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Proposed Regulation
Agency Background Document

Agency name	Board of Physical Therapy
Virginia Administrative Code (VAC) citation(s)	18VAC112-20
Regulation title(s)	Regulations Governing the Practice of Physical Therapy
Action title	Practice of dry needling
Date this document prepared	5/23/16

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Orders 17 (2014) and 58 (1999), and the *Virginia Register Form, Style, and Procedure Manual.*

Brief summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of the proposed new regulation, proposed amendments to the existing regulation, or the regulation proposed to be repealed. Alert the reader to all substantive matters or changes. If applicable, generally describe the existing regulation.

The proposed regulatory action will replace Guidance Document 112-9 on dry needling. It includes reference to the statutory requirement for referral and direction from a medical practitioner, requirements for additional training and the content of such training, a requirement informed consent, and the disclosure to patients on the difference between acupuncture and dry needling.

Acronyms and Definitions

Please define all acronyms used in the Agency Background Document. Also, please define any technical terms that are used in the document that are not also defined in the "Definition" section of the regulations.

FSBPT = Federation of State Boards of Physical Therapy
FDA = Food and Drug Administration

Legal basis

Please identify the state and/or federal legal authority to promulgate this proposed regulation, including: 1) the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable; and 2) promulgating entity, i.e., agency, board, or person. Your citation should include a specific provision authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency/board/person's overall regulatory authority.

18VAC112-20-10 et seq. Regulations Governing the Practice of Physical Therapy are promulgated under the general authority of Chapter 24 of Title 54.1 of the Code of Virginia. Section 54.1-2400 (6) provides the Board of Physical Therapy the authority to promulgate regulations to administer the regulatory system:

> ***§ 54.1-2400 -General powers and duties of health regulatory boards***
> *The general powers and duties of health regulatory boards shall be:*
> *...*
> *6. To promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system. Such regulations shall not conflict with the purposes and intent of this chapter or of Chapter 1 (§ 54.1-100 et seq.) and Chapter 25 (§ 54.1-2500 et seq.) of this title. ...*

In the statutory definition of physical therapy, the practice of dry needling is not addressed, but treatment may be interpreted to include such practice:

§ 54.1-3473. Definitions.
As used in this chapter, unless the context requires a different meaning:...
"Practice of physical therapy" means that branch of the healing arts that is concerned with, upon medical referral and direction, the evaluation, testing, treatment, reeducation and rehabilitation by physical, mechanical or electronic measures and procedures of individuals who, because of trauma, disease or birth defect, present physical and emotional disorders. The practice of physical therapy also includes the administration, interpretation, documentation, and evaluation of tests and measurements of bodily functions and structures within the scope of practice of the physical therapist. However, the practice of physical therapy does not include the medical diagnosis of disease or injury, the use of Roentgen rays and radium for diagnostic or therapeutic purposes or the use of electricity for shock therapy and surgical purposes including cauterization.

Purpose

Please explain the need for the new or amended regulation. Describe the rationale or justification of the proposed regulatory action. Describe the specific reasons the regulation is essential to protect the health, safety or welfare of citizens. Discuss the goals of the proposal and the problems the proposal is intended to solve.

The purpose of the action is to specify the qualifications for and limitations of the practice of dry needling as performed by physical therapists. For physical therapists, dry needling is not an entry level skill for which competency has been assured through an accredited educational program and national examination. It is an advanced procedure that requires additional training, referral and direction and informed consent. Without a regulatory standard, the Board cannot hold a physical therapist accountable for requirements specific to dry needling. Therefore, the Board has determined that regulations are necessary to protect the health and safety of patients who may receive dry needling in the course of a physical therapy treatment.

Substance

Please briefly identify and explain the new substantive provisions, the substantive changes to existing sections, or both. A more detailed discussion is provided in the "Detail of changes" section below.

New section 121 on the performance of dry needling includes reference to the statutory requirement for referral and direction from a medical practitioner, requirements for additional training and the content of such training, a requirement informed consent, and the disclosure to patients on the difference between acupuncture and dry needling.

Issues

Please identify the issues associated with the proposed regulatory action, including: 1) the primary advantages and disadvantages to the public, such as individual private citizens or businesses, of implementing the new or amended provisions; 2) the primary advantages and disadvantages to the agency or the Commonwealth; and 3) other pertinent matters of interest to the regulated community, government officials, and the public. If there are no disadvantages to the public or the Commonwealth, please indicate.

1) The Board believes the proposed regulation offers protection for patients who receive a dry needling procedure during the course of physical therapy treatment. Regulatory requirements for referral, training, and informed consent provide greater assurance of competency and accountability than the guidance document that currently exists. The Board does not believe there are disadvantages to the public as the procedure is limited in scope and relatively safe to perform.
2) There are no advantages or disadvantages to the agency or the Commonwealth.
3) The Director of the Department of Health Professions has reviewed the proposal and performed a competitive impact analysis. The Board is authorized under 54.1-2400 to "*promulgate regulations in accordance with the Administrative Process Act (§ 9-6.14:1 et seq.) which are reasonable and necessary to administer effectively the regulatory system.*" There is no restraint on competition as a result of promulgating this regulation. To the contrary, this regulation addresses the practice of a procedure that one profession contends is solely within its scope of practice but which has been safely performed by physical therapists in Virginia with appropriate training and referral for more than a decade.

Requirements more restrictive than federal

Please identify and describe any requirement of the proposal which is more restrictive than applicable federal requirements. Include a rationale for the need for the more restrictive requirements. If there are no applicable federal requirements or no requirements that exceed applicable federal requirements, include a statement to that effect.

There are no applicable federal requirements.

Localities particularly affected

Please identify any locality particularly affected by the proposed regulation. Locality particularly affected means any locality which bears any identified disproportionate material impact which would not be experienced by other localities.

There are no localities particularly affected.

Public participation

Please include a statement that in addition to any other comments on the proposal, the agency is seeking comments on the costs and benefits of the proposal and the impacts of the regulated community.

In addition to any other comments, the Board of Physical Therapy is seeking comments on the costs and benefits of the proposal and the potential impacts of this regulatory proposal. Also, the agency/board is seeking information on impacts on small businesses as defined in § 2.2-4007.1 of the Code of Virginia. Information may include 1) projected reporting, recordkeeping and other administrative costs, 2) probable effect of the regulation on affected small businesses, and 3) description of less intrusive or costly alternative methods of achieving the purpose of the regulation.

Anyone wishing to submit written comments may do so via the Regulatory Townhall website, www.townhall.virginia.gov, or by mail to Elaine Yeatts at Department of Health Professions, 9960 Mayland Drive, Suite 300, Richmond, VA 23233 or elaine.yeatts@dhp.virginia.gov or by fax to (804) 527-4434. Comments may also be submitted through the Public Forum feature of the Virginia Regulatory Town Hall web site at: http://www.townhall.virginia.gov. Written comments must include the name and address of the commenter. In order to be considered, comments must be received by 11:59 pm on the last day of the public comment period.

A public hearing will be held following the publication of this stage and notice of the hearing will be posted on the Virginia Regulatory Town Hall website (**http://www.townhall.virginia.gov**) and on the Commonwealth Calendar website (https://www.virginia.gov/connect/commonwealth-calendar). Both oral and written comments may be submitted at that time.

Economic impact

Please identify the anticipated economic impact of the proposed new regulations or amendments to the existing regulation. When describing a particular economic impact, please specify which new requirement or change in requirement creates the anticipated economic impact.

Projected cost to the state to implement and enforce the proposed regulation, including: **a) fund source / fund detail; and** **b) a delineation of one-time versus on-going expenditures**	a) As a special fund agency, the Board must generate sufficient revenue to cover its expenditures from non-general funds, specifically the renewal and application fees it charges to practitioners for necessary functions of regulation; b) The agency will incur no additional costs for mailings to the Public Participation Guidelines mailing lists, conducting a public hearing, and sending notice of final regulations to regulated entities. Since most mailings to the PPG list are handled electronically, there is very little cost involved. Every effort will be made to incorporate those into anticipated mailings and Board meetings already scheduled. There are no on-going expenditures.
Projected cost of the new regulations or changes to existing regulations on localities.	There is no cost to localities.
Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.	Licensed physical therapists
Agency's best estimate of the number of such entities that will be affected. Please include an estimate of the number of small businesses affected. Small business means a business entity, including its affiliates, that: a) is independently owned and operated and; b) employs fewer than 500 full-time employees or has gross annual sales of less than $6 million.	There is no estimate of the number affected since the Board does not require a separate credential to practice dry needling. There are 7786 physical therapists currently licensed in Virginia. There is no estimate of small businesses; some PT's have their own practice and others practice within large health care systems.
All projected costs of the new regulations or changes to existing regulations for affected individuals, businesses, or other entities. Please be specific and include all costs including: **a) the projected reporting, recordkeeping, and other administrative costs required for compliance by small businesses; and** **b) specify any costs related to the development of real estate for commercial or residential purposes that are a consequence of the proposed regulatory changes or new regulations.**	If a physical therapist chooses to obtain additional education and training to add dry needling as a modality for his/her patients' benefit, there are a variety of courses offered. Most involve multi-day seminars with hands-on training and cost approximately $1,000.
Beneficial impact the regulation is designed to produce.	Greater assurance of advanced skill in dry needling and accountability for its safe performance.

Alternatives

Please describe any viable alternatives to the proposal considered and the rationale used by the agency to select the least burdensome or intrusive alternative that meets the essential purpose of the action. Also, include discussion of less intrusive or less costly alternatives for small businesses, as defined in § 2.2-4007.1 of the Code of Virginia, of achieving the purpose of the regulation.

The issue of whether dry needling is within the scope of the practice of physical therapy has been debated for a number of years. In 2007-2008, a Task Force of physical therapists, licensed acupuncturists and a physician reviewed the issue in Virginia and recommended that the Board adopt guidance on the qualifications necessary to perform the technique and the disclosure to patient to distinguish dry needling from acupuncture.

Recently, the American Academy of Medical Acupuncture raised the issue again in a letter to Governor McAuliffe in opposition to the practice by physical therapists. The Board reviewed the letter and reiterated its position and that of the Federation of State Boards of Physical Therapy that "acupuncture is an entire discipline and profession where as dry needling is merely one technique which should be available to any professional with the appropriate background and training."

Recent legal opinions and decisions appear to reinforce the authority of the Board of Physical Therapy to determine whether dry needling is within the scope of practice for physical therapy. A lawsuit filed by the NC Board of Acupuncture against the NC Board of Physical Therapy Examiners was dismissed without prejudice by the Court on April 26, 2016. On May 9, 2016, the Attorney General of Texas wrote that a Court would likely rule that the "Board of Physical Therapy Examiners has authority to determine that trigger point dry needling is within the scope of practice of physical therapy."

Since it is acknowledged that dry needling in physical therapy is an advanced skill, the Board does find it necessary to set out the requirements for referral, training, and informed consent to safely perform it on patients. Currently, a Guidance Document has such specifications, but it is not enforceable and is more appropriately regulatory in nature. Counsel for the Board has advised that the language in Guidance Document 112-9 is prescriptive and therefore should be included in 18VAC112-20-10 et seq.

Regulatory flexibility analysis

Pursuant to § 2.2-4007.1B of the Code of Virginia, please describe the agency's analysis of alternative regulatory methods, consistent with health, safety, environmental, and economic welfare, that will accomplish the objectives of applicable law while minimizing the adverse impact on small business. Alternative regulatory methods include, at a minimum: 1) the establishment of less stringent compliance or reporting requirements; 2) the establishment of less stringent schedules or deadlines for compliance or reporting requirements; 3) the consolidation or simplification of compliance or reporting requirements; 4) the establishment of performance standards for small businesses to replace design or operational standards required in the proposed regulation; and 5) the exemption of small businesses from all or any part of the requirements contained in the proposed regulation.

As noted above, the practice of dry needling must be included in regulation in order to assure the health and safety of patients and have accountability for competent practice by physical therapists. There are no alternative regulatory methods.

Public comment

Please summarize all comments received during the public comment period following the publication of the NOIRA, and provide the agency response.

There was a comment period on the NOIRA from November 30, 2015 to December 30, 2015. On the Virginia Regulatory Townhall, there were 1496 comments.

Commenter	Comment	Agency response
1266 commenters	Opposed dry needling regulation for physical therapy because 1) it is the practice of acupuncture; 2) PT's do not have adequate training; 3) it is outside the scope of practice for physical therapy. Two incidents of adverse reaction were noted by commenters.	The Board believes that 1) dry needling is not the practice of acupuncture but a modality to address hyperirritable loci or trigger points in the muscle to elicit a physiological response. It differs in the treatment goal and method; 2) PT's have doctoral degrees with extensive education in anatomy, pathophysiology and manual skills, so the additional training specific to dry needling is sufficient; and 3) the Federation of State Boards of Physical Therapy has commissioned an analysis of competencies and has determined that dry needling is within a PT's scope of practice. At least 30 states permit the practice. Several court decisions have affirmed that it is the prerogative of the board governing physical therapy to determine whether it is within their scope of practice. Since there is no public action against a licensee for dry needling, the agency cannot respond to the adverse action reports.
230 commenters	Supported dry needling as practiced by physical therapists – many of the commenters were patients who attested to the benefits of dry needling in their healing and pain control.	The Board concurs with the commenters who cite the education and training of PT's to perform dry needling, the safety and effectiveness of the procedure, and the evidence that it is within their scope of practice.
Acupuncture Society of Virginia	Opposed the proposal to authorize dry needling because it is outside the scope of practice of physical therapy and would exceed the Board's authority to adopt regulations; cited the statutory definition of the practice of physical therapy; dry needling constitutes the illegal practice of medicine. Dry needling can cause harm and should not be performed by	Board counsel can determine whether regulations relating to dry needling exceed its statutory authority. In regard to the 1996 rule of the FDA, it was a reclassification of acupuncture needles from Class III to Class II and that acupuncture needles are only for use by qualified practitioners of acupuncture as determined by the states. A legal analysis by a firm that does significant work on FDA regulatory issues has advised FSBPT that the ruling indicates that the FDA would not involve

	minimally educated practitioners. Dry needling is the practice of acupuncture. Acupuncture needles are a Class II medical device and sales are limited to qualified practitioners of acupuncture (1996 statement of the FDA).	itself in determining who was a "qualified practitioner," leaving that up to the states. Indeed, this board is not aware of any challenge by the FDA to use of needles by physical therapists in the 30 states in which it is allowed. The needles used by PT's are called solid filaform needles. The response to the other comments is the same as above.
Council of Colleges of Acupuncture and Oriental Medicine	The Council offered the same points in opposition as the Acupuncture Society. In addition, the Council noted that there is no national standard for education and training of physical therapists in dry needling. Noted social media sites in other states offer dry needling for unapproved purposes.	The comment about a lack of a national standard for education and training outside of an accredited physical therapy program is correct. Such training is becoming incorporated into PT doctoral programs which must be accredited by the Commission on Accreditation in Physical Therapy Education of the American Physical Therapy Association. Any complaints of unethical or incompetent practice will be investigated by the Department of Health Professions on a case-by-case basis.
American Academy of Medical Acupuncture	Acupuncture cannot be mastered in a weekend course; dry needling is an invasive procedure that can cause harm in the hands of minimally educated practitioners. Dry needling represents a departure from the traditional scope of practice for PT.	The Board agrees with the comment but does not agree that dry needling is outside of the scope of practice for PT who have extensive education in anatomy and physiology
American Academy of Physical Medicine and Rehabilitation	Dry needling is an invasive procedure and should only be performed by practitioners with training in the routine use if needles. Poses a threat to the public.	The Board appreciates the comment and believes that PT's have the basic knowledge and training in anatomy, etc., to safely perform invasive procedures for which they are then specifically and sufficiently trained.
Diane Slivinski, L.Ac.	Opposed to allowing PT's to do dry needling as it is the practice of acupuncture, and 54 hours of training is insufficient.	Same response as above.

Family impact

Please assess the impact of this regulatory action on the institution of the family and family stability including to what extent the regulatory action will: 1) strengthen or erode the authority and rights of parents in the education, nurturing, and supervision of their children; 2) encourage or discourage economic self-sufficiency, self-pride, and the assumption of responsibility for oneself, one's spouse, and one's children and/or elderly parents; 3) strengthen or erode the marital commitment; and 4) increase or decrease disposable family income.

There is no impact on the family.

Detail of changes

Please list all changes that are being proposed and the consequences of the proposed changes; explain the new requirements and what they mean rather than merely quoting the proposed text of the regulation. If the proposed regulation is a new chapter, describe the intent of the language and the expected impact. Please describe the difference between existing regulation(s) and/or agency practice(s) and what is being proposed in this regulatory action. If the proposed regulation is intended to replace an emergency regulation, please follow the instructions in the text following the three chart templates below.

For changes to existing regulation(s), please use the following chart:

Proposed new section number, if applicable	Proposed change, intent, rationale, and likely impact of proposed requirements
121	A. Dry needling is an invasive procedure which requires referral and direction in accordance with § 54.1-3482 of the Code of Virginia. Referral should be in writing; if the initial referral is received orally, it shall be followed up with a written referral. *Subsection D of § 54.1-3482 specifies that: "Invasive procedures within the scope of practice of physical therapy shall at all times be performed only under the referral and direction of a licensed doctor of medicine, osteopathy, chiropractic, podiatry, or dental surgery, a licensed nurse practitioner practicing in accordance with his practice agreement, or a licensed physician assistant acting under the supervision of a licensed physician."* *In order to ensure that the requirement was met for performance of dry needling, the Board requires that there be a written referral in the patient record.* B. Dry needling is not an entry level skill but an advanced procedure that requires additional training. The training shall be specific to dry needling and shall include emergency preparedness and response, contraindications and precautions, secondary effects or complications, palpation and needle techniques, and physiological responses. *To determine the competencies necessary to safely perform dry needling, the Federation of State Boards of Physical Therapy contracted with a research firm to conduct an analysis. In July of 2015, the report was issued setting out the job tasks and specialized knowledge necessary for performance of dry needling. The Board used the Analysis and course content from reputable providers to set out the subject areas that must be included in training for dry needling. Although the current guidance document specifies that 54 hours of coursework in dry needling is necessary, the Board did not specific the number of hours in regulation for three reasons: 1) the hours necessary to achieve minimal competency may vary; physical therapists who have had little experience in practice may need more hours to develop the competencies for*

	dry needling, while those who have had more experience and other advanced education may not need basic level training; 2) there are no hours specified in the regulations of most other states; and 2) there are no hours of training specified for other highly specialized or invasive practices, such as the performance of electromyography (EMG). Results from the Analysis of Competencies for Dry Needling by Physical Therapists indicate that 86% of the knowledge requirements related to competency in dry needling is acquired during the course of PT clinical education, and on 14% of the knowledge requirements must be acquired through post-graduate education or specialized training in dry needling. All physical therapy education programs are now at the doctoral level, and some have already introduced dry needling into the curriculum. C. Prior to the performance of dry needling, the physical therapist shall obtain informed consent form from the patient or his representative. The informed consent shall include the risks and benefits of the technique and shall clearly state that the patient is not receiving an acupuncture treatment. The informed consent form shall be maintained in the patient record. *Requirements for informed consent for an invasive procedure are similar to those for medicine. Patients should understand the potential risks and benefits of the procedure and should be told that they are not receiving an acupuncture treatment which focuses on energy flow and meridians from a holistic approach to practice.*