to have closed up before the fat was introduced into the area. She was not able to quote specific language from any medical studies nor could she provide direct evidence that this might be the case here, but she believed it to be a possible explanation.

65. Dr. Garcia, on the other hand, testified that while he “believe[d] that the operation here was designed to place this [fat] in the subcutaneous tissue,” it was his opinion that “fat was injected into the muscle.” He concluded this from his review of the autopsy dissection materials and his reliance on a 2019 published study.

The Del Vecchio Study

66. Each doctor finds support for his or her conclusions in the work of Dr. Daniel Del Vecchio, principally from an article titled, “Subcutaneous Migration: A Dynamic Anatomical Study of Gluteal Fat Grafting” (the “Article”), authored by Dr. Simeon Wall, Jr., Dr. Del Vecchio, and others, and published in the May 2019 issue of *Plastic and Reconstructive Surgery Journal*, received into evidence. The Article reports the results of a very small study conducted prior to September 2018. The researchers injected dyed applesauce into the subcutaneous space of “four hemibuttocks from two cadavers” under different conditions in an effort to determine how the fat would migrate.

67. Dr. Stover also introduced into evidence a video featuring Dr. Del Vecchio. The video establishes that vessels do penetrate the fascia and create the weakest points in the fascia, confirming Dr. Stover’s testimony (“they pierce the fascia where the fascia has its weaknesses”). Dr. Del Vecchio’s video demonstrates that even when a cannula is kept “superficial,” “not in the deep muscle” and “not subjacent to the muscle,” injected fat can track through the muscle even when injected superficially.

68. The undersigned recognizes that while the Article represents the only impartial medical evidence presented at hearing, since each of the BBL experts have some degree of partiality to their particular side of the case, it has certain inherent limitations noted by its authors, including that its findings are based on injections of applesauce, not human fat, into cadavers, not living humans, outside a clinical setting, and that only two cadavers were used, such that the range of variance in human fascia strength, integrity, and many other properties, was not represented. The Article notes that “different cadaver[s]” have “different subcutaneous capacities and different tissue tolerances” (further noting that “some limitations that deserve discussion,” including that “fascial perforations were made, followed by fat grafting, but not simultaneously with fat grafting. This may have underrepresented the

amount of fat that could get beneath the fascia given an inadvertent pass.”). Dr. Garcia agreed, noting that “applesauce ha[s] a different flow and dispersion characteristics as opposed to human fat.”

69. Despite its obvious shortcomings from real life BBL surgery, the Article does at least address some of the competing theories presented at hearing. The Article discusses four gluteal injection scenarios (one on each hemibuttocks used), of which scenarios 2 and 3 are most relevant here.

70. In scenario 2, “a random pattern of [15] cannula perforations was made in the gluteus maximus fascia at its point of maximum projection before fat insertion.” Under this scenario, “the fascia permitted only a small amount (1 cc) of proxy fat and dye to be noted beneath each perforation; no proxy fat spread deeper into the muscle or beneath it. ... In this scenario, despite suffering multiple perforations, fascial integrity remained robust and maintained a barrier function under extremely high pressures.” With regard to “limitations that deserve discussion” regarding scenario 2, the authors cautioned that “fascial perforations were made, followed by fat grafting, but not simultaneously with fat grafting,” as they would be in a real-life clinical setting. “This,” the authors observed, “may have underrepresented the amount of fat that could get beneath the fascia given an inadvertent pass.”

71. Consequently, the most the authors could conclude based on scenario 2 is that: “During intended ‘subcutaneous only’ Brazilian buttock lift, inadvertent passes beneath the gluteus maximus fascia most certainly occur. However, the volumes of fat placed during these passes are not likely to be of significant enough volume to cause deep intramuscular migration into the submuscular space.” The Article suggests that 25 ccs of injected fat could end up in the gluteal muscle under scenario 2, the “inadvertent pass’ scenario,” but concludes, “it is unlikely” this amount of fat “would be significant enough to cause vascular or sciatic nerve injury in the deep muscular space, by means of deep intramuscular migration.”

72. “In scenario 3, 15 random defects in the gluteus maximus fascia were created with a 6-mm Baker punch biopsy knife.” After fat insertion in this scenario, the researchers observed that:

the submuscular space contained a significant amount of proxy fat. Applesauce and dye were noted within the muscle, but the largest quantity of fat could be seen to emanate from underneath the most inferolateral portion of the muscle which, in the prone position, is the most dependent space. ... The 6-mm fascial fenestrations in scenario 3 allowed the proxy fat to flow freely beneath the muscle in exactly the same pattern as did subfascial injections in the deep intramuscular migration article.

73. In sum, the Article suggests fascial perforations (scenario 2) allow fat to flow beneath the fascia, but that the amount of fat that enters the gluteal muscle is “unlikely” to cause the type of vascular injury that would lead to a pulmonary fat embolism. Further, the Del Vecchio article suggests that 6 mm holes in the fascia would allow fat injected properly into the subcutaneous layer to flow freely into the muscle, potentially leading to severe vascular and/or nerve injury that could cause a pulmonary fat embolism.

Dr. Stover’s Conclusions

74. Dr. Stover testified that, based on Dr. Del Vecchio’s presentations and her experience, she believes fat she injected into the subcutaneous space migrated through the fascia and into the muscle. She believes this was potentially caused by inadvertent punctures she may have made in G.R.’s fascia during the pre-tunneling or blunt dissection portion of the procedure. Dr. Stover further testified that punctures to the fascia were more likely to have been made during the blunt dissection portion of the procedure than during the injection portion, because by the time she started making injections, she had already “created” the “space and pocket” during the blunt dissection. While doing this, she testified to the fact that she followed all the

recommendations and best practices to avoid crossing the fascia during the injection portion.

75. Dr. Stover acknowledged that she may have damaged the fascia, punctured the fascia, or passed into the muscle near vessels (perhaps repeatedly) during the “pre-tunneling” or “blunt dissection” portion of the procedure, during which time no fat syringe was attached to the cannula and She was not injecting fat. During this portion of the procedure, Dr. Stover made between one dozen and two dozen cannula passes and immediately proceeded to the injection portion of the procedure.

76. Dr. Stover explained further that the punctures she may have made during the blunt dissection portion of the procedure, would most resemble the “six millimeter punch out of the fascia” described in scenario 3 of the Article because, when “you keep sliding [a four-millimeter cannula] forward it could drive enough to make a six-millimeter defect,” or tear in the fascia. She likened this to a tear in a pair of pantyhose that were pulled by the edge of metal probe. Dr. Garcia was not recalled to rebut or refute this testimony concerning Dr. Stover’s theory, but nonetheless, it stands as an admission by Dr. Stover that punctures to the gluteal muscles could have resulted from the 6 mm tear in the fascia.

77. To the extent scenario 2 from the Article is analogous to what occurred during G.R.’s procedure, Dr. Stover highlighted the differences between the conditions present in the static, cadaver study and the dynamic, clinical setting in which Dr. Stover was operating. In the study, Dr. Stover noted they made a perforation with the cannula, a one-time poke, and it is afterwards that they injected. So even the Article itself mentioned how this may not really show what happens during a live surgery, because, in the Article, they did one poke only, which is different from passing the cannula repeatedly, resulting in the amount of fat ending up under the fascia, which “could be more in a real-life situation.”

78. In this context, Dr. Stover presented credible, uncontradicted testimony (by any other witness who was present at G.R.'s surgery) that, during the injection portion of the BBL procedure, she always injects, and did in the case of G.R., in a retrograde fashion, meaning she inserts the cannula to its deepest point and injects as she withdraws the cannula. As such, it is possible, though not likely, based upon the totality of the evidence, that even if Dr. Stover damaged the fascia or passed into the muscle after the blunt dissection, she may have only injected fat after she had withdrawn from the muscle.

Dr. Garcia's Conclusions

79. In support of his opinion that "fat was injected into the muscle" here, Dr. Garcia testified there was "loose injected fat" in the muscle. This, however, only restates the significant question identified above: How did that loose injected fat get there?

80. On direct examination, in response to the question, "Is it possible for the fat that we are describing in these photos to have migrated from the subcutaneous layer into these muscles?" Dr. Garcia testified: "To the best of my knowledge that would never happen." Dr. Garcia's answer, albeit direct and based upon his broad experience, assumes that the fascia has not been damaged and he is considering only whether fat injected into the subcutaneous area with an intact, undamaged fascia will not migrate into the muscle.

81. Dr. Garcia focused on the Article's conclusion that "the gluteus maximus fascia, even with multiple cannula perforations, prevented subcutaneous injections to cross into the muscle, even under very high injection pressures."

82. Dr. Garcia opined that, based on the results of the Article, and his extensive experience in studying the risks associated with gluteal fat grafting, there is no other explanation for the deposited fat found in G.R.'s

muscles than Respondent's having directly injected it into the muscle. His position in this regard is credited.

83. Further, Dr. Garcia opined that the fat present in G.R.'s muscles was not the result of one inadvertent pass through G.R.'s fascia, but several hundred. While this number may be somewhat exaggerated, since there is no way to accurately determine the exact number, there were a large number of passes through G.R.'s fascia, not just one or two.

84. Dr. Garcia testified that Dr. Stover took preventative measures to avoid intramuscular injections during G.R.'s surgery. For example, she stated that oftentimes muscles will twitch if a medical instrument comes into contact with the muscle during a procedure and she observes for muscle twitches while injecting fat. However, as noted previously, Dr. Stover acknowledged that, because the muscles in the area that she was working were thin, it was possible that the muscles either did not twitch or that she did not notice them twitch. Without the twitch warning from the muscles, it became even more likely Dr. Stover could have inadvertently perforated the gluteal muscles during the multiple passes and mistakenly injected some undetermined amount of fat.

85. Dr. Stover further acknowledged that because BBLs are a blind procedure, it was possible that her cannula could have passed through the gluteal fascia at any point during the procedure.

86. Dr. Stover also testified that she primarily injected fat on G.R.'s lateral hips and away from the "danger zone" where the fat was found in the autopsy photographs.

87. However, the Article revealed that no matter where in the gluteal anatomy fat is injected intramuscularly (under the fascia), it will migrate into the deeper planes of the muscles.

88. Dr. Garcia confirmed that, even if Dr. Stover had limited her intramuscular injections to the lateral hip area, the fat could follow a

pressure gradient to the deeper planes and structures, as observed in the autopsy photographs.

89. Ultimately, Dr. Stover's claim that she did not violate the standard of care is refuted by the results of G.R.'s autopsy. The clinical observations of injected fat in G.R.'s gluteal muscles show that Respondent repeatedly perforated G.R.'s gluteal fascia and injected fat intramuscularly, resulting in G.R.'s sudden and tragic demise.

CONCLUSIONS OF LAW

90. DOAH has jurisdiction over the subject matter of this proceeding and over the parties hereto pursuant to sections 120.569, 120.57(1), and 456.073(5), Florida Statutes.

91. This is a proceeding whereby Petitioner seeks to revoke Respondent's license to practice medicine. Petitioner has the burden to prove the allegations in its AC by clear and convincing evidence. *Reich v. Dep't of Health, Bd. of Med.*, 973 So. 2d 1233, 1235 (Fla. 4th DCA 2008) (citing *Dep't of Banking & Fin. v. Osborne Stern & Co.*, 670 So. 2d 932 (Fla. 1996)); and *Ferris v. Turlington*, 510 So. 2d 292 (Fla. 1987). As stated by the Supreme Court of Florida:

clear 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 testimony must be precise and lacking in confusion as to the facts at issue. The evidence must be of such a weight that it produces in the mind of the trier of fact a firm belief or conviction, without hesitancy, as to the truth of the allegations sought to be established.

In re Henson, 913 So. 2d 579, 590 (Fla. 2005) (quoting *Slomowitz v. Walker*, 429 So. 2d 797, 800 (Fla. 4th DCA 1983)). This burden of proof may be met where the evidence is in conflict; however, "it seems to preclude evidence that

is ambiguous.” *Westinghouse Elec. Corp. v. Shuler Bros., Inc.*, 590 So. 2d 986, 988 (Fla. 1st DCA 1991).

92. Because the Medical Practice Act, section 458.331, authorizes suspension or revocation of a professional license, it is penal in nature and must be strictly construed in favor of the licensed physician. *Breesmen v. Dep’t of Prof’l Reg., Bd. of Med.*, 567 So. 2d 469, 471 (Fla. 1st DCA 1990).

93. A hearing involving disputed issues of material fact under section 120.57(1) is a de novo hearing, and Petitioner’s initial action carries no presumption of correctness. § 120.57(1)(k), Fla. Stat.; *Moore v. Dep’t of HRS*, 596 So. 2d 759 (Fla. 1st DCA 1992).

94. The grounds proving the Department’s assertion that Dr. Stover’s license should be disciplined must be those specifically alleged in the AC. *See, e.g., Trevisani v. Dep’t of Health*, 908 So. 2d 1108 (Fla. 1st DCA 2005); *Kinney v. Dep’t of State*, 501 So. 2d 129 (Fla. 5th DCA 1987); and *Hunter v. Dep’t of Prof’l Reg.*, 458 So. 2d 842 (Fla. 2d DCA 1984).

95. Due process prohibits the Department 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 Env’tl. Prot.*, 824 So. 2d 208, 210 (Fla. 4th DCA 2002); and *Delk v. Dep’t of Prof’l Reg.*, 595 So. 2d 966, 967 (Fla. 5th DCA 1992).

96. Petitioner’s AC charges Respondent with violating section 458.331(1)(t), which prohibits medical doctors from committing medical malpractice as defined in section 456.50. It further provides that medical malpractice shall not be construed to require more than one instance, event, or act. § 458.331(1)(t)1., Fla. Stat.

97. Florida law recognizes that physicians owe their patients a duty to “use the ordinary skills, means, and methods that are recognized as necessary and which are customarily followed in the particular type of case according to the standards of those who are qualified by training and

experience to perform similar services in the community or in a similar community.” *Brooks v. Serrano*, 209 So. 2d 279, 280 (Fla. 4th DCA 1968). The Board may discipline a physician for “failure to practice medicine with that level of care, skill, and treatment which is recognized by a reasonably prudent similar physician as being acceptable under similar conditions and circumstances.” §§ 458.331(1)(t) and 456.072(2), Fla. Stat.; *See also Fox v. Dep’t of Health*, 994 So. 2d 416, 418 (Fla. 1st DCA 2008). Section 458.331(1)(t) further provides, “The board shall give great weight to the provisions of s.766.102 when enforcing this paragraph.” Section 766.102(3), Florida Statutes, provides, “[t]he existence of a medical injury shall 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.”

98. There is no dispute that injecting fat intramuscularly or sub-muscularly during gluteal fat grafting procedures falls below the level of care, skill, and treatment recognized in Florida for this procedure.

99. The Department proved by clear and convincing evidence that Dr. Stover injected fat into G.R.’s gluteal muscles during a gluteal fat grafting procedure or BBL, which constitutes both medical malpractice, as defined in section 456.50, and a violation of rule 64B8-9.009(2)(f). This conclusion does not mean that Dr. Stover performed the BBL on G.R. resulting in misplaced fat injections either intentionally, recklessly, or without regard for G.R.’s safety, nor did the Department present any evidence to support such a finding. Moreover, Dr. Stover was not charged with failing to utilize the best practices, procedures, and instrumentation in performing the BBL on G.R., nor did the Department present any evidence to support such a finding. Finally, Dr. Stover was not charged with medical malpractice regarding the “pre-tunneling” or blunt dissection portion of G.R.’s

BBL procedure, nor did the Department present any evidence to support such a finding.

100. Despite Dr. Stover's best intentions and considerable experience and skill, maybe more than any physician in Florida performing BBLs on males and transgender women, the evidence here is clear and convincing that fat was found in the gluteal muscles, with some of that fat migrating to G.R.'s lungs to create a fatal embolism. This is evident from the autopsy performed on G.R., from the uncontroverted evidence that the fat appeared in the gluteal muscles, and from the expert testimony from Dr. Garcia that he was certain the fat was injected, whether intentionally (not proven), negligently, or inadvertently. The fact is, with all the passes preparing the subcutaneous area to receive fat injections, Dr. Stover used her best practices to only inject fat when withdrawing the cannula from the patient, rather than when inserting the syringe into the patient. No clear and convincing evidence was presented by either party that the fat somehow migrated from the subcutaneous area into the gluteal muscles.

101. Dr. Stover's superior experience in performing BBLs on men and transgender women made her keenly aware of the unique problems facing a surgeon due to sometimes thinner patients who require special care and expertise on the surgeon's part to prepare the subcutaneous area to receive the fat injections. Despite all her experience and training, the clear and convincing evidence here points to Dr. Stover making errors that resulted in fat being injected, albeit not intentionally or recklessly, into G.R.'s gluteal muscles. This action violated rule 64B8-9.009(2)(f), and, pursuant to section 458.331(1)(t), constitutes medical malpractice. What remains to be determined is what penalty should apply.

The Penalty

102. Penalties in a licensure discipline case may not exceed those in effect at the time a violation was committed. *Willner v. Dep't of Prof'l Reg., Bd. of*

Med., 563 So. 2d 805, 806 (Fla. 1st DCA 1990), *rev. denied*, 576 So. 2d 295 (Fla. 1991).

103. Section 456.079 requires the Board of Medicine to adopt disciplinary guidelines for specific offenses. Penalties imposed must be consistent with any disciplinary guidelines prescribed by rule. *See Parrot Heads, Inc. v. Dep't of Bus. & Prof'l Reg.*, 741 So. 2d 1231, 1233-34 (Fla. 5th DCA 1999).

104. Section 456.072(4) provides that in addition to any other discipline imposed for violation of a practice act, the board shall assess costs related to the investigation and prosecution of the case.

105. Rule 64B8-8.001(2)(t) provides that the recommended range of penalty for a first-time violation of section 458.331(1)(t) is from one-year of probation to revocation and an administrative fine from \$1,000.00 to \$10,000.00.

106. Rule 64B8-8.001(2)(nn) provides that the recommended range of penalty for a first-time violation of section 458.331(1)(nn) is from one year probation to revocation and an administrative fine from \$1,000.00 to \$10,000.00.

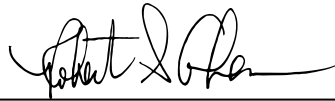
107. In mitigation of the penalty to be imposed, Dr. Stover offers (1) her long and unblemished career and her substantial experience of thousands of surgeries without any serious complications; (2) the clear and unequivocal testimony both she and Dr. Garcia, the Department's expert, offered that she intended to use a subcutaneous-only strategy and to avoid subfascial, intramuscular, or submuscular fat injections in G.R.'s BBL procedure; and (3) Dr. Stover's credible and uncontroverted testimony that she followed all prevailing safety recommendations, best practices, and employed instruments in performance of G.R.'s BBL procedure. Despite all these precautions and her clean professional record, Dr. Stover perforated the gluteal muscles, which led to fat repeatedly being injected into those muscles, resulting in the worst possible result, the death of her patient due to her negligence.

108. The undersigned finds, however, that despite the tragic result in G.R.'s case, these factors gravitate toward mitigation of the penalty to be imposed on Dr. Stover. Accordingly, she should receive penalties resulting from her actions in the lower- to mid-range of the penalty matrix.

RECOMMENDATION

Based on the foregoing Findings of Fact and Conclusions of Law, it is RECOMMENDED that the Board of Medicine enter a final order finding Respondent violated section 458.331(1)(t) and/or 458.331(1)(nn); imposing a one-year probation upon Respondent's license to practice medicine, together with a \$5,000 fine; and imposing costs of investigation and prosecution.

DONE AND ENTERED this 13th day of August, 2021, in Tallahassee, Leon County, Florida.



ROBERT S. COHEN
Administrative Law Judge
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Filed with the Clerk of the
Division of Administrative Hearings
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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.