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Final 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	8/13/19

This information is required for executive branch review and the Virginia Registrar of Regulations, pursuant to the Virginia Administrative Process Act (APA), Executive Order 14 (as amended, July 16, 2018), the Regulations for Filing and Publishing Agency Regulations (1 VAC7-10), and the *Virginia Register Form, Style, and Procedure Manual for Publication of Virginia Regulations*.

Brief Summary

Please provide a brief summary (preferably no more than 2 or 3 paragraphs) of this regulatory change (i.e., new regulation, amendments to an existing regulation, or repeal of an existing regulation). Alert the reader to all substantive matters. If applicable, generally describe the existing regulation.

The final regulatory action on dry needling includes reference to the statutory requirement for referral and direction from a medical practitioner, requirements for additional post-graduate training and the content of such training, and a requirement for informed consent.

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

Statement of Final Agency Action

Please provide a statement of the final action taken by the agency including: 1) the date the action was taken; 2) the name of the agency taking the action; and 3) the title of the regulation.

On August 13, 2019, the Board of Physical Therapy amended 18VAC112-20-10 et seq., Regulations Governing the Practice of Physical Therapy.

Mandate and Impetus

Please list all changes to the information reported on the Agency Background Document submitted for the previous stage regarding the mandate for this regulatory change, and any other impetus that specifically prompted its initiation. If there are no changes to previously-reported information, include a specific statement to that effect.

The impetus for this action is advice from Board Counsel that guidance on training and performance of dry needling needed to be stated in regulation. 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. Previously, a Guidance Document had such specifications, but it was not enforceable and was more appropriately regulatory in nature. Counsel for the Board advised that the language in Guidance Document 112-9 was prescriptive and therefore should be included in 18VAC112-20-10 et seq.

Legal Basis

Please identify (1) the agency or other promulgating entity, and (2) the state and/or federal legal authority for the regulatory change, including the most relevant citations to the Code of Virginia or Acts of Assembly chapter number(s), if applicable. Your citation must include a specific provision, if any, authorizing the promulgating entity to regulate this specific subject or program, as well as a reference to the agency or promulgating entity'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 regulatory change, including a description of: (1) the rationale or justification, (2) the specific reasons the regulatory change is essential to protect the health, safety or welfare of citizens, and (3) the goals of the regulatory change and the problems it's 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, and a requirement for documentation of informed consent.

After publication of the original proposed regulation, a Regulatory Advisory Panel was convened to consider comment and to identify any additional safeguards that should be included in regulation, the following clarifications and changes were added:

In subsection B, it is stated that dry needling is not an entry level skill but an advanced procedure that requires additional training. The term “post-graduate” was added prior to clarify that the additional training must occur subsequent to one’s graduate education in physical therapy.

Subdivision 2 of subsection B was added to specify that the training must consist of didactic and hands-on laboratory education and must include passage of a theoretical and practical examination. The hands-on laboratory education must be face-to-face.

Subdivision 3 of subsection B was added to specify that the training must be in a course approved or provided by a sponsor listed in regulations on continuing education.

Subdivision 4 was added to specify that the practitioner cannot practice beyond the scope of the highest level of his training.

Subsection C was amended to delete that requirement that the informed consent must clearly state that the patient is not receiving an acupuncture treatment.

Subsection D was added to provide that dry needling can only be performed by a physical therapist trained pursuant to subsection B and cannot be delegated to a physical therapist assistant or other support personnel.

Issues

Please identify the issues associated with the regulatory change, 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, include a specific statement to that effect.

- 1) The Board believes the amended 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 previous guidance document. 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 list all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any requirement of the regulatory change which is more restrictive than applicable federal requirements. If there are no changes to previously-reported information, include a specific statement to that effect.

There are no applicable federal requirements.

Agencies, Localities, and Other Entities Particularly Affected

Please list all changes to the information reported on the Agency Background Document submitted for the previous stage regarding any other state agencies, localities, or other entities that are particularly affected by the regulatory change. If there are no changes to previously-reported information, include a specific statement to that effect.

Other State Agencies Particularly Affected - None

Localities Particularly Affected - None

Other Entities Particularly Affected - None

Public Comment

Please summarize all comments received during the public comment period following the publication of the previous stage, and provide the agency response. Ensure to include all comments submitted: including those received on Town Hall, in a public hearing, or submitted directly to the agency or board. If no comment was received, enter a specific statement to that effect.

The Board published re-proposed regulations for the practice of dry needling on May 27, 2019 with a public comment period that closed on July 26, 2019. A public hearing was conducted on June 27, 2019.

At the public hearing, Janet Borges, a licensed acupuncturist, spoke in opposition to the proposed regulation because there is no standard respective to training, no continuing education requirements, and no competency standard to protect the patient. Dry needling potentially increases risk of harm. She cited requirements for physical therapists in Maryland and the hours of training for physicians to perform acupuncture; she also requested the Board to amend the regulation with greater specificity for competency and safety standards.

Tom Bohanon, a licensed physical therapist, spoke on behalf of the Virginia Physical Therapy Association in support of the regulation. He noted the due diligence of the Board in developing the regulation. The treatment modality of dry needling is within the scope of practice for physical therapists who have doctoral-level training in anatomy and physiology.

There were 852 comments recorded on the Virginia Regulatory Townhall. A number of commenters used multiple entries or duplicated their comments.

There were 484 persons who commented in opposition to the proposed regulation. Their primary argument was that dry needling constitutes the practice of acupuncture and allowing physical therapists to perform it dilutes and encroaches on their practice. The commenters noted the difference in training required for a license in acupuncture versus dry needling and commented that there were no accredited programs or educational standards for physical therapists. Several commenters cited cases of patient harm from performance of dry needling. Finally, there was objection to deleting the requirement in the re-proposed regulation that physical therapists disclose that dry needling is not acupuncture.

There were 244 persons who commented in support of the proposed regulation. They noted that physical therapists receive extensive education and training in the musculoskeletal system and anatomy but also receive post-graduate training in the safe and effective use of dry needling. Commenters stated that dry needling is an evidence-based modality of treatment, different from acupuncture in that its purpose is trigger point release and muscle activation. Several noted that they refer their patients for acupuncture since dry needling is not intended to replace that practice.

Also in support of the proposed regulations were 96 persons who specifically identified themselves as patients (or a family member of a patient) who had received dry needling treatment from a physical therapist. These patients noted the significant benefit they received as it alleviated severe pain, kept them off pain medication, restored functioning, and found it to be both safe and effective. Several commented that they had received both dry needling from a physical therapist and acupuncture from an acupuncturist and that they had very different methods and goals.

There were four comments received electronically or by hard copy. There were:

Michelle Lau, President of the American Alliance of Acupuncture and the Council of Acupuncture and Oriental Medicine Associations, commented that it was a public safety and consumer interest issue. Dry needling is acupuncture and requires an acupuncture license.

Matthew Stanley, identified as a former lobbyist for the Acupuncture Society of Virginia and board member of the National Certification Commission for Acupuncture and Oriental Medicine, but represented his own view of opposition to the proposed regulation. He commented that dry needling does fall under the scope of practice of acupuncture and presented three cases of patient harm. He also reiterated the position of the American Medical Association and the American Academy of Medical Acupuncture (AAMA) that dry needling is an invasive procedure that should be performed by practitioners with standards for physician acupuncturist or licensed acupuncturists.

David Groopman, M.D., commented as a Fellow of AAMA, and noted that dry needling demands clinical experience and acumen way beyond that of a physical therapist. He noted that physicians must have 300 hours to practice acupuncture.

Raymond Metzger, P.T., commented that the PT Board in North Carolina has recently prevailed in a lawsuit challenging whether dry needling is within the scope of practice of physical therapy.

Agency Response to Comment in opposition:

Comment: Dry needling is a type of acupuncture or a simplified form of acupuncture.

The Board believes that dry needling is not the practice of acupuncture but a treatment method to address hyperirritable loci or trigger points in the muscle to elicit a physiological response. It is a modality that differs in the treatment goal and method from acupuncture, and as such, is not reserved for one profession.

Comment: PTs lack the knowledge and have insufficient training to perform dry needling.

PTs have doctoral degrees with extensive education in anatomy, pathophysiology and manual skills, so the additional post-graduate training specific to dry needling is sufficient. 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.

Comment: Dry needling is outside the scope of practice of physical therapy.

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. In 2018, the Supreme Court of North Carolina upheld the decision of an appellate court affirmed the conclusion that dry needling fell within the statutory definition of physical therapy in that state. Board counsel in Virginia has determined that the Board has statutory authority to adopt regulations relating to dry needling.

Comment: It is an invasive procedure that presents a public health and safety risk; commenters cite reports of injury to patients.

The Board concurs that it is an invasive procedure and requires referral in accordance with provisions of the Code of Virginia. Any complaints of unethical or incompetent practice will be investigated by the Department of Health Professions on a case-by-case basis.

Comment: There is a lack of a national standard for education and training outside of an accredited physical therapy program.

Training is being incorporated into PT doctoral programs which must be accredited by the Commission on Accreditation in Physical Therapy Education of the American Physical Therapy Association. However, the Board acknowledged the lack of a national standard and added criteria for coursework, passage of a practical and theoretical examination, and approval or credentialing by continuing education providers already recognized by the Board. Since there is training for different levels of dry needling, the Board also prohibits a PT from performing the procedure beyond the scope of the highest level of the practitioner's training. Finally, the

practice of dry needling is limited to PTs and may not be delegated to a PTA or any other support personnel.

Detail of Changes Made Since the Previous Stage

*Please list all changes made to the text since the previous stage was published in the Virginia Register of Regulations and the rationale for the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. * Please put an asterisk next to any substantive changes.*

New chapter-section number, if applicable	New requirement from previous stage	Updated new requirement since previous stage	Change, intent, rationale, and likely impact of updated requirements
121	Requirement for training in dry needling to be in a course “certified by FSBPT” or approved by a sponsor that is recognized in section 131 to provide continuing education	The phrase “certified by FSBPT” is deleted because the Federation is no longer <i>certifying</i> courses. It will continue to recognize coursework that may be approved for continuing education, so FSBPT remains on the list in section 131 as a body that can offer or approve CE.	The only intent is consistency with the revised policy of the Federation of State Boards of Physical Therapy. There is no substantive difference and no impact of the change from proposed regulations.

Detail of All Changes Proposed in this Regulatory Action

*Please list all changes proposed in this action and the rationale for the changes. Explain the new requirements and what they mean rather than merely quoting the text of the regulation. * Please put an asterisk next to any substantive changes.*

New chapter-section number, if applicable	New requirement	Change, intent, rationale, and likely impact of updated 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.	<i>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</i>

		<p><i>assistant acting under the supervision of a licensed physician.”</i> <i>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.</i></p>
	<p>Subsection B states that: 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.</p> <p>The term “post-graduate” was added to clarify that the additional training must occur subsequent to one’s graduate education in physical therapy.</p> <p>Subdivision 2 of subsection B was added to specify that the training must consist of didactic and hands-on laboratory education and shall include passage of a theoretical and practical examination. The hands-on laboratory education shall be face-to-face.</p> <p>Subdivision 3 of subsection B was added to specify that the training must be in a course approved or provided by a sponsor listed in regulations on continuing education.</p>	<p><i>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 specify 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 many other states; and 3) 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 the remaining 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 aspects of dry needling into the curriculum.</i></p> <p><i>While the RAP and the Board agreed that a specific number of training hours was not advisable, it is necessary to specify standards for the training to be sure it includes both didactic and hands-on laboratory experiences. There must also be an examination that validates that the therapist has minimal competency in the theoretical and practical aspects of dry needling. While the Board will not have examination results, it would require evidence of training and passage of an examination should there be a complaint about the competency of the physical therapist.</i></p>

		<p><i>The Board also concurred that an additional assurance of the validity of a course in dry needling was necessary by requiring that it be offered by a recognized continuing education sponsor. Such a requirement also benefits the PT because he/she will be able to count the hours of training as fulfillment of CE requirements for renewal of licensure.</i></p> <p><i>In a review of courses that currently offer training, it was noted that several offer basic training that qualifies a PT to do dry needling in certain muscle groups or anatomical areas. Additional hours and coursework is required for more advanced practice in dry needling. Therefore, the Board added subdivision 4 to specify that the PT must only practice to the level of his training.</i></p>
	<p>Subsection C requires that prior to the performance of dry needling, the physical therapist must obtain informed consent form from the patient or his representative. The informed consent form shall be maintained in the patient record.</p>	<p>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</p>
	<p>Subsection D is added to provide that dry needling can only be performed by a physical therapist trained pursuant to subsection B and cannot be delegated to a physical therapist assistant or other support personnel.</p>	<p><i>It has always been understood by the RAP and the Board that the practice of dry needling was only appropriate for PTs and could not be delegated to others. In reviewing regulations from several other states, it was noted that such a prohibition was clearly stated in regulation.</i></p>