

PROPOSED REGULATION PUBLICATION FORMS (Revised 4/10)

Title 10

DEPARTMENT OF HEALTH AND MENTAL HYGIENE

Subtitle38 BOARD OF PHYSICAL THERAPY EXAMINERS

10.38.12 Dry Needling

Authority: Health Occupations Article, §§13-101 and 13-206, Annotated Code of Maryland

Is There EmergencyText ThatIs Identical To The ProposedText:

Yes No

Is There An Incorporation By Reference Document Associated With This Proposal?

Yes No

Does This Proposal Have An Impact On Environmental Hazards Affecting The Health Of Children As Defined In Health-General Article, §13-1501(C)?

Yes (explain) No

Does This Proposal Include An Increase Or Decrease In A Fee For A License?

Yes, complete (1)—(8) No, skip (1)—(8) and proceed to Notice of Proposed Action

- (1) Explain/justify why an increase or decrease is necessary:
- (2) How much money is needed to operate effectively or to eliminate an operating fund deficit?
- (3) In what year was the most recent fee increase?
- (4) Is the fee revenue retained by the Proposing Unit or passed through to a national organization that administers a uniform licensing exam?
- (5) Describe any measures taken to mitigate the need for increased revenue:
- (6) Describe any special circumstances that have had an adverse impact on the Proposing Unit's operating expenses.

- (7) Describe any consideration given by the Proposing Unit as to the hardship a fee increase may have on the regulated profession.
- (8) Describe any efforts to solicit the opinions of licensees regarding the Proposing Unit's effectiveness and performance.

Notice of Proposed Action

The Secretary of Health and Mental Hygiene proposes to adopt new Regulations .01—.04 under a new chapter COMAR 10.38.12 Dry Needling.

This action was considered at a public meeting on August 20, 2013, notice of which was given by publication on the Board's website at <http://dhmh.maryland.gov/bphte/SitePages/boards.aspx> to State Government Article, §10-506(c)(1), Annotated Code of Maryland.

Statement of Purpose

The purpose of this action is to establish guidelines for the provision of dry needling as an intervention performed by physical therapists.
See "Background and Analysis of Proposal to Establish Guidelines for Dry Needling" in the Special Documents section of this issue of the Maryland Register for further details.

**Comparison to Federal Standards
(Check one option)**

- There is no corresponding federal standard to this proposed action.
- or
- There is a corresponding federal standard to this proposed action, but the proposed action **is not** more restrictive or stringent.

The corresponding federal standard is: _____

EXPLAIN why the proposed action **is not** more restrictive or stringent than the corresponding federal standard:

- or
In compliance with Executive Order 01.01.1996.03, this proposed action **is** more restrictive or stringent than corresponding federal standards as follows:

- (1) Regulation citation and manner in which it is more restrictive than the applicable federal standard:
- (2) Benefit to the public health, safety or welfare, or the environment:
- (3) Analysis of additional burden or cost on the regulated person:
- (4) Justification for the need for more restrictive standards:

Impact Statements
Part A
(check one option)

Estimate of Economic Impact

The proposed action has no economic impact.

Or

The proposed action has an economic impact. (If this is checked, complete the following form in its entirety)

I. Summary of Economic Impact. Physical Therapists who have not completed the required training required for dry needling may incur a cost to obtain that training.

II. Types of Economic Impact.	Revenue (R+/R-) Expenditure (E+/E-)	Magnitude
A. On issuing agency:	NONE	
B. On other State agencies:	NONE	
C. On local governments:	none Benefit (+) Cost (-)	Magnitude
D. On regulated industries or trade groups:	(-)	Indeterminate
E. On other industries or trade groups:	NONE	
F. Direct and indirect effects on public:	NONE	

III. Assumptions. (Identified by Impact Letter and Number from Section II.)

D. To the extent that a physical therapist has or has not completed the required training to perform dry needling, there will be a cost to the physical therapist. This amount cannot be determined as it will vary between each individual physical therapist.

Part B
Economic Impact on Small Businesses
(check one option)

The proposed action has minimal or no economic impact on small businesses.

or

The proposed action has a meaningful economic impact on small businesses. An analysis of this economic impact follows.

Impact on Individuals with Disabilities
(check one option)

The proposed action has no impact on individuals with disabilities.

or

The proposed action has an impact on individuals with disabilities as follows:
(Agency to complete this assessment)

Opportunity for Public Comment

Comments may be sent to Michele Phinney, Director, Office of Regulation and Policy Coordination, Department of Health and Mental Hygiene, 201 W. Preston Street, Room 512, Baltimore, Maryland 21201, or call (410) 767-6499 or TTY: 800-735-2258, or fax to (410) 767-6483, or email to dhmh.regs@maryland.gov. Comments will be accepted through

Part C

(For legislative use only; not for publication)

- A. Fiscal Year in which regulations will become effective: FY 2014
- B. Does the budget for fiscal year in which regulations become effective contain funds to implement the regulations?
 Yes No N/A
- C. If "yes", state whether general, special (exact name), or federal funds will be used:
- D. If "no", identify the source(s) of funds necessary for implementation of these regulations:
- E. If these regulations have no economic impact under Part A, indicate reason briefly:
- F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason. It is incumbent upon the individual licensee to comply with the requirements of the proposed regulation, not upon a small business.

.01 Scope.

This chapter establishes standards for the provision of dry needling as an intervention performed by physical therapists.

.02 Definitions.

A. *In this chapter, the following terms have the meanings indicated.*

B. *Terms Defined.*

(1) *"Board" means the State Board of Physical Therapy Examiners.*

(2) "Dry needling" means a physical therapy intervention, also known as intramuscular manual therapy, that:

(a) Involves the insertion of one or more solid needles, a type of mechanical device, into or through the skin to effect change in muscles and tissues for the purpose of alleviating identified impairments;

(b) Requires ongoing evaluation, assessment, and re-evaluation of the impairments;

(c) Is only utilized in parts of the body with neuromuscular or musculoskeletal links to the impairments; and

(d) Is not performed for the purposes of detoxification, smoking cessation, stress relief, or any condition outside the scope of physical therapy.

.03 Minimum Education and Training Necessary to Perform Dry Needling.

A. In order to perform dry needling, a physical therapist shall have at least 80 total hours of instruction, to include:

(1) A total of at least 40 hours of instruction in the following dry needling-specific course content areas:

(a) Theory and application of dry needling;

(b) Dry needling technique, including spine and extremities;

(c) Dry needling indications and contraindications;

(d) Infection control, the Occupational Safety and Health Administration's Bloodborne Pathogen Protocol, and safe handling of needles; and

(e) Documentation of dry needling; and

(2) At least 40 hours of practical, hands-on instruction in the application and technique of dry needling, under the supervision of a licensed healthcare practitioner competent in dry needling

procedures who has completed the requisite coursework under §A(1) of this regulation and has practiced dry needling for at least 5 years.

B. The instruction required under §A(1) of this regulation shall be provided by a continuing education course sponsored by the:

(1) American Physical Therapy Association;

(2) The APTA of Maryland; or

(3) The Federation of State Boards of Physical Therapy.

C. A continuing education course taken before the effective date of this regulation shall qualify for instruction if the same course, in substantially similar form, is later sponsored by the American Physical Therapy Association, the APTA of Maryland, or the Federation of State Boards of Physical Therapy.

D. All instruction required under this regulation shall include an assessment of competency.

E. The instruction required under §A(1) of this regulation shall be offered:

(1) In person at a face-to-face session; or

(2) In real time through electronic means that allow for simultaneous interaction between the instructor and the participants.

F. A physical therapist may not fulfill any portion of the practical, hands-on instruction required under §A(2) of this regulation with online or distance learning.

G. A physical therapist shall have practiced physical therapy for at least 2 years before performing dry needling in the State.

H. Upon request of the Board, a physical therapist practicing dry needling shall provide documentation that substantiates appropriate education and training as required by this regulation.

I. A physical therapist who practices dry needling without the education and training required by this regulation shall be subject to discipline pursuant to COMAR 10.38.10.04A(4).

J. This regulation shall take effect 1 year after the effective date of the rest of this chapter.

.04 Standards of Practice in Performing Dry Needling.

A. A physical therapist shall:

(1) Fully explain dry needling to the patient in advance of treatment; and

(2) Obtain written informed consent specific to dry needling that shall be included in the patient's medical record.

B. A physical therapist shall perform dry needling in a manner consistent with standards set forth in the Maryland Occupational Safety and Health Act, Labor and Employment Article, Title 5, Annotated Code of Maryland.

C. A physical therapist shall document the provision of dry needling services in accordance with the documentation requirements of COMAR 10.38.03.02-1.

D. A physical therapist who practices dry needling in a manner inconsistent with the standards of practice enumerated in this regulation shall be subject to discipline pursuant to COMAR 10.38.10.04A(14).

E. Dry needling is not within the scope of practice of limited physical therapy and shall only be performed by a licensed physical therapist.

JOSHUA M. SHARFSTEIN, M.D.
Secretary of Health and Mental Hygiene

SPECIAL DOCUMENTS
MARYLAND REGISTER, VOLUME __, ISSUE __

**DEPARTMENT OF HEALTH AND MENTAL HYGIENE
BACKGROUND AND ANALYSIS OF PROPOSAL TO
ESTABLISH GUIDELINES FOR DRY NEEDLING**

On August 31, 2012, the Secretary of Health and Mental Hygiene released a call for public comment on proposed regulations developed by the Board of Physical Therapy Examiners for dry needling as an intervention performed by physical therapists. During the 30-day period following the call for comment, the Department received over 950 comments. Approximately 800 of the comments were in support of physical therapists providing dry needling; a significant portion of those comments were from patients, with additional comments from physical therapists and other health care providers. Approximately 153 of the comments received were in opposition to the practice; these comments were primarily from licensed acupuncturists and organizations representing licensed acupuncturists in Maryland and other states. Following the public comment period, the Secretary requested that the Board modify the regulations in three key areas – adequacy of training, a transition plan for the practice, and oversight of the practice.

After reviewing the Secretary’s request and the public comments, the Board made significant changes to the draft regulations, particularly in the areas identified by the Secretary. The Department is now proposing these regulations, pursuant to State Government Article, §10-101, that would set guidelines for the practice of dry needling by physical therapists beginning July 1, 2014. The Department and the Board have carefully considered input from multiple stakeholders in the development of these regulations and believe that the citizens of Maryland will be served by these proposed regulations.

1. Background
2. Process
3. Analysis

1. Background

In 1989, Maryland became the first jurisdiction in the United States to allow dry needling by licensed physical therapists, after the Board opined that dry needling was within the scope of the practice of physical therapy. On August 17, 2010, the State Attorney General responded to a request from the State Board of Acupuncture for an opinion concerning the provision of dry needling by physical therapists. Specifically, the questions posed were whether the insertion of “acupuncture needles” into a patient was within the definition of “practice of physical therapy” in Maryland and whether it was appropriate for the Board to include dry needling within the scope of the practice of physical therapy without legislation.¹

The Attorney General noted in his Opinion that “[t]he authority to use acupuncture needles for therapeutic purposes is not necessarily reserved exclusively to licensed acupuncturists.”² The Opinion also states:

“In our opinion, the Physical Therapy Board may determine that dry needling is within the scope of practice of physical therapy if it conducts rulemaking under the State Administrative Procedure Act and adopts a regulation that relates dry needling to the statutory definition of practice of physical therapy.”³

The Opinion clearly noted that the Board should consider standards for education and training that would best ensure public safety during the provision of dry needling.⁴ Following the issuance of the Opinion, the Board set out to adopt a regulation formally relating dry needling to the practice of physical therapy.

2. Process

The Board engaged many stakeholders during the process of developing the regulations, including experts in the field, the Federation of State Boards of Physical Therapy, the American Physical Therapy Association, physical therapy licensing boards in other states, physical therapy educators, the Board of Acupuncture, the public (including physical therapy licensees in the State), and the Secretary. The Board began by hosting a Dry Needling Task Force, which met on January 6, 2011, to discuss a framework for the regulations. The Board also formed a committee of the Board that met on a regular basis to draft the regulations and met with certain stakeholders, including the Board of Acupuncture. Following the public comment period initiated by the Secretary, the Board undertook some of these steps again to implement the changes requested by the Secretary. This multi-year process has ultimately benefited the citizens of Maryland by increasing the safeguards required for public protection, including those related to education and training.

The Board considered the following topics to be of utmost importance during the development of regulations:

- Adequacy of education and training
- Definition and other terminology
- Informed consent
- Clean needle requirements and needle management
- Limitations on the application of dry needling
- Documentation
- Board oversight
- Delegation to other personnel
- Transition plan for physical therapists currently practicing dry needling
- Standards for education and training for physicians who perform acupuncture

3. Analysis

As noted above, Maryland became the first jurisdiction to specifically allow dry needling by licensed physical therapists, in 1989. As of July 1, 2013, 26 of the 53 United States jurisdictions that regulate the practice of physical therapy, including Virginia, West Virginia, and the District of Columbia, specifically allow dry needling by licensed physical therapists; only nine jurisdictions specifically prohibit licensed physical therapists from practicing dry needling.⁵ In addition, physical therapists in the United States Army and with the United States Department of Veteran Affairs currently utilize dry needling to treat patients. With the proposed regulations,

the Board is attempting to regulate this growing area of physical therapy practice in a progressive and proactive fashion, while maintaining its efforts to adequately and responsibly protect the public.

The proposed regulations cover a number of critical areas of concern related to the provision of dry needling, including education and training, needle management techniques, documentation, informed consent, a restriction on delegation, and discipline. The regulations were developed with an understanding that the training of physical therapists, 96% of which is currently at the doctoral level, include significant instruction specific to the musculoskeletal system and the neuromuscular system. Accredited education programs in physical therapy must include extensive instruction in anatomy, histology, physiology, biomechanics, kinesiology, neuroscience, pharmacology, pathology, clinical sciences, clinical interventions, clinical application, and screening. The basic anatomical, physiological, and biomechanical knowledge necessary for the safe and competent provision of dry needling is taught as part of the core education for physical therapists; specific dry needling skills are supplemental to that core knowledge. (Although some physical therapy education programs have begun including dry needling in their curriculum, dry needling training is not specifically required in entry-level education for physical therapists.) Furthermore, certain content areas relevant to the competent provision of dry needling, such as surface anatomy and skeletal muscle physiology, are part of the national physical therapist licensing examination. Taking into consideration the comprehensive basic preparation that all physical therapists receive in entry level programs, the regulations propose two categories of training – dry needling-specific education (40 hours), and hands-on training in the application and technique of dry needling (40 hours). The regulations also require sponsorship for those courses by a national organization or its affiliate, so that they meet the highest standards possible. All education and training must include an assessment of competency for the didactic work and a demonstration of the hands-on techniques.

The 80 total hours of dry-needling specific education and training required by the proposed regulations exceeds the hours of training required by every other jurisdiction that specifically allows for dry needling by licensed physical therapists and delineates specific training requirements for the practice. The Commonwealth of Virginia, in Guidance Document 112-9, indicates that “[a] physical therapist using dry needling must complete at least 54 hours of post professional training.”⁶ North Carolina also requires a minimum of 54 hours of training before a physical therapist can perform dry needling.⁷ Louisiana and Missouri both have minimum dry-needling training requirements of 50 hours for physical therapists; Colorado requires a physical therapist to receive 46 hours of training before practicing dry needling.⁸ In every jurisdiction, as in the proposed regulations, all of the required dry-needling specific training is in addition to the entry-level education of a physical therapist.

The proposed regulations also clarify for patients the status of physical therapists who currently provide dry needling, while also protecting the public from substandard practice. Although the standards of practice regulation will take effect immediately, a one-year delayed effective date of the education and training regulation will allow physical therapists who currently practice dry needling to ensure that they have a sufficient knowledge base for the practice. Additionally, the regulations now provide for retroactive approval of certain continuing education courses, to ensure that experienced, competent physical therapists providing dry needling do not have to start their training over from the beginning.

Although not specifically included in the regulations, the Board has also proposed a number of oversight mechanisms intended to allow the Board to assess the practice of dry needling to determine if the regulations are providing for the safety of patients in the State or if further regulatory changes are needed. Specifically, the Board will:

- Collect information, at the time of license renewal, about whether licensed physical therapists are providing dry needling (in effect creating an informal “registry” of dry needling practitioners);
- Provide information on the Board’s website for the public and licensees regarding dry needling, and offer a vehicle for any questions or complaints regarding dry needling from the public;
- Develop a patient feedback/evaluation form;
- Collect and review data on patient complaints pertaining to dry needling;
- Collect information on the content of educational courses used to fulfill the requirements of the regulations;
- Collect information on nationwide trends in dry needling, specifically licensure and discipline;
- Provide annual reports to the General Assembly and the Department, including data and observations on the practice of dry needling in Maryland, for at least the first five years following the promulgation date; and
- Hold at least one public forum, two years following the promulgation date, seeking public feedback on dry needling and its provision in Maryland.

Finally, the regulations recognize that discipline of physical therapists who practice dry needling without the required education and training or without observing the standards of practice is an important part of oversight over the practice. (The Board notes that, since 1989, it has only received two complaints related to the provision of dry needling by physical therapists.) The proposed regulations note specific areas of the existing disciplinary guidelines that may provide the basis for disciplinary actions for dry needling-related violations.

¹ 95 Op. Att’y Gen. 138

² *Id.* at 150.

³ *Id.*

⁴ *Id.* at 150-51.

⁵ FEDERATION OF STATE BOARDS OF PHYSICAL THERAPY, DRY NEEDLING RESOURCE PAPER 8-9 (4th ed. 2013).

⁶ *Id.* at 27-28.

⁷ *Id.* at 26-27.

⁸ *Id.* at 22-26.

Frequently Asked Questions about Dry Needling Regulations

Q: What is Dry Needling?

A: Dry Needling is a therapeutic intervention used by trained and licensed physical therapists that involves the insertion of one or more solid needles into or through the skin to effect change in muscles and tissues for the purpose of alleviating identified impairments.

Q: How long have physical therapists been performing dry needling in the State of Maryland?

A: Since 1989. Maryland was the first state to permit dry needling by physical therapists. As of July 1, 2013, 26 of the 53 United States jurisdictions that regulate the practice of physical therapy, including Virginia, West Virginia, and the District of Columbia, specifically allow dry needling by licensed physical therapists.

Q: What are the training requirements for dry needling?

A: Eighty (80) total hours and two years of professional practice beyond minimal licensure requirements. Currently, 96% of all training for physical therapists is at the doctoral level from accredited programs. Licensure also requires passage of the National Physical Therapy Examination.

Q: Will there be “grandfathering”?

A: **No.** The standards of practice regulation will take effect immediately. There will be a one-year delayed effective date of the education and training regulation which will allow physical therapists who currently practice dry needling to ensure that they have a sufficient knowledge base for the practice.

Q: Will the Maryland Board of Physical Therapy Examiners monitor the implementation of dry needling regulations?

A: **Yes.** The Board will collect information, at the time of license renewal, about whether licensed physical therapists are providing dry needling (in effect creating an informal “registry” of dry needling practitioners).

Additionally, the Board will provide annual reports to the General Assembly and the Department, including data and observations on the practice of dry needling in Maryland, for at least the first five years following the promulgation date.

The Board will also hold at least one public forum, two years following the promulgation date, seeking public feedback on dry needling and its provision in Maryland.

Q: Will there be additional information provided to the public?

A: **Yes.** The regulations require written informed consent specific to dry needling to be included in the patient’s medical record.

The Maryland Board of Physical Therapy Examiners will provide information on the Board’s website for the public and licensees regarding dry needling, and offer a vehicle for any questions or complaints regarding dry needling from the public. Further, the Board will develop a patient feedback/evaluation form for public use.