STATE OF FLORIDA
DIVISION OF ADMINISTRATIVE HEARINGS

FLORIDA STATE ORIENTAL MEDICAL ASSOCIATION,

Petitioner,

vs. Case No. 18-2508RP

DEPARTMENT OF HEALTH, BOARD OF PHYSICAL THERAPY PRACTICE,

Respondent,

and

FLORIDA PHYSICAL THERAPY ASSOCIATION, INC.,

Intervenor.
_____/

FINAL ORDER

A final hearing was conducted in this case on July 12, 13, and 19, 2018, in Tallahassee, Florida, before Lawrence P. Stevenson, a duly-designated Administrative Law Judge with the Division of Administrative Hearings.

APPEARANCES

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STATEMENT OF THE ISSUE

At issue in this proceeding is whether proposed Florida Administrative Code Rule 64B17-6.008 (the "Proposed Rule) constitutes an invalid exercise of delegated legislative authority.

PRELIMINARY STATEMENT

On February 23, 2018, Respondent, Department of Health, Board of Physical Therapy Practice (the "Board"), published the Proposed Rule, titled "Minimum Standards of Practice for Dry Needling in the Practice of Physical Therapy," in the Florida Administrative Register, Vol. 44, No. 38, pp. 906-907.

On May 14, 2018, Petitioner, Florida State Oriental Medical Association ("FSOMA"), filed its Amended Petition to Determine the Invalidity of Proposed Rule 64B17-6.008 (the "Petition"). The Petition alleged that the Proposed Rule was an "invalid exercise of delegated legislative authority" pursuant to sections 120.52(8) and 120.56, Florida Statutes.

The Division of Administrative Hearings ("DOAH") assigned DOAH Case No. 18-2508RP to this matter. On May 16, 2018, the case was assigned to Administrative Law Judge Suzanne Van Wyk. Also on May 16, 2018, the case was transferred to the undersigned, who scheduled the final hearing for July 12 and 13, 2018.

On May 18, 2018, the Florida Physical Therapy Association, Inc. ("FPTA"), filed an unopposed Motion to Intervene, which was granted by order dated May 23, 2018.

Several documents were presented for and granted official recognition. On July 5, 2018, FSOMA filed a request for official recognition of the Board's November 22, 2010, Final Order on Petition for Declaratory Statement of Cecille Riggs. FPTA's Motion for Official Recognition, filed on July 11, 2018, requested official recognition of chapters 67-537, 73-354, 78-278, and 89-124, Laws of Florida; and the Board's August 30, 2017, Final Order on Petition for Declaratory Statement of Robert Stanborough. Both the FSOMA and FPTA motions were granted.

Official recognition was also taken of a bill from the 2015 legislative session, CS/HB 515, as well as an accompanying staff analysis by the House Health and Human Services Committee. On July 23, 2018, FSOMA filed a written objection on the ground that the bill never passed the Legislature and is therefore

irrelevant to this proceeding. FSOMA's objection is overruled, though the undersigned concedes that the documents in question are of limited utility.

The parties were also granted leave to supplement the officially recognized legislative history post-hearing. With its proposed final order, FPTA filed a Notice of Filing Supplemental Legislative Materials that included the following:

1. Ch. 57-67, Laws of Fla.;

2. Fla. S. Comm. on H.R.S., SB 1163 (1973) Staff Evaluation (Apr. 1973);

3. Fla. S. Comm. on H.R.S., SB 155 (1978), Staff Analysis (Jan. 18, 1978);

4. Fla. H.R. Comm. on Reg'd Indus., HB 44 (1980), Staff Report (Jan. 31, 1980);

5. Ch. 80-375, Laws of Fla.

6. Fla. S. Gov. Ops. Comm., SB 168 (1980) Fact Sheet (May 22, 1980).

No objection was made to official recognition of these items. Therefore, official recognition is taken of the six named items of legislation and staff analysis.

The final hearing was begun on July 12 and 13, 2018. A third day of hearing was held, by consent of the parties, on July 19, 2018.

At the final hearing, FSOMA presented the testimony of George Parente, accepted as an expert in acupuncture and physical therapy; and of David Bibbey, accepted as an expert in

acupuncture. FSOMA's Exhibits 1, 2 (tabs 5, 6A, 6B, 7A, 7C, 7D, 7E and 7F only), 3 through 7, 9, 10, 15, 19, 22, 25, 27, 30, 38 (page 1 only), 41 through 46, 51, 54, and 59 were admitted into evidence. The Board presented the testimony of Allen Hall, the Board's executive director; Edo Zylstra, accepted as an expert in physical therapy, including dry needling; Robert Sillevis, accepted as an expert in physical therapy, with a specialty in orthopedic manual therapy; and Robert Howard Rowe. The Board's Exhibits 1 through 11, 13 through 18, 19 (page 1 only), 20, 21, and 23 through 26 were admitted into evidence. FPTA presented the testimony of Jan Dommerholt, accepted as an expert in physical therapy and dry needling; Mark T. McElroy, accepted as an expert in physical therapy, including dry needling; Burton Reed, accepted as an expert in physical therapy and dry needling; Adnan Sammour, accepted as an expert in acupuncture and dry needling; Timothy M. Johnson; and Tad P. Fisher, the chief executive officer of FPTA. FPTA's Exhibits 1, 2, 4, 5, 10, 11, 12 (tabs A, D, and F only), 13 through 17, 19 through 23, 25, 26 (tab A only), and 27 were admitted into evidence.[1/]

The six-volume Transcript of the final hearing was filed with DOAH on September 7, 2018. At the final hearing, the parties requested, and were granted, a filing date of October 1, 2018, for their proposed final orders. FSOMA timely filed its

Proposed Final Order on October 1, 2018. The Board and FPTA timely filed their joint Proposed Final Order on October 1, 2018. On October 8, 2018, FSOMA filed an unopposed Motion to Amend its Proposed Final Order, which is hereby GRANTED.

Except where otherwise noted, citations to the Florida Statutes refer to the 2018 edition.

FINDINGS OF FACT

A. Parties

1. FSOMA is a member association established to protect and promote the practice and profession of acupuncture. Approximately 350 of FSOMA's 650 members are licensed acupuncturists practicing in Florida, as regulated by chapter 457, Florida Statutes. Three of those acupuncturist members are also licensed physical therapists ("PTs") in Florida. Most of the other FSOMA members are students seeking master's degrees in acupuncture.

2. The Board was legislatively created within the Department of Health to oversee the regulation of the practice of physical therapy in the State of Florida. § 486.023(1), Fla. Stat. Five of the seven Board members must be Florida-licensed PTs who have been engaged in the practice of physical therapy for at least four years immediately prior to their appointment. § 486.023(2), Fla. Stat. The Board's powers and duties include the ability to "establish or modify minimum standards of

practice, and adopt rules pursuant to sections 120.536(1) and 120.54 to implement the provisions of [chapter 486]." § 486.025, Fla. Stat.

3. FPTA is a not-for-profit professional association organized in compliance with section 501(c)(6) of the Internal Revenue Code. It is a voluntary membership organization that is a component chapter of a national organization, the American Physical Therapy Association ("APTA"). As of May 2018, FPTA's membership included 3,319 licensed PTs, 698 Florida-licensed physical therapist assistants, 1,851 students pursuing Doctor of Physical Therapy degrees, and 539 students pursuing physical therapist assistant degrees.

B. Applicable statutes

4. Section 457.102(1) defines "acupuncture" as follows:

> (1) "Acupuncture" means a form of primary health care, based on traditional Chinese medical concepts and modern oriental medical techniques, that employs acupuncture diagnosis and treatment, as well as adjunctive therapies and diagnostic techniques, for the promotion, maintenance, and restoration of health and the prevention of disease. Acupuncture shall include, but not be limited to, the insertion of acupuncture needles and the application of moxibustion to specific areas of the human body and the use of electroacupuncture, Qi Gong, oriental massage, herbal therapy, dietary guidelines, and other adjunctive therapies, as defined by board rule. (emphasis added).

5. Section 486.021(11), Florida Statutes, defines the "practice of physical therapy" as follows, in relevant part:

> (11) "Practice of physical therapy" means the performance of physical therapy assessments and the treatment of any disability, injury, disease, or other health condition of human beings, or the prevention of such disability, injury, disease, or other condition of health, and rehabilitation as related thereto by the use of the physical, chemical, and other properties of air; electricity; exercise; massage; the performance of acupuncture only upon compliance with the criteria set forth by the Board of Medicine, when no penetration of the skin occurs; the use of radiant energy, including ultraviolet, visible, and infrared rays; ultrasound; water; the use of apparatus and equipment in the application of the foregoing or related thereto; the performance of tests of neuromuscular functions as an aid to the diagnosis or treatment of any human condition; or the performance of electromyography as an aid to the diagnosis of any human condition only upon compliance with the criteria set forth by the Board of Medicine . . . . (emphasis added).

C. Proposed Rule

6. The full text of the Proposed Rule is as follows:

> 64B17-6.008 Minimum Standards of Practice for Dry Needling in the Practice of Physical Therapy
>
> (1) For the purpose of this rule, "dry needling" is a skilled technique based on western medical concepts performed by a physical therapist using apparatus or equipment of filiform needles to penetrate the skin and/or underlying tissues to affect change in body structures and functions for the evaluation and management of

neuromusculoskeletal conditions, pain, movement impairments, and disability.

(2) The minimum standards of practice for dry needling in the practice of physical therapy shall include competence demonstrated by successful completion of education that includes the subject areas listed in the following paragraphs, and that is accredited, sponsored, or approved by the Commission on Accreditation in Physical Therapy Education, the American Physical Therapy Association, the Florida Physical Therapy Association, the Federation of State Boards of Physical Therapy, or any branch of the United States Armed Forces:

(a) Evidence-based instruction on the theory of dry needling practice;

(b) Selection and safe handling of needles and other apparatus and equipment, including hygiene and infection control pursuant to relevant standards of the United States Centers for Disease Control and Prevention or the United States Occupational Safety and Health Administration;

(c) Dry needling indications and contraindications;

(d) Anatomical review for safety and effectiveness as it applies to dry needling;

(e) Psychomotor skills needed to physically perform dry needling; and

(f) Postintervention care, including an adverse response or emergency.

(3) The education shall include a face-to-face component with interaction with the course instructor and an in-person examination of cognitive and psychomotor skills related to dry needling.

(4) A physical therapist who performs or offers to perform dry needling shall supply the Department, upon request, with written documentation of his or her competence to perform dry needling.

(5) A physical therapist shall not delegate the practice of dry needling to a physical therapist assistant, unlicensed personnel, or any other person who is not a physical therapist.

Rulemaking Authority 486.025 FS. Law Implemented 486.021(11) FS. History--New _____.

D. Amended Petition

7. In its Amended Petition, FSOMA asserts that the Proposed Rule constitutes an invalid exercise of delegated legislative authority because dry needling is outside the scope of physical therapy practice under section 486.021(11). In purporting to establish standards of practice for dry needling, the Board is presuming, without statutory authority, that dry needling is within the scope of practice of physical therapy. FSOMA states that dry needling is simply acupuncture by another name and that the statutory definition of "practice of physical therapy" expressly prohibits PTs from employing acupuncture techniques that penetrate the skin.

8. FSOMA notes that section 457.102(1) provides that "[a]cupuncture shall include, but not be limited to, the insertion of acupuncture needles and the application of moxibustion to specific areas of the human body . . . ." In the

practice of dry needling, PTs insert acupuncture needles into the human body. Therefore, dry needling meets the statutory definition of acupuncture and violates the physical therapy practice act, which allows PTs to perform acupuncture only "when no penetration of the skin occurs."

9. FSOMA further asserts that dry needling does not fall under any of the permitted modalities listed in section 486.021(11), i.e., "the use of physical, chemical, and other properties of air; electricity; exercise; massage; the performance of acupuncture only upon compliance with the criteria set forth by the Board of Medicine, when no penetration of the skin occurs; the use of radiant energy, including ultraviolet, visible, and infrared rays; ultrasound; [or] water . . . ."

10. FSOMA also contends that the Proposed Rule does not adequately train physical therapists in the insertion of filiform needles into the human body, which poses an increase in the potential for harm to patients as well as to the profession of acupuncture. FSOMA is concerned that patients will confuse dry needling with acupuncture, and that the harm to patients caused by ill-trained PTs performing dry needling will be associated in the public mind with the practice of acupuncture.

11. Finally, FSOMA argues that dry needling by PTs constitutes cultural misappropriation of traditional Chinese

medicine. PTs claim that dry needling is founded entirely on concepts of western medicine, which has a marginalizing effect on the profession of acupuncture. FSOMA made this claim as a ground for standing to bring this rule challenge.

12. The Board and FPTA have challenged FSOMA's standing to bring this proceeding, on the ground that acupuncturists have no recognized interest in the adoption of rules by a competing profession. FSOMA's standing is dependent on the claim that dry needling constitutes the practice of acupuncture and is therefore an illicit encroachment on the profession practiced by the 350 FSOMA members who are licensed acupuncturists. If dry needling by PTs is not the practice of acupuncture, then the Board's objection to FSOMA's standing is well taken.

E. Dry needling

13. Dry needling was initially developed in the 1940s by Janet Travell, M.D., in collaboration with David Simons, M.D., through studies of injection therapy during which empty, i.e. "dry," hypodermic needles were thought to be effective in treating "myofascial trigger points," which are contractures in muscles usually caused by overuse or trauma.[2/]

14. Over time, the hypodermic needle used by Dr. Travell has given way to the solid filiform needle as the instrument of choice among PTs who perform dry needling. The Proposed Rule specifically states that dry needling is done with "filiform

needles." The Food and Drug Administration ("FDA") classifies the needle used in dry needling as an "acupuncture needle," defined as "a device intended to pierce the skin in the practice of acupuncture. The device consists of a solid, stainless steel needle. The device may have a handle attached to the needle to facilitate the delivery of acupuncture treatment." 21 C.F.R. § 880.5580(a). It is a prescription device and must be labeled for single use only. 21 C.F.R. § 880.5580(b).[3/]

15. FSOMA points to the 1996 FDA order adopting 21 C.F.R. § 880.5580, in which the FDA stated that the sale of these needles "must be clearly restricted to qualified practitioners of acupuncture as determined by the States." 61 Fed. Reg. 64616 (Dec. 6, 1996) [FR Doc No: 96-31047]. FSOMA contends that the quoted language clearly restricts the use of acupuncture needles to licensed practitioners of acupuncture and that the use of these devices by PTs in dry needling is the practice of acupuncture in violation of their own practice act.

16. The Board and FPTA respond by emphasizing the "as determined by the States" language in the FDA's order. They note that the FDA places the onus on manufacturers and distributers to properly label prescription devices with either "Rx only," "R only," or a caution statement identifying the practitioner(s) licensed by applicable state law to use the device. 21 C.F.R. § 801.109(a)-(b).

17. Mark McElroy, a former major in the United States Air Force and an expert in orthopedic physical therapy, testified that he began using dry needling technique while serving as a PT in the Air Force. Mr. McElroy testified that when performing dry needling in the Air Force, he would use Red Coral Myotech Dry Needles because they are stiffer than acupuncture needles and easier to grip. At the hearing, Mr. McElroy read the label on these needles as stating, "Federal law restricts the device to the sale, buy [sic], or the order of qualified practitioners of physical therapy and acupuncture as determined by the states."

18. The Board and FPTA further note that the FDA defines an acupuncture needle differently than does Florida's acupuncture rule. Under 21 C.F.R. § 880.5580(a), an acupuncture needle is a "solid, stainless steel needle" of indeterminate diameter. Florida Administrative Code Rule 64B1-3.001(4) provides for use of a "filiform," i.e., threadlike, needle without designating any particular material. Both definitions call for use of "solid" needles, but contain no other overlapping criteria.

19. The undersigned observes that the FDA's use of the term "acupuncture needle" appears to be shorthand rather than prescriptive. The summary to the 1996 FDA order describes the devices as "acupuncture needles for the practice of acupuncture

and substantially equivalent devices of this generic type," which further supports the Board and FPTA's view that the FDA's regulation of acupuncture needles does not control the outcome of this proceeding. PTs indisputably perform dry needling with devices that the FDA has labeled "acupuncture needles"; however, this fact alone is not dispositive of the question whether PTs are performing "acupuncture" under Florida law when they dry needle.

20. A February 2013 educational resource paper produced by APTA, Description of Dry Needling in Clinical Practice, provides the following useful description of the practice of dry needling:

> Dry needling is a skilled intervention that uses a thin filiform needle to penetrate the skin and stimulate underlying myofascial trigger points, muscular and connective tissues for the management of neuromusculoskeletal pain and movement impairments. Dry needling [DN] is a technique used to treat dysfunctions in skeletal muscle, fascia, and connective tissue, and diminish persistent peripheral nociceptive input, and reduce or restore impairments of body structure and function leading to improved activity and participation.
>
> The physiological basis for DN depends upon the targeted tissue and treatment objectives. The treatment of myofascial trigger points (referred to as TrPs) has a different physiological basis than treatment of excessive muscle tension, scar tissue, fascia, and connective tissues. TrPs are hyperirritable spots within a taut band of

> contractured skeletal muscle fibers that produce local and/or referred pain when stimulated. TrPs are divided into active and latent TrPs dependent upon the degree of irritability. Active TrPs are spontaneously painful, while latent TrPs are only painful when stimulated, for example, with digital pressure.
>
> * * *
>
> DN can be divided into deep and superficial DN. Deep DN has been show to inactivate TrPs by eliciting local twitch response (LTR), which are modified by the central nervous system.

21. Once the PT identifies a trigger point through palpation of the area, he inserts a needle deep into the tissue so that it touches the muscle and then stimulates the muscle using an up-and-down "pistoning" motion until a "twitch response" is elicited.

22. Mr. McElroy described the process as follows:

> I would clean the area, clean my hands, put on gloves, take my dry needle, covering the area, making sure that I use all of the precautions that I've always been taught,[4/] insert the needle, look for that trigger point or that soft tissue that I'm trying to elicit the breakdown. I use a pistoning action, an up-and-down motion, looking for a twitch response.
>
> * * *
>
> Once I find the twitch response, the majority of the time I take the needle, I discard that needle. I then palpate along that same muscle area to see if I can find another--elicit another trigger response from the patient that is painful. Once

> again, I take another needle, I'll insert that needle, I'll piston up and down looking for another twitch response. I may do that anywhere from two to five times and then I'm done.[5/]

23. Dr. Jan Dommerholt, an expert in physical therapy and dry needling, described the twitch response reaction as follows:

> A twitch response is an involuntary spinal cord reflex that actually--it's just like a knee jerk if you go to the doctor and they tap the reflex hammer on your knee. If everything functions properly, you can't really stop that, it happens no matter what. And that's part of the test. That goes through your spinal cord.
>
> A twitch response is the same thing. It's when a needle hits the right spot, there's a signal to the spinal cord, and it brings it back and makes the muscle contract, that part of the muscle contract[s] very rapidly. So that's a very objective sign that you're in the right location.
>
> And you keep needling until the twitch responses subside. And usually immediately the patient has improved range of motion and their pain is significantly less.

24. Dr. Dommerholt testified that in his practice, which is focused on chronic pain patients, dry needling allows the patient to "actually move again" and participate in exercises and other treatments. Dr. Dommerholt stated that dry needling is never used as an isolated procedure; it is always part of a larger physical therapy program. However, dry needling is generally the first treatment used because it offers the patient immediate relief from pain.

25. The Board and FPTA presented an array of experts who testified as to the safety and efficacy of dry needling. Mr. McElroy, Dr. Edo Zylstra, Dr. Robert Sillevis, and Mr. Burton Reed are board-certified orthopedic clinical specialists, signifying their expertise in orthopedic physical therapy. In addition, Dr. Sillevis and Mr. Reed are fellows of the American Academy of Orthopedic Manual Physical Therapists, signifying their expertise in manual orthopedic physical therapy, which is a subspecialty within orthopedics. Dry needling is considered a subcomponent of the orthopedic manual physical therapy subspecialty.

26. Mr. Reed testified that in his practice he found dry needling to be effective for treatment of athletes, who tend to have "overuse problems" because they are "hard on their bodies and encounter strains and sprains." Both Mr. Reed and Dr. Zylstra testified about their experiences training National Football League ("NFL") PTs and treating NFL players with dry needling. Mr. Reed has also used dry needling on major and minor league baseball players and professional soccer players.

27. Mr. McElroy began using dry needling during his time at Andrews Air Force Base to treat individuals suffering from musculoskeletal or soft tissue sports injuries. During his deployment, he gained the majority of his dry needling experience treating Special Forces operators who sustained

musculoskeletal injuries. Mr. McElroy explained that dry needling is generally effective for athletes who overexert themselves by going from "zero to hero" in their workouts, as well as for military personnel who require expedited recovery in order to deploy as scheduled.

F. Training and safety

28. FSOMA has alleged that the Proposed Rule does not adequately train PTs in the insertion of filiform needles into the human body and carries the potential for harm to patients and to the profession of acupuncture. Rather than establish specific course requirements and hours of study to be completed before a PT is allowed to dry needle, the Proposed Rule merely establishes what FSOMA witness David Bibbey termed an "expectation of competency" that is likely to be tested only after something has gone wrong and the Department of Health makes an inquiry.

29. Under Florida law, an applicant for licensure as an acupuncturist must prove that he or she:

> Has completed 60 college credits from an accredited postsecondary institution as a prerequisite to enrollment in an authorized 3-year course of study in acupuncture and oriental medicine, and has completed a 3-year course of study in acupuncture and oriental medicine, and effective July 31, 2001, a 4-year course of study in acupuncture and oriental medicine, which meets standards established by the board by rule, which standards include, but are not

> limited to, successful completion of academic courses in western anatomy, western physiology, western pathology, western biomedical terminology, first aid, and cardiopulmonary resuscitation (CPR).

§ 457.105(2)(b), Fla. Stat.

30. FSOMA emphasizes that Florida acupuncturists must be trained in western anatomy, physiology, pathology, and biomedical terminology, as well as the principles of Chinese medicine.

31. David Bibbey is an expert in acupuncture who has studied some of the academic literature on dry needling. Mr. Bibbey runs a private acupuncture practice in Crystal River and has served as an adjunct professor at the Florida College of Integrative Medicine in Orlando. Mr. Bibbey's office is an externship location for a training program in Gainesville. Mr. Bibbey has no experience in physical therapy or dry needling.

32. Mr. Bibbey testified as to the amount of training that a candidate for licensure as an acupuncturist must complete before being allowed to perform the invasive technique of inserting acupuncture needles into a patient's body. The Board of Acupuncture requires that a candidate complete a course with a minimum of 2,700 hours of supervised instruction. Of those 2,700 hours, 660 hours must be supervised clinical instruction, described by Mr. Bibbey as "either observing, doing case study,

or under direct supervision of a licensed acupuncturist." Mr. Bibbey described "case study" as "an opportunity to review on a case-by-case basis the circumstances that might bring [a patient] to the [acupuncturist's] office in terms of a health condition and how that person might be assessed, what your treatment options are, communication, follow-up instruction, [and] clinical decision-making."

33. Mr. Bibbey testified that the typical clinical internship begins with observation during the first four semesters. After about 560 hours of observation in clinic, which include case study and supervised involvement in noninvasive procedures, and after demonstrating an understanding of proper needle insertion, the acupuncture student starts to employ the invasive procedure of inserting acupuncture needles through the skin and into the body, under supervision. This supervised performance of the invasive procedure continues through the remainder of the clinical program.

34. FSOMA contrasts these licensure requirements with the "minimal study requirements" for PTs under the Proposed Rule. FSOMA notes that the Proposed Rule merely sets forth subject areas without requiring a minimum number of training hours and provides no direct supervision in a clinical setting before the PT may commence dry needling in their practice.

35. FSOMA points to a policy statement issued by the American Medical Association ("AMA") at its 2016 Annual Meeting stating that dry needling is "an invasive procedure and . . . should only be performed by practitioners with standard training and familiarity with routine use of needles in their practice, such as licensed medical physicians and licensed acupuncturists." The press release announcing the AMA policy specifically mentioned PTs in terms of "lax regulation and nonexistent standards" surrounding the invasive practice of dry needling.

36. FSOMA contends that section 486.021(11) generally prohibits PTs from performing invasive procedures. FSOMA argues that, with the exception of electromyography for diagnostic purposes, none of the practices within the scope of physical therapy practice are invasive. All of the therapeutic practices contained in the statute are non-invasive.

37. FSOMA asserts that the Proposed Rule's failure to require assurance of competence prior to the performance of dry needling means that the Board intends to ask for such assurance only after it receives a complaint that a patient has been injured by dry needling. FSOMA states that relying on after-the-fact enforcement of competency requirements does not adequately protect the public.

38. Through Mr. Bibbey's testimony, FSOMA introduced data indicating that the incidence of adverse events for dry needling is "about triple" that for acupuncture. Mr. Bibbey specifically referenced an article in the March 2015 edition of the journal Physiotherapy Alberta, titled "FAQ Dry Needling Adverse Events." The authors compiled the results of several studies to conclude that the incidence of "adverse events" in acupuncture treatment is 8.6 percent. The incidence of adverse events in dry needling was found to be 19.18 percent. "Adverse events" included a very wide range of outcomes, from minor and expected things such as bruising, bleeding, and/or pain up to serious events such as pneumothorax. For both forms of treatment, the vast majority of adverse events was minor and required no follow-up treatment.

39. FSOMA went on to argue that the similarity between acupuncture and dry needling means that the public could confuse the two, and that the adverse results caused by poorly trained PTs performing dry needling could harm the reputation of acupuncture in the state. Mr. Bibbey testified that allowing PTs to practice dry needling under the inadequate standards of the Proposed Rule "may lead to a chilling effect on the trust and use of acupuncture, both through patient harm and confusion over what is and what isn't acupuncture."

40. George Parente, who is licensed in Florida as both a PT and an acupuncturist, agreed with Mr. Bibbey on the impact of

dry needling by PTs on the practice of acupuncture. The lack of required training raises safety issues for the patient. If there are injuries caused by PTs conducting dry needling, the public will likely associate those injuries with the needle-insertion practices of acupuncturists. The cultural distinctions between acupuncture and dry needling will be lost on the general public. Mr. Parente asserted that there is no difference between acupuncture and the dry needling performed by PTs, though he conceded that he has no hands-on experience in dry needling. He believes that dry needling is just "a clever play on words at the very best."

41. The Board and FSOMA countered with testimony from their experts that the training standards set forth in the Proposed Rule are entirely adequate, that dry needling by PTs presents no greater risk to the public than does acupuncture, and that there is more than adequate evidence from other states that PTs performing dry needling has had no negative effect on the status of acupuncture.

42. Dr. Dommerholt testified that 35 states already allow PTs to perform dry needling in their scope of practice, with no notable ill effects. Dr. Dommerholt has provided dry needling training and education in the United States since 1997 and founded Myopain Seminars, one of the country's largest providers of dry needling education and training. Dr. Dommerholt is

licensed as a PT in Maryland, where dry needling has been approved as a PT technique since 1984. Dr. Dommerholt testified that since 1984, the practice of acupuncture has grown substantially in Maryland, leading him to conclude that perhaps dry needling by PTs has a positive effect on the profession of acupuncture.

43. Dr. Sillevis, who is licensed as a PT in Florida and Indiana, has extensively performed dry needling and is active in the profession nationally. Dr. Sillevis testified that he is aware of only one serious injury resulting from a PT performing dry needling since 2014, and this was outside the United States. In his experience performing dry needling, he draws a drop of blood in about one out of 25 patients.

44. Dr. Sillevis' clinic was the first in Indiana to have PTs perform dry needling. Over time, dry needling by PTs has become more widespread in Indiana and the practice of acupuncture has grown. Dr. Sillevis testified that there were no acupuncture schools in his region when he started dry needling, but there are now two. He also noted an increase in the number of acupuncture clinics. Dr. Sillevis has observed the same thing in Boulder, Colorado, where acupuncture practice became more prevalent as PTs began dry needling.

45. Dr. Sillevis has worked with acupuncturists and often refers patients to acupuncturists because of their abilities as

clinicians. Acupuncturists perform their own assessments and do not need Dr. Sillevis to direct the course of care. Dr. Sillevis stated that a PT addresses a patient's problem and solves it; the patient leaves and does not come back. An acupuncturist, on the other hand, "establishes a relationship for life."

46. Healthcare Providers Service Organization ("HPSO") is the main malpractice insurance carrier for APTA. In a letter to APTA's vice president for government affairs, dated January 24, 2018, the president of the healthcare division of HPSO discussed the risk experience of dry needling. For the five-year period ending in 2017, HPSO's underwriter managed 3,413 PT claims. Out of those, 34 arose from the practice of dry needling, the most common injury alleged being pneumothorax. The 34 claims came from 19 different states, indicating that no single state was the driver of loss. The total incurred loss from dry needling claims was $341,290. From these numbers, HPSO's underwriter did not foresee the practice of dry needling "as having any immediate claim or rate impact."

47. Dr. Adnan Sammour is a Florida licensed medical doctor trained in both acupuncture and dry needling, and accepted as an expert in both disciplines. Dr. Sammour supervises PTs and focuses roughly half his private practice on treatment of musculoskeletal pain. He testified that PTs are "the most

qualified" to perform dry needling because they do "hands-on" work with patients and have a better depth of knowledge about the musculoskeletal system than other practitioners, including physicians.

48. Dr. Sammour further opined that PTs performing dry needling in Florida will not pose an increased risk of patient injury. He testified that sticking the needle is "the easiest part" of acupuncture practice. Most of acupuncture training is about meridian theory and diagnosing the energy imbalance. He noted that unlicensed medical assistants use needles on patients, and that patients even inject themselves with insulin or testosterone without formal training. In his opinion, dry needling by PTs is "very safe."

49. Dr. Sillevis testified, "In essence, teaching somebody dry needling is extremely simple. It doesn't take much to poke a hole in the skin, right? So the skill isn't that difficult. It is how you use the skill is where the learning curve is."

50. Dr. Dommerholt testified that he was a co-author of one of the studies compiled by the authors of the Physiotherapy Alberta article cited by Mr. Bibbey. His study found that the risk of a significant adverse event in dry needling to be less than .04 percent. Dr. Dommerholt also believed that comparison of adverse events between acupuncture and dry needling is

misleading because dry needling involves greater needle depth and more vigorous manipulation of the needle.

51. Dr. Dommerholt, Mr. McElroy, Mr. Reed, Dr. Sillevis, and Mr. Rowe reviewed the Proposed Rule and opined that it provides adequate standards for PTs to safely perform dry needling in Florida and creates no increased risk of patient injury. Mr. Rowe added that he believes the Board "did a great job selecting the appropriate list of competencies."

52. Dr. Dommerholt testified that dry needling is a manual therapy that falls within the basic skill set of a PT. The APTA includes dry needling in its practice guide.

53. Dr. Zylstra referenced a study produced by Human Resources Research Organization ("HumRRO") for the Federation of State Boards of Physical Therapy ("FSBPT") showing that 86 percent of the competencies needed for dry needling are already covered in physical therapy coursework, the other 14 percent being mostly about the safe handling of needles.[6/]

54. Robert Rowe is a PT who acts as the executive director of the Institute of Higher Learning at Brooks Rehabilitation Hospital in Jacksonville. He has taught PT for 25 years. Mr. Rowe testified that there are many states where PTs have been dry needling for years and have coexisted with acupuncturists "and nobody is going out of business and nobody is having problems." He testified that he regularly refers to

acupuncturists, has great respect for them, and would never advocate for something that would harm their profession.

55. Mr. Rowe testified that FSOMA's allegations of potential patient harm from PTs performing dry needling do not ring true. He noted that dry needling has been performed by PTs in many states for years, and that if there were high injury rates "our insurance would be skyrocketing." Mr. Rowe made the common sense observation that if there were evidence that the acupuncture profession has been harmed in the states that allow PTs to perform dry needling, "that data would be presented in this hearing, because that's powerful data . . . . [I]f it was true, it would exist and it would be presented. And I'm sure that that hasn't been presented because it doesn't exist because it's untrue."

56. Based on the foregoing findings, it is found that FSOMA has failed to demonstrate that dry needling, as described at hearing and practiced by PTs in other states, would increase the potential for harm to patients in Florida. The Board and FPTA presented preponderant evidence affirmatively demonstrating the benefits of dry needling. The dangers cited by FSOMA were largely speculative, while the witnesses for the Board and FPTA testified as to the actual experience of patients in the states where dry needling by PTs is allowed.

57. Because it is found below that dry needling is "acupuncture" as defined in section 457.102(1) and that section 486.021(11) as currently written does not allow PTs to practice dry needling in Florida, there is no need for an ultimate finding as to the adequacy of the training prescribed in the Proposed Rule. It is observed that if the Board did have statutory authority to adopt standards of practice for dry needling in the practice of physical therapy, then FSOMA would in all likelihood lack standing to challenge those standards.

G. Confusion

58. Mr. Bibbey testified that allowing PTs to introduce dry needling as "an alternate term" to describe acupuncture could lead to confusion over what is and is not acupuncture in Florida. Mr. Parente was concerned that the harm caused by inadequately trained PTs practicing dry needling will be associated with the profession of acupuncture. FSOMA offered no evidence of actual patient confusion in the 35 states that already allow PTs to perform dry needling.

59. Dr. Dommerholt, Mr. McElroy, Dr. Zylstra, and Dr. Sammour opined that neither patients nor providers will confuse dry needling with acupuncture. Mr. McElroy testified that when he was stationed in Okinawa, he performed dry needling and supervised a physician's assistant who performed acupuncture. Mr. McElroy stated that the procedures were

thoroughly explained to patients and there was never any confusion about the differences between dry needling and acupuncture.

60. Dr. Zylstra, who practices in Michigan, testified that he has had an acupuncturist working in his physical therapy clinic. He and members of his family have had acupuncture treatments. He stated that he refers patients for acupuncture if their complaints relate to a systemic disease process or if they complain of problems with sleep, stress, or allergies. Dr. Zylstra testified that once the use of the needle is explained to a patient, there is no confusion between dry needling and acupuncture.

61. Mr. Reed likewise testified that if people come into his physical therapy office seeking acupuncture, he refers them to an acupuncturist. If a patient presents with something that Mr. Reed cannot treat, such as a head cold, he might refer that patient to an acupuncturist. Mr. Reed testified that he explains the difference between dry needling and acupuncture to patients as a precaution, having been cited for unlicensed activity by the Department of Health in 2016 for using dry needling in his practice. (The Department of Health subsequently withdrew the citation.) Mr. Reed stated that he always speaks highly of acupuncture when he talks to patients.

62. It is understood that in the public mind, "acupuncture" has become the generic term for "therapeutic insertion of needles" in the same sense that "Kleenex" has become the generic term for "paper tissue." FSOMA has a valid point that the general public could be confused by the concept of dry needling by PTs, at least until the practice comes into more common usage and understanding. However, there was no evidence provided that any such confusion has prevailed in the states where dry needling by PTs is allowed or that any actual patient of a PT did not understand the distinction between dry needling and acupuncture at the time of treatment.

63. Based on the foregoing findings, it is found that FSOMA failed to demonstrate that the practice of dry needling by PTs in Florida would cause patients to confuse dry needling by a PT with acupuncture performed by a licensed acupuncturist. The Board and FPTA presented preponderant evidence affirmatively demonstrating that there is no appreciable patient confusion in states where PTs are allowed to perform dry needling.

H. Invasive procedures

64. As to the alleged prohibition in section 486.021(11) on PTs performing invasive procedures, the Board and FPTA respond that nothing in the cited statute provides for such an exclusion. They point out that the only techniques specifically

prohibited by section 486.021(11) are found in paragraphs (b) and (c), not heretofore quoted:

> (b) The use of roentgen rays and radium for diagnostic and therapeutic purposes and the use of electricity for surgical purposes, including cauterization, are not "physical therapy" for purposes of this chapter.
>
> (c) The practice of physical therapy does not authorize a physical therapy practitioner to practice chiropractic medicine as defined in chapter 460, including specific spinal manipulation. For the performance of specific chiropractic spinal manipulation, a physical therapist shall refer the patient to a health care practitioner licensed under chapter 460.

65. The Board and FPTA argue that FSOMA's construction of section 486.021(11) would render the specific exclusion of these techniques meaningless and unnecessary. The undersigned rejects this logic. The fact that the Legislature chose to expressly forbid PTs from engaging in certain specific practices does not mean that the Legislature intended to allow PTs to perform any and all other practices not expressly forbidden by the statute.

66. Section 486.021(11) allows PTs to use "the physical, chemical, and other properties of air; electricity; exercise; massage; the performance of acupuncture only upon compliance with the criteria set forth by the Board of Medicine, when no penetration of the skin occurs; the use of radiant energy, including ultraviolet, visible, and infrared rays; ultrasound; water; [and] the use of apparatus and equipment in the

application of the foregoing or related thereto." (emphasis added).

67. FSOMA argues that there is no conceivable reading of the quoted language that would define acupuncture needles as "apparatus and equipment" in the application of the enumerated treatment modalities. Indeed, counsel for FSOMA took most of the Board and FPTA's expert witnesses through a litany of questions: "Does dry needling use the physical, chemical or other properties of air? Of electricity? Of exercise? Of massage? Does it use radiant energy? Ultrasound? Water?" The witnesses had to answer the questions in the negative.

68. The Board and FPTA argue that "apparatus and equipment" must include the acupuncture needles used in dry needling, but are forced to rely on a negative implication: if FSOMA's reading of the statute were correct, then PTs would also be denied the use of wound debridement tools such as scalpels, forceps, tweezers, and scissors, all of which are used by PTs in Florida to remove necrotic tissue from ulcers and wounds. Mr. Reed, who has experience performing wound debridement on burn victims and diabetic ulcers, credibly testified that debridement is an invasive procedure.

69. The Board and FSOMA did not make an affirmative demonstration of the statutory and/or rule basis for PTs to perform wound debridement; they established only that

debridement is in fact performed by some PTs. Dr. Dommerholt testified that PTs nationwide perform wound debridement in hospital settings, and Mr. Reed testified that he has done some debridement procedures in his clinics. Absent a demonstration of the statutory authority for PTs to perform debridement, the fact that PTs perform the procedure is of little assistance in determining whether section 486.021(11) authorizes PTs to perform dry needling.

70. It should also be noted that the only provision of section 486.021(11) that expressly authorizes an invasive procedure places significant constraints on the performance of that procedure by a PT. The statute allows "the performance of electromyography as an aid to the diagnosis of any human condition only upon compliance with the criteria set forth by the Board of Medicine." Florida Administrative Code Rule 64B8-37.001 sets forth the Board of Medicine's prerequisites to the performance of electromyography by a PT:

> Pursuant to Section 486.021(11), F.S., the Board of Medicine sets forth the following criteria for the performance of electromyography by physical therapists.
>
> (1) Before a physical therapist may perform electromyography as an aid to the diagnosis of any human condition, he must be trained and competent in:
>
> (a) Inserting and adjusting electrodes.

(b) Reading and identifying normal and abnormal signals on the grid.

(c) Interpreting the audible signals.

(2) In addition to the requirements of subsection (1), a physical therapist must receive no less than the following formal education within an accredited post-secondary educational institution:

(a) Human dissection.

(b) Human physiology.

(c) Neurology.

(d) Neuro-anatomy and neuro-physiology offered at a graduate level.

(e) Pathological conditions.

(3) In addition to having completed the formal study requirements of subsection (2), outlined above, the physical therapist must have completed 200 hours of testing human subjects under the direct supervision of a licensed physician or licensed physical therapist who has previously met these qualifications and should be able to present evidence of having performed 100 tests on neurologically involved patients, with findings corroborated by a licensed physician or licensed physical therapist who has previously met these qualifications.

71. Section 486.021(11) twice mentions invasive procedures. In the first instance, it forbids PTs from penetrating the skin when performing acupuncture. In the second, it requires compliance with the criteria set forth by the Board of Medicine. The Board of Medicine's adopted criteria include proof of basic training and prerequisite coursework,

200 hours of supervised testing of human subjects, and 100 corroborated tests before a PT may perform electromyography. The Board of Medicine's rule does not leave a PT free to act as the judge of his own competence in the area of electromyography, as FSOMA alleges the Proposed Rule would effectively allow for dry needling.

72. Mr. Parente, who has been licensed as a PT since 1986, testified as to an "old adage" that applies to physical therapy: "Thou shalt not break the skin." The experts testifying on behalf of the Board and FPTA uniformly rejected the notion that PTs are forbidden from performing invasive procedures. These experts may be correct in their general understanding of the current scope of practice for PTs in the United States. Nonetheless, section 486.021(11) governs the scope of practice in Florida and is found to contain a general presumption against PTs performing invasive procedures without prior demonstration of their qualifications and competence. More to the point of the instant case, section 486.021(11) includes a specific prohibition on the performance of invasive acupuncture procedures by PTs.

I. Dry needling as acupuncture

73. The statutory definition of acupuncture states that it "shall include . . . the insertion of acupuncture needles . . . to specific areas of the human body." § 457.102(1), Fla. Stat.

FSOMA compares the definition of acupuncture with the Proposed Rule's definition of dry needling as "a physical therapist using apparatus or equipment of filiform needles to penetrate the skin and/or underlying tissues." FSOMA argues that when PTs practice "dry needling" by inserting acupuncture needles into their patients, they are performing precisely the same acts that acupuncturists perform when they insert acupuncture needles into their patients.

74. Mr. Bibbey opined that the similarity between dry needling and acupuncture is not limited to the use of acupuncture needles. He stated, "[I]t's not simply just the tool. It's the tool, the target tissue, the physiological effect, and the therapeutic effect are all one and the same with acupuncture and dry needling."

75. Mr. Bibbey's description of the needling technique used in acupuncture was as follows:

> The procedure--you know, again, with the insertion of the needle is, again, identifying the target tissue, and depending on the target tissue in question, there can be manipulation of the needle, which would include a variety of techniques--twirling, spinning the needle, scratching the needle, lifting, thrusting the needle, pistoning the needle--a variety of techniques where you raise and drive the needle into the target tissue without removing the needle from the body. So you may insert to a depth, you're going to bring it up to a depth just under the surface of the skin itself, and reapply it to the target tissue.

76. FSOMA notes the similarity between Mr. Bibbey's description of acupuncture technique and Mr. McElroy's discussion of the "pistoning" used in dry needling to obtain a "twitch response." See Finding of Fact 22, supra. Mr. Bibbey testified that although acupuncture's theoretical basis lies in traditional Chinese medicine and dry needling is based on "western medical concepts," the needling technique and therapeutic goals are essentially the same, regardless of the terminology used to express them.

77. Mr. Bibbey opined that myofascial trigger points and acupuncture points "are one and the same." Acupuncturists find acupuncture points by using the same technique of palpation that PTs use to locate trigger points. Mr. Bibbey testified that palpation and the location of trigger points for diagnostic and identification purposes are taught in acupuncture training.

78. Mr. Parente also testified that dry needling and acupuncture are "one and the same." He went on to say:

> I don't see how you can separate the two. You're using the same tool . . . . [T]echnically, there isn't any place on the human body that doesn't have some form of channel in terms of traditional Chinese medicine, and whether or not you're even thinking along those lines, there's other ways to apply them even within the realm of Chinese medicine, okay. So to me, I don't know how you can separate the two.

79. Unsurprisingly, the Board and FPTA disagree that dry needling is acupuncture. They concede FSOMA's point that the statutory definition of acupuncture includes "the insertion of acupuncture needles . . . to specific areas of the human body." However, they contend that a fair reading of section 457.102(1) should include the entire sentence in question:

> Acupuncture shall include, but not be limited to, the insertion of acupuncture needles and the application of moxibustion to specific areas of the human body and the use of electroacupuncture, Qi Gong, oriental massage, herbal therapy, dietary guidelines, and other adjunctive therapies, as defined by board rule. (emphasis added).

80. The Board and FPTA point to Florida Administrative Code Rule 64B1-4.010, adopted by the Board of Acupuncture and titled, "Traditional Chinese Medical Concepts, Modern Oriental Medical Techniques." They argue that this rule provides a definition of "specific areas of the human body" that distinguishes acupuncture from dry needling. Rule 64B1-4.010 provides:

> Traditional Chinese medical concepts and modern oriental medical techniques shall include acupuncture diagnosis and treatment to prevent or correct malady, illness, injury, pain, addictions, other conditions, disorders, and dysfunction of the human body; to harmonize the flow of Qi or vital force; to balance the energy and functions of a patient; and to promote, maintain, and restore health; for pain management and palliative care; for acupuncture anesthesia; and to prevent disease by the use or

> administration of: stimulation to acupuncture points, ah-shi points, auricular points, channels, collaterals, meridians, and microsystems which shall include the use of: akabane; allergy elimination techniques; breathing; cold; color; correspondence; cupping; dietary guidelines; electricity; electroacupuncture; electrodermal screening (EDS); exercise; eight principles; five element [sic]; four levels; hara; heat; herbal therapy consisting of plant, animal, and/or mineral substances; infrared and other forms of light; inquiring of history; jing-luo; listening; moxibustion; needles; NAET; observation; oriental massage--manual and mechanical methods; palpation; physiognomy; point micro-bleeding therapy; pulses; qi; xue and jin-ye; ryodoraku; san-jiao; six stages; smelling; tongue; tai qi; qi gong; wulun-baguo; yin-yang; zang-fu; Ayurvedic, Chinese, Japanese, Korean, Manchurian, Mongolian, Tibetan, Uighurian, Vietnamese, and other east Asian acupuncture and oriental medical concepts and treatment techniques; French acupuncture; German acupuncture including electroacupuncture and diagnosis; and, the use of laboratory test and imaging findings. (emphasis added).

81. The Board and FPTA argue that the underscored language of the rule defines "specific areas of the human body" as "acupuncture points, ah-shi points, auricular points, channels, collaterals, meridians, and microsystems."[7/] They argue that these "specific areas" do not correspond to the areas of the human body treated by PTs in dry needling, essentially because the theories of acupuncture and dry needling are so different. As Dr. Dommerholt testified in a discussion of an academic study on the correlation between acupuncture points and trigger

points, "[M]ost acupuncture points do not have a pain indication, which is the main indication of trigger points."

82. Mr. Bibbey, on the other hand, testified as to a high correlation between trigger points and acupuncture points, based on his broad definition of the latter. There are 14 meridian channels that cover 100 percent of the body and consist mostly of paired organs: the spleen and stomach; kidney and bladder; liver and gallbladder; lung and large intestine; heart and small intestine; pericardium and triple warmer; and du and ren. Mr. Bibbey explained that acupuncture points may or may not be located along defined meridians. Other acupuncture points are not predefined and must be identified by palpation. These acupuncture points, called "de-meridian," provided the basis for Mr. Bibbey's opinion that "any target tissue that you put an acupuncture needle into becomes an acupuncture point." Under Mr. Bibbey's expansive definition, there would necessarily be a high correspondence between acupuncture points and trigger points, in the sense that it would be difficult to identify a trigger point that is not also an acupuncture point.

83. Both sides offered academic articles on the subject of the correspondence, if any, between acupuncture points and myofascial trigger points. The articles introduced by the Board and FPTA were more recent and more methodologically rigorous,

but both sets of articles constitute uncorroborated hearsay and are not relied upon herein.

84. In the absence of contrary evidence, Mr. Bibbey's credible expert testimony as to the 100-percent coverage of the body by the meridian channels is accepted. If the meridian channels include the entire body, then the language of Board of Acupuncture rule 64B1-4.010 emphasized by the Board and FPTA does not operate as a limitation on the statutory language that acupuncture includes "the insertion of acupuncture needles . . . to specific areas of the human body."

85. The plain reading of the Board of Acupuncture rule supports the conclusion drawn from Mr. Bibbey's expert testimony. "Acupuncture points, ah-shi points, auricular points, channels, collaterals, meridians, and microsystems" is a laundry list that appears to cover every possible area of the human body. Mr. Bibbey's testimony was that an "acupuncture point" is essentially any point on the human body into which an acupuncturist decides to place a needle. This testimony is not inconsistent with the definitional language of either the acupuncture statute or rule. The Board and FPTA offered no evidence that the quoted language in the rule operates as a limitation on the statutory language, beyond the clear theoretical differences between dry needling and acupuncture.

86. It is accepted that dry needling does not approach the human body on the same theoretical basis as acupuncture. Dry needling is a specific technique used by PTs in treatment programs to alleviate pain and restore range of motion. Unlike acupuncture, dry needling is not an entire system of medicine. Nonetheless, dry needling is "the insertion of acupuncture needles . . . to specific areas of the human body."

87. Dry needling may not constitute the practice of acupuncture in any real world sense, but in the statutory sense it does. Because it meets the definition of "acupuncture" set forth in section 457.102(1), dry needling is prohibited in the practice of physical therapy by section 486.021(11), which allows PTs to perform acupuncture only "when no penetration of the skin occurs."

88. Tad Fisher, FPTA's executive director, offered testimony that summed up the state of the law as to dry needling: "[T]he statutes don't necessarily keep up with the evolution of the health care professions that they're regulating . . . ." The evidence presented at the hearing demonstrated the safety and efficacy of dry needling as performed by PTs in other states, but could not overcome the plain, if perhaps outdated, language of the Florida Statutes.

CONCLUSIONS OF LAW

89. The Division of Administrative Hearings has jurisdiction over the parties and the subject matter of this proceeding pursuant to section 120.56, Florida Statutes.

90. Section 120.56(1)(a) provides that "any person substantially affected by a proposed rule may seek an administrative determination of the invalidity of the rule on the ground that the rule is an invalid exercise of delegated legislative authority."

91. Section 120.56(1)(b) provides that a petition challenging the validity of a proposed rule must state the particular provisions alleged to be invalid and a statement of the facts or grounds for the alleged invalidity, and facts sufficient to show that the petitioner would be substantially affected by the proposed rule.

92. Section 120.56(2)(a) provides that in challenges to proposed rules, "[t]he petitioner has the burden to prove by a preponderance of the evidence that the petitioner would be substantially affected by the proposed rule. The agency then has the burden to prove by a preponderance of the evidence that the proposed rule is not an invalid exercise of delegated legislative authority as to the objections raised."

93. Section 120.56(2)(c) provides that in a proceeding to determine the invalidity of a proposed rule, "the proposed rule is not presumed to be valid or invalid."

94. Section 120.56(1)(e) provides that a rule challenge proceeding is de novo in nature and that the standard of proof is a preponderance of the evidence. The Administrative Law Judge should consider and base the decision upon all of the available evidence, regardless of whether the evidence was placed before the agency during its rulemaking proceedings. Dep't of Health v. Merritt, 919 So. 2d 561, 564 (Fla. 1st DCA 2006)(concluding that the Legislature has overruled the court's holding in Board of Medicine v. Florida Academy of Cosmetic Surgery, 808 So. 2d 243 (Fla. 1st DCA 2002), that an administrative law judge's role in a proposed rule challenge is limited to a review of the record and a determination as to whether the agency action was supported by legally sufficient evidence).[8/]

95. To establish itself as a "person substantially affected" in this case, FSOMA must satisfy the elements of associational standing established in Florida Home Builders Association v. Department of Labor, 412 So. 2d 351, 353-354 (Fla. 1982):

> After reviewing the legislative history and purpose of chapter 120, we have concluded that a trade or professional association

> should be able to institute a rule challenge under section 120.56 even though it is acting solely as the representative of its members. To meet the requirements of section 120.56(1), an association must demonstrate that a substantial number of its members, although not necessarily a majority, are "substantially affected" by the challenged rule. Further, the subject matter of the rule must be within the association's general scope of interest and activity, and the relief requested must be of the type appropriate for a trade association to receive on behalf of its members.

96. When an association seeks standing to challenge an administrative rule, its individual members are not required to participate; rather, "associational standing" for administrative challenges is contingent on the organization's demonstration that a substantial number of its members would be substantially affected by the rule. NAACP, Inc. v. Fla. Bd. of Regents, 863 So. 2d 294, 300 (Fla. 2003). There is no requirement that the association demonstrate "immediate and actual harm." Id.

97. To prove standing under the doctrine, the association must show that: (1) a substantial number of its members, although not necessarily a majority, are "substantially affected" by the challenged rule; (2) the subject matter of the challenged rule is within the association's general scope of interest and activity; and (3) the relief requested is of the type appropriate for the association to receive on behalf of its members. Fla. Home Builders,, 412 So. 2d at 351; St. Johns

Riverkeeper, Inc. v. St. Johns River Water Mgmt, 54 So. 3d 1051, 1054 (Fla. 5th DCA 2011); Rosenzweig v. Dep't of Transp. 979 So. 2d 1050, 1053-1054 (Fla. 1st DCA 2008).

98. FSOMA has standing to bring this rule challenge proceeding. It has shown that a substantial number of its members (350 licensed acupuncturists out of a total membership of 650) will be substantially affected by the Proposed Rule should it be adopted. FSOMA alleges that the Proposed Rule would allow PTs to practice acupuncture by inserting acupuncture needles into the bodies of their patients, in violation of the physical therapy scope of practice act limiting PTs' performance of acupuncture to non-invasive therapies. Acupuncturists licensed under chapter 457 have a clear interest in preventing the entrance of unqualified persons into their profession. See Dep't of Prof'l Reg, Bd. of Dentistry v. Fla. Dental Hygienist Ass'n, 612 So. 2d 646, 651 (Fla. 1st DCA 1993)(claim of illegality, as opposed to mere encroachment upon competitive economic interests, is significant when determining standing)[9/]; Fla Med. Ass'n v. Dep't of Prof'l Reg., 426 So. 2d 1112, 1117 (Fla. 1st DCA 1983)(medical association and physician had standing to challenge Board of Optometry rule that "allows optometrists to provide a form of treatment for which they are not qualified, and which has not been authorized by the legislature under Chapter 463"). The relief requested, a

determination that the Proposed Rule is an invalid exercise of delegated legislative authority, is appropriate for the association to receive because such a determination will protect the profession of acupuncture and the practices of a substantial number of FSOMA's members.

99. This conclusion is not inconsistent with the findings that FSOMA failed to demonstrate that dry needling by PTs would harm or confuse patients. Acupuncturists have an independent interest in the integrity of their professional credentials and should be allowed to challenge a Proposed Rule they allege would allow the unlicensed practice of acupuncture. The competence of the unlicensed practitioners is beside the point.

100. The undersigned specifically rejects FSOMA's assertion that it is substantially affected by virtue of the concept of "cultural misappropriation." FSOMA provided little evidence to flesh out the concept beyond conclusory assertions and made no effort to demonstrate that protection from cultural misappropriation is within the zone of interest protected by any statute or rule at issue in this proceeding.

101. FSOMA has proven by a preponderance of the evidence that a substantial number of its members would be substantially affected by the Proposed Rule. Therefore, the burden shifts to the Board to prove by a preponderance of the evidence that the proposed rule is not an invalid exercise of delegated

legislative authority as to the objections raised. The Board has failed to carry this burden.

102. Section 120.52(8) states as follows:

> "Invalid exercise of delegated legislative authority" means action which goes beyond the powers, functions, and duties delegated by the Legislature. A proposed or existing rule is an invalid exercise of delegated legislative authority if any one of the following applies:
>
> (a) The agency has materially failed to follow the applicable rulemaking procedures or requirements set forth in this chapter;
>
> (b) The agency has exceeded its grant of rulemaking authority, citation to which is required by s. 120.54(3)(a)1.;
>
> (c) The rule enlarges, modifies, or contravenes the specific provisions of law implemented, citation to which is required by s. 120.54(3)(a)1.;
>
> (d) The rule is vague, fails to establish adequate standards for agency decisions, or vests unbridled discretion in the agency;
>
> (e) The rule is arbitrary or capricious. A rule is arbitrary if it is not supported by logic or the necessary facts; a rule is capricious if it is adopted without thought or reason or is irrational;
>
> (f) The rule imposes regulatory costs on the regulated person, county, or city which could be reduced by the adoption of less costly alternatives that substantially accomplish the statutory objectives.
>
> A grant of rulemaking authority is necessary but not sufficient to allow an agency to adopt a rule; a specific law to be implemented is also required. An agency may

> adopt only rules that implement or interpret the specific powers and duties granted by the enabling statute. No agency shall have authority to adopt a rule only because it is reasonably related to the purpose of the enabling legislation and is not arbitrary and capricious or is within the agency's class of powers and duties, nor shall an agency have the authority to implement statutory provisions setting forth general legislative intent or policy. Statutory language granting rulemaking authority or generally describing the powers and functions of an agency shall be construed to extend no further than implementing or interpreting the specific powers and duties conferred by the same statute.

103. In this case, FSOMA challenges the Proposed Rule based on section 120.52(8)(b), (c), (d), and (e). Each of these potential reasons for invaliding the proposed rule is addressed below.

Section 120.52(8)(b), Florida Statutes

104. A rule must be authorized by a grant of rulemaking authority and must implement specific powers and duties provided by the enabling statute. SW Fla. Water Mgmt. Dist. v. Save the Manatee Club, Inc., 773 So. 2d 594, 599 (Fla. 1st DCA 2000).

105. The Proposed Rule cites section 486.025 as its grant of rulemaking authority. Section 486.025 provides as follows, in relevant part:

> The board may administer oaths, summon witnesses, take testimony in all matters relating to its duties under this chapter, establish or modify minimum standards of practice, and adopt rules pursuant to

> ss. 120.536(1) and 120.54 to implement the provisions of this chapter . . . .

106. The Proposed Rule purports to adopt minimum standards of practice for dry needling in the practice of physical therapy. On its face, the Proposed Rule appears to be within the Board's legislatively delegated rulemaking authority.

107. However, the Proposed Rule attempts to sidestep the central question of whether dry needling is authorized by section 486.021(11) by simply assuming that it is. The undersigned has concluded that dry needling meets the definition of acupuncture found in section 457.102(1), i.e., "the insertion of acupuncture needles . . . to specific areas of the human body." Section 486.021(11) provides that PTs may perform acupuncture only "when no penetration of the skin occurs." Therefore, dry needling is beyond the scope of practice for Florida PTs. The Proposed Rule exceeds the grant of rulemaking authority because it would expand the scope of physical therapy practice, not merely establish a standard of practice as authorized by section 486.025.

Section 120.52(8)(c), Florida Statutes

108. The Proposed Rule cites section 486.021(11) as the law implemented. The Proposed Rule clearly "enlarges, modifies, or contravenes" the provision of section 486.021(11) stating that PTs may perform acupuncture "only upon compliance with the

criteria set forth by the Board of Medicine, when no penetration of the skin occurs." Dry needling meets the statutory definition of acupuncture and is an invasive procedure that penetrates the skin.

Section 120.52(8)(d), Florida Statutes

109. FSOMA argues that the Proposed Rule is vague, fails to establish adequate standards for agency decisions, and vests unbridled discretion in the regulating agencies. The test for vagueness of a rule or statute is "whether men of common understanding and intelligence must guess at [the provision's] meaning" and differ as to its application. Dep't of HRS v. Health Care and Ret. Corp. of Am., 593 So. 2d 539, 541 (Fla. 1st DCA 1992)(quoting State v. Cumming, 365 So. 2d 153, 156 (Fla. 1978), and State v. Rodriguez, 365 So. 2d 157, 159 (Fla. 1978)). See also Witmer v. Dep't of Bus. and Prof'l Reg., 662 So. 2d 1299, 1302 (Fla. 4th DCA 1995).

110. Much of the argument as to vagueness, inadequate standards, and unbridled discretion goes to the minimum standards for dry needling practice set forth in subsection (2) of the Proposed Rule. FSOMA noted the absence of specific course requirements, enumerated hours of study, or direct supervision in a clinical setting to be completed before a PT is allowed to dry needle. FSOMA also noted that a PT would not be

required to document his competence before beginning to perform dry needling.

111. The undersigned noted that rule 64B8-37.001, the Board of Medicine rule establishing the criteria for the performance of electromyography by PTs, requires proof of basic training and prerequisite coursework, 200 hours of supervised testing on human subjects, and 100 corroborated tests before a PT may perform electromyography.

112. The undersigned found that dry needling is "acupuncture" as defined in section 457.102(1) and that section 486.021(11) as currently written does not allow PTs to practice dry needling in Florida. These findings made unnecessary an ultimate finding as to the adequacy of the training prescribed in the Proposed Rule.

113. The Board lacks statutory authority to adopt any rule on the subject of dry needling by PTs. This lack of authority renders academic any ultimate findings of fact or conclusions of law as to the text of this Proposed Rule.

114. If the Board were held to have statutory authority to adopt standards of practice for dry needling in the practice of physical therapy, then FSOMA would probably lack standing to challenge them. See, e.g., State, Bd. of Optometry v. Fla. Soc. of Opthalmology, 538 So. 2d 878 (Fla. 1st DCA 1988)(absent direct impact, statutory exclusivity, or a shared professional

relationship, persons and associations generally lack standing to challenge the rules of a competing profession). Again, there would be no need for findings and conclusions critiquing the specific text of this Proposed Rule.

115. No conclusion of law needs be reached as to whether the Proposed Rule is vague, fails to establish adequate standards for agency decisions, and vests unbridled discretion in the Board.

Section 120.52(8)(e), Florida Statutes

116. Finally, Petitioners contend that the Proposed Rule is arbitrary and capricious. Section 120.52(8)(e) provides: "A rule is arbitrary if it is not supported by logic or the necessary facts; a rule is capricious if it is adopted without thought or reason or is irrational." Similarly, case law provides that an "arbitrary" decision is one not supported by facts or logic, or despotic, and a "capricious" decision is one taken irrationally, or without thought or reason. Bd. of Clinical Lab. Pers. v. Fla. Ass'n of Blood Banks, 721 So. 2d 317, 318 (Fla. 1st DCA 1998); Bd. of Trustees of the Int. Imp. Trust Fund v. Levy, 656 So. 2d 1359, 1362 (Fla. 1st DCA 1995). In undertaking this analysis, the undersigned is mindful that these definitions:

> [A]dd color and flavor to our traditionally dry legal vocabulary, but do not assist an objective legal analysis. If an

> administrative decision is justifiable under any analysis that a reasonable person would use to reach a decision of similar importance, it would seem that the decision is neither arbitrary nor capricious.

Dravo Basic Materials Co., Inc. v. Dep't of Transp., 602 So. 2d 632, 635 n.3 (Fla. 2d DCA 1992).

117. As discussed at length above, the Proposed Rule assumes without foundation that the Board possesses statutory authority to adopt a rule establishing standards of practice for dry needling by licensed PTs. A simple reading of the physical therapy scope of practice statute, section 486.021(11), in light of the definition of "acupuncture" in section 457.102(1), makes plain that dry needling is not within the statutory scope of practice for PTs in the State of Florida. The Board had no basis for moving forward with the Proposed Rule.

118. The Proposed Rule is not supported by logic or the necessary facts. It is, therefore, arbitrary.

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, it is

ORDERED that:

Proposed Florida Administrative Code Rule 64B17-6.008 is an invalid exercise of delegated legislative authority.

DONE AND ORDERED this 28th day of January, 2019, in Tallahassee, Leon County, Florida.

LAWRENCE P. STEVENSON
Administrative Law Judge
Division of Administrative Hearings
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Filed with the Clerk of the
Division of Administrative Hearings
this 28th day of January, 2019.

ENDNOTES

[1/] It is noted that FSOMA Exhibit 52 and FPTA Exhibit 27 are the same document.

[2/] FSOMA disagrees with the notion that Dr. Travell and her associates devised the concept of dry needling entirely on their own, given the extensive academic work in traditional Chinese medicine that was already occurring in the West at that time.

[3/] Title 21 C.F.R. § 801.109 defines "prescription devices" as "[a] device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which 'adequate directions for use' cannot be prepared . . . ." To enjoy an exemption from the labeling requirements of 21 U.S.C. § 352(f)(1), a prescription device must be, among other things, "[i]n the possession of a practitioner, such as physicians, dentists, and veterinarians, licensed by law to use or order the use of such device" and "sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice." 21 C.F.R. § 801.109(a)(1).

[4/] Acupuncturists also employ the clean needle technique described by Mr. McElroy. Dr. Dommerholt, who teaches dry needling technique, recommends the use of gloves by the practitioner.

[5/] Mr. McElroy had the common verbal tic of frequently inserting the words "you know" into his speech. To make the quotes more readable, the undersigned has taken the liberty of deleting the "you knows" without indicating their deletion by ellipses. Mr. McElroy's verbatim quotes may be found at pages 618-619 of the Transcript.

[6/] Dr. Zylstra served on the FSBPT task force that reviewed the authors' data and ultimately approved the report, titled "Analysis of Competencies for Dry Needling by Physical Therapists," and issued by HumRRO on July 10, 2015.

[7/] The undersigned is not entirely persuaded that the underscored items in the rule are intended to define the statutory term "specific areas of the human body," but the assertion is accepted arguendo in the discussion that follows.

[8/] The parties argued as to the extent to which deference should be given to the Board's interpretation of section 486.021(11). The undersigned concludes that no special level of deference is due because this case turns on a straightforward reading of the plain language of two statutes. Any entitlement to deference is further undercut by the fact that one of the statutes in question is section 457.102(1), the scope of practice act for acupuncture. The Board cites no authority for the proposition that its interpretation of another regulatory board's practice act is entitled to deference. See also Art. V, § 21, Fla. Const., prohibiting "an officer hearing an administrative action" from deferring to an agency's interpretation of a state statute or rule.

[9/] The undersigned is aware of Florida Medical Association v. Department of Health, Board of Acupuncture, Case No. 01-0025RP, FO at 62-64 (Fla. DOAH Aug. 23, 2001), in which Administrative Law Judge Ella Jane P. Davis concluded that the application of the dental hygienist case should be limited to cases in which professional associations are challenging proposed rules by their own licensing boards. The undersigned notes that ALJ Davis' conclusion was an inference, not a direct statement made by the court in the dental hygienist case. In the instant case, the undersigned has concluded that there is no limiting principle that would allow associations and members of a

profession to contest illegal encroachments on their profession by the state regulatory board to which they answer, but leave them without a remedy where a different state board undertakes the same illegal act.

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NOTICE OF RIGHT TO JUDICIAL REVIEW

A party who is adversely affected by this Final Order is entitled to judicial review pursuant to section 120.68, Florida Statutes. Review proceedings are governed by the Florida Rules of Appellate Procedure. Such proceedings are commenced by filing the original notice of administrative appeal with the agency clerk of the Division of Administrative Hearings within 30 days of rendition of the order to be reviewed, and a copy of the notice, accompanied by any filing fees prescribed by law, with the clerk of the District Court of Appeal in the appellate district where the agency maintains its headquarters or where a party resides or as otherwise provided by law.