

**BEFORE THE
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA**

In the Matter of the First Amended
Accusation Against:

Ralph Anthony Highshaw, M.D.

Physician's & Surgeon's
Certificate No A 56419

Respondent.

Case No.: 800-2020-071080

**DENIAL BY OPERATION OF LAW
PETITION FOR RECONSIDERATION**

No action having been taken on the petition for reconsideration, filed by December 21, 2023, and the time for action having expired at 5:00 p.m. on December 21, 2023, the petition is deemed denied by operation of law.

BEFORE THE
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the First Amended
Accusation Against:

Ralph Anthony Highshaw, M.D.

Physician's and Surgeon's
Certificate No. A 56419

Respondent.

Case No.: 800-2020-071080

DECISION

The attached Proposed Decision is hereby adopted as the Decision and Order of the Medical Board of California, Department of Consumer Affairs, State of California.

This Decision shall become effective at 5:00 p.m. on December 21, 2023.

IT IS SO ORDERED: November 21, 2023.

MEDICAL BOARD OF CALIFORNIA



Laurie Rose Lubiano, J.D., Chair
Panel A

**BEFORE THE
MEDICAL BOARD OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA**

In the Matter of the First Amended Accusation Against:

RALPH ANTHONY HIGHSHAW, M.D.,

Physician's and Surgeon's Certificate No. A 56419,

Respondent.

Agency Case No. 800-2020-071080

OAH No. 2022080399

PROPOSED DECISION

Julie Cabos Owen, Administrative Law Judge, Office of Administrative Hearings (OAH), State of California, heard this matter by videoconference on October 2, 3, and 4, 2023. Reji Varghese (Complainant) was represented by Karolyn M. Westfall, Deputy Attorney General. Ralph Anthony Highshaw, M.D. (Respondent) was represented by Michael J. Khouri and Robert K. Weinberg, Attorneys at Law.

Testimony and documents were received in evidence. The record closed and the matter was submitted for decision on October 4, 2023.

FACTUAL FINDINGS

Jurisdictional Matters

1. On November 27, 1996, the Medical Board of California (Board) issued Physician's and Surgeon's Certificate Number A 56419 to Respondent. That license is scheduled to expire on July 31, 2024.

2. On April 11, 2023, Complainant filed the First Amended Accusation while acting in his official capacity as the Executive Director of the Board. Respondent had filed a Notice of Defense to the original Accusation, and this hearing was scheduled.

Respondent's Involvement with Superior Health Centers

3. Respondent is board certified in urology. Since approximately 2016, he has been practicing medicine in Florida, specializing in urology.

CREATION OF NEUROPATHY SOLUTIONS AND ELITE MEDICAL GROUP

4. About 2018, Neuropathy Solutions, Inc. (Neuropathy Solutions) was incorporated in the State of California by Vivienne Reign (Reign), a non-physician. Reign was listed as the President, Chief Executive Officer (CEO), Chief Financial Officer (CFO), and sole Director of Neuropathy Solutions. A chiropractor, Philip Straw (Dr. Straw), was the Secretary. Elisabeth Eropkin (Eropkin) was the agent for service of process. The addresses for Neuropathy Solutions, its officers, directors, and agent for service of process were all listed as: 17748 Sky Park Circle #240, Irvine, California.

5. Neuropathy Solutions purportedly engaged in business as a management company. It actually operated multiple medical clinics under the name Superior Health Centers where it employed medical professionals to provide

regenerative medicine treatment at the clinics. The regenerative medicine treatments included the injection of stem cell products and the use of platelet rich plasma (PRP).

6. In about 2019, Reign recruited Respondent to act as Medical Director of five Superior Health Centers clinics in Southern California, including one in Corona. In furtherance of this business relationship, Respondent was to form a separate medical group under the name, "Elite Medical Group, PC," which would provide medical services at Superior Health Centers.

7. As Medical Director for the five Superior Health Centers clinics, Respondent was responsible for supervising nurse practitioners (NPs) who provided regenerative medicine treatments to patients at the clinics. He was also responsible for creating protocols for the NPs.

8. On March 1, 2019, Respondent incorporated Elite Medical Group PC (EMG) in the State of California. Respondent was listed as the President, Secretary, Chief Executive Officer, Chief Financial Officer, and sole Director of Elite. Eropkin was the agent for service of process. The addresses for EMG, its officers, directors, and agent for service of process were listed as: 17748 Sky Park Circle #240, Irvine, California, the same address as Neuropathy Solutions.

9. The Board has never issued a fictitious name permit to Respondent under any business name. Respondent has never held a fictitious name permit on file with the Board for Elite Medical Group, Superior Health Centers, or any other medical practice in the State of California.

10. The Board has never issued a fictitious name permit to any business named "Neuropathy Solutions" or "Neuropathy Solutions, Inc."

11. The Board has never issued a fictitious name permit to any business named "Superior Health Centers."

12. The California Secretary of State has no record of any corporation doing business as Superior Health Centers.

MANAGEMENT SERVICES AGREEMENT

13. On April 25, 2019, EMG, represented by Respondent, entered into a Management Services Agreement (MSA) with Neuropathy Solutions (identified in the MSA as "Manager" or "Company"), represented by Reign. The address listed for Neuropathy Solutions was 17748 Sky Park Circle, Suite 240, Irvine, California.

14. Pursuant to the MSA, beginning April 25, 2019, Respondent would serve as the Medical Director for EMG, and would receive \$1,500 per month from Neuropathy Solutions for each clinic location he oversaw. The MSA listed five clinic locations that were leased and managed by Neuropathy Solutions: Walnut Creek, Placentia, Gardena, Corona, and Glendale.

15. Pursuant to the MSA, Neuropathy Solutions would maintain EMG's patient records and, upon termination of the MSA, Neuropathy Solutions would have the right to maintain those medical records. Specifically, the MSA provided:

2.10. Medical Records; Patient Privacy.

Manager [i.e., Neuropathy Solutions] shall provide maintenance and storage of EMG medical records on behalf of EMG; provided, however, that pursuant to Section 10 EMG is ultimately responsible to maintain professional

records regarding all patients of EMG Practice as required by the laws of the state in which EMG is located. [¶] . . . [¶]

10. Records.

EMG shall maintain professional records regarding all patients of EMG Practice as required by the laws of the state in which EMG is located (with assistance of Manager pursuant to this Agreement). EMG acknowledges and agrees that Manager shall have the right, upon receiving valid legal consent of any EMG patient, to maintain a copy of any EMG patient professional records and any copies of such records shall become the property of the Manager. Manager shall also have the right to retain such records upon termination of this Agreement. All non-professional records relating to EMG Practice (other than patient medical records) shall become the property of the Manager. All records relating to the services of the Manager which are created and maintained by the Manager, shall remain the sole property of the Manager. The parties shall permit each other access during normal business hours to such books and records upon reasonable notice, provided notice within forty-eight (48) hours shall be deemed reasonable notice.

(Exhibit 12, pp. A121, A129-A130.)

///

///

16. Pursuant to the MSA, EMG was required to reimburse Neuropathy Solutions its costs and to pay Neuropathy Solutions any remaining revenue. Consequently, all profits were paid to Neuropathy Solutions. Specifically:

EMG shall reimburse Manager for all Direct Costs and Indirect Costs incurred by Manager in providing the Management Services hereunder..... In addition to payment of all such monthly expenses described above, EMG will also pay the Manager a fee equal to any remaining Revenues.

(Exhibit 12, p. A140.)

17. Neuropathy Solutions had the right to "immediately terminate" the MSA on multiple grounds, including "at any time, with or without cause, upon providing seven (7) days prior notice to EMG." (Exhibit 12, p. A125.) EMG had no reciprocal right of termination.

18. Pursuant to the MSA, immediately upon termination of the MSA, EMG was to surrender to Neuropathy Solutions all furnishings and equipment, and EMG would relinquish its rights to its accounts receivable. Specifically, the MSA provided:

Termination. Upon termination or non-renewal of this Agreement, EMG shall:

7.1.1. Surrender to the Manager any and all Furnishings, Equipment, and other items provided by the Manager in good order and condition (reasonable wear and tear resulting from their proper use alone, excluded);

[¶] . . . [¶]

7.3. Collection of Accounts Receivable. Subsequent to the termination of this Agreement and until all sums due to the Manager from EMG have been paid in full, the Manager shall have the option to collect EMG outstanding receivables up to the amount due and payable to the Manager by EMG and to apply the proceeds thereof to the payment of all sums due to the Manager from EMG.

[¶] . . . [¶]

9.1. Grant of Security Interest. As security for the full and timely payment of all amounts which may at any time and from time to time be owed by EMG to the Manager pursuant to this Agreement, EMG hereby grants to the Manager (a) a continuing security interest in all of EMG past, present and future accounts, accounts receivable, contract rights and reimbursement rights (the "General Receivables and Rights"), and (b) the proceeds thereof. . . .

(Exhibit 12, pp. A126, A128.)

SCREENING OF PATIENTS FOR SUPERIOR HEALTH CENTERS TREATMENT

19. In 2019, Superior Health Centers advertised on at least one social media platform, Facebook, offering stem cell injections to relieve pain. Prospective patients attended seminars at a Superior Health Center clinic where they were provided information about the pain-relief benefits of stem cell injections. Respondent was not

involved in the marketing or sales of the regenerative medicine products offered at Superior Health Centers.

20. While at a Superior Health Centers clinic, individual prospective patients completed a New Patient Application. Staff employed by Neuropathy Solutions would recommend treatment options and pricing, obtain non-refundable payment for the product and treatment (sometimes arranging financing through various lenders), and schedule the patients for regenerative medicine treatment. The staff also completed paperwork, including Informed Consent documents, prior to the administration of treatment.

21. The patients returned to a Superior Health Center clinic for treatment on a later date, after the stem cell products had been ordered and shipped to the clinic. An NP would meet with them on that date to administer treatment.

22. Superior Health Centers maintained the treatment records of patients who received regenerative medicine treatment at the clinics.

23. In a December 15, 2021 Board interview, Respondent admitted he did not own Superior Health Centers and he did not know the locations of the clinics.

24. Respondent was never physically present at any of the clinics.

Respondent's Supervision of NP Alexa Benson

25. NP Alexa Benson testified at the administrative hearing in a respectful manner. However, her testimony was at times confused and self-serving, and it lacked credibility on several issues discussed more fully below.

///

26. NP Benson had worked at Superior Health Centers clinics, including the Corona clinic, since September 2018. At that time, she worked for Neuropathy Solutions through a temporary employment contract, under the supervision of a chiropractor, Dr. Straw. NP Benson acknowledged that, as an NP, she is required to have a physician supervisor, and she was not legally permitted to work under the supervision of a chiropractor.

27. No physicians were ever present at Superior Health Centers.

28. Pursuant to the MSA, NP Benson came under Respondent's supervision beginning April 25, 2019. Respondent was the only physician supervising NPs at Superior Health Centers at that time. The NPs were then considered employees of EMG, hired by Respondent in consultation with Neuropathy Solutions. All other Superior Health Centers staff were hired by Neuropathy Solutions and were not EMG employees.

29. NP Benson testified she and Respondent never completed a delegation of services agreement, but it "was something [they] were working on." NP Benson admitted she provided care to patients under Respondent's supervision without a signed delegation of services agreement in place.

30. NP Benson acknowledged she was required to have protocols in place to work under Respondent's supervision. She testified they "created them together," communicating by telephone and emails, and they went through several revisions to arrive at the final protocols. NP Benson testified that it took about four months for them to develop the final protocols.

31. NP Benson admitted that she was providing injections to patients under Respondent's supervision prior to completion of the final protocols.

32. As early as April 9, 2019, employees of Neuropathy Solutions attempted to obtain information from Respondent to enable the NPs to competently perform their duties. In an April 9, 2019 email to Respondent, Jared Solancho forwarded numerous questions NP Benson sought to have Respondent answer as follows:

Hello, Dr. Highshaw, I've spoken with our NP [Benson] and here are the questions and information our Nurse Practitioners will need to competently perform their duties when on-boarding:

What do you want an NP to know?

What is the correct Introduction to Regenerative Medicine?

Who will provide proper training?

What are the protocols for NPs to follow to treat with regenerative medicine?

NP's must have actual protocols or they're not supposed to work in California. - Alexa

What are indications for use/capabilities?

How much does one typically inject into one particular area?

Protocol for each joint/area?

Can we inject 4cc into one area?

What is the minimum amount you can inject for efficacy?

What is the maximum amount you can inject at a time? for one particular area?

What are absolute contraindications with stem-cells?

What type of patients are acceptable for stem-cells?

What do we do when presented with a diabetic toe? Active infection?

What are acute illnesses that we need to look out for?

Your time and knowledge is greatly appreciated, we look forward to hearing from you!

(Exhibit JJ.)

33. There was no evidence of any response from Respondent to Solancho's April 9, 2019 email. Rather, the evidence confirmed NP Benson's admission that, after April 25, 2019, she worked under Respondent's supervision without protocols in place for several months.

34. The lack of properly-documented protocols at Superior Health Centers after April 25, 2019, is corroborated in a May 2019 email exchange regarding the scheduling of patients for penile injections, detailed below.

35. In her September 2021 Board interview, NP Benson noted that Respondent was "hired" and "brought on" to help train NPs to do penile injections for erectile dysfunction (ED). (Exhibit 22, p. A504.) On May 3, 2019, Abby Lowder, Vice President of Operations at Superior Health Centers, emailed NPs research articles regarding the use of stem cell injections for ED. The May 3, 2019 email noted:

Dr. Tony Highshaw, a board certified urologist, has consulted us on the protocol:

1. 8,000,000 - 37,000,000 ADRCs
2. Tourniquet at the base of the penis.
3. Inject into both sides of the corpora cavernosa
4. Leave tourniquet on for 30 minutes.

[Respondent] is available to discuss. His phone is [. . .].

(Exhibit LL, p. B120.)

36. In a May 4, 2019 response to the May 3, 2019 email, a NP complained:

There is no written protocol attached and the suggested protocol that you summarized requires ADRC which we don't have the equipment to obtain. You had also mentioned the addition of an anesthetic which we do not have in the office. Also, what do we tell the patient post procedure? What is he to expect and do at home? I know everyone is excited to start these treatments but until everything is in place (protocols, equipment, etc) this is not safe and doing this on Monday is not possible. I've had this conversation with you before regarding including your NP's in the process so that everything is in place before we start scheduling patients, so I'm disappointed to see that once

again we have a patient scheduled without proper preparation.

(Exhibit LL, p. B120.)

37. On May 4, 2019, Lowder forwarded the NP's email to Eropkin, who forwarded it to Respondent with the following explanation and request:

Can you read below from the message from the NP who is supposed to handle the injection Monday for ED? I sent her everything you had sent me and she is still claiming there is no "protocol" on this. I even sent the text messages you had sent that outlines how to do this.

Do you know what equipment she is referring to so we can get this ordered? We have rescheduled this patient I believe 2x times, so I would like to handle the injection because of this reason!

Any help would be appreciated!

(Exhibit LL, p. B119.)

38. On May 4, 2019, Respondent responded to administrators at Superior Health Centers, "Makes no sense. Same protocol[,] different stem cells. Just need a tourniquet for penis." (Exhibit LL, p. B119.) Respondent did not respond directly to the NP. No written protocols were attached to the email.

///

///

39. Ultimately, NP Benson and Respondent arrived at a protocol for intra-articular injections. At hearing, two protocols entitled "Intra-Articular Protocol" were presented in evidence. One protocol was dated June 19, 2019 (Exhibit 24), and the other was dated October 14, 2019 (Exhibit 30). Their text appeared virtually identical, except for the dates. Neither version of the Intra-Articular Protocol was signed by Respondent or NP Benson.

40. NP Benson identified the June 19, 2019 Intra-Articular Protocol as the "final version." However, there was no indication on the document that it was a final version, as opposed to the virtually identical version dated October 14, 2019. Additionally, a June 13, 2019 email from NP Benson to Respondent indicates their collaboration began on that date and, pursuant to NP Benson's four-month completion estimate, would have yielded final protocols in about October 2019. The June 13, 2019 email specifically stated:

It was a pleasure to finally speak with you! I am pleased to know that you are as academically/research minded as I am. I look forward to collaborating with you to advance the practice of Regenerative Medicine. Protocol template attached[.]

(Exhibits OO, PP.)

41. The clear and convincing evidence established that after Respondent became the supervising physician at Superior Health Centers on April 25, 2019, he did not have final intra-articular injection protocols in place for NP Benson or the other NPs until several months after June 13, 2019. However, the evidence did not establish on what specific date the final intra-articular injection protocols were in place.

42. Under Respondent's supervision, NP Benson was the lead NP at Superior Health Centers, and she was responsible for training new NPs. The Intra-Articular Protocol they created included sections regarding experience, training and evaluation of competency as follows:

Experience, Training and/or education required for the procedure.

1. Nurse Practitioner licensed to practice in the state of California from the Board of Registered Nursing.
2. Prior to first injection, all written and videotaped protocols will be reviewed.

Evaluation of competency

1. NP Orientee will perform three procedures satisfactorily as evaluated by Lead NP or Medical Director prior to independent practice.

Scope of MD supervision

1. This will be determined by competency and comfort of Lead NP.
2. Lead NP will discuss all concerns related to training with the Medical Director.

(Exhibit 24, p. A592; Exhibit 30, p. A713.)

///

43. The Intra-Articular Protocol also contained a section entitled, "Criteria for MD consult," which stated, "1. Consult Lead NP or Medical Director for any questions at any time." (Exhibit 24, p. A595; Exhibit 30, p. A716.) The Intra-Articular Protocol did not set forth any specialized circumstances under which the NPs were to immediately communicate with a patient's physician concerning the patient's condition.

44. The Intra-Articular Protocol did not specify the extent of Respondent's supervision of the NPs, but rather ambiguously allowed the scope of his supervision to "be determined by [NP] competency and [the] comfort of [NP Benson]." (Exhibit 24, p. A592; Exhibit 30, p. A713.) The Intra-Articular Protocol did not specify the method for periodic review of an NP's competence after the initial evaluation of competency.

45. The Intra-Articular Protocol included a list of "Absolute Contraindications" and "Contraindications" (Exhibit 24, pp. A592-A593; Exhibit 30, pp. A713-A714), and provided procedural guidelines for injecting into knees, wrists, elbows, ankles, hips, and shoulders. However, the Intra-Articular Protocol did not indicate for what diagnoses, conditions, or medical indications the injections could be performed.

46. The Intra-Articular Protocol contained a section entitled "Documentation," which provided an exemplar of how to document a procedure as follows:

This is our current documentation guidelines from A21. I can share all of them with you or you can write your own.
"Prepped L knee with chlorhexidine using aseptic technique.
Inserted 27 gauge needle using (lateral/medial)patellar approach, no blood return, injected (name of product here).

Band aid applied. Patient tolerated procedure well. Post injection instructions reviewed, pt verbalized understanding. Follow-up in 2 weeks."

(Exhibit 24, pp. 595-A596; Exhibit 30, pp. A716-A717.)

47. Neither version of the Intra-Articular Protocol required the NP perform a good faith examination of the patient prior to administration of injections, nor did the protocols require documentation of that examination.

48. Neither version of the Intra-Articular Protocol required the NP to obtain and document informed consent from the patient.

49. Neither version of the Intra-Articular Protocol identified which NPs, other than NP Benson, could perform the intra-articular injections.

50. Both the June 19, 2019 and October 14, 2019 Intra-Articular protocols failed to meet all statutory and regulatory requirements for specific items that must be included in protocols. (See Legal Conclusions.)

Treatment of Patient A

51. In 2019, Patient A, a then 72-year-old male had a medical history that included high blood pressure, prior heart attack, and chronic knee pain. At that time, Patient A's wife learned of Superior Health Centers through a Facebook advertisement offering stem cell injections to relieve pain.

52. In September 2019, Patient A and his wife attended a seminar at the Superior Health Centers clinic in Corona. The seminar was conducted by a male who

informed Patient A and his wife that the stem cell injections would make Patient A pain-free.

53. On September 20, 2019, Patient A and his wife returned to the Superior Health Center clinic in Corona to discuss price and treatment options. Patient A completed a Superior Health Centers New Patient Application. He and his wife met with the same male from the seminar who explained that the stem cell treatment he recommended for Patient A's knees would cost \$13,250.00, and he provided Patient A with paperwork to obtain financing.

54. On September 20, 2019, Patient A signed a Superior Health Centers Program Agreement wherein he agreed to pay \$13,250 to Neuropathy Solutions, dba Superior Health Centers, for treatment that included regenerative medicine injections into his left and right knees. During this visit, Patient A applied for and received financing for the full \$13,250 to pay Neuropathy Solutions, dba Superior Health Centers, for product and services. The Superior Health Centers Program Agreement advised Patient A in writing several times that all regenerative injection purchases are custom ordered and are non-refundable. (Exhibit 17, pp. A229, A252.) Patient A was scheduled to return for regenerative medicine injections in both knees.

55. On October 9, 2019, Patient A and his wife arrived at the Superior Health Centers clinic in Corona for his scheduled regenerative medicine injection.

56. At the October 9, 2019 visit, Patient A and his wife met with NP Benson for the first and only time.

57. A document entitled "Informed Consent for Regenerative Medicine Procedures," dated October 9, 2019, was contained in Patient A's medical records from Superior Health Centers. The informed consent document has Patient' A's name

printed on it, but he did not sign it. NP Benson testified it is her custom and practice to discuss the risks and benefits of procedures with patients, but she does not give patients any documents to sign.

58. NP Benson testified that the Superior Health Centers administrators typically scheduled patients for treatment. NP Benson acknowledged that, prior to meeting with a patient, she received no documents indicating the condition for which the patient was receiving the regenerative medicine injections.

59. NP Benson does not know who performed Patient A's initial screening and evaluation or what type of evaluation was conducted on September 20, 2019. She believed a chiropractor typically performed evaluations first and then referred patients to her, and she insisted this is what occurred with Patient A. However, NP Benson's testimony about a prior chiropractic examination of Patient A is not credited because it is contrary to Patient A's and his wife's accounts, and there are no chiropractor notes in Patient A's medical chart from Superior Health Centers.

60. NP Benson maintained that she performed a physical examination on Patient A to see if he "met conditions for getting injections." However, her assertion is not credible. No physical examination is documented in Patient A's chart. Moreover, there was no requirement in the Intra-Articular Protocol that a good faith examination must be performed. Additionally, when Patient A met NP Benson for his scheduled treatment, his \$13,250 payment was non-refundable, and NP Benson did not explain the effect of a physical examination wherein Patient A failed to "meet conditions for getting injections."

61. When asked if she diagnosed Patient A with any condition, NP Benson vaguely responded, "It seemed he had pain in his joints probably related to bone

issues." She did not provide a diagnosis, nor was a diagnosis or medical indication for the knee and shoulder injections documented in Patient A's treatment records. Additionally, the Intra-Articular Protocol does not list the diagnoses, conditions, or medical indications for which intra-articular joint injections in knees and shoulders should be given.

62. On October 9, 2019, NP Benson extracted PRP from Patient A, combined it with stem cell regenerative products, and injected the mixed product into Patient A's left and right knees. NP Benson noticed she had leftover product, and she asked Patient A if he was experiencing pain in any other part of his body. Patient A told NP Benson that his shoulder hurt, and NP Benson injected the remaining product into Patient A's right shoulder.

63. NP Benson's procedure note for Patient A stated only:

First extracted PRP (3cc each syringe), then added 1 cc CoreCyte and .5 cc Polycyte to each syringe for a total of 4.5cc of Regen Med product in two syringes. Next, using aseptic technique, both knees were cleaned and prepped. Applied topical anesthetic (Ethyl Chloride spray) to area. Inserted 27 gauge needle using lateral approach, no blood returned, Injected mixed product as above to each knee. Bandaid applied. Patient tolerated procedure well. Post Injection instructions reviewed, patient verbalized understanding. [follow up] in 2-3 weeks.

(Exhibit 17, p. A259.)

///

64. Patient A's treatment note, signed by NP Benson, contains no documentation of a physical examination, a medical diagnosis or indication for the knee or shoulder injections, or any reference to the additional injection in Patient A's shoulder.

65. Patient A's records from Superior Health Centers contained a document entitled "Tissue Utilization Record," dated October 9, 2019, to document the product and lot numbers used. On that form, NP Benson listed the "procedure site" as: "[bilateral] knees/ [bilateral lower extremities for peripheral neuropathy]/ back / shoulder." (Exhibit 17, p. A263.)

66. Within a few days after receiving the regenerative medicine treatment at Superior Health Centers in Corona, Patient A developed a fever, inability to move his feet, and a burning sensation in his back.

67. On October 14, 2019, Patient A called Superior Health Centers numerous times complaining of pain in his knees. A staff member, Humberto Gomez, spoke to Patient A and advised him "that was expected and to follow the post procedure instructions." (Exhibit 17, p. A265.) Gomez forwarded Patient A's messages to "Dr. Benson to [follow up] with him regarding knee and lack of mobility in the right knee." (*Ibid.*)

68. On October 14, 2019, NP Benson contacted Patient A and spoke to his wife. In Patient A's chart, NP Benson noted Patient A's wife "reported that her husband had been developing worsening pain to the knee along with bilateral swelling and weakness to both lower extremities. She also reported subjective fevers/chills, all symptoms progressively worsening over the weekend (3 days). I instructed her to go to the [Emergency Room (ER)] immediately." (Exhibit 17, p. A264.)

69. On October 14, 2019, Patient A went to the ER at Corona Regional Medical Center for swelling and weakness in both legs. Patient A was later transferred and admitted to Kaiser Permanente hospital in Riverside for several weeks. Patient A's hospital diagnoses included septic shock, paraplegia, rhabdomyolysis (a breakdown of muscle tissue that releases damaging protein into blood), acute infective arthritis, spinal epidural abscess, and bacterial arthritis of right knee. Patient A was eventually discharged to a skilled nursing facility.

70. On October 15, 2019, at 10:37 a.m., an unidentified staff member at Superior Health Centers noted in Patient A's chart: "Dr. Ong from Kaiser called concerned about [Patient A]. He stated that [the patient] was severely swollen and had no mobility from his knee down. He gave his personal line [. . .] to get questions answered about side [e]ffects. I sent text to [NP Benson] after the phone call to call the doctor back." (Exhibit 17, p. A265.)

71. On October 15, 2019, NP Benson spoke to Dr. Ong. NP Benson noted in Patient A's chart:

[I] spoke with her [*sic*] admitting doctor MD Ong. He requested information on what procedure [Patient A] had received. I informed him that we gave [Patient A] a Predictive Biotech product called CoreCyte that contains stem cells, anti-inflammatory, and growth factors. He informed me that the [patient] was in acute renal failure and possible heart failure and asked if I had seen any side effects with this medication and I reported that I had not seen such effects after injecting this product for the last 8

months and that Predictive Biotech had not reported any serious adverse effects (SAE's) to date.

(Exhibit 17, p. A264.)

72. NP Benson did not call Respondent to inform him about Patient A's complaints (pain, swelling, weakness, fever, chills), her referral of Patient A to the ER, or her conversation with Dr. Ong regarding Patient A's lack of mobility, acute renal failure, and possible heart failure. NP Benson acknowledged the protocols do not indicate when to call a supervising physician, and she noted, "You have to use common sense."

73. Respondent was ultimately informed of Patient A's hospitalization when he "got a call from someone at the clinic and talked to [Reign] and [then to NP Benson]." Respondent testified he "would have liked to be called when the patient initially reported pain." However, he acknowledged the protocols do not specify that NPs must contact the supervising physician when patients call complaining of pain or other concerning symptoms.

Expert Testimony

74. Complainant offered the testimony of Elizabeth Romero, M.D., to establish the standard of care in this case. Dr. Romero received her medical degree from the University of Rochester School of Medicine in 1992. Dr. Romero is licensed to practice medicine in California and has been a medical expert reviewer for the Board for several years. She is board certified in family medicine, and she has practiced primary care, naturopathic, and regenerative medicine.

///

75. Dr. Romero defined "regenerative medicine," as medicine that uses stem cells and other products for regenerating human plasma to repair cartilage or skin or for improving the potential for rapid healing. It is a form of alternative or complementary medicine.

76. Dr. Romero provided an expert report setting forth her opinions about Respondent's supervision of NPs and NP Benson's care and treatment of Patient A. That report was admitted into evidence at the hearing, and Dr. Romero testified in general conformity with her report. She testified generally that Respondent's protocols were insufficient to provide for proper supervision of an NP.

77. Dr. Romero noted that the standard of care for physician supervision of NPs requires NPs to have standardized protocols in place prior to the NPs being authorized to practice medicine. Additionally, the physician and NPs must comply with all laws and regulations governing the practice of medicine and nursing.

78. Dr. Romero also noted regenerative medicine treatment may be provided to a patient only "after informed consent and a good faith prior examination of the patient, and medical indication exists for the treatment[.]" (Bus. & Prof. Code, § 2234.1, subd. (1).)

79. A good faith examination consists of obtaining a patient medical history and examining the area on which the practitioner intends to perform the procedure. This ensures the treatment can be safely provided.

80. The standard of care requires the history and physical be documented in the patient's chart.

///

81. Dr. Romero found Respondent committed an extreme departure from the standard of care in supervising NP Benson's treatment of Patient A. In her report, Dr. Benson wrote:

There was an extreme departure from the standard of care for the regenerative medicine therapy provided to [Patient A] for not performing a good faith medical examination and the lack of a documented medical indication, prior to the administration of the regenerative medicine therapy on both of his knees, shoulder and back as required by the California Business and Professions Code 2234.1.

(Exhibit 26, p. A631.)

82. Dr. Romero understands that Respondent did not provide the direct patient care to Patient A. However, she opined that Respondent, through his deficient supervision of NP Benson, committed an extreme departure from the standard of care for providing alternative or complementary medicine without a good faith examination or documented medical indication. Dr. Benson noted that a supervising physician is responsible for the circumstances under which NPs provide care, and NP Benson could only practice medicine as specified in established protocols. Those protocols should include the criteria for providing alternative or complementary medicine under Business and Professions Code section 2234.1. The Intra-Articular Protocol did not outline the requirements of a good faith examination or specified medical indication before performing regenerative treatment on patients. Respondent was required to have complete protocols in place, and the protocols under which NP Benson were working were deficient; thus, Respondent's supervision of NP Benson was deficient. Therefore, Respondent committed an extreme departure from the standard of care by

failing to have complete protocols in place, resulting in injections to Patient A's knees and shoulder without a prior good faith examination and no documented medical indications.

83. Dr. Romero also opined that Respondent committed several simple departures from the standard of care regarding Patient A's treatment.

84. Dr. Romero credibly noted that Respondent, through deficient protocols, failed to require NP Benson obtain informed consent prior to the shoulder injection. According to Dr. Romero, NP Benson's provision of the additional shoulder injection, without obtaining and documenting informed consent, is attributable to Respondent's improper supervision. In her report, Dr. Romero wrote, "There was a simple departure from the standard of care for the regenerative medicine therapy provided to [Patient A's] shoulder and back for not providing an informed consent specific to these areas." (Exhibit 26, p. A631.) Dr. Romero opined the general informed consent form found in Patient A's file (even if it had been signed) was insufficient to obtain informed consent for the shoulder injections. It does not specify the procedure, medical indication, or potential complications. Consequently, Respondent committed a simple departure from the standard of care regarding this deficiency.

85. Dr. Romero also opined that Respondent committed a simple departure from the standard of care in failing to require documentation of the shoulder injection in a separate procedure note. She opined the lack of an additional procedure note for Patient A's shoulder injection was attributable to Respondent's improper supervision. However, this opinion is not persuasive. The Intra-Articular Protocol provides for documentation of procedures and includes an exemplar for how to document the provision of injections. NP Benson did not follow the established protocol of

documenting procedures. Consequently, this simple departure from the standard of care was not established by clear and convincing evidence.

86. Dr. Romero also opined that Respondent committed several simple departures from the standard of care in his general supervision of NPs.

87. Dr. Romero opined credibly that the lack of specific medical indications (rather than only listed contraindications) for the procedures listed in the Intra-Articular Protocol constitutes a simple departure from the standard of care. Business and Professions Code section 2836.1 specifies that a protocol must specify under what circumstances an NP may furnish drugs or services.

88. Dr. Romero opined credibly that the lack of a delegation of services agreement between Respondent and the NPs at Superior Health Centers constitutes a simple departure from the standard of care.

89. Dr. Romero also opined credibly, "The lack of evidence that [Respondent] had performed a periodic review of the [NP's] competence, including peer review and review of the provisions of the standard procedures of the clinic constitute a simple departure [from the standard of care]." (Exhibit 26, p. A632.) This opinion was established by clear and convincing evidence. The Intra-Articular Protocol indicated that an NP was initially evaluated for competency by performing three procedures satisfactorily as evaluated by NP Benson or Respondent. Thereafter, the "Scope of MD supervision" was "determined by competency and comfort of Lead NP." There was no provision for Respondent's periodic review of NP competence in 2019, either in the Intra-Articular Protocol or in other evidence submitted at hearing.

///

Respondent's Testimony

90. Respondent testified at the administrative hearing in a respectful and professional manner. His testimony was generally credible except as noted below.

SUPERVISION OF NPs

91. Respondent agreed that NP Benson's chart notes for Patient A did not contain documentation of a good faith examination or a diagnosis or medical indication for the injections. He admitted NP Benson's documentation was insufficient.

92. According to Respondent, the NPs at Superior Health Centers were responsible for evaluating patients, reviewing informed consents, injecting the patients with PRP and stem cells, and following up with phone calls to patients. Respondent acknowledged part of his duty as Medical Director of the Superior Health Centers clinics was to prepare standardized protocols for the NPs and that the NPs could not practice medicine autonomously. He did not adequately explain why the Intra-Articular Protocol failed to specify that the NPs must conduct a good faith examination, determine a medical indication, and provide informed consent before injecting patients.

93. Respondent acknowledged patients were sold non-refundable treatment prior to meeting with the NPs. Respondent denied that any unlicensed Neuropathy Solutions staff referred patients to the NPs for injections. He noted that the non-clinical staff scheduled the patients to see the NPs, but they did not do any good faith examinations or clinical diagnoses. He testified patients were referred through a chiropractor or other health professional who conducted a prior history and physical on patients. This testimony differs from Respondent's admission in his December 15, 2021 Board interview that he did not know "how patients are referred to [the clinics, or]

how the patients come into the clinic." However, Respondent had surmised, "They basically come through [an] alternative [medicine] doc[tor] or whatever -- the chiropractic doctors, I presume." (Exhibit 23, pp. A567-A568.) Nevertheless, Respondent's presumption is not corroborated by the evidence. Moreover, a prior physical examination by an outside provider does not eliminate the statutory requirement for the provider of regenerative medicine to conduct the good faith examination.

94. Respondent testified he does not know who was responsible for going over the informed consent forms with patients. However, he admitted previously signing a declaration under penalty of perjury wherein he stated, "Employees of Neuropathy Solutions were also actively involved in obtaining completed paperwork prior to the preparation for and performance of the injections of regenerative medicine products into patients. Such paperwork included the completion of Informed Consent documents by the patient prior to the injections." (Exhibit 32, p. A756.)

CORPORATE PRACTICE OF MEDICINE

95. Respondent admitted he violated the law governing the corporate practice of medicine when he entered into the contractual relationship with Reign and Neuropathy Solutions.

96. Respondent insisted he did not intend to violate the law. He became involved with Neuropathy Solutions when Reign, a trusted friend, approached him to become Medical Director of her clinics. At that point, Respondent was practicing medicine in Florida. Respondent knew Reign owned Neuropathy Solutions and that she operated wellness clinics called Superior Health Centers where patients received

regenerative injections. When Reign asked if he would be willing to serve as Medical Director for Superior Health Centers, he agreed.

97. He created EMG at Reign's urging. Although Respondent did not understand the need to form a separate corporation to serve as Medical Director for Reign's company, Reign informed him this was the correct process. He trusted her and followed her advice. He did not consult the Board's website before creating EMG.

98. Respondent had his Florida attorney review the MSA, and the attorney noted nothing illegal. However, Respondent has since learned that the "corporate practice of medicine in California is bad" because the physician "is supposed to evaluate patients without being influenced by another entity." Respondent testified that, if he previously had this knowledge, he would not have entered into the contractual agreement with Reign.

99. In December 2022, Respondent completed a course entitled, "Corporate Practice of Medicine and Fee-Splitting: Ensuring Compliance with the Prohibitions, Leveraging Exceptions." (Exhibits NNN, YYY.)

100. Respondent never applied for a fictitious name permit for EMG.

101. Respondent no longer owns EMG. He sold the practice for \$2,000 in October or November 2021. He did not want to be attached to the corporation after settling the lawsuit brought by Patient A.

FUTURE PLANS

102. Respondent lives and practices medicine in Florida. When asked if he planned to return to work in California, Respondent stated, "Yes. This is my home." He acknowledged he has not lived in California since 2013, and any return to California is

subject to a discussion with his wife. Respondent confirmed that, if placed on probation, he intended to return to California to practice as a urologist. However, he later testified that, since he owns a home in Florida, and his wife and children live in Florida, he has no plans to return to California to practice medicine.

Character Evidence

103. Respondent has the support of colleagues and patients who submitted reference letters on his behalf. The letter writers met Respondent through his urology practice, and they collectively described Respondent as dedicated, compassionate, responsible, professional, and courteous.

Costs

104. Complainant submitted the Declaration of Deputy Attorney General Karolyn Westfall (DAG) as evidence of the costs of prosecution in this matter. The DAG's declaration indicates the Department of Justice, Office of the Attorney General, billed the Board \$39,190 in prosecution costs through September 21, 2023.

105. Respondent presented no evidence regarding ability to pay costs.

LEGAL CONCLUSIONS

Relevant Law

STANDARD OF PROOF

1. The standard of proof which must be met to establish the charging allegations is "clear and convincing evidence." (*Ettinger v. Board of Medical Quality*

Assurance (1982) 135 Cal.App.3d 853, 856.) This means the burden rests on Complainant to establish the charging allegations by proof that is clear, explicit, and unequivocal--so clear as to leave no substantial doubt and sufficiently strong to command the unhesitating assent of every reasonable mind. (*Katie V. v. Superior Court* (2005) 130 Cal.App.4th 586, 594.)

UNPROFESSIONAL CONDUCT, GROSS NEGLIGENCE, REPEATED NEGLIGENCE

2. The Board has the authority to revoke or suspend a physician's license for engaging in unprofessional conduct. (Bus. & Prof. Code, §§ 2004, 2234.) Unprofessional conduct includes "violating or attempting to violate, directly or indirectly, assisting in or aiding and abetting the violation of, or conspiring to violate any provision of this chapter" (Bus. & Prof. Code, § 2234, subd. (a)); gross negligence (Bus. & Prof. Code, § 2234, subd. (b)); and repeated negligent acts (Bus. & Prof. Code, § 2234, subd. (c)).

3. Gross negligence is defined as "the want of even scant care or an extreme departure from the ordinary standard of conduct." (*Gore v. Board of Medical Quality Assurance* (1980) 110 Cal.App.3d 184, 196-197.)

4. "In order to be subject to discipline for unprofessional conduct, [a physician] must have demonstrated an unfitness to practice medicine by conduct which breaches the rules or ethical code of his profession or conduct which is unbecoming to a member in good standing of that profession." (*Shea v. Board of Medical Examiners* (1978) 81 Cal.App.3d 564, 578.)

///

///

///

MAINTAINING ADEQUATE AND ACCURATE RECORDS

5. Business and Professions Code section 2266 provides, "The failure of a physician and surgeon to maintain adequate and accurate records relating to the provision of services to their patients constitutes unprofessional conduct."

REGENERATIVE MEDICINE

6. Business and Professions Code section 2234.1 provides, in pertinent part:

(a) A physician and surgeon shall not be subject to discipline pursuant to subdivision (b), (c), or (d) of Section 2234 solely on the basis that the treatment or advice he or she rendered to a patient is alternative or complementary medicine, including the treatment of persistent Lyme Disease, if that treatment or advice meets all of the following requirements:

(1) It is provided after informed consent and a good-faith prior examination of the patient, and medical indication exists for the treatment or advice, or it is provided for health or well-being.

(2) It is provided after the physician and surgeon has given the patient information concerning conventional treatment and describing the education, experience, and credentials of the physician and surgeon related to the alternative or complementary medicine that he or she practices.

///

(3) In the case of alternative or complementary medicine, it does not cause a delay in, or discourage traditional diagnosis of, a condition of the patient.

(4) It does not cause death or serious bodily injury to the patient.

(b) For purposes of this section, "alternative or complementary medicine," means those health care methods of diagnosis, treatment, or healing that are not generally used but that provide a reasonable potential for therapeutic gain in a patient's medical condition that is not outweighed by the risk of the health care method.

UNLICENSED PRACTICE

7. Business and Professions Code section 2051 defines the licensed practice of medicine as follows:

The physician's and surgeon's certificate authorizes the holder to use drugs or devices in or upon human beings and to sever or penetrate the tissues of human beings and to use any and all other methods in the treatment of diseases, injuries, deformities, and other physical and mental conditions.

8. Business and Professions Code section 2052, subdivision (a), describes the unlicensed practice of medicine as follows:

///

[A]ny person who practices or attempts to practice, . . . any system or mode of treating the sick or afflicted in this state, or who diagnoses, treats, operates for, or prescribes for any ailment, blemish, deformity, disease, disfigurement, disorder, injury, or other physical or mental condition of any person, without having at the time of so doing a valid, unrevoked, or unsuspended [medical license] or without being authorized to perform the act pursuant to a certificate obtained in accordance with some other provision of law is guilty of a public offense. . . .

9. Business and Professions Code section 2264 provides:

The employing, directly or indirectly, the aiding, or the abetting of any unlicensed person or any suspended, revoked, or unlicensed practitioner to engage in the practice of medicine or any other mode of treating the sick or afflicted which requires a license to practice constitutes unprofessional conduct.

NURSE PRACTITIONER SUPERVISION AND PRACTICE

10. Business and Professions Code section 2836.1 provides, in pertinent part:

Neither this chapter nor any other provision of law shall be construed to prohibit a nurse practitioner from furnishing or ordering drugs or devices when all of the following apply:

(a) The drugs or devices are furnished or ordered by a nurse practitioner in accordance with standardized procedures or protocols developed by the nurse practitioner and the supervising physician and surgeon when the drugs or devices furnished or ordered are consistent with the practitioner's educational preparation or for which clinical competency has been established and maintained.

(b) The nurse practitioner is functioning pursuant to standardized procedure, as defined by Section 2725, or protocol. The standardized procedure or protocol shall be developed and approved by the supervising physician and surgeon, the nurse practitioner, and the facility administrator or the designee.

(c)(1) The standardized procedure or protocol covering the furnishing of drugs or devices shall specify which nurse practitioners may furnish or order drugs or devices, which drugs or devices may be furnished or ordered, under what circumstances, the extent of physician and surgeon supervision, the method of periodic review of the nurse practitioner's competence, including peer review, and review of the provisions of the standardized procedure. [1]

(d) The furnishing or ordering of drugs or devices by a nurse practitioner occurs under physician and surgeon supervision. Physician and surgeon supervision shall not be construed to require the physical presence of the physician,

but does include (1) collaboration on the development of the standardized procedure, (2) approval of the standardized procedure, and (3) availability by telephonic contact at the time of patient examination by the nurse practitioner.

11. California Code of Regulations, title 16, section 1474 provides:

Following are the standardized procedure guidelines jointly promulgated by the Medical Board of California and by the Board of Registered Nursing:

(a) Standardized procedures shall include a written description of the method used in developing and approving them and any revision thereof.

(b) Each standardized procedure shall:

(1) Be in writing, dated and signed by the organized health care system personnel authorized to approve it.

(2) Specify which standardized procedure functions registered nurses may perform and under what circumstances.

(3) State any specific requirements which are to be followed by registered nurses in performing particular standardized procedure functions.

///

- (4) Specify any experience, training, and/or education requirements for performance of standardized procedure functions.
- (5) Establish a method for initial and continuing evaluation of the competence of those registered nurses authorized to perform standardized procedure functions.
- (6) Provide for a method of maintaining a written record of those persons authorized to perform standardized procedure functions.
- (7) Specify the scope of supervision required for performance of standardized procedure functions, for example, immediate supervision by a physician.
- (8) Set forth any specialized circumstances under which the registered nurse is to immediately communicate with a patient's physician concerning the patient's condition.
- (9) State the limitations on settings, if any, in which standardized procedure functions may be performed.
- (10) Specify patient record keeping requirements.
- (11) Provide for a method of periodic review of the standardized procedures.

///

///

MEDICAL CORPORATIONS AND MOSCONE-KNOX ACT

12. Business and Professions Code section 2400 states, in pertinent part: “Corporations and other artificial legal entities shall have no professional rights, privileges, or powers[.]” However, the provisions of Business and Professions Code section 2400 do not apply to a medical corporation:

practicing pursuant to the Moscone-Knox Professional Corporation Act [(Moscone-Knox Act), found at Corporations Code section 13400 et. seq.], when such corporation is in compliance with the [Moscone-Knox Act] and all other statutes and regulations . . . pertaining to such corporations and the conduct of their affairs.

(Bus. & Prof. Code, § 2402.)

13. Additionally, Business and Professions Code section 2406 allows for the formation of medical corporations to render medical services as authorized by the Moscone-Knox Act. Specifically:

A medical corporation . . . is a corporation that is authorized to render professional services, as defined in Section 13401 of the Corporations Code, so long as that corporation and its shareholders, officers, directors, and employees rendering professional services who are physicians and surgeons, psychologists, registered nurses, optometrists, podiatrists, chiropractors, acupuncturists, naturopathic doctors, physical therapists, occupational therapists, . . . physician assistants, marriage and family therapists, clinical

counselors, or clinical social workers, are in compliance with the [Moscone-Knox Act], the provisions of this article, and all other statutes and regulations . . . pertaining to the corporation and the conduct of its affairs.

With respect to a medical corporation . . . , the governmental agency referred to in the Moscone-Knox Professional Corporation Act is the board.

14. "Professional services" means "any type of professional services that may be authorized pursuant to a license, certification, or registration authorized by the Business and Professions Code." (Corp. Code, § 13401, subd, (a).)

15. Corporations Code section 13401.5, subdivision (a), allows specified non-physician licensed professionals (including podiatrists, chiropractors, registered nurses, acupuncturists, physician assistants) to be shareholders, officers, directors, or licensed employees of a medical corporation "so long as the sum of all shares owned by those licensed persons does not exceed 49 percent of the total number of shares of the [medical corporation], and so long as the number of those licensed persons owning shares in the [medical corporation] does not exceed the number of persons licensed by the [Board]."

16. Corporations Code section 13408.5 provides that a medical corporation "shall not be formed so as to cause any violation of law."

17. Business and Professions Code section 2286 provides:

It shall constitute unprofessional conduct for any licensee to violate, to attempt to violate, directly or indirectly, to assist

in or abet the violation of, or to conspire to violate any provision or term of Article 18 (commencing with Section 2400), of the Moscone-Knox Professional Corporation Act (Part 4 commencing with Section 13400) of Division 3 of Title I of the Corporations Code), or of any rules and regulations duly adopted under those laws.

18. Business and Professions Code section 2410 prohibits a medical corporation from engaging in unprofessional conduct and requires the medical corporation to "observe and be bound by such statutes and regulations to the same extent as a licensee under this chapter."

FICTITIOUS NAME PERMIT

19. Business and Professions Code section 2415, subdivision (a), requires a physician and surgeon who wishes to practice under a fictitious name "as a sole propriety, or in a partnership, group, or professional corporation," to obtain a fictitious name permit from the Board.

20. Business and Professions Code section 2285 provides, in pertinent part:

The use of any fictitious, false, or assumed name, or any name other than his or her own by a licensee either alone, in conjunction with a partnership or group, or as the name of a professional corporation, in any public communication, advertisement, sign, or announcement of his or her practice without a fictitious-name permit obtained pursuant to Section 2415 constitutes unprofessional conduct.

Causes for Discipline

FIRST CAUSE FOR DISCIPLINE (AIDING AND ABETTING THE UNLICENSED PRACTICE OF MEDICINE BY AN NP)

21. NPs cannot practice medicine autonomously, and thus, NP Benson could only practice medicine as specified in established protocols. Under the MSA, on April 25, 2019, Respondent took over as Medical Director of five Superior Health Centers clinics, and he was the only physician supervising NPs at Superior Health Centers at that time. Respondent did not have completed protocols in place from April 25, 2019, until after June 13, 2019. NP Benson admitted that she was providing injections to patients under Respondent's supervision prior to completion of the protocols. Consequently, Respondent aided and abetted the unlicensed practice of medicine by an NP under his supervision from April 25, 2019, until the completion of the required protocols after June 13, 2019.

22. Cause exists to revoke or suspend Respondent's physician's and surgeon's certificate, pursuant to Business and Professions Code sections 2227, 2234, subdivision (a), 2052, 2264, and 2836.1, of the Code, and California Code of Regulations, title 16, sections 1379, 1471, and 1472, in that he aided and abetted the unlicensed practice of medicine by NP Benson, by supervising a nurse practitioner who was providing regenerative medicine treatment without having sufficient standardized procedures or protocols in place. (Factual Findings 3 through 89.)

SECOND CAUSE FOR DISCIPLINE (GROSS NEGLIGENCE)

23. A supervising physician is responsible for the circumstances under which NPs provide care, and NP Benson could only practice medicine as specified in

established protocols. Those protocols should include the criteria for providing alternative or complementary medicine under Business and Professions Code section 2234.1. However, the Intra-Articular Protocol did not outline the requirements of a good faith examination or specified medical indication before performing regenerative treatment on patients. Respondent was required to have complete protocols in place, and the protocols under which NP Benson were working were deficient; thus, Respondent's supervision of NP Benson was deficient. Therefore, Respondent committed an extreme departure from the standard of care by failing to have complete protocols in place, resulting in injections to Patient A's knees and shoulder without a prior good faith examination and no documented medical indications.

24. Cause exists to revoke or suspend Respondent's physician's and surgeon's certificate, pursuant to Business and Professions Code sections 2227, 2234, subdivision (b), 2234.1, and 2836.1, and California Code of Regulations, title 16, sections 1379, 1471, and 1472, for his gross negligence in the complementary treatment of Patient A, through his deficient supervision of NP Benson in failing to have sufficient protocols in place, including requiring performance of a good faith examination and documented medical indication for the treatment. (Factual Findings 3 through 89.)

THIRD CAUSE FOR DISCIPLINE (REPEATED NEGLIGENT ACTS)

25. In addition to failing to require a good faith examination and documented medical indication for treatment, Respondent's protocols also failed to specify that informed consent must be obtained prior to treatment. The protocols further failed to specify under what circumstances an NP may furnish drugs or services. Additionally, Respondent failed to provide for a periodic review of an NP's competence. The Intra-Articular Protocol indicated that an NP was initially evaluated

for competency by performing three procedures satisfactorily as evaluated by NP Benson or Respondent. Thereafter, the "Scope of MD supervision" was "determined by competency and comfort of [NP Benson]." There was no provision for Respondent's periodic review of NP Benson's or any other NP's competence in 2019.

26. Cause exists to revoke or suspend Respondent's physician's and surgeon's certificate, pursuant to Business and Professions Code sections 2227, 2234, subdivision (c), 2234.1, and 2836.1, and California Code of Regulations, title 16, sections 1379, 1471, and 1472, for his repeated negligent acts in the complementary treatment of Patient A, through his deficient supervision of NP Benson in failing to have sufficient protocols in place, including requiring performance of a good faith examination, documented medical indication for the treatment, and informed consent before treatment, specifying under what circumstances an NP may furnish drugs or services, and providing for a periodic review of an NP's competence. (Factual Findings 3 through 89.)

FOURTH CAUSE FOR DISCIPLINE (FAILURE TO MAINTAIN ADEQUATE AND ACCURATE RECORDS)

27. Respondent admitted that NP Benson's documentation of Patient A's treatment was deficient. As her supervisor, Respondent was responsible for requiring adequate and accurate documentation in patients' records. In this case, the Intra-Articular Protocol failed to require, and Patient A's records lacked, documented performance of a good faith examination, medical indication for the treatment, and informed consent before treatment to Patient A's shoulder.

28. Cause exists to revoke or suspend Respondent's physician's and surgeon's certificate, pursuant to Business and Professions Code sections 2227, 2234,

2266, and 2836.1, and California Code of Regulations, title 16, sections 1379, 1471, and 1472, in that Respondent, through his deficient supervision of NP Benson, failed to maintain adequate and accurate records regarding his care and treatment of Patient A. (Factual Findings 3 through 89.)

FIFTH CAUSE FOR DISCIPLINE (AIDING AND ABETTING THE UNLICENSED PRACTICE OF MEDICINE BY NEUROPATHY SOLUTIONS)

29. Neuropathy Solutions had been operating Superior Health Centers clinics and providing medical services prior to Respondent's or any other physician's involvement. Although it purportedly provided "management services," Neuropathy Solutions was not hired to provide administrative staff for Respondent's own medical practice. Rather, Respondent was paid \$1,500 per month to act as "Medical Director" of clinics owned and operated by Neuropathy Solutions, to provide the supervisory status as physician, and thus enable the NPs at Superior Health Centers to practice medicine under protocols. Respondent never saw patients and never visited the clinics. Additionally, although Respondent formed a "separate" corporation to provide NP services, EMG had the same address and agent for process as Neuropathy Solutions.

30. Neither Respondent nor EMG owned the clinics for which he was "Medical Director." Neuropathy Solutions, a corporation comprised solely of non-physicians, owned and operated Superior Health Centers, a business that offered patient evaluations and medical treatment. Neuropathy Solutions advertised and made management decisions for Superior Health Centers. Neuropathy Solutions owned and maintained the patients' medical records, when the records should have been retained by Respondent, a licensed physician. Neuropathy Solutions selected and maintained ownership of the medical equipment and medical supplies at Superior Health Centers. Neuropathy Solutions controlled the hiring and firing of all clinic staff except the NPs

whom Respondent hired in consultation with Neuropathy Solutions. Consequently, a non-physician owned corporation illegally controlled Respondent's practice of medicine at Superior Health Centers.

31. Cause exists to revoke or suspend Respondent's physician's and surgeon's certificate, pursuant to Business and Professions Code sections 2227, 2234, subdivision (a), 2052, subdivision (b), 2264, 2400, and 2410, in that Respondent aided and abetted the unlicensed practice of medicine by Neuropathy Solutions and Vivienne Reign, by entering into an agreement with and/or allowing the lay corporation Neuropathy Services, dba Superior Health Centers, to exert authority and control over his medical practice, EMG. (Factual Findings 3 through 101.)

SIXTH CAUSE FOR DISCIPLINE (VIOLATION OF MOSCONE-KNOX PROFESSIONAL CORPORATIONS ACT AND/OR CORPORATE PRACTICE OF MEDICINE BAN)

32. Cause exists to revoke or suspend Respondent's physician's and surgeon's certificate, pursuant to Business and Professions Code sections 2227, 2234, subdivision (a), 2286, 2400, 2402, 2406, and 2410, Corporations Code sections 13401 and 13408.5, and California Code of Regulations, title 16, sections 1343 and 1347, in that Respondent violated, directly or indirectly, and assisted in or abetted the violation of the Moscone-Knox Professional Corporation Act and the ban on the corporate practice of medicine by entering into an agreement with and allowing the lay corporation Neuropathy Services, dba Superior Health Centers, to exert authority and control over his medical practice, EMG. (Factual Findings 3 through 101.)

///

///

SEVENTH CAUSE FOR DISCIPLINE (USE OF FICTITIOUS NAME WITHOUT FICTITIOUS NAME PERMIT)

33. Cause exists to revoke or suspend Respondent's physician's and surgeon's certificate, pursuant to Business and Professions Code sections 2227, 2234, 2285, 2415, and 2410, and California Code of Regulations, title 16, sections 1344, 1347, and 1350.2, in that Respondent practiced medicine under the name Elite Medical Group, PC, and Superior Health Centers, without obtaining a fictitious-name permit. (Factual Findings 3 through 101.)

EIGHTH CAUSE FOR DISCIPLINE (GENERAL UNPROFESSIONAL CONDUCT)

34. As demonstrated by his violations set forth above, Respondent committed unprofessional conduct as defined by the Business and Professions Code and thus engaged in conduct which breached the rules of the medical profession.

35. Cause exists to revoke or suspend Respondent's physician's and surgeon's certificate, pursuant to Business and Professions Code sections 2227, 2234, and 2410, and Corporations Code section 13410, in that Respondent engaged in unprofessional conduct. (Factual Findings 3 through 101.)

Analysis re: Appropriate Discipline

36. Complainant established that in 2019, Respondent aided and abetted the unlicensed practice of medicine, violated the Moscone-Knox Act, and committed gross negligence and repeated negligent acts due to his deficient NP protocols. The remaining question is the nature of the discipline to be imposed against Respondent's certificate for his violations.

///

37. To determine the appropriate level of discipline, the Board considers factors set forth in statutes and regulations. Typically, the Board will consider factors to determine rehabilitation, including the nature and severity of the offenses, total criminal record, time elapsed since the offenses, compliance with terms of parole, probation, or restitution, and any evidence of rehabilitation submitted by the licensee. (Cal. Code Regs., tit. 16, § 1360.1; Bus. & Prof. Code, § 2229.) The Board will also look to the "Manual of Model Disciplinary Orders and Disciplinary Guidelines," 12th Edition/2016 (Guidelines) to determine the appropriate discipline. (Cal. Code Regs., tit. 16, § 1361.) Disciplinary actions can include license revocation, suspension, probation, or public reprimand. (Bus. & Prof. Code, § 2227.)

38. Respondent's aiding and abetting the unlicensed practice of medicine, gross negligence, and other violations stemmed from his lax approach to supervising a medical practice in 2019. In joining Neuropathy Solutions, Respondent allowed a lay corporation to control his practice of medicine. He was a supporting actor who never visited the clinics and was only peripherally involved in patient care through the delayed protocols and periodic chart review. This superficial approach to the practice of medicine created the risk of great harm to patients.

39. However, Respondent has been practicing medicine for decades without discipline, and his current violations appear limited to a specific origin and time. Respondent no longer owns EMG, and he is no longer involved with Neuropathy Solutions or Superior Health Centers. He has acknowledged his violations. Consequently, outright revocation is not warranted. A period of probation with education courses, a medical recordkeeping course, and an ethics course will provide adequate public protection while assisting in Respondent's rehabilitation.

///

Costs

40. Pursuant to Business and Professions Code section 125.3, Complainant is entitled to recover the reasonable costs of enforcement of this matter. Complainant has incurred reasonable costs in the amount of \$39,190, as set forth in Factual Findings 104-105.

41. To ensure that cost awards do not deter licentiates with potentially meritorious claims or defenses from exercising their right to a hearing, the Board must use its discretion to reduce or eliminate costs by considering the following factors: the licentiate's ability to obtain dismissal or reduction of the charges; the licentiate's subjective good faith belief in the merits of his or her position; whether the licentiate raised a colorable challenge to the proposed discipline; the licentiate's financial ability to pay; and whether the scope of the investigation was appropriate in light of the alleged misconduct. (*Zuckerman v. State Board of Chiropractic Examiners (Zuckerman)* (2002) 29 Cal.4th 32, 45.)

42. Considering all of the *Zuckerman* factors, there is no basis for reducing the award of Complainant's reasonable costs. In this case, Complainant established all causes for discipline against Respondent, and Respondent has provided no evidence of inability to pay. Consequently, Respondent shall be required to pay the costs of enforcement of this matter in the amount of \$39,190.

ORDER

Physician's and Surgeon's Certificate Number A56419, issued to Respondent, Ralph Anthony Highshaw, M.D., is revoked. However, the revocation is stayed, and

Respondent is placed on probation for five years upon the following terms and conditions.

1. Notification

Within seven days of the effective date of this Decision, Respondent shall provide a true copy of this Decision and Accusation to the Chief of Staff or the Chief Executive Officer at every hospital where privileges or membership are extended to Respondent, at any other facility where Respondent engages in the practice of medicine, including all physician and locum tenens registries or other similar agencies, and to the Chief Executive Officer at every insurance carrier which extends malpractice insurance coverage to Respondent. Respondent shall submit proof of compliance to the Board or its designee within 15 calendar days.

This condition shall apply to any change(s) in hospitals, other facilities or insurance carrier.

2. Obey All Laws

Respondent shall obey all federal, state and local laws, all rules governing the practice of medicine in California and remain in full compliance with any court ordered criminal probation, payments, and other orders.

3. Quarterly Declarations

Respondent shall submit quarterly declarations under penalty of perjury on forms provided by the Board, stating whether there has been compliance with all the conditions of probation.

Respondent shall submit quarterly declarations not later than 10 calendar days after the end of the preceding quarter.

4. General Probation Requirements

Compliance with Probation Unit

Respondent shall comply with the Board's probation unit.

Address Changes

Respondent shall, at all times, keep the Board informed of Respondent's business and residence addresses, email address (if available), and telephone number. Changes of such addresses shall be immediately communicated in writing to the Board or its designee. Under no circumstances shall a post office box serve as an address of record, except as allowed by Business and Professions Code section 2021, subdivision (b).

Place of Practice

Respondent shall not engage in the practice of medicine in Respondent's or patient's place of residence, unless the patient resides in a skilled nursing facility or other similar licensed facility.

License Renewal

Respondent shall maintain a current and renewed California physician's and surgeon's license.

Travel or Residence Outside California

Respondent shall immediately inform the Board or its designee, in writing, of travel to any areas outside the jurisdiction of California which lasts, or is contemplated to last, more than 30 calendar days.

In the event Respondent should leave the State of California to reside or to practice Respondent shall notify the Board or its designee in writing 30 calendar days prior to the dates of departure and return.

5. Interview with the Board or its Designee

Respondent shall be available in person upon request for interviews either at Respondent's place of business or at the probation unit office, with or without prior notice throughout the term of probation.

6. Non-practice While on Probation

Respondent shall notify the Board or its designee in writing within 15 calendar days of any periods of non-practice lasting more than 30 calendar days and within 15 calendar days of Respondent's return to practice. Non-practice is defined as any period of time Respondent is not practicing medicine as defined in Business and Professions Code sections 2051 and 2052 for at least 40 hours in a calendar month in direct patient care, clinical activity or teaching, or other activity as approved by the Board. If Respondent resides in California and is considered to be in non-practice, Respondent shall comply with all terms and conditions of probation. All time spent in an intensive training program which has been approved by the Board or its designee shall not be considered non-practice and does not relieve Respondent from complying with all the terms and conditions of probation. Practicing medicine in another state of the United States or Federal jurisdiction while on probation with the medical licensing authority of that state or jurisdiction shall not be considered non-practice. A Board-ordered suspension of practice shall not be considered as a period of non-practice.

In the event Respondent's period of non-practice while on probation exceeds 18 calendar months, Respondent shall successfully complete the Federation of State

Medical Board's Special Purpose Examination, or, at the Board's discretion, a clinical competence assessment program that meets the criteria of Condition 18 of the current version of the Board's "Manual of Model Disciplinary Orders and Disciplinary Guidelines" prior to resuming the practice of medicine.

Respondent's period of non-practice while on probation shall not exceed two years.

Periods of non-practice will not apply to the reduction of the probationary term.

Periods of non-practice for Respondent residing outside of California, will relieve Respondent of the responsibility to comply with the probationary terms and conditions with the exception of this condition and the following terms and conditions of probation: Obey All Laws; General Probation Requirements; and Quarterly Declarations.

7. Probation Monitoring Costs

Respondent shall pay the costs associated with probation monitoring each and every year of probation, as designated by the Board, which may be adjusted on an annual basis. Such costs shall be payable to the Medical Board of California and delivered to the Board or its designee no later than January 31 of each calendar year.

8. Costs

Respondent shall pay to the Board costs associated with its enforcement of this matter pursuant to Business and Professions Code section 125.3 in the amount of \$39,190. Respondent shall be permitted to pay these costs in a payment plan approved by the Board, with payments to be completed no later than three months prior to the end of the probation term.

If Respondent has not complied with this condition during the probationary term, and Respondent has presented sufficient documentation of his good faith efforts to comply with this condition, and if no other conditions have been violated, the Board, in its discretion, may grant an extension of the Respondent's probation period up to one year without further hearing in order to comply with this condition. During the one-year extension, all original conditions of probation will apply.

9. Supervision of Physician Assistants and Advanced Practice Nurses

During probation, Respondent is prohibited from supervising physician assistants and advanced practice nurses.

10. Education Course

Within 60 calendar days of the effective date of this Decision, and on an annual basis thereafter, Respondent shall submit to the Board or its designee for its prior approval educational program(s) or course(s) which shall not be less than 40 hours per year, for each year of probation. The educational program(s) or course(s) shall be aimed at correcting any areas of deficient practice or knowledge and shall be Category I certified. The educational program(s) or course(s) shall be at Respondent's expense and shall be in addition to the Continuing Medical Education (CME) requirements for renewal of licensure. Following the completion of each course, the Board or its designee may administer an examination to test Respondent's knowledge of the course. Respondent shall provide proof of attendance of the additional 40 hours of CME in satisfaction of this condition.

11. Professionalism Program (Ethics Course)

Within 60 calendar days of the effective date of this Decision, Respondent shall enroll in a professionalism program, that meets the requirements of Title 16, California

Code of Regulations (CCR) section 1358.1. Respondent shall participate in and successfully complete that program. Respondent shall provide any information and documents that the program may deem pertinent. Respondent shall successfully complete the classroom component of the program not later than six months after Respondent's initial enrollment, and the longitudinal component of the program not later than the time specified by the program, but no later than one year after attending the classroom component. The professionalism program shall be at Respondent's expense and shall be in addition to the CME requirements for renewal of licensure.

A professionalism program taken after the acts that gave rise to the charges in the Accusation, but prior to the effective date of the Decision may, in the sole discretion of the Board or its designee, be accepted towards the fulfillment of this condition if the program would have been approved by the Board or its designee had the program been taken after the effective date of this Decision.

Respondent shall submit a certification of successful completion to the Board or its designee not later than 15 calendar days after successfully completing the program or not later than 15 calendar days after the effective date of the Decision, whichever is later.

12. Medical Record Keeping Course

Within 60 calendar days of the effective date of this Decision, Respondent shall enroll in a course in medical record keeping approved in advance by the Board or its designee. Respondent shall provide the approved course provider with any information and documents that the approved course provider may deem pertinent. Respondent shall participate in and successfully complete the classroom component of

the course not later than six months after Respondent's initial enrollment. Respondent shall successfully complete any other component of the course within one year of enrollment. The medical record keeping course shall be at Respondent's expense and shall be in addition to the CME requirements for renewal of licensure. A medical record keeping course taken after the acts that gave rise to the charges in the Accusation, but prior to the effective date of the Decision may, in the sole discretion of the Board or its designee, be accepted towards the fulfillment of this condition if the course would have been approved by the Board or its designee had the course been taken after the effective date of this Decision. Respondent shall submit a certification of successful completion to the Board or its designee not later than 15 calendar days after successfully completing the course, or not later than 15 calendar days after the effective date of the Decision, whichever is later.

13. Violation of Probation

Failure to fully comply with any term or condition of probation is a violation of probation. If Respondent violates probation in any respect, the Board, after giving Respondent notice and the opportunity to be heard, may revoke probation and carry out the disciplinary order that was stayed. If an Accusation, or Petition to Revoke Probation, or an Interim Suspension Order is filed against Respondent during probation, the Board shall have continuing jurisdiction until the matter is final, and the period of probation shall be extended until the matter is final.

14. License Surrender

Following the effective date of this Decision, if Respondent ceases practicing due to retirement or health reasons or is otherwise unable to satisfy the terms and conditions of probation, Respondent may request to surrender his license. The Board

reserves the right to evaluate Respondent's request and to exercise its discretion in determining whether or not to grant the request, or to take any other action deemed appropriate and reasonable under the circumstances. Upon formal acceptance of the surrender, Respondent shall within 15 calendar days deliver Respondent's wallet and wall certificate to the Board or its designee and Respondent shall no longer practice medicine. Respondent will no longer be subject to the terms and conditions of probation. If Respondent re-applies for a medical license, the application shall be treated as a petition for reinstatement of a revoked certificate.

15. Completion of Probation

Respondent shall comply with all financial obligations (i.e., probation costs) not later than 120 calendar days prior to the completion of probation. Upon successful completion of probation, Respondent's certificate shall be fully restored.

DATE: **11/01/2023**

Julie Cabos-Owen

JULIE CABOS-OWEN

Administrative Law Judge

Office of Administrative Hearings