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Revised 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	11/27/17

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 of the proposed regulatory action. Alert the reader to all substantive matters or changes.

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 post-graduate training and the content of such training, and a requirement for informed consent.

Acronyms and Definitions

Please define all acronyms used in this 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

Legal basis

Please identify the (1) the agency (includes any type of promulgating entity) and (2) the state and/or federal legal authority for the proposed regulatory action, including the most relevant citations to the Code of Virginia or General Assembly chapter number(s), if applicable. Your citation should 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’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.

Revised proposed substance

Please briefly identify and explain the new substantive provisions, substantive changes to existing sections, or both where appropriate, being introduced in the revised proposed regulation.

Upon recommendation of the Regulatory Advisory Panel, which was convened to consider comment on proposed regulations and to identify any additional safeguards that should be included in regulation, the following clarifications and changes have been proposed:

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” is added prior to clarify that the additional training must occur subsequent to one’s graduate education in physical therapy.

Subdivision 2 of subsection B is 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.

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

Subdivision 4 is added to specify that the practitioner shall not practice beyond the scope of the highest level of his training.

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

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.

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 on 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.

<p>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</p>	<p>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.</p>
<p>Projected cost of the new regulations or changes to existing regulations on localities.</p>	<p>There is no cost to localities.</p>
<p>Description of the individuals, businesses, or other entities likely to be affected by the new regulations or changes to existing regulations.</p>	<p>Licensed physical therapists</p>
<p>Agency’s best estimate of the number of such entities that will be affected. Please include an estimate of the number of small</p>	<p>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</p>

<p>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.</p>	<p>no estimate of small businesses; some PT's have their own practice and others practice within large health care systems.</p>
<p>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.</p>	<p>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.</p>
<p>Beneficial impact the regulation is designed to produce.</p>	<p>Greater assurance of advanced skill in dry needling and accountability for its safe performance.</p>

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 in other jurisdictions 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 from previous proposed stage

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

Commenter	Comment
American Medical Society for Sports Medicine	AMSSM is in favor of proposed regulation; fully-trained PTs should be allowed to perform dry needling. Dry needling is proven to be a safe and effective treatment for neuromusculoskeletal conditions, pain, movement impairments, and disability. Agrees with written referral and informed consent. Concern about lack of specificity for additional training; more clarity is needed as well as requirement for some portion of CE in dry needling.
Council of Colleges of Acupuncture & Oriental Medicine	CCAOM opposes the proposed regulations for the following reasons: 1) dry needling is acupuncture; is an invasive procedure that uses acupuncture needles & is part of the armamentarium of acupuncture; 2) acupuncture uses biomedical terminology so use of such language cannot be basis for defining dry needling as distinct from acupuncture; 3) physical therapists are prohibited from performing surgery and dry needling is an incisive procedure; 4) no national standard in PT for education and training in dry needling, so risk of public harm; 5) Attendance

	in dry needling courses not restricted to PTs who have a doctoral level degree; 6) PT regulators must specify training; 7) PT regulators must conduct adverse event monitoring through appropriate reporting; 8) PT in states where dry needling is allowed have exceeded the intended scope of practice
American Academy of Medical Acupuncture	AAMA submitted its policy statement on dry needling. It is an invasive procedure using acupuncture needles that has medical risk. It should only be performed by practitioners with extensive training and licensure to perform these procedures, such as licensed medical physicians or licensed acupuncturists.
American Academy of Physical Medicine and Rehabilitation	AAPM&R submitted its 2012 position paper which is basically identical to the policy statement of the AAMA.
Geller Law Group on behalf of the Acupuncture Society of Virginia (ASVA)	ASVA opposes the proposed regulation and the practice of dry needling by physical therapists for the following reasons: 1) It is an invasive procedure outside the scope of practice for PT; presents a public health and safety risk; and is an overstep of the regulatory authority of the Board. The practice of acupuncture is carved out of the practice of medicine and defined in statute. The AMA position is that the practice should be “performed by practitioner with standard training and familiarity with routine use of needles in their practice, such as licensed medical physicians and licensed acupuncturists.” 2) Nothing in the statutory definition of the practice of PT extends the scope to include insertion of acupuncture needles; 3) the Board has overstep its authority by attempting to add the practice of acupuncture to the practice of PT. Included exhibits on AMA statement and claim report update from CNA on physical therapy liability.
Brigitte Fox, L.Ac. AcuWorks	Opposes the proposed regulations. States that: 1) dry needling is the practice of acupuncture; 2) requirements for licensure to perform acupuncture necessary to protect the public; and 3) proposed regulations lack any minimum training requirement. Practitioners should treat patients in accordance with their expertise and scope of practice.

Comments received by Email

Commenter	Comment
Michelle Wright, L.Ac. Naples, NY	Opposes dry needling by physical therapists, who are not legally and safely qualified to perform acupuncture. Dry needling is one style and technique in acupuncture. Standard for a physician to practice acupuncture is 300 hours of post-doctoral training, and PTs do not have same preparation for invasive procedures. No standard for training practitioner in dry needling and no means of assessment of competency for instructors, so the public is at risk. Dry needling by PT is an intentional misrepresentation to the public. Cites recent reports of serious injuries associated with non-acupuncturists practicing dry needling; lack of education and supervised clinical training could be a direct correlation to such injuries.
Joan Choi, L.Ac.	Acupuncture is a unique profession; dry needling by PT will injure acupuncturists. They need to get acupuncture license; need to protect acupuncture profession.
David S. Groopman, M.D.	Opposes dry needling by physical therapists. It is acupuncture, and extensive training & practice necessary to minimize incidence of adverse events. Weekend courses are no substitute for lengthy and comprehensive training. References the position of the American Academy of Medical Acupuncture (noted above)

Jun Xu, M.D. Greenwich, CT	Dangerous to patient safety to expand PT practice. Reviewed training and education for medical and acupuncture profession and licensure. Unsafe and inadequate training puts patients at risk.
Arthur Yin Fan, PhD L.Ac.	Practice of dry needling just a rebranding of acupuncture. Weekend training is inadequate; education should match requirement for licensed acupuncturists.
Dianna Paulsen	Have gone to a licensed acupuncturist for procedures; would not want a PT without extensive training to practice dry needling.

Comments received at the Public Hearing on February 7, 2017

Commenter	Comment
Susan Ole (in favor)	Had trouble breathing, voice, swallowing, and range of motion in shoulders, arms and neck after cervical surgery. Two months of therapy had no success, but dry needling worked "like a miracle". Voice returned, breathing relieved, neck had range of motion because of dry needling. Therapist was well qualified and did much more than muscle relaxers could. Most outstanding difference between dry needling and acupuncture was the way that acupuncture relates to energies, with no mention of muscles. Physical Therapist works with muscles and bones only.
Tom Bohanon (in favor)	Clinician and past president of the Virginia Physical Therapy Association. Physical therapists are highly educated and get trained at the doctoral level. Based on FSBPT study, 86% of clinical training for dry needling occurs at entry level program (clean and sterile techniques, anatomy with cadaver). Dry needling is a different modality than acupuncture. Physical therapists trained on treatment techniques to the neuromuscular and neuromusculoskeletal system, which trigger point dry needling is.
Blaze Williams (in favor)	Faculty at VCU and current vice president of the sports section of the American Physical Therapy Association. Echo comments of Tom Bohanon. As a physical therapy educator, physical therapists educated in anatomy through gross anatomy, physiology, neuroanatomy, neurophysiology, kinesiology, and functional anatomy. More than ample education to receive additional training in dry needling
Erik Wijtmans (in favor)	30 years as licensed physical therapist, on teaching faculty at ODU, clinical instructor certified by APTA. Teaches dry needling courses to dentists, nurses, nurse practitioners, physicians, physician assistants, chiropractors and acupuncturists. Physical therapy education is at least 8900 hours (5400 in undergraduate, 3400 in graduate school). Dry needling not an entry level skill, taught in post graduate curriculum. Needles being used are solid filiform, specifically made for physical therapists to use in dry needling. Safety and accuracy paramount. Informally surveyed acupuncturists in his classes, they say ashi points are not the same as myofascial trigger points, same for chi response being different from needling response. Dry needling is a tool in the physical therapist tool box. Regulations state that therapist shall obtain full consent from patient; including disclosure that patient is not receiving acupuncture.
Dorthea Martin (in favor)	Agree with previous gentlemen regarding education and continuing education. Previous physical therapists did exercises and manipulation, with no effect. Current one does dry needling, which has been life-changing. Aside from needles, completely different than acupuncture (trigger points, experience).

Judith Vaughn (in favor)	After rectal surgery was in tremendous pain, unaided by physician or specialists. Manipulation also ineffective, but dry needling “literally saved my life”. Dry needling has also helped her plantar fasciitis in both feet, frozen shoulder and rotator cuff.
Amy Casdor-Gonzales (in favor)	Pursued numerous modalities for physical pain, but nothing helped until myofascial release physical therapy enhanced by dry needling. Physical therapists who practice this are well trained, studied hard, and know what they are doing
Juanita Puffinbarger (in favor)	My recovery would not be possible without dry needling. When dry needling began she understood it was not acupuncture. What is in place is more than adequate. Patient care should be primary purpose, regulations should keep them informed and covered.
Ian Scott (in favor)	Been all around the world and experienced numerous remedies and solutions, including acupuncture. Used dry needling as alternative to surgery and now pain free, with complete function.
Susan Stuart (in favor)	Quality of life was poor, scared of needles, multiple pain management doctors. Directed to dry needles instead of opioids. Physical therapists explained procedures, showed exactly what they were doing and how muscles linked. Feels like physical therapists taught her more about her own body than Richmond’s top neurosurgeon. Has gone in with level 10 pain and left after needling to go shopping, “miraculous”.
Bruce Allen (in favor)	Chronic pain in right hip, traditional physical therapy offered no relief. Two session of dry needling did more than all previous therapy combined.
Yun Fan (opposed)	Acupuncture and dry needling is the same as a person changing clothes, they look different, but underneath are the same thing. There is no difference
Rebecca Reynolds (opposed)	Nurse practitioner, also acupuncturist and certified in dry needling. Dry needling acupuncture effective modality. Regulation as they stand now are not adequate to become proficient in dry needling (don’t discuss pneumothorax, forbidden points in pregnancy).Orthopedic acupuncture is close to dry needling, which covers item B in proposed changes. Proposing that dry needling is not acupuncture (item C) is an alternative fact, a majority of dry needling points are classis acupuncture points or ashi points. Saying dry needling is not acupuncture is like saying kinesiology is not physical therapy. Dry needling is trigger point localized acupuncture.
Arthur Fan (opposed)	MD, PhD, RAC. Dry needling another name/form for acupuncture, according to WHO. Dry needling brought to Us by acupuncture researcher (Dr. Janet Travell) who used another name to attract more students. Indication and needling activity/techniques are the same as acupuncture. Education requirements are too low, allowing many other people to do it as well (nurse, MD, exercise trainer)
Aubrey Fisher (opposed)	Licensed acupuncturist. Commonwealth of Virginia defines acupuncture as “stimulation of certain points on or near the surface of the body by insertion of needles to prevent or modify the perception of pain or to normalize physiological functions...” Board of Physical Therapy defines dry needling as, “filiform needles to penetrate the skin and/or underlying tissues to affect changes in body structure and function for evaluation and management of neuromuscular conditions, pain, movement, impairments, and disabilities. This is a definition of acupuncture. Language used by Physical Therapists is same as what is already in acupuncture statutes. Acupuncture therapy includes treatment strategy of dry needling, including reactive points also known as hyperirritable loci or trigger points, to relieve musculoskeletal and

	connective tissue disorders. Acupuncture is more than energy flow and meridians, our channel systems are based on fascial, neurological, circulatory and muscular maps as they relate to body's anatomy and physiology,
Stephanie Penum (opposed)	Licensed acupuncturist in VA and AZ. Dry needling and trigger point dry needling is a term practiced by acupuncturists because it is a treatment strategy, not just a treatment modality. The North Carolina case, which was dismissed without prevalence, only occurred because the NC Board of Acupuncture did not exhaust all of their administrative processes; it was not a ruling in favor of dry needling for physical therapists. There is now another lawsuit pending against the North Carolina Board of Physical Therapy, as the Acupuncture Board has exhausted their methods. When the Texas Attorney General said it would most likely rule in favor of the Physical Therapy Board making trigger point dry needling within the scope of practice, which was an opinion not a ruling. These statements are misleading to the public and those reading the proposal. Adverse action reports have been sent out in other states, just not Virginia (Colorado- skier lung was punctured; Maryland- teachers nerve in leg was punctured; Arizona- needles were inserted through patients clothing and needles were disposed in public recycling bin; Georgia-dry needling was performed on a minor without consent from a parent/guardian).
Sarah Steed (opposed)	National Board Certified Acupuncturist. Had patients come to her practice that were injured by dry needling done by a physical therapist, which needed several treatments to recover. Had other patients who were not helped by pain medication, physical therapy, dry needling or chiropractic. There are side effects to dry needling, we just never hear about them.
Bridget Fox (opposed)	Registered Nurse turned acupuncturist. Specialization has occurred throughout human history, including subspecialties within professions. This is to benefit the patient. Physical therapy was borne out of this specialization, as an alternative to surgery. Good physical therapist should not have to do dry needling, rehab should not include needles. This regulation is grasping at another treatment option, "let me stick needles in him". Four years of acupuncture school only covers the tip of the iceberg, any less training is sad and will do more harm than good.
Sarah Hung (opposed)	Licensed acupuncturist. Dry needling is acupuncture, specifically a form of orthopedic acupuncture (taught in schools and has continuing education classes about). No minimum training standards in the regulations is a public safety concern, even though the American Medical Association recommends a minimum level for physical therapists similar to those for acupuncturists. Proposed courses also don't include clinical supervision. Medical doctors need 100 hours of clinical supervision to do acupuncture; it cannot just be a weekend course. I also support what everyone else on the opposed side has said.
Diane Lowry (opposed)	Licensed acupuncturist. The insertion of FDA regulated acupuncture needles into trigger points for providing therapeutic relief falls under the purview of acupuncture, dry needling is not distinct. Dry needling presents a threat to public safety without adequate education, supervised clinical training and independent competency examination. Dry needling is not safe, and injuries range from pneumothorax to nerve damage. This has caused insurance companies to call it an emerging area of risk. Additionally the draft regulation has no minimum

	training standard, which is against the American Medical Association policy.
Janet Borgess (opposed)	Licensed Acupuncturist. Modality of dry needling is physical intervention that uses filiform acupuncture needles to stimulate points on the body. Where and how to insert the needle is supposedly based only on Western medical concepts, which was the original intent of Janet Travell. Valuable modality; we all want to help our patients. However, dry needling, motor point needling, myofascial needling, trigger point needling, and integrated dry needling are all styles of acupuncture. The only difference is the training and intent of practitioner inserting needle. Licensed acupuncturists practice all of these styles. Regulations as they stand risk intentionally putting public in danger by allowing physical therapists to independently decide if they have advanced procedural skill. Physical therapists have reportedly been doing dry needling since 2003, without a 100% safety record. Current draft may make it more convenient for Board of Physical Therapy to protect itself from public complaint, but it does not protect public safety. Further, to have a patient sign a disclosure that says they are not receiving acupuncture and then treating with acupuncture is confusing and deceptive.
Ian Hurdibaugh (opposed)	Abstained from comment
Pamela Howard (opposed)	Licensed and board certified acupuncturist. In the last 4 years delivered over 10,000 treatments to over 1,000 patients. As a patient had great success with acupuncture to treat lateral epicondylitis. Continuing education classes for orthopedic acupuncture addresses motor points of the muscles of the body (class based on Dr. Janet Travell and Matt Calveston- an acupuncturist).
Kelly Sherman (opposed)	Board certified acupuncturist. Respect physical therapists scope of practice and the care they give their patients. Patient centered care to me is integrative care. That means I can refer patients to physical therapists for care and they can refer patients to me, to help in the form of trigger point therapy.
Matthew Stanley (opposed)	Representing Acupuncture Society of Virginia. The Society is opposed to physical therapists practicing procedure called dry needling, as it falls under scope of practice of acupuncture, defined by Virginia Statute pursuant to section 54.12-900. Not been demonstrated how dry needling does not fit under such definition. No statute that provides legal authority for physical therapists or any other health practitioners to expand scope of practice via regulation to include dry needling. We believe Board of Physical Therapy is in violation of state law. Proposed regulation identifies it as an advanced procedure that requires advanced training but does not recommend or require any specific post graduate training hours (can be completed in as little as a weekend with no prior experience in the safe use of needles). Number of serious injuries from dry needling, which cause the American Medical Association to become critical of the lax regulation and nonexistent standards around this invasive procedure (need to meet standards required for acupuncturists and physicians to keep patients safe). Largest company insuring physical therapists called it an emerging area of risk. No provision of these regulations provides protections for patient safety. Acupuncturists in Virginia need at least 1,365 hours of acupuncture specific training, including 775 hours of didactic material specific to acupuncture and 660 hours of supervised clinical training. Even medical doctors with training in use of invasive medical devices need 300 hours of training in acupuncture (more than

<p>a weekend). No difference in training requirements for physical therapists without doctorate level degree and entry level physical therapists with less than two years of training. Virginia Department of Planning and Budget Economic Impact Analysis of the regulation state that “54 hours of professional training is required under the existing guidance, while the proposed regulation does not state a specific number of training hours”.</p>
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Comments posted on the Virginia Regulatory Townhall

Of the 2051 comments posted on the Townhall, there were 1786 unique comments (not duplicated by multiple entries).

There were 610 in support of the proposed regulation. Comments in support included:

- Great clinical utility (important tool in “toolbox”)
 - Should be adjunct modality offered with additional continuing education and certification
 - More specific and effective than ultrasound in releasing chronic contracted muscles
 - Mandate reporting of any patient injuries to track whether training is sufficient
 - Recognition of “open access” to a physical therapist’s treatment must be maintained
 - Insurance will usually cover dry needling but not acupuncture
- Physical Therapists help people move better- dry needling provides relief of musculoskeletal/ nervous system deficits
- Not the same as acupuncture
 - Inactivate muscular trigger points; useful in pain control, muscle length/stretching, and neuromuscular re-education
 - Can be done without pain medication
 - Targeting only skeletal muscles
 - Helpful with fibromyalgia, myofascial pain,
 - Trigger points and myofascial dysfunction are muscle disorders. The experts in muscle anatomy, physiology, function, and pathology are physical therapists
 - Focus on hyperirritable loci in muscle tissue
 - Dry needling is an extension of manual stimulation of trigger points
 - Differs from acupuncture in clinical reasoning, technique and goal of treatment
 - Only similarity is needle being used
 - Trigger point dry needling focuses on targeting specific muscles that can lead to pain and looks to minimize the presents of active trigger points which have been associated with various types of pain. Acupuncture focuses on meridians and energy flow to restore balance within the body's system.
- Education requirement for certificate (50ish hours)

- PTs know anatomy, physiology, neuromuscular re-education, soft tissue dysfunction
- FSMB study shows 86% of KSA required for dry needling is obtained when graduating from accredited program
- Don't let doctors dictate PT practices
 - Physician referral only adds to bureaucratic issues/red tape

There were 1176 comments opposed to the proposed regulations. Comments in opposition included:

- Educational requirements not strict enough
 - Not as strict educational requirements (20-30 hours vs MD education and 300 hours in acupuncture)
 - Outside scope of practice for physical therapist
 - Could damage internal organs (lungs, liver) along with nerves that PTs don't have training in
 - Invasive procedure
 - Need certification of clean needle techniques
 - Mixture of Eastern and Western Medicine (PTs have no eastern training)
 - Regulations have no minimum for training
 - Follow California's example
 - No independent, agency-accredited training programs for "dry needling," no standardized curriculum, no means of assessing the competence of instructors in the field, and no independently administered competency examinations
 - Give acupuncturist PT designation if dry needling is to fall under that scope of practice
- Comparison to acupuncture
 - Existence of trigger points as primary sources of pain has never been confirmed
 - Does not work beyond contextual effects (neurophysical phenomenon)
 - No animal model to study trigger points, can't confirm existence as local pathophysiology
 - Simplified acupuncture- same techniques, tools, indications, same points (just different names)
 - Trigger points are acupoints or ASHI points
 - WHO, AMA and AAPMR has clear definition that dry needling is acupuncture (non physicians should have 1500 hours training)
 - Constitutes acupuncture under VA and FDA law currently
 - medicalacupuncture.org/Portals/2/PDFs/AAMADryNeedlingPolicyOct15.pdf
 - <https://www.aapmr.org/practice/resources/positionpapers/AAPMR%20Documents/AAPMR-Position-on-Dry-Needling.pdf>
- Public safety risk having PT's do it (public confusion, lower quality of treatment)

- Minimizes therapeutic value of acupuncture
- PTs trying to capture market share
- American Society of Acupuncturist position
 - Dry needling pseudonym for acupuncture that has been adopted by health providers who lack legal ability to practice acupuncture within scope of practice
 - American Academy of Medical Acupuncture set industry standard of 300 hours of postdoctoral training with examination at end by independent testing board

Agency Response to Comment in opposition:

- Dry needling pseudonym for acupuncture or a simplified form of acupuncture.

The Board believes that 1) 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, and as such, is not reserved for one profession.

- 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 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.

- 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. Board counsel in Virginia can determine whether regulations relating to dry needling exceed its statutory authority.

- 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. To date, there is no public action in Virginia against a physical therapist for dry needling, but any complaints of unethical or incompetent practice will be investigated by the Department of Health Professions on a case-by-case basis.

- FDA-regulated acupuncture needles into trigger points for practice of acupuncture.

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 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.

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

Training is beginning to be incorporated into some 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.

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.

*Please list separately all differences between the **proposed** regulation that was published in the Virginia Register of Regulations and this **revised proposed** regulation.*

Proposed new section number	Proposed requirement	Revised Proposed requirement	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		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

	<p>referral is received orally, it shall be followed up with a written referral.</p>		<p>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.</p>
	<p>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.</p>	<p>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” is added prior to clarify that the additional training must occur subsequent to one’s graduate education in physical therapy.</p> <p>The 2nd sentence of subsection B is numbered as subdivision 1.</p> <p>Subdivision 2 of subsection B is 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><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</i></p>	<p>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</p>

		<p><i>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>Subdivision 3 of subsection B is added to specify that the training must be in a course certified by FSBPT or approved or provided by a sponsor listed in regulations on continuing education.</p> <p><i>The Board concurred that an additional assurance of the validity of a course in dry needling was necessary by requiring that it be certified by the Federation or be approved 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>Subdivision 4 is added to specify that the practitioner shall not practice beyond the scope of the highest level of his training.</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>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 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 aspects of dry needling into the curriculum.</p>
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	<p>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.</p>	<p>Subsection C is amended to delete that requirement that the informed consent must clearly state that the patient is not receiving an acupuncture treatment.</p> <p><i>The deletion was requested by the acupuncturist who served on the RAP. Acupuncturists contend that dry needling is the same thing as acupuncture and wanted the statement deleted. PTs may choose to tell patients that they are not receiving an acupuncture treatment which focuses on energy flow and meridians from a holistic approach to practice.</i></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>	