15CV012012

FILED
2015 SEP -2 P 2:14
WAKE COUNTY, C.S.C.
BY _____

STATE OF NORTH CAROLINA

COUNTY OF WAKE

IN THE GENERAL COURT OF JUSTICE
SUPERIOR COURT DIVISION
15 CVS _____

NORTH CAROLINA ACUPUNCTURE LICENSING BOARD,

Plaintiff,

v.

NORTH CAROLINA BOARD OF PHYSICAL THERAPY EXAMINERS,

Defendant.

VERIFIED COMPLAINT FOR DECLARATORY JUDGMENT AND FOR PERMANENT INJUNCTION

NOW COMES the plaintiff North Carolina Acupuncture Licensing Board (the "Acupuncture Board"), through counsel, and pursuant to the Uniform Declaratory Judgment Act, N.C. Gen. Stat. § 1-253, *et seq.*, complains of the defendant North Carolina Board of Physical Therapy Examiners (the "PT Board") as follows:

PRELIMINARY STATEMENT

1. The Acupuncture Board brings this action seeking a declaration from this Court that:

a. the practice known as "dry needling," "trigger point therapy," and/or "intramuscular therapy" (together referenced herein as "dry needling"), an invasive medical treatment in which Food and Drug Administration ("FDA") regulated acupuncture needles (solid filiform needles, sometimes referenced as filament needles) are used to puncture a patient's skin and muscle tissue for therapeutic purposes,

constitutes the practice of acupuncture pursuant to Chapter 90, Article 30 of the North Carolina General Statutes; and

b. the practice of "dry needling" by individuals who are neither licensed by the Acupuncture Board nor who fall within one of the exceptions stated in N.C. Gen. Stat. § 90-452(b) is the unlawful practice of acupuncture.

2. The Acupuncture Board seeks a permanent injunction to prevent such unsafe and unlawful practice of acupuncture for the protection of the people of North Carolina. At present, with the endorsement of the PT Board, physical therapists are performing "dry needling" on patients in North Carolina without the clinical training and education requirements established by the North Carolina General Assembly for the practice of acupuncture.

3. The PT Board sought to expand the scope of physical therapy practice to include "dry needling" through the administrative rulemaking process; however, the North Carolina Rules Review Commission ("RRC") rejected the PT Board's proposed rule, determining the proposed rule to be outside the scope of the PT Board's statutory authority. Despite the RRC's ruling, the PT Board has advised and continues to advise its licensees that "dry needling" is within the scope of practice of physical therapy and that physical therapists may continue to perform "dry needling" without *any* training requirements.

4. The Acupuncture Board is informed and believes that injuries to patients have already occurred in North Carolina and elsewhere as a result of physical therapists performing "dry needling" without the clinical training and education required of licensed acupuncturists. Through this action, the Acupuncture Board seeks to prevent further harm to the public as a result of continued unsafe and unlawful practice of acupuncture by physical therapists.

PARTIES AND JURISDICTION

5. The Acupuncture Board is a board duly established by N.C. Gen. Stat. § 90-453 which maintains its offices and records in Wake County, North Carolina. The Acupuncture Board is charged by the General Assembly with the responsibility of promoting the health, safety, and welfare of the people of North Carolina through the enforcement of Chapter 90, Article 30 of the North Carolina General Statutes. *See* N.C. Gen. Stat. § 90-450, *et seq.* ("the Acupuncture Practice Act").

6. The Acupuncture Board's powers and duties include the authority to file suit in Superior Court to enjoin the unauthorized practice of acupuncture. N.C. Gen. Stat. § 90-454(4) (citing N.C. Gen. Stat. § 90-452).

7. The PT Board is a board duly established by N.C. Gen. Stat. § 90-270.25 and is charged with safeguarding the public health, safety, and welfare against unqualified or incompetent practitioners of *physical therapy* throughout North Carolina. N.C. Gen. Stat. §§ 90-270.24(4) and .26. The PT Board has no jurisdiction over the practice of acupuncture.

8. This Court has jurisdiction over this matter and over the parties pursuant to N.C. Gen. Stat. §§ 1-75.4 and 1-253 *et seq.*

9. Venue is proper in this Court pursuant to N.C. Gen. Stat. § 1-82.

FACTUAL BACKGROUND

"Dry Needling" Is the Practice of Acupuncture

10. The North Carolina General Assembly defined the "practice of acupuncture" to include "the insertion of acupuncture needles" as well as "the application of moxibustion to specific areas of the human body based upon acupuncture diagnosis as a primary mode of

therapy." N.C. Gen. Stat. § 90-451(3).

11. The North Carolina General Assembly defined "acupuncture" as "a form of health care developed from traditional and modern Chinese medical concepts that employ acupuncture diagnosis and treatment, and adjunctive therapies and diagnostic techniques for the promotion, maintenance and restoration of health and the prevention of disease." N.C. Gen. Stat. § 90-451(3).

12. "The application of moxibustion" is a form of heat therapy. It refers to the practice of burning "moxa sticks or small moxa cones," which are made with herbs such as *artemisia vulgaris* (mugwort). Moxa sticks are held over a point or area of the patient's body to warm it. Moxa cones can be applied to a needle that has been inserted into an acupuncture point, or they can be applied to the patient's skin indirectly by using salt or some other substance as insulation at specific "moxibustion points." In treating patients, acupuncturists in North Carolina sometimes use "needling" without "moxibustion;" sometimes use "moxibustion" without "needling;" and sometimes use both.

13. Acupuncture as currently practiced in North Carolina combines ancient Chinese concepts with modern advances in anatomy, physiology, and neuroscience.

14. Acupuncture incorporates many different needling techniques, including the technique traditionally known as ashi point needling. Ashi point needling acupuncture, which has been performed for over 2,000 years, is the insertion of needles into specific areas of the body, called "ashi points," to relieve pain.

15. "Dry needling" is "the use of solid needles (contrasted with the use of hollow hypodermic needles that are used for injections) to treat muscle pain by stimulating and breaking

muscular knots and bands." American Academy of Medical Acupuncture, Policy on Dry Needling, Dec. 9, 2014 (a copy of which is attached hereto as Exhibit A).

16. While the terms "dry needling" or "trigger point needling" were not used in the Western medical lexicon until within the last 40 years, the "trigger points" into which needles are inserted during "dry needling" are the same as the traditional "ashi points" which have been effectively utilized by acupuncturists for over 2,000 years to relieve their patients' pain.

17. The solid needles used in "dry needling" are identical to acupuncture needles in all material respects and are in fact FDA-defined and regulated acupuncture needles.

18. "Dry needling" can involve the use of acupuncture needles which are up to four inches in length.

19. The United States Food and Drug Administration ("FDA") identifies an acupuncture needle 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).

20. The FDA has recognized that as a "medical device" acupuncture needles pose a significant potential for injuries including the perforation of blood vessels and organs, sepsis, and excessive trauma.

21. The FDA regulates acupuncture needles as controlled class II medical devices. 21 C.F.R. § 880.5580(b). The FDA does not separately identify or classify "dry needles" in any way.

22. Acupuncture needles are also regulated by the FDA as a prescription medical device and are available only for purchase and use by persons legally authorized to practice

acupuncture. 21 CFR § 880.5580(b)(1); 21 CFR § 801.109.

23. The acupuncture needles used in "dry needling" must carry a specific FDA warning as required under 21 CFR § 880.109(b)(1) stating, "Caution: Federal law restricts this device to sale by or on the order of a [*qualified practitioner of acupuncture* licensed by the law of the State in which he practices to use or order the use of the device]." (emphasis added).

24. In adopting these regulations, the FDA was explicit that acupuncture needles "must be clearly restricted to *qualified practitioners of acupuncture* as determined by the States." 61 Fed. Reg. 64616 (Dec. 6, 1996) (emphasis added) (pp. 64616-17 are attached hereto as Exhibit B).

25. In order to receive payment from private insurance companies and government sources, such as Medicaid, for services rendered to patients, medical providers must code their procedures pursuant to Current Procedural Terminology as determined by the American Medical Association ("CPT codes"). There is no separate CPT billing code for "dry needling." Upon information and belief, at least some physical therapists are intentionally miscoding "dry needling" procedures that they administer to patients as "manual therapy" in order to obtain insurance and government payments for those procedures.

26. Physical therapists performing "dry needling" use "ashi points" to insert acupuncture needles through the skin into "knots" of muscle tissue (regardless of whether they are called "ashi points" or "trigger points") for therapeutic purposes.

27. "Dry needling" is the practice of acupuncture, and thus may not be performed in North Carolina by individuals who are not authorized to perform acupuncture as enumerated in N.C. Gen. Stat. § 90-452.

The RRC Determined That "Dry Needling" is Outside the Scope of Physical Therapists' Practice

28. Pursuant to N.C. Gen. Stat. § 90-452, the only individuals who may lawfully perform acupuncture in North Carolina are licensed acupuncturists, students studying under the direct supervision of a licensed acupuncturist, licensed physicians (for whom the American Board of Medical Acupuncturists requires a 300-hour acupuncture-specific certification program), and licensed chiropractors (who are required by 21 NCAC 10.0208 to have completed an additional 200 hours of acupuncture training beyond their normal requirements for licensure).

29. There is no provision in N.C. Gen. Stat. § 90-452 that authorizes physical therapists to practice acupuncture in any form.

30. "Dry needling" is outside the scope of practice of physical therapists in North Carolina as set out in N.C. Gen. Stat. § 90-270.24(4).

31. In its Summer 2002 Newsletter for its licensees, the PT Board confirmed that "dry needling" is outside the scope of practice of physical therapists in North Carolina. The following Question and Answer appeared in that publication on page four:

> **Forum: Questions and Answers**
>
> **Question:** Is dry needling within the scope of practice of physical therapists in North Carolina?
>
> **Answer:** NO. Dry needling is a form of acupuncture. In North Carolina, a practitioner who performs acupuncture must have a license from the NC Board of Acupuncture.

A complete copy of the PT Board's Summer 2002 Newsletter is attached hereto as Exhibit C.

32. Neither the definitions of "acupuncture" nor "the practice of acupuncture" stated in N.C. Gen. Stat. § 90-451 nor the definition of "physical therapy" stated in N.C. Gen. Stat. § 90-270.24(4) have been modified by the General Assembly since 2002.

33. There is no provision in the physical therapists' statutory scope of practice which

authorizes physical therapists to puncture their patients' skin and muscle tissue for therapeutic purposes.

34. Section 90-270.24(4) does make reference to the use of "assistive devices;" however, assistive devices are aids such as crutches, walkers, or orthotic devices. In contrast, acupuncture needles are FDA-controlled *medical* devices in the realm of *surgical implements*.

35. The statutory definition of "physical therapy" specifically excludes surgery. N.C. Gen. Stat. § 90-270.24.

36. The North Carolina Medical Society ("NCMS") defines surgery as:

> The diagnosis or therapeutic treatment of conditions or disease processes by any instrument causing localized alteration or transposition of live human tissue or organs, including, but not limited to: lasers, ultrasound, ionizing radiation, scalpels, probes *and needles* in which human tissue or organs are cut, burned, vaporized, frozen, sutured, probed, manipulated by closed reduction for major dislocations and fractures, or otherwise altered by any mechanical, thermal, light-based, electromagnetic, or chemical means.

NCMS 2013 Policy Manual, p. 156, available at http://www.ncmedsoc.org/wp-content/uploads/2013/06/2013-policy-manual.pdf (emphasis added).

37. "Dry needling" is not part of physical therapists' standard course of study or training, nor is "dry needling" a technique that is tested as part of the examination of qualifications of applicants for licensure as a physical therapist in North Carolina required by N.C. Gen. Stat. § 270.26.

38. In an effort to expand the scope of physical therapy practice in North Carolina by administrative rule, in 2014 the PT Board proposed rule 21 NCAC 48C .0104, entitled "Dry Needling" ("the Proposed Rule") (a copy of which is attached hereto as Exhibit D), which defined "dry needling" as "a technique using the insertion of a solid filament needle, without

medication, into or through the skin to treat various impairments."

39. The Proposed Rule went on to state that prior to a physical therapist performing "dry needling" in North Carolina, among other things, the applicant must complete a minimum of 54 hours of classroom education from a "dry needling" training program for physical therapists from a program approved by the PT Board. The Proposed Rule contained no provisions for any supervised, or unsupervised, clinical training of "dry needling" techniques or needle placement.

40. In contrast, newly licensed acupuncturists must have completed a three-year postgraduate acupuncture college or training program as approved by the Acupuncture Board in addition to a Clean Needle Technique Course provided by the Council of Colleges of Acupuncture and Oriental Medicine. N.C. Gen. Stat. § 90-455(a). These requirements result in a graduate course of study of at a minimum 1,905 hours for licensed acupuncturists as currently required by the Accreditation Commission for Acupuncture and Oriental Medicine ("ACAOM"), which is the national accrediting body recognized by the U.S. Department of Education. 21 NCAC 01.0101(6)(a); ACAOM Accreditation Manual, p. 26, available at http://www.acaom.org/documents/accreditation_manual_712.pdf. The two acupuncture colleges located in North Carolina require at least 2,198 and 2,564 hours to graduate from their masters programs in acupuncture and oriental medicine. A significant component of those hours take the form of supervised, clinical training regarding needle placement and needling techniques.

41. The Proposed Rule came on for hearing before the RRC on January 15, 2015.

42. A number of parties, including the Acupuncture Board, objected to the Proposed Rule as failing to comply with the standards of N.C. Gen. Stat. § 150B-21.9(a) in that, *inter alia*,

it exceeded the authority delegated to the PT Board by the General Assembly.

43. The RRC, after hearing comments both in support and in opposition to the Proposed Rule, formally objected to the Proposed Rule as "address[ing] a matter not within the authority delegated to the agency by the General Assembly, as required by G.S. 150B-21.9(a)." A copy of the RCC's January 26, 2015, letter to the PT Board is attached hereto as Exhibit E.

44. The PT Board did not seek judicial review of the RRC's decision as permitted by N.C. Gen. Stat. § 150B-21.8(d).

The PT Board Is Advising its Licensees That They May Continue to Perform "Dry Needling" Without Any Specific Education or Training Requirements

45. On January 16, 2015, one day after the RRC rejected the PT Board's attempt to expand the scope of physical therapy practice through the rule making process without statutory authority, the PT Board posted a notice on its official website (www.ncptboard.org) advising its licensees that they may continue to perform "dry needling" ("the January 16 Notice"). A copy of the January 16 Notice is attached hereto as Exhibit F.

46. The January 16 Notice states that, notwithstanding the RRC's determination that the Proposed Rule was outside the PT Board's statutory authority, the PT Board believed, based upon a 2011 informal advisory letter from the Attorney General's Office and the opinion of the RRC's staff counsel (which the RRC itself did not adopt), that "dry needling" is within the scope of practice of physical therapy in North Carolina.

47. The January 16 Notice goes on to state that "there are *no regulations* to set the specific requirements for engaging in "dry needling" [for physical therapists in North Carolina]." (emphasis added).

48. The Acupuncture Board requested on or about June 3, 2015, that the PT Board

remove the January 16 Notice, but as of the date of this filing the notice remains prominently displayed on the PT Board's website homepage under a heading entitled "Important Information." A screen capture of the PT Board's website homepage as of the date of this filing is attached hereto as Exhibit G.

49. Thus, physical therapists are currently performing "dry needling" in North Carolina with the endorsement of the PT Board but without statutory authority or regulation.

50. A critical responsibility of the Acupuncture Board is to protect the public from the unsafe use of acupuncture needles. As such, the Acupuncture Board has a significant and compelling interest in ensuring and clarifying that acupuncture needles cannot legally be used for therapeutic purposes by physical therapists.

51. There is an important need to resolve the controversy that exists between the PT Board and the Acupuncture Board regarding the legality of "dry needing" and whether it is authorized under the physical therapy scope of practice.

52. The continued, unregulated, practice of "dry needling" by physical therapists in North Carolina, as endorsed by the PT Board, unnecessarily exposes patients to an unregulated practice and an increased risk of injury as a result of insufficient training in acupuncture.

53. The Acupuncture Board is informed and believes that injuries to patients in North Carolina have occurred as a result of physical therapists' deficient performance of "dry needling," including, but not limited to, an incident resulting in a pneumothorax (collapsed lung) in Asheville, North Carolina, which required the patient to undergo surgery for correction.

54. This type of avoidable injury to North Carolinians suffered at the hands of insufficiently trained providers is precisely the type of harm which N.C. Gen. Stat. § 90-452(b)

seeks to prevent by limiting those who may practice acupuncture in this State to licensed acupuncturists, medical doctors, and chiropractors.

55. The Acupuncture Board has attempted in good faith to resolve this controversy with the PT Board consistent with N.C. Gen. Stat. § 150B-19.1(d) and other applicable law, including initiating direct discussions with representatives of the PT Board prior to instituting this action. These efforts have been unsuccessful.

56. Given the PT Board's continued endorsement of "dry needling" by physical therapists, notwithstanding the RRC's determination that the practice is outside the statutory scope of physical therapy in North Carolina, no adequate administrative remedies exist for the Acupuncture Board, and to the extent that any such remedies may have existed, they have now been exhausted.

FIRST CLAIM FOR RELIEF
Declaratory Judgment

57. Plaintiff repeats and incorporates by reference the allegations previously stated herein.

58. The Acupuncture Board seeks a declaration from the Court that a physical therapist's "insertion of acupuncture needles," or any similar needle, by physical therapists engaged in "dry needling" constitutes the unlawful "practice of acupuncture" pursuant to N.C. Gen. Stat. §§ 90-451 and 452.

59. Justiciable issues exist with respect to whether "dry needling" is acupuncture and whether the practice of "dry needling" by individuals who are neither licensed by the Acupuncture Board nor fall within one of the exceptions stated in N.C. Gen. Stat. § 90-452(b) is the unlawful practice of acupuncture.

60. By advising its licensees that they may lawfully perform "dry needling" without an acupuncture license, the PT Board is exceeding its statutory authority and jurisdiction by endorsing the violation of N.C. Gen. Stat. § 90-452(b) and, more importantly, is endangering the people of North Carolina by unnecessarily increasing the risk of injury as a result of acupuncture being performed by physical therapists who are not licensed acupuncturists and who lack the specific training necessary to provide acupuncture treatments safely.

61. All known parties who have a direct interest in this controversy are parties to this litigation.

62. Pursuant to the Uniform Declaratory Judgment Act, N.C. Gen. Stat. § 1-253, *et seq.*, the plaintiff Acupuncture Board seeks a declaration from this Court to settle the rights of the respective parties and for the safety of the general public to remove the uncertainty created by the PT Board's endorsement of the unauthorized practice of acupuncture by physical therapists and to permit the Acupuncture Board to cause physical therapists who are not licensed to practice acupuncture to cease and desist from such practice.

SECOND CLAIM FOR RELIEF
Permanent Injunction

63. Plaintiff repeats and incorporates by reference the allegations previously stated herein.

64. A permanent injunction requiring the PT Board to remove the January 16 Notice (and any other similar notices) from its official website, and other means of dissemination, and requiring the PT Board to advise its licensees that "dry needling" is not within the scope of physical therapy practice in North Carolina is necessary to protect the public from the safety risks posed by the unauthorized practice of acupuncture by physical therapists.

PRAYER FOR RELIEF

WHEREFORE, the plaintiff Acupuncture Board respectfully prays that the Court:

1. Enter a judgment declaring that

a. "Dry needling" is the practice of acupuncture as defined by Chapter 90, Article 30 of the North Carolina General Statutes;

b. "Dry needling" is outside the authorized scope of practice for physical therapists as defined in N.C. Gen. Stat. § 90-270.24(4).

c. the practice of "dry needling" by individuals who are neither licensed by the Acupuncture Board nor fall within one of the exceptions stated in N.C. Gen. Stat. § 90-452(b) is the unlawful practice of acupuncture; and

2. Enter a permanent injunction requiring the PT Board to remove the January 16 Notice from its official website or other means of dissemination and to advise its licensees that "dry needling" is not within the scope of physical therapy practice in North Carolina;

3. Enter a judgment authorizing the Acupuncture Board to notify physical therapists not licensed to practice acupuncture in North Carolina to cease and desist from doing so and to seek appropriate court action and to enjoin the unlawful practice of acupuncture by physical therapists in the event their conduct does not cease;

4. Tax all costs of this action against the defendant PT Board; and

5. Grant the plaintiff Acupuncture Board such other and further legal and equitable relief as the Court deems just and proper.

Respectfully submitted, this the 2nd day of September, 2015.

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Attorneys for Plaintiff North Carolina Acupuncture Licensing Board

STATE OF NORTH CAROLINA
COUNTY OF WAKE

IN THE GENERAL COURT OF JUSTICE
SUPERIOR COURT DIVISION
15 CVS _____

NORTH CAROLINA ACUPUNCTURE LICENSING BOARD,

Plaintiff,

v.

NORTH CAROLINA BOARD OF PHYSICAL THERAPY EXAMINERS,

Defendant.

VERIFICATION OF COMPLAINT

NOW COMES Emmylou "Junie" Norfleet, first being duly sworn, and deposes and says that she is the Chair of the plaintiff North Carolina Acupuncture Licensing Board ("Acupuncture Board"); that in her official capacity as Chair of the Acupuncture Board she has read the foregoing Complaint prepared on the Acupuncture Board's behalf; and that on behalf of the Acupuncture Board she verifies, based on her own knowledge, the truth of the factual allegations stated in the Complaint, except for those allegations stated upon information and belief, which she believes in good faith to be true.

Respectfully submitted, this the 1 day of September, 2015.

Emmylou "Junie" Norfleet
Chair, North Carolina Acupuncture Licensing Board

State of North Carolina)
Buncombe County)

Sworn to and subscribed before me on this the 1st day of September, 2015.

Natalie H. Iannucci
Notary Public

My commission expires: 06/09/2020

NATALIE H. IANNUCCI NOTARY PUBLIC BUNCOMBE COUNTY, NC

AAMA Policy on Dry-Needling

Marshall H. Sager, DO, FAAMA
Rey Ximenes, MD, FAAMA

The American Academy of Medical Acupuncture (AAMA) is the premier North American organization of physician acupuncturists. The AAMA is committed to insuring public health and safety by ensuring that all persons practicing any type of medicine, including acupuncture, are properly trained and educated. It is imperative that courts and medical bodies maintain and preserve strict standards of education and training in acupuncture before any person undertakes inserting a needle into a patient. An ill-trained practitioner could, as a result of lack of education or ignorance, cause substantial medical injury.

Acupuncture, like Western Medicine is a complex subject. It cannot be mastered in a weekend or in a month. All AAMA members in addition to four (4) years of medical school (MD or DO), must have 300 hours of didactic and clinical acupuncture education and training. A non-physician must have in excess of 2,000 hours of clinical and didactic education and training before they can become certified to treat patients in most states.

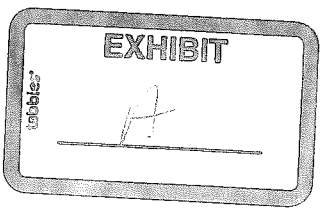
Dry needling is the use of solid needles (contrasted with the use of hollow hypodermic needles that are used for injections) to treat muscle pain by stimulating and breaking muscular knots and bands. Unlike trigger point injections used for the same purpose, no anesthetics are used in dry needling. There is controversy regarding the definition of dry needling. Licensed medical physicians and licensed acupuncturists consider dry needling as Western Style Acupuncture or Trigger Point Acupuncture whereby the insertion sites are determined by tender painful areas and tight muscles. These sites may be treated alone or in combination with known acupuncture points. Other practitioners take the position that dry needling is different from acupuncture in that it is not a holistic procedure and does not use meridians or other Eastern medicine paradigms to determine the insertion sites.

Dry needling is an invasive procedure. Needle length can range up to 4 inches in order to reach the affected muscles. The patient can develop painful bruises after the procedure and adverse sequelae may include hematoma, pneumothorax, nerve injury, vascular injury and infection. Post procedure analgesic medications may be necessary (usually over the counter medications are sufficient).

There has been controversy in the United States as to who is qualified to practice dry needling. Since it is an invasive procedure using needles, many take the position that it should only be performed by licensed acupuncturists or licensed medical physicians (M.D. or D.O.). In Illinois, this sentiment was echoed by a decision to reverse legislation permitting physical therapists to perform dry needling. These and other practitioners were performing this procedure who are not trained nor do they otherwise routinely use needles in their practices.

The AAMA recognizes dry needling as an invasive procedure using acupuncture needles that has associated medical risks. Therefore, the AAMA maintains that this procedure should be performed only by practitioners with extensive training and familiarity with routine use of needles in their practice and who are duly licensed to perform these procedures, such as licensed medical physicians or licensed acupuncturists.

December 9, 2014
Adopted unanimously
Board of Directors of AAMA



Therefore, a regulatory flexibility analysis as provided in Public Law 96–354, the Regulatory Flexibility Act, is not required.

Paperwork Reduction Act

This regulation imposes no reporting/recordkeeping requirements necessitating clearance by OMB.

(Catalog of Federal Domestic Assistance Program Nos. 96.001, Social Security-Disability Insurance; 96.002, Social Security-Retirement Insurance; 96.004, Social Security-Survivors Insurance; 96.006, Supplemental Security Income)

List of Subjects in 20 CFR Part 404

Administrative practice and procedure, Blind, Disability benefits, Old-Age, Survivors and Disability Insurance, Reporting and recordkeeping requirements, Social Security.

Dated: December 2, 1996.

Shirley S. Chater,

Commissioner of Social Security.

For the reasons set forth in the preamble, part 404, subpart P, chapter III of title 20 of the Code of Federal Regulations is amended as set forth below:

PART 404—FEDERAL OLD-AGE, SURVIVORS AND DISABILITY INSURANCE (1950–)

Subpart P—[Amended]

1. The authority citation for subpart P of part 404 continues to read as follows:

Authority: Secs. 202, 205(a), (b), and (d)–(h), 216(i), 221(a) and (i), 222(c), 223, 225, and 702(a)(5) of the Social Security Act (42 U.S.C. 402, 405(a), (b), and (d)–(h), 416(i), 421(a) and (i), 422(c), 423, 425, and 902(a)(5)).

2. Appendix 1 to subpart P of part 404 is amended by revising item 1 of the introductory text before part A to read as follows:

Appendix 1 to Subpart P—Listing of Impairments

* * * * *

1. Growth Impairment (100.00): December 7, 1998.

* * * * *

[FR Doc. 96–31037 Filed 12–5–96; 8:45 am]

BILLING CODE 4190–29–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket Number 94P–0443]

Medical Devices; Reclassification of Acupuncture Needles for the Practice of Acupuncture

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing that it is reclassifying acupuncture needles for the practice of acupuncture and substantially equivalent devices of this generic type from class III (premarket approval) into class II (special controls). FDA is also announcing it has issued an order in the form of a letter to the Acupuncture Coalition reclassifiying acupuncture needles. This action is in response to petitions filed by the Acupuncture Coalition and in keeping with, but not dependent upon, the recommendation of FDA's Anesthesiology Devices Advisory Panel (the Panel). This action is being taken because the agency believes that there is sufficient information to establish that special controls will provide reasonable assurance of the safety and effectiveness of acupuncture needles.

EFFECTIVE DATE: December 6, 1996.

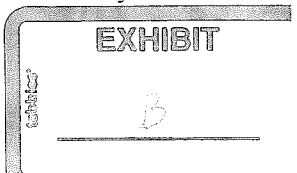
FOR FURTHER INFORMATION CONTACT: Timothy A. Ulatowski, Center for Devices and Radiological Health (HFZ–480), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–443–8879.

SUPPLEMENTARY INFORMATION: On December 6, 1995, FDA filed reclassification petitions from the Acupuncture Coalition, which includes representatives of the following manufacturers: Carbo (Mfg.), China; Hwa-To, China; Chung Wha, South Korea; Taki, South Korea; Dong Bang, South Korea; Tseng Shyh Co., Taiwan; HCD, France; Sedatelec, France; Seirin-Kasei (Mfg.), Japan; Ito Co., Japan; and Ido-No-Nippon-Sha, Japan, requesting reclassification of acupuncture needles from class III to class II. On March 29, 1996, FDA issued an order (Ref. 1) in the form of a letter, to the petitioners reclassifying acupuncture needles for the practice of acupuncture and substantially equivalent devices of this generic type from class III to class II. Section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)) and § 860.134 (21 CFR 860.134) provide for the reclassification by order of devices not in commercial distribution before May 28, 1976, the date of enactment of the Medical Device Amendments.

Under section 513(f)(2) of the act and § 860.134, FDA may refer a reclassification petition to an appropriate panel. Although FDA did not refer the reclassification petitions submitted by the Acupuncture Coalition to a panel, the Anesthesiology Devices Advisory Panel (the Panel) had previously considered the classification of acupuncture needles and other acupuncture devices and recommended that acupuncture needles be placed into class II, as reported in the **Federal Register** of November 2, 1979 (44 FR 63292 at 63299) (Ref. 2). The supplemental data sheet completed by the Panel on November 30, 1976 (Ref. 3), listed sepsis, excessive trauma, and perforation of blood vessels and organs as specific risks, and recommended restricting the device to prescription use. FDA's decision to reclassify acupuncture needles as class II is in keeping with, but not dependent upon, the recommendation of the Panel.

FDA determined that acupuncture needles could safely be reclassified from class III to class II with the implementation of special controls. Acupuncture needles are devices intended to pierce the skin in the practice of acupuncture. The device consists of a solid, stainless steel needle and may have a handle attached to the needle to facilitate the delivery of acupuncture treatment.

The order identified the special controls needed to provide reasonable assurance of the safety and effectiveness of acupuncture needles. Those special controls are in compliance with: (1) Labeling provisions for single use only and the prescription statement in § 801.109 (21 CFR 801.109) (restriction to use by or on the order of qualified practitioners as determined by the States), (2) device material biocompatibility, and (3) device sterility. FDA believes that information for use, including: Indications, effects, routes, methods, and frequency and duration of administration; and any hazards, contraindications, side effects, and precautions are commonly known to qualified practitioners of acupuncture. Therefore, under § 801.109(c), such indications do not need to be on the dispensing packaging, but sale must be clearly restricted to qualified practitioners of acupuncture as determined by the States. Guidance on the type of information needed to support biocompatibility and sterility of



acupuncture needles is available in the General Hospital Branch guidance document entitled "Guidance on the Content of Premarket Notification (510(k)) Submissions for Hypodermic Single Lumen Needles" (draft), April 1993 (Ref. 4). A copy of this guidance document is available from the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850–4307, 301–443–6597 or 800–638–2041 and FAX 301–443–8818.

Consistent with the act and the regulations, after thorough review of the clinical data submitted in the petitions, and after FDA's own literature search, on March 29, 1996, FDA sent the Acupuncture Coalition a letter (order) reclassifying acupuncture needles for general acupuncture use, and substantially equivalent devices of this generic type, from class III to class II (special controls). As required by § 860.134(b)(7), FDA is announcing the reclassification of the generic type of device. Additionally, FDA is amending part 880 (21 CFR part 880) to include the classification of acupuncture needles for the practice of acupuncture by adding new § 880.5580.

Environmental Impact

The agency has determined that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Under 21 CFR 25.24(e)(2), the reclassification of a device is categorically exempt from environmental assessment and environmental impact statement requirements. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because reclassification of devices from class III to class II will relieve some manufacturers of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

Paperwork Reduction Act of 1995

FDA concludes that the labeling requirements in this final rule are not subject to review by the Office of Management and Budget because they do not constitute a "collection of information" under the Paperwork Reduction Act of 1995 (Pub. L. 104–13). Rather, the proposed warning statements are "public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)).

References

The following references have been placed on display in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. FDA letter (order) to the Acupuncture Coalition dated March 29, 1996.

2. Classification of anesthesiology devices, development of general provisions; 44 FR 63292 at 63299, November 2, 1979.

3. Anesthesiology Devices Advisory Panel's supplemental data sheet, November 30, 1976.

4. Guidance on the Content of Premarket (510(k)) Submissions for Hypodermic Single Lumen Needles (draft), April 1993.

List of Subjects in 21 CFR Part 880

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 880 is amended as follows:

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

1. The authority citation for 21 CFR part 880 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. New § 880.5580 is added to subpart F to read as follows:

§ 880.5580 Acupuncture needle.

(a) *Identification.* An acupuncture needle is 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.

(b) *Classification.* Class II (special controls). Acupuncture needles must comply with the following special controls:

(1) Labeling for single use only and conformance to the requirements for prescription devices set out in 21 CFR 801.109,

(2) Device material biocompatibility, and

(3) Device sterility.

Dated: November 20, 1996.

D. B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 96–31047 Filed 12–5–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

24 CFR Part 5

[Docket No. FR–4154–C–02]

RIN 2501–AC36

Revised Restrictions on Assistance to Noncitizens; Correction

AGENCY: Office of the Secretary, HUD.

ACTION: Interim rule, correction.

SUMMARY: On November 29, 1996 (61 FR 60535), HUD published an interim rule implementing the changes made to Section 214 of the Housing and Community Development Act of 1980 by the Use of Assisted Housing by Aliens Act of 1996. Section 214 prohibits HUD from making certain financial assistance available to persons other than United States citizens, nationals, or certain categories of eligible noncitizens. The November 29, 1996 interim rule incorrectly provided for a public comment due date of November 29, 1996. The public comment due date should have been January 28, 1997, 60 days after publication of the November 29, 1996 interim rule. The purpose of this document is to correct the due date for public comments in the November 29, 1996 rule.

North Carolina Board of Physical Therapy Examiners
NEWSLETTER

ISSUE 28 SUMMER 2002

Collaboration to Controversy and Back Again

By Judy A. White, PT, Chair

For over two years, the NCBPTE has been involved with the development and processing of rules changes. These rules changes were primarily undertaken to modernize the language of PT practice to reflect the current practice of physical therapists and to provide more clarification of such areas as supervision and disciplinary processes. Many of you attended one of our three (3) statewide information sessions during which you gave valuable feedback and suggestions. In addition, a public hearing was held in Raleigh. As the Chair of NCBPTE, I can assure both the public and the licensees that, through the diligence and conscientiousness of Ben Massey, Executive Director, and John Silverstein, legal counsel, the rules process met *more* than a minimum requirement level. Publication and public information were highly visible and legislatively appropriate throughout the rules process. The NCBPTE is fortunate to have the commitment to excellence that Ben and John provide. In fact, the North Carolina Board is recognized nationally for its standards of excellence and efficiency!

After the proposed rules changes had already been approved by the Rules Review Commission in July, 2001, we were informed in February, 2002 that the national and state occupational therapy community were greatly concerned about these proposed rules. Their professional concerns were focused primarily on what was perceived as an attempt to "greatly expand the PT scope of practice" through the rules process. Many of you may have been challenged by your co-workers about an expansion of PT practice. I suggest that this was truly the crux of the controversy presented by the North Carolina Occupational Therapy Association (NCOTA). As we communicated to them, I communicate to you now: these rules are NOT an expansion of the scope of PT practice. The NCOTA was able to present their concerns to the North Carolina Joint Legislative Administrative Procedure Oversight Committee (JLAPOC) in March and we were able to respond about their concerns to the JLAPOC members. Generally, legislators prefer to avoid "turf battles" and attempts by professions to limit one another. In addition, legislative action that might reduce consumers' choice is often not encouraged. Fortunately for all of us, the JLAPOC advised the two groups to work these issues out in a collaborative manner. Given that PTs and OTs have worked collaboratively for most of our professional lives, we were prepared and ready to proceed. We knew that collaboration, and *not* confrontation, was the best method for reconciliation.

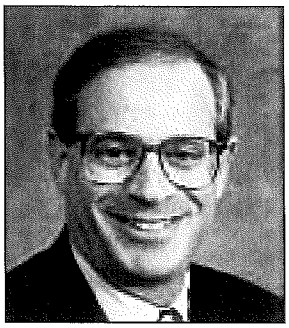
Professional licensure boards and professional associations have differences that need to be understood as a part of the negotiations process between the NCBPTE and the NCOTA. In 1951, the NC General Assembly created the NCBPTE to administer and enforce the Physical Therapy Practice Act, to ensure minimum level of competence, and to exercise disciplinary authority over licensees when their competence is below the minimum level required to protect the public. Indeed our purpose is to protect the public health, safety, and welfare. A professional association consists of voluntary members and is generally committed to the needs and interests of its members and profession. The NCBPTE does *not* participate in legislative lobbying activities, whereas a professional association, such as the NCPTA or NCOTA could actively participate in legislative change activities. Although these differences between the NCBPTE and the NCOTA did not prevent resolution, it was important to understanding what limitations each group had relative to legislative activities.

After several meetings and a change proposed by the NCOTA, we were indeed able to move beyond the controversy and reach a consensual agreement. We were able to return to our previous state of collaboration and fully focus on working together to serve those who benefit from the collaborative services that OT's and PT's provide. I especially want to thank Lynn Losada, President of NCOTA, for her role in facilitating a responsible approach to our resolution.

Now it is your responsibility to further facilitate the transition from confrontation to collaboration. Be willing to correct the existing misinformation or erroneous perceptions. Resume your previous professional relationships in which PTs and OTs work in common and collaboratively to help individuals gain maximum function and improve their quality of life. It is time to move forward with the public once again at the center. If you have more questions or concerns about this issue, please do not hesitate to communicate with Ben or myself. We are anxious to rectify misperceptions and to reconvene a positive atmosphere of collegiality.

Process Served

By John M. Silverstein, Board Attorney



Regular readers of this Newsletter, the Board's Web page or the *North Carolina Register* have been apprised of the Board's nearly two year effort to modify and update the N.C. Administrative code rules that define and describe the nature of the practice of physical therapy in North Carolina. Nearly 20 separate rules were involved, most of which were either new or had not been changed in more than 10 years.

The process to adopt, amend or repeal a rule is delineated in North Carolina's Administrative Procedure Act (Chapter 150B, Article 2A). It starts with a Notice of Rule Making Proceedings that is published in the *North Carolina Register*, and is followed by publication of the proposed rules in the Register, a public hearing and public comment period, and review by the Rules Review Commission and the General Assembly. A proposed rule is subject to modification at each step along its journey. In fact, as a result of comments received during three statewide hearings held by the Board in 2001, and proposals made by the Rules Review Commission, the Board made several changes to the proposed rules first published in March, 2001, before adopting them in September.

By the time rules are presented to the Legislature for final review, most groups that might be impacted have had the opportunity to provide input, and of the thousands of rules that are presented to the Legislature for review each year, only a handful receive legislative scrutiny. Unfortunately, one Board rule relating to the scope of practice of physical therapy became subject to that scrutiny this year. In February, the Board became aware that occupational therapists were concerned that 21 NCAC 48C.0101 (Permitted Practice) actually expanded the scope of practice of physical therapy and infringed upon the scope of practice of occupational therapy.

On February 12, 2002, representatives of the Board met with representatives of the N.C. Occupational Therapy Association (NCOTA) to see if there was a way to resolve the concerns raised by the OT's. At that time, the OT's were committed to seeking a modification of the rule in the General Assembly. Since the rules were scheduled to become effective on October 1, 2002, and the rule could not be modified by that date if the process outlined above was followed, the OT's requested that the Board endorse a proposal to introduce a bill in the Legislature to modify 21 NCAC 48C .0101.

The Board's representatives opposed the introduction of a bill for two basic reasons: (1) changing the rule in the Legislature would limit the ability of those who had responded to publication in the Register and notice of public hearings to comment on any new change and (2) any bill introduced in the Legislature would be subject to amendment by any Legislator. With the two groups at an impasse, the NCOTA took the matter to the Legislature by filing a request with the Joint Legislative Oversight Committee (JLOC), which is the entity that initially reviews rules, to propose a modification in 21 NCAC 48C.0101. At its meeting on March 27, 2002, the JLOC was requested by the NCOTA to introduce a bill requesting a modification. However, the Committee members commenting on the proposal made it clear that they preferred that the groups work out their differences to avoid a Legislative solution that might be detrimental to the interests of both groups.

With that impetus, representatives of the Board met with representatives of the NCOTA to see if they could reach common ground. It quickly became apparent that the OT position that PT's were attempting to expand their scope of practice into areas traditionally reserved for OT's was based on sincere concerns. The Board representatives assured the OT's that there was never any intent to expand the scope of PT practice. The rule was designed to, among other things, modernize the language defining elements of "activities of daily living" that had traditionally been offered as a component of the practice of physical therapy.

The Board's representatives maintained that the process was of utmost importance to the Board. Since the rule about which the OT's had been concerned was adopted following compliance with all the requirements of the Administrative Procedure Act, the Board's representatives felt strongly that any modification to that rule should be accomplished in the same manner. While the NCOTA continued to prefer the quicker resolution offered by Legislative involvement, the Board continued to reject this alternative as fraught with risk, and unwarranted in light of the Board's compliance.

Several meetings between the two groups followed, and the results have been mutually beneficial. The NCOTA recommended changes in 21 NCAC 48C .0101 that were acceptable to the Board. The Board has agreed to support the proposed changes before the Rules Review Commission and Legislature, and to involve OT representatives at each step of the rule-making process. That process has already begun, and we are anticipating that the modified rule (as set forth elsewhere in this Newsletter) will be effective April 1, 2003.

Dialogue and compromise prevented a potentially damaging rift between the two professions. Passionate advocacy led to careful consideration; initial distrust was replaced by mutual respect. It was appropriate to reexamine the rule in light of the objections raised by the NCOTA, and it is appropriate to recommend the restructuring that will satisfy those objections. Judy White, Board Chair, and Ben Massey, Executive Director, deserve a great deal of credit for helping defuse a potentially volatile situation and working toward a reasonable resolution.

North Carolina Board of Physical Therapy Examiners

Board Orders / Consent Orders / Other Board Actions
Jan. 2002 – June 2002

Suspension

Parcell, James L. PT (Suspension)

Location: Winston-Salem, NC, Forsyth County
License #: P-3320
Conduct: Documenting and billing for treatments that were not performed.
Discipline: 6 month suspension, 1 month active and the remaining period stayed with conditions (executed Mar. 21, 2002)

Probation

Russell, Elise, PTA (Probation)

Location: Melbane, NC, Alamance County
License #: A-613
Conduct: Being under the influence of intoxicating liquors while in the performance of her duties as a physical therapist assistant.
Discipline: Probation for 24 months with restrictions and conditions (executed June 13, 2002)

Joint Statement Regarding Proposed Rule 21 NCAC 48C.0101 From: NCBPTE & NCOTA

The North Carolina Board of Physical Therapy Examiners (NCBPTE) will amend (21 NCAC 48C.0101) to respond to issues raised by the North Carolina Occupational Therapy Association (NCOTA). This rule relates to the scope of physical therapy practice. NCOTA thanks the NCBPTE for its willingness to review the issues and address its concerns.

The May 15, 2002 *North Carolina Register* published a notice to announce rulemaking to clarify Physical Therapy Scope of Practice. A draft of the proposed changes is attached to this statement.

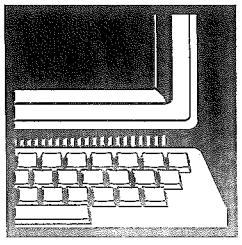
NCBPTE desires to preserve and protect the quality of physical therapy services. NCOTA was concerned about the scope of the rule and sought its clarification. During the past several months, NCBPTE and NCOTA met many times to determine the best and most expeditious means by which these issues could be resolved. Both groups are pleased by the result and are grateful for the dialogue. We believe this resolution will enable OT and PT practitioners to continue to work as colleagues in providing quality health care to the citizens of North Carolina.

2002 Appointments

Governor Michael Easley has reappointed Patricia Stavrakas Hodson, PT and James C. Harvell, MD to serve three-year terms on the NC Board of Physical Therapy Examiners. The Board is fortunate to have these experienced Board members reappointed and is grateful for their willingness to serve the citizens of North Carolina for another three years. The appointment to replace outgoing public member, Gloria Lewis, is still pending.

Important Notice!!!

Barring any unforeseen complications, the Physical Therapy Board's rules that were proposed in January 2000 are scheduled to become effective in August 2002. As soon as the official rules are forwarded to the Board Office, they will be posted on the Web page (www.ncptboard.org). Please read the rules carefully as there have been numerous changes *(see article by Silverstein in Issue 25, Fall 2000 of the Board Newsletter).*



Change of Address/Name Changes/E-mail Address Changes

Don't forget to keep the Board updated of changes in home and work addresses. This can now be done by the licensee on the Licensure Board's Web page (www.ncptboard.org) or by letter, fax (919-490-5106), or call the Board's office @ 919-490-6393 or 800-800-8982.

ADDRESS

NC Board of PT Examiners
18 West Colony Place, Suite 140
Durham, NC 27705
919-490-6393
800-800-8982
Fax 919-490-5106
E-mail:
NCPTBoard@mindspring.com
Web page: www. ncptboard.org

Calendar of Events

July 11, 2002.....Investigative Committee Meeting*
Aug. 13, 2002.....Public Hearing for Proposed Rules Change**
Aug. 13, 2002.....Investigative Committee Meeting*
Aug. 14, 2002.....End of Comment Period for Proposed Rules Change
Sept. 12, 2002.....Board Meeting**
Oct. 7, 2002.....Deadline for returning ballots to NCPTA office for election to the Board.
Dec. 5, 2002.....Board Meeting**

*Dates are tentative / please confirm on Web page or contact Board Office (800-800-8982).
**For details, see Web page (www.ncptboard.org).

Summary of Fees for 2002

Renewal (PT & PTA)	$60.00
Revival Fee and Renewal Fee	90.00
Application Fee PT & PTA	120.00
Exam Cost (PT & PTA)**	285.00
Exam Retake Fee	50.00
Verification/Transfer Fee	25.00
Licensee Directory	10.00
License Card	10.00
Labels of Licensees (PT or PTA)	60.00
Certificate Replacement	20.00

**Plus PT or PTA Application Fee

Licensure Statistics *(As of June 1, 2002)*

	Licensed in NC	Reside in NC	Work in NC
PTs	4,649	3,633	3,076
PTAs	2,092	1,846	1,530

Forum: Questions and Answers

Question: Is dry needling within the scope of practice of physical therapists in North Carolina?

Answer: NO. Dry needling is a form of acupuncture. In North Carolina, a practitioner who performs acupuncture must have a license from the NC Board of Acupuncture.

Question: Can physical therapists independently determine impairment ratings (percentages) for disability?

Answer: NO. The physical therapist cannot determine impairment ratings independently, but should serve in the role of assisting physicians in making the final determination. The physical therapist may serve as an adjunct to the physician; however, ultimately it is the physician's responsibility to recommend a percentage of impairment.

7000 copies of this public document were printed at a cost of $1,037.00 or .148 cents per copy.

North Carolina
Board of Physical Therapy Examiners
18 West Colony Place, Suite 140
Durham, N.C. 27705

21 NCAC 48C .0104 has been adopted as published in 29:02 NCR 172 as follows:

21 NCAC 48C .0104 DRY NEEDLING

(a) "Dry Needling," "Intramuscular Manual Therapy," "Trigger Point Dry Needling" and "Intramuscular Needling" are used interchangeably to describe a technique using the insertion of a solid filament needle, without medication, into or through the skin to treat various impairments.

(b) Prior to a physical therapist performing dry needling in North Carolina, the physical therapist shall submit an application to the Board containing proof of completion of a course of study approved by the Board. The course of study shall include:

(1) a minimum of 54 hours of in person classroom education;

(2) instruction in clinical techniques of dry needling;

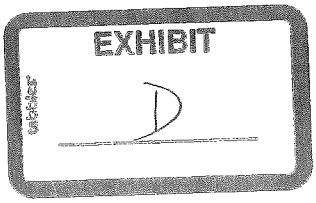
(3) instruction in indications and contraindications of dry needling; and

(4) certification of completion of all program requirements.

(c) Dry needling cannot be delegated to physical therapist assistants or physical therapy aides.

(d) The Board shall maintain a list of programs approved to provide the required dry needling training for physical therapists. This information shall be available on the Board's website (www.ncptboard.org).

History Note: *Authority G.S.90-270.24; 90-270.26;*
Eff. February 1, 2015.



STATE OF NORTH CAROLINA
OFFICE OF ADMINISTRATIVE HEARINGS

Mailing address:
6714 Mail Service Center
Raleigh, NC 27699-6714

Street address:
1711 New Hope Church Rd
Raleigh, NC 27609-6285

January 26, 2015

Sent via email: benmassey@ncptboard.org
Ben F. Massey, Jr., Rulemaking Coordinator
Board of Physical Therapy Examiners
18 West Colony Place, Suite 140
Durham, North Carolina 27706

Re: 21 NCAC 48C .0104

Dear Mr. Massey:

At its January 15, 2015 meeting, the Rules Review Commission objected to the above-identified Rule in accordance with G.S. 150B-21.10.

The Commission objected to this Rule based upon lack of statutory authority. 21 NCAC 48C .0104, as adopted by the agency, addresses a matter not within the authority delegated to the agency by the General Assembly, as required by G.S 150B-21.9(a).

Please respond to this letter in accordance with the provisions of G.S. 150B-21.12. If you have any questions regarding the Commission's action, please let me know.

Sincerely,

Abigail M. Hammond

Abigail M. Hammond
Commission Counsel

cc: John M. Silverstein – jms@satiskysilverstein.com

EXHIBIT
E

Notice

Date: January 16, 2015

Re: Proposed Rules presented to the Rules Review Commission

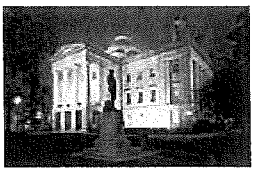
On January 15, 2015, the Rules Review Commission voted unanimously to approve 19 rules submitted by the Board to be effective February 1, 2015. *(Updated rules will be posted on the Board's website next week.)* The RRC also voted 5-3 to reject the Board's proposed rule on dry needling due to insufficient statutory authority. However, based on an Advisory Letter from the Attorney General's Office submitted to the Acupuncture Licensing Board in 2011, and the opinion of the RRC Staff Counsel reviewing the NCBPTE rules for statutory compliance, dry needling is within the scope of practice of physical therapy. Therefore, in light of the RRC action, and in view of the fact the Board has already determined that dry needling is within the scope of the practice of physical therapy, the Board believes physical therapists can continue to perform dry needling so long as they possess the requisite education and training required by N.C.G.S. § 90-270.24(4), but there are no regulations to set the specific requirements for engaging in dry needling. With regard to the establishment of specific criteria for education and training, the Board's Position Statement on Intramuscular Manual Therapy and Dry Needling is not considered to be a rule, and physical therapists must therefore comply with 21 NCAC 48C .0101(a).

EXHIBIT

F

North Carolina Board of Physical Therapy Examiners

Wednesday, September 2, 2015



The North Carolina Board of Physical Therapy Examiners

Created in 1951 by the General Assembly to establish and maintain minimum standards for the practice of physical therapy to protect the safety and welfare of the citizens of North Carolina

2016 Voting

Click Here

Biographies for Board Candidates for 2016 Appointments

(Posted – July 28, 2015)

Continuing Competence

Continuing Competence Reporting

Continuing Competence Audits: How to Respond

Important Information

Fall 2014 Newsletter

Jan 16, 2015

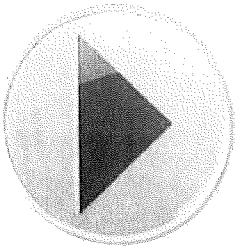
Important Notice from Rules Review Commission Meeting on Jan 15, 2015 regarding the Proposed Board Rules, including the proposed rule concerning dry needling.

Print Renewal Card

Quick Links

- Verify a NC PT or PTA
- Locate Licensees by County
- License Verification Request to another State
- News & Reports to NCPTA
- Disciplinary Actions
- Continuing Competence
- Jurisprudence Exercise
- Application Forms
- Foreign Educated
- How to Revive Your License
- Military Trained Technician Application for PTA Licensure

Watch the Presentation: PTA Scope of Work & Supervision Requirements in NC Online Educational Opportunity - 2013



EXHIBIT

October 6

(The video was updated June 2013, licensees may take the updated version one time for credit (1 point))