

*Information Summary and Recommendations*

# Physical Therapy Dry Needling

## Sunrise Review (Review Draft)

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For more information or additional  
copies of this report contact:

Health Systems Quality Assurance  
Office of the Assistant Secretary  
PO Box 47850  
Olympia, WA 98504-7850  
360-236-4612

John Wiesman, DrPH, MPH  
Secretary of Health

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## THE SUNRISE REVIEW PROCESS

A sunrise review is an evaluation of a proposal to change the laws regulating health professions in Washington. The Washington State Legislature's intent, as stated in chapter 18.120 RCW, is to permit all qualified people to provide health services unless there is an overwhelming need for the state to protect the interests of the public by restricting entry into the profession. Changes to the scope of practice should benefit the public.

The Sunrise Act (RCW 18.120.010) says a health care profession should be regulated or scope of practice expanded only when:

- Unregulated practice can clearly harm or endanger the health, safety or welfare of the public, and the potential for the harm is easily recognizable and not remote or dependent upon tenuous argument;
- The public needs and can reasonably be expected to benefit from an assurance of initial and continuing professional ability; and
- The public cannot be effectively protected by other means in a more cost-beneficial manner.

If the legislature identifies a need and finds it necessary to regulate a health profession not previously regulated, it should select the least restrictive alternative method of regulation, consistent with the public interest. Five types of regulation may be considered as set forth in RCW 18.120.010(3):

1. *Stricter civil actions and criminal prosecutions.* To be used when existing common law, statutory civil actions, and criminal prohibitions are not sufficient to eradicate existing harm.
2. *Inspection requirements.* A process enabling an appropriate state agency to enforce violations by injunctive relief in court, including, but not limited to, regulation of the business activity providing the service rather than the employees of the business, when a service being performed for people involves a hazard to the public health, safety or welfare.
3. *Registration.* A process by which the state maintains an official roster of names and addresses of the practitioners in a given profession. The roster contains the location, nature and operation of the health care activity practices and, if required, a description of the service provided. A registered person is subject to the Uniform Disciplinary Act (chapter 18.130 RCW).
4. *Certification.* A voluntary process by which the state grants recognition to a person who has met certain qualifications. Non-certified people may perform the same tasks, but may not use "certified" in the title.<sup>1</sup> A certified person is subject to the Uniform Disciplinary Act.
5. *Licensure.* A method of regulation by which the state grants permission to engage in a health care profession only to people who meet predetermined qualifications. Licensure protects the scope of practice and the title. A licensed person is subject to the Uniform Disciplinary Act.

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<sup>1</sup> Although the law defines certification as voluntary, many health care professions have a mandatory certification requirement such as nursing assistants-certified, home care aides, and pharmacy technicians.

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## EXECUTIVE SUMMARY

### Background and Proposal

In March of 2016, Senator Randi Becker, Chair of the Senate Health Care Committee requested the Department of Health (department) conduct a sunrise review of a proposal to add dry needling to the physical therapist scope of practice. The Physical Therapy Association of Washington (PTWA) (applicant) provided an applicant report addressing how the proposal meets the sunrise criteria in chapter 18.120 RCW. PTWA provided a 2015 dry needling practice analysis prepared by the Human Resources Research Organization (HumRRO) as the basis for the proposal. Additionally, Senator Becker asked the department to “review the evidence on the efficacy of dry needling.”

Senate Bill (SB) 6374, included with the request, would create an endorsement on the physical therapy license. This endorsement would be available to physical therapists that have completed one year of full time physical therapy practice and 54 hours of education and training in dry needling. Dry needling is defined in the bill as “a skilled intervention that uses a thin filiform needle to penetrate the skin and stimulate underlying myofascial trigger points, muscular, and connective tissues for the management of neuromusculoskeletal pain and movement impairments. Dry needling does not include the stimulation or treatment of acupuncture points and meridians. ‘Dry needling’ is also known as intramuscular manual therapy or trigger point manual therapy.”

There has been a nationwide debate about whether physical therapists should be practicing dry needling. The issues being considered include whether dry needling is acupuncture, whether it is in the physical therapy scope of practice, and whether physical therapists have sufficient training to safely add it to their statutory scope of practice. This debate has been contentious and has been resolved in many different ways across the states. (See pages 16-17 for details on how other states approach the issue of dry needling by physical therapists.)

### Recommendations

The department does not support the applicant’s proposal to add dry needling to the physical therapy scope of practice. The proposal as submitted does not meet the sunrise criteria for increasing a profession’s scope of practice.

#### *Rationale:*

- Dry needling is an invasive procedure with potential serious risks of injury.
- The applicant did not demonstrate that 54 hours of training is sufficient to ensure professional ability of physical therapists to perform dry needling. The required training proposed in the bill was not based on the HumRRO practice analysis cited in the applicant report.
- There is no supervised clinical experience requirement. Physical therapists have vast training in anatomy and physiology, including supervised clinical experience. However, physical therapist training does not include invasive techniques like needling of anatomic structures.
- The applicant report states that the majority of education necessary to perform dry needling is taught in entry-level physical therapy doctoral education. However, not all

physical therapists practicing in Washington have completed doctoral-level training and a doctorate is not required for licensure.

- During the development of the HumRRO analysis, only physical therapists were consulted. There was no apparent collaboration with other types of health care providers, such as East Asian Medicine Practitioners (EAMP) and medical acupuncturists, who have more training and expertise in needling. The department finds that this type of collaboration would be helpful in identifying minimum training and clinical oversight requirements for safe and effective safe use of needles.

In addition, there are other challenges to implementing the proposed bill, SB 6374:

- The definition of dry needling is problematic because it states that dry needling does not include the stimulation or treatment of acupuncture points and meridians. Since many trigger points correspond with acupuncture points and meridians, this definition is confusing and would be difficult to enforce.
- Section 2 does not limit the dry needling endorsement to physical therapists who have received their Doctorate of Physical Therapy (DPT), even though the applicant report uses doctoral level training as the basis for its assessment of physical therapists' substantial training in anatomy and physiology. The current physical therapy statute and rules allow full licensure with a baccalaureate physical therapy degree, or a baccalaureate degree plus an advanced physical therapy degree or certificate.

### **Recommendation:**

The department recommends:

- Further study to identify the appropriate level of training needed for physical therapists to safely perform dry needling that includes supervised clinical experience. Collaboration with needling experts, such as EAMPs and medical acupuncturists is strongly encouraged to identify core training and supervised clinical oversight for physical therapists to safely perform this procedure.
- Any future proposed bills to add dry needling to the physical therapy scope of practice should clearly limit the definition to treatment of trigger points within the practice of physical therapy.
- The applicant group should acknowledge the overlap between dry needling and acupuncture. Proposed legislation should clearly include authority for physical therapists to perform acupuncture in the limited practice of dry needling and should clearly authorize them to use acupuncture needles in this limited practice.



## SUMMARY OF INFORMATION

### Proposal and Bill Draft

In March of 2016, Senator Randi Becker, Chair of the Senate Health Care Committee, requested the department conduct a sunrise review of a proposal to add dry needling to the physical therapist scope of practice. The request included Senate Bill SB 6374 for consideration. PTWA provided an applicant report addressing how the proposal meets the sunrise criteria in chapter 18.120 RCW. Additionally, Senator Becker asked the department to “review the evidence on the efficacy of dry needling.”

SB 6374 would create an endorsement on the physical therapy license, available to physical therapists that have completed one year of full time physical therapy practice and 54 hours of education and training in dry needling. Dry needling is defined in the bill as “a skilled intervention that uses a thin filiform needle to penetrate the skin and stimulate underlying myofascial trigger points, muscular, and connective tissues for the management of neuromusculoskeletal pain and movement impairments. Dry needling does not include the stimulation or treatment of acupuncture points and meridians. ‘Dry needling’ is also known as intramuscular manual therapy or trigger point manual therapy.”

### Background

There has been a nationwide debate about whether physical therapists should be practicing dry needling. The issues being discussed include whether dry needling is acupuncture, whether it is in the physical therapy scope of practice, and whether physical therapists have sufficient training to safely add it to their legislative scope of practice. This debate has been contentious and has been resolved in many different ways across the states. (See pages 16-17 for details on how other states approach the issue of dry needling by physical therapists.)

Recent activity in Washington regarding dry needling includes:

- On October 10, 2014, the King County Superior Court issued an order for partial summary judgement against Kinetacore, et al., enjoining them from inserting acupuncture needles or any similar needles for the purpose of dry needling in Washington. The judgement stated that a person that penetrates the tissues of human beings with acupuncture needles is practicing medicine.
- In December of 2014, the Board of Physical Therapy passed a motion that it would not address the issue of dry needling until the legislature provides further direction.
- On April 15, 2016, the Washington State Attorney General issued a formal opinion<sup>2</sup> on whether the practice of dry needling is within a licensed physical therapist’s scope of practice as defined in chapter 18.74 RCW. This was done at the request of Representative Eileen Cody. The attorney general opinion was that the current physical therapy scope of practice does not encompass dry needling, but noted that the legislature could expand the scope by amending the physical therapy statute.

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<sup>2</sup> <http://www.atg.wa.gov/ago-opinions/scope-practice-physical-therapy>, accessed August 16, 2016.

The applicant group states that dry needling is used to treat dysfunctions in skeletal muscle, fascia, and connective tissue, diminish persistent peripheral nociceptive (pain) inputs, and reduce or restore impairments of body structure and function leading to improved movement and function (APTA Resource Paper 2013). The applicant further states that physical therapists' practice of dry needling has the potential to reduce the cost of more expensive medical procedures or treatments such as imaging, surgery, and opioid pain medication. The applicant asserts that physical therapists have the proper education in the biomedical sciences, are already treating neuro-musculoskeletal injuries and conditions associated with trigger point myofascial pain, and are the ideal practitioners to provide dry needling.

There appear to be multiple schools of thought on dry needling. The Travell and Simons trigger point manual includes trigger point injection in the form of dry needling or injection of local anesthetic. Integrative Dry Needling (IDN) is based on Dr. Yun-tao Ma's systemic concepts that allow practitioners to view and treat the human body as an inter-related organism, yet allows the clinical freedom to adapt the treatment for each patient.<sup>3</sup> Gunn Intramuscular Stimulation (IMS) uses acupuncture needles to treat myofascial pain syndrome (MFPS). It is part of a program of treatment for MFPS that may also include massage, physical therapy, and stretching.<sup>4</sup>

Many East Asian Medicine Practitioners (EAMP) and associations representing them oppose the proposal to add dry needling to the physical therapy scope of practice and state that dry needling is a subset of acupuncture. They add that acupuncture is more than traditional Chinese medicine and includes many styles, several of which were developed in the 20<sup>th</sup> century. Many trigger points correlate with traditional acupuncture points and meridians. Acupuncturists and EAMPs also use needling techniques to treat "ashi" points, which they state are the same as trigger points. They describe ashi points as tender points that react to local pressure and create either local or radiating pain and may or may not correspond to a channel-based acupuncture point.

### **Applicant Definition of the Problem and Why the Change in Regulation is Necessary**

The applicant report states that allowing physical therapists to perform dry needling benefits Washington patients and that it is a safe, effective and appropriate tool for physical therapists to use in treating musculoskeletal impairments. The endorsement approach in SB 6374 will ensure safe practice by defining educational requirements to perform the technique. The applicant further states that the risk of adverse effects when physical therapists have performed dry needling and all reported adverse events were considered mild, such as bruising and pain while being needled.

The applicant report asserts that no one health care profession owns a skill or modality and professions can share modalities if they have the appropriate education, training, and legal authority. A profession is not defined by one modality. It states that the Attorney General Opinion (AGO 2016 No. 3) supports the idea of overlapping scopes of practice, stating "...nothing in the statutes governing East Asian medicine show legislative intent to make it the only health care practice that uses inserted solid needles."

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<sup>3</sup> <https://integrativedryneedling.com/>, accessed August 16, 2016.

<sup>4</sup> As described by UW Medical Center

The applicant also asserts that adding dry needling to the physical therapist scope of practice would be cost-effective. Access to dry needling treatment improves outcomes and facilitates patient participation with other physical therapy techniques like manual therapy and active exercise. The applicant report states that patients who are already receiving physical therapy prefer to receive treatment within Western medical models, and other practitioners that perform dry needling, like orthopedic doctors and naturopaths, are usually more expensive. It adds that patients who are not able to receive this treatment will require many more sessions of physical therapy to treat their condition. (The applicant report did not provide evidence of these assertions.)

### **Dry Needling Compared to Acupuncture**

According to the applicant report, dry needling is a technique that originates in Western medicine. It uses a thin filiform needle to penetrate the skin and stimulate underlying myofascial trigger points, muscular, and connective tissues to treat musculoskeletal dysfunctions, diminish persistent peripheral nociceptive (pain) inputs, and reduce or restore impairments of body structure and function. Trigger points are described as taut bands of muscle fibers and the applicant attributes the work of Janet Travell, M.D. and David Simons, M.D. with the theoretical origin of dry needling and mapping of myofascial trigger points.

Dry needle practice originally involved injection of taut bands of muscle with medication or saline, but it was discovered later that it was the needle piercing the skin that caused the change in the muscle rather than what was injected. Practitioners have adopted variations on the original approach to include superficial and deep needling techniques. There are also variations in the needling technique used by physical therapists, with some referring to the thrusting technique and others leaving the needle in the muscle for a specified amount of time.

The applicant report argues dry needling is not acupuncture because it differs in historical, philosophical, indicative and practical context and is based on Western neuroanatomy and modern scientific study of the musculoskeletal and nervous systems. It states dry needling does not rely on traditional Eastern medicine theories where acupuncture is used to stimulate acupuncture points and meridians to restore energy flow (also known as qi) within the body. It adds that acupuncture points are predetermined points mapped out on the body based on thousands of years of empirical study in Chinese medicine. In response to EAMPs' assertion that dry needling is the same as ashi point needling, the applicant group states that although ashi points more closely correlate with trigger points, ashi points are treated in the context of the whole treatment, not just a stand-alone treatment.

The Washington East Asian Medicine Association (WEAMA) and many EAMPs state that ashi acupuncture and dry needling are indistinguishable from one another from a regulatory and legislative standpoint. They state that the procedure and tools are the same; the targets of the procedure, trigger points, are the same as ashi acupuncture points; the manipulation techniques are the same; and the response to the needling is the same. They add that acupuncture has measurable effects on autonomic regulation, neuroendocrine mechanisms, the cardiovascular system, etc.; so to say that acupuncture only works "to restore energy flow" is a gross misrepresentation. They add further that physical therapists use acupuncture studies to support dry needling, so they must understand that the same therapeutic phenomena are occurring in the body.

The department received comments from some physical therapists stating that acupuncture nomenclature is sometimes used in dry needling training. They state that this nomenclature is used in randomized controlled trials investigating effectiveness of using acupuncture needles. They also state that acupoints and trigger points are anatomically at very similar, if not identical, locations, making it more reliable in identifying the exact insertion location, angulation and depth of the needle placement, which is required when using standardized interventions or needling protocols in the confines of randomized controlled trials.”<sup>5</sup>

## **Acupuncture Needles**

Another debate brought to our attention during this review is whether physical therapists are authorized to purchase acupuncture needles, which are regulated by the Federal Food and Drug Administration (FDA). Lawyers representing the APTA and the National Center for Acupuncture Safety and Integrity (NCASI) interpret regulations of acupuncture needles differently.

### **APTA legal analysis**

The APTA analysis interprets FDA regulations as meaning that acupuncture needles are for use by qualified practitioners as determined by the states. They believe the FDA was clearly signaling that it would not involve itself in determining who is a qualified practitioner to use acupuncture needles, leaving this decision to the states.

### **Legal counsel for NCASI**

This analysis interprets the FDA regulations to mean that federal law restricts the devices to sale by or on the order of “qualified practitioners of acupuncture” as determined by the states. They cite the definition of acupuncture needle in 21 CFR 880.5580 as “intended to pierce the skin in the practice of acupuncture” to mean that sale of these needles for a purpose other than the practice of acupuncture is outside the scope of the FDA’s approval.

### **FDA regulations**

FDA regulations for acupuncture needles are:

#### **21 CFR 880.5580 Acupuncture needle.**

(a) *Identification.* An acupuncture needle is a device intended to pierce the skin in the practice of acupuncture. The device consists of a solid, stainless steel needle. The device may have a handle attached to the needle to facilitate the delivery of acupuncture treatment.

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

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

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<sup>5</sup> Letter from American Academy of Manipulative Therapy, received August 16, 2016.

## **21 CFR 801.109 Prescription devices.**

A device which, because of any potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use is not safe except under the supervision of a practitioner licensed by law to direct the use of such device, and hence for which “adequate directions for use” cannot be prepared, shall be exempt from section 502(f)(1) of the act if all the following conditions are met:

(a) The device is:

(1)(i) In the possession of a person, or his agents or employees, regularly and lawfully engaged in the manufacture, transportation, storage, or wholesale or retail distribution of such device; or

(ii) In the possession of a practitioner, such as physicians, dentists, and veterinarians, licensed by law to use or order the use of such device; and

(2) Is to be sold only to or on the prescription or other order of such practitioner for use in the course of his professional practice.

(b) The label of the device, other than surgical instruments, bears:

(1) The statement “Caution: Federal law restricts this device to sale by or on the order of a \_\_\_\_\_”, the blank to be filled with the word “physician”, “dentist”, “veterinarian”, or with the descriptive designation of any other practitioner licensed by the law of the State in which he practices to use or order the use of the device...

### **Acupuncture labels**

Department staff researched purchasing acupuncture needles online, and found the following language through AcuDepot, Acupuncture Needles & Alternative Healthcare Medical Supplies:<sup>6</sup>

NOTE: Federal law restricts the sale of Acupuncture Needles to or on the order of qualified practitioners of acupuncture as determined by the states. According to this regulation, all of our customers are required to provide their Acupuncture License on the first purchase of Acupuncture Needles.

### **Do physical therapists use the same needle as EAMPs?**

Further complicating this issue, the applicants do not acknowledge that physical therapists that perform dry needling use acupuncture needles. The HumRRO analysis makes the statement, “Needles of similar design are used by practitioners of Acupuncture and Oriental Medicine,”<sup>7</sup> which is an inaccurate statement because the needles are not similar, but exactly the same. The applicants sometimes acknowledge they use the same

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<sup>6</sup> <http://acudepot.com/collections/acupuncture-needles/products/dong200>, accessed August 30, 2016.

<sup>7</sup> Analysis of Competencies for Dry Needling by Physical Therapists, HumRRO, p. 1, Appendix B, p. 81.

tool as acupuncturists. At other times, they state the needles look the same but are made through a different process of heating that changes the molecular structure of the needle.<sup>8</sup>

There is an FDA-approved needle that states on the label it is for use in dry needling. Please note that the FDA still classifies this as an acupuncture needle (classified under medical devices as “Needle, Acupuncture, Single Use”). There is no new classification for physiotherapy or dry needling needles. “Physiotherapy Needles” is listed as the proprietary name of the device, not the classification, on the FDA website.<sup>9</sup>

## Education and Training

As of January 1, 2016, the APTA has designated a DPT as the standard for all entry-level physical therapist education programs nationally. However, this has been an evolution over many years that started with a baccalaureate degree program as the required degree prior to 1979. APTA passed a resolution to begin shifting to a post-baccalaureate degree requirement by 1990, and this requirement has evolved to the current DPT entry-level standard. As of August 2010, over 96 percent of accredited physical therapy programs offered the DPT.<sup>10</sup>

However, Washington’s physical therapy law accepts a baccalaureate degree in physical therapy, or baccalaureate degree plus an advanced degree or certification in physical therapy, as the minimum education for physical therapy licensure. Depending on when a currently licensed physical therapist was credentialed, he or she could hold a bachelor’s, master’s, or doctoral degree. The University of Washington’s Doctor of Physical Therapy Program requires 162 credits, 4,860 hours of class and lab time, and 1,500 hours of supervised clinical education. This training includes:

- 218 hours of gross and musculoskeletal anatomy;
- 83 hours of physiology; and
- 60 hours of neuroscience.<sup>11</sup>

The applicant report states that the overwhelming majority of education necessary for physical therapists to practice dry needling, including anatomical, physiological, and biomechanical knowledge, is taught in the entry-level physical therapy doctoral education.<sup>12</sup> It states that specific dry needling skills are supplemental to doctoral-level education. The applicant report also cites two studies suggesting physical therapists have knowledge, training and skills necessary to clinically diagnose and manage musculoskeletal injuries beyond most non-orthopedic physicians.<sup>13</sup>

The applicant report relies on a 2015 practice analysis on dry needling from the nonprofit organization, Human Resources Research Organization (HumRRO) as the basis of its proposal, including the educational requirements in the proposed bill. HumRRO was commissioned by the Federation of State Boards of Physical Therapy (FSBPT) to organize this practice analysis to

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<sup>8</sup> Jan Dommerholt testimony at the public hearing. See hearing summary, Appendix C, p. 188.

<sup>9</sup> <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfml/details.cfm?lid=447790>, accessed August 16, 2016.

<sup>10</sup> American Physical Therapy Association, *Today’s Physical Therapist: A Comprehensive Review of a 21<sup>st</sup>-Century Health Care Profession*.

<sup>11</sup> Applicant report, Appendix B, pp. 50-51.

<sup>12</sup> Per applicant report, this is demonstrated by the HumRRO analysis. See applicant report, Appendix B, p. 14.

<sup>13</sup> Applicant report, Appendix B, p. 51.

determine the knowledge requirements needed to be competent in dry needling. This analysis stated that the overwhelming majority of education necessary for physical therapists to perform dry needling is taught in entry-level physical therapy education. The report listed 16 specialized knowledge requirements that require advanced, specialized training for dry needling. These include emergency preparedness tasks, secondary effects or complications associated with dry needling on other systems such as the cardiovascular system, contraindications, palpation techniques, needle insertion, needle manipulation techniques, and physiological responses to dry needling.

HumRRO concluded that 14 percent of the knowledge related to competency in dry needling must be acquired through post-graduate or specialized training. The only skill determined not to be in entry-level physical therapy education is the handling of the needle and psychomotor skills.

The applicant report states that the proposed legislation is based on the HumRRO practice analysis. However, there are inconsistencies between the applicant report and the HumRRO analysis on which it relies. These include:

- HumRRO does not identify training requirements. It identifies knowledge areas, tasks, and skills that require advanced or specialized training for physical therapists to perform dry needling.
- HumRRO acknowledges that there does not appear to be widespread agreement regarding the minimum number of practice hours necessary to perform dry needling, and that the acquisition of knowledge and skills is dependent on more than just the number of hours of deliberate practice.<sup>14</sup>
- The applicant report assumes a DPT as the entry-level training in the proposal, but it is not clear whether the HumRRO analysis makes this same assumption. The HumRRO task force members were not all DPTs and this analysis was done at the national level.

In addition, the department identified some challenges with the HumRRO analysis, which include:

- HumRRO and FSBPT convened a task force with experts in dry needling to consolidate information and construct a final list of competencies. However, the task force only included representation of physical therapists. It did not include representation from medical acupuncturists or others experienced in using needles in medical practice. It also did not include EAMPs, who have the most training and experience in filiform needle insertion techniques, needle manipulation techniques, physiological responses, and contraindications.
- HumRRO states that 86 percent of the knowledge needed to safely perform dry needling is acquired during physical therapy entry-level education. This analysis is problematic because:
  - The HumRRO analysis identifies the entry-level physical therapy knowledge and skills required at the time of licensure. Licensure requirements and scopes of practice vary considerably from state-to-state.

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<sup>14</sup> HumRRO Analysis footnote, Appendix B, p. 93.



- Entry-level education for Washington licensure only requires a baccalaureate physical therapy degree.
- The HumRRO analysis did not consider information specific to Washington, the task force members are not Washington-licensed physical therapists, and it appears that the physical therapists surveyed in this process represented a sample from across the country.

Because of these limitations, the department finds that the applicant report does not support the dry needling education requirements in the proposal.

### **Dry Needling Training**

PTWA's applicant report listed a number of dry needling courses currently being offered, including:<sup>15</sup>

- Kinetacore:
  - 54 contact hours (Level I and Level II, each level is 27 contact hours over three days) to earn the certificate. Approximately 40 of these hours is on needle handling.
  - Requires one year of physical therapy practice before registering for the course.
  - There is an additional level, functional therapeutics that is also 27 contact hours.
  - To qualify for the Level II course, you must have completed Level I and logged 200 dry needling treatments or have completed Level I and Functional Therapeutics and logged 100 dry needling treatments. Each level requires passing theoretical and practical exams to gain certificate and move to the next level.
- Integrative Dry Needling:
  - 54 contact hours (foundation and advanced courses, each 27 contact hours over three days). Approximately 39 of these hours is needle handling.
  - Foundation course is the prerequisite to take the advanced course.
- Institute of Advanced Musculoskeletal Treatments (IAMT):
  - 54 contact hours (Level I and Level II, each level is 27 contact hours).<sup>16</sup> Approximately 49 of these hours is needle handling.
  - There is a level III course that does not specify the length of the course, but is described as combining manual therapy interventions with dry needling techniques and functional retraining to restore biomechanics and normalize function in patients.
- Myopain Seminars:
  - 81 contact hours (DN-1, DN-2, and DN-3 advanced course, each level is 27 contact hours over three days). Approximately 70 percent is needle handling.

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<sup>15</sup> The applicant provided three different tables of information on these courses and the department has attempted to synthesize the information from those tables, Appendix B, pp. 66-68, pp. 139-154, and pp. 167-169.

<sup>16</sup> The department received conflicting information on whether these courses are 20 or 27 contact hours.



- Each course must be taken in order and requires passing practical and theoretical exams to gain certificate.
- Spinal Manipulative Institute:
  - 54 hours of hands-on dry needling education (DN-1 and DN-2, each 27 hours over three days).<sup>17</sup> Approximately 70 percent of each course is hands-on practical application (needle handling).
  - Students receive a comprehensive lecture on safe/clean dry needling technique, major and minor adverse events and relative/absolute contraindications. They then begin immediately handling needles and continue to do so during the practical components of the DN-1 and DN-2 courses.

These individual training companies determine course content and how to determine competency at the end of the program. The courses vary in length and content.

We received comments from others that included additional dry needling training examples such as:

- IMS Dry Needling as taught by Steven Goodman, MD. “IMS is an elaborated technique of trigger point dry needling that is based on a comprehensive model of diagnosis and treatment of neuropathic-myofascial pain syndromes. This model was developed from the clinically recognized work of C.C. Gunn, M.D.”<sup>18</sup> This is a 27-hour course designed to provide intensive instruction in the identification of appropriate patients for, and the safe practice of, IMS. Contains lectures, demonstrations and practical sessions where students act as models for the instructor or fellow participants.<sup>19</sup>
- Military training requirements vary. The United States Army requires evidence of appropriate dry needling education in either entry-level or postgraduate education, with supervision required for the first 25 cases before practicing independently.<sup>20</sup> The U.S. Army – Baylor Doctoral Program in Physical Therapy three-day basic and three-day advanced post-professional dry needling course includes a brief review with specific instruction on needle insertion techniques that avoid important anatomic structures.<sup>21</sup>

### **Acupuncture training**

Acupuncture programs include master’s in Acupuncture and master’s in Acupuncture and Oriental Medicine. Washington state licensure as an EAMP requires successful completion of a minimum of 500 hours of supervised clinical training in East Asian medicine, including acupuncture. Bastyr University’s (Kenmore, Washington) acupuncture program features an integrated approach to acupuncture education that includes Western pathology and biomedicine clinical skills in its training.<sup>22</sup>

<sup>17</sup> The department received conflicting information on whether these courses are 24 or 27 contact hours.

<sup>18</sup> LearnIMS website, <http://www.learnims.com/>, accessed August 30, 2016.

<sup>19</sup> <http://www.learnims.com/#!course-session-outline/c1v3j>, accessed August 30, 2016.

<sup>20</sup> Applicant report (Appendix B, p. 59).

<sup>21</sup> Letter submitted by Shane Koppenhaver, PT, PdD, Lieutenant Colonel and Director/Associate Professor, U.S. Army Baylor University Doctoral Program in Physical Therapy, Appendix B, pp. 485-486.

<sup>22</sup> According to comments received from Skye Sturgeon, DAOM, L.Ac., Department Chair of Bastyr University’s Acupuncture & East Asian Medicine program.

Tri-State College of Acupuncture (New York, New York) offers unique training that includes classical and modern acupuncture theories to integrate East-West perspectives. Its programs teach three styles of acupuncture: traditional Chinese medicine (TCM), Japanese acupuncture, and Acupuncture Physical Medicine (APM). APM uses hands-on assessment by palpation to identify myofascial imbalances and trigger points, and teaches trigger point needling that is integrated throughout the three-year program.

Extensive trigger point needling training begins in the first year of the program with a hands-on course in structural and functional anatomy, 100 hours of supervised clinical practice which includes acupuncture point location and basic needling skill, and progresses in the second and third years of the acupuncture program. There are 100 hours of supervised clinical training in APM in the second year, 78 hours of supervised clinic rotations in APM after the second year, 250 hours of an acupuncture clinical internship which includes APM, TCM and Japanese acupuncture, and a 25-hour advanced techniques class during the third year.

Tri State College also offers an Acupuncture Integrative Medicine (AIM) Program for physicians and dentists. This 300-hour program provides core foundational training in acupuncture medicine with a strong emphasis on acupuncture trigger point needling. Of the 300-hour course, 150 hours are clinical and 150 are didactic training.<sup>23</sup>

## **Evidence of Harm**

### **Evidence of Safe Dry Needling - Provided by Applicant:**

The applicant report states that dry needling is safe when performed by physical therapists. It included studies on dry needling safety such as:

- Journal of Manual and Manipulative Therapy (Brady 2013) reported risk from PTs performing dry needling is less than 0.04 percent;
- Study by Brady of 7,629 dry needling treatments showed no instances of pneumothorax (lung collapse);
- A 2012 request from APTA to CNA, the largest healthcare malpractice insurer of physical therapists to provide information on claims against PTs nationally related to dry needling. CNA found no trends relative to dry needling in 5,800 claims and stated “CNA does not foresee the practice of dry needling by a licensed physical therapist as having an immediate claim or rate impact.”
- The FSBPT’s Disciplinary Database of disciplinary actions taken by physical therapy regulators across the country showed:
  - In 2013, a physical therapist in Maryland was disciplined for not documenting dry needling on a patient. This practitioner had not received dry needling training and was found to be working outside of his individual competency.

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<sup>23</sup> <http://www.tsca.edu/site/prospective/doctors/>, accessed September 7, 2016, and per phone conversation and written follow up with Peter Dubitsky, Director of Clinical Training at Tri-State College of Acupuncture.

- In 2014, discipline was taken against two Arizona physical therapists for performing dry needling through clothing. One of these physical therapists was also licensed in Ohio, and action was taken in that state in 2015 based on the Arizona action.

The applicant report added that there are also risks from acupuncture, and comparisons of risk with dry needling by physical therapists must be taken in light of the inherent risk in inserting a needle into muscle tissue. It cited a prospective acupuncture study that showed 8.6% of 229,233 patients who received 2.2 million acupuncture treatments experience at least one adverse event. This represents a total of 24,377 adverse events reported (one event per 90 treatments).

It also included a statement that although the risk of pneumothorax<sup>24</sup> is low in the practice of dry needling, there was a Canadian Olympic athlete who suffered a double pneumothorax after acupuncture was performed by a massage therapist. However the applicant noted that baseline physical therapy education is much more thorough and intensive than that of a massage therapist.

### **Evidence of Harm from Dry Needling - Provided by EAMPs and Others:**

WEAMA and others submitted additional information about adverse events and the risk involved with dry needling. This included high profile cases reported in news stories of athletes who have had serious complications from dry needling:

- In Colorado, a physical therapist punctured freeskier Torin Yater-Wallace's right lung with an acupuncture needle, causing damage to the lung that led to pneumothorax. He required surgery to treat the pneumothorax and was hospitalized for five days.
- Letter from Emily Kuykendall was submitted, which stated she suffered a punctured nerve in her leg from a physical therapist performing dry needling, causing serious pain and suffering, which necessitated drug therapy.
- 2016 CNA report, Physical Therapy Professional Liability Exposure: 2016 Claim Report Update.
  - This report cites an example of a patient who underwent three dry needling procedures with a physical therapist to treat a calf injury and acquired a bacterial infection requiring intravenous therapy and two surgical procedures. It states that although this claim resolved for significantly less than the other allegations in the same category (failure to supervise or monitor), "the claim deserves attention because it involves dry needle therapy, which represents an emerging area of risk."
  - This report also provided examples of dry-needling claims related to improper insertion techniques, including three patients hospitalized for pneumothorax.

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<sup>24</sup> A leak in the space between the lung and chest wall that results in a collapsed lung.

WEAMA also noted that not all dry needling resources are in agreement on the safety of dry needling during pregnancy, noting that Dr. Gunn of IMS dry needling considers dry needling to be contraindicated during pregnancy.

## Other States

Many states have looked at the issue of physical therapists performing dry needling and have come to a number of different conclusions. The department received information on other states from the applicant and others. However, since this is an ongoing debate nationally, information is constantly changing. The department conducted independent research on how other states have addressed this issue and is providing information collected as of August 30, 2016. (See Appendix E, pages 599-609 for a table of state regulations and decisions).

- Five states permit dry needling by statute:
  - Arizona, A.R.S. 32-2001(4). Rules require 24-hour course approved by one of five physical therapy organizations.
  - Delaware, 24 Delaware Code, Section 2602(6)(10). Rules require two years of active physical therapy practice and successful completion of a dry needling program of 54 hours.
  - Georgia, Georgia Code 43-33-3(7)(D). Does not appear to require additional dry needling training.
  - Tennessee, (House Bill No. 25, 4/9/15). Rules require 50 hours of instruction in musculoskeletal and neuromuscular systems; anatomical basis of pain mechanisms, chronic pain, and referred pain; trigger points; and universal precautions. Also require 24 hours of dry needling specific instruction.
  - Utah, Utah Code 58-24b-102(14). Rules require two years in active physical therapy practice and successful completion of a course in trigger point dry needling that includes 300 hours, with 54 hours of in-person instruction and 250 supervised patient treatment sessions.
- Four states and the District of Columbia permit dry needling by rule or have rules pending: Colorado, Louisiana, Montana (pending), and Wyoming,
- Eighteen states permit dry needling by AG opinion or licensing board opinion/determination: Alaska, Arkansas, Iowa, Kentucky, Mississippi, Nebraska, Nevada, New Hampshire, Maryland, New Mexico, North Carolina, North Dakota, Ohio, Rhode Island, Texas, Virginia, West Virginia, Wisconsin.

Of note, Maryland's 2010 AG opinion stated "...the physical therapy board may determine that dry needling is within the scope of practice of physical therapy if it conducts rulemaking...and adopts a regulation that relates dry needling to the statutory definition of physical therapy. Any such process should consider standards for education and training that presumable would be at least as strict as those set by the legislature for physicians who use acupuncture needles..." There are currently proposed Maryland rules to require 80 hours of instruction with 40 hours in specific dry needling-specific content and 40 hours of practical hands-on instruction in the application and technique of dry needling, but these do not appear to have been adopted.

- Some states, Illinois, Kansas, Massachusetts, and Oregon appear to be unresolved on the issue.

Of note in Oregon, a 2014 Court of Appeals Appellate Commissioner issued an opinion that dry needling is not within the scope of practice of chiropractic medicine. The Oregon Physical Therapist Licensing Board stated this opinion was not applicable to physical therapy. However, the board later stated that it holds to a previous board opinion that dry needling is likely within the physical therapy scope of practice, but is an advanced intervention requiring post graduate training. It further stated “in the interest of public safety, until a measure of evidence based training and education can be determined, the board strongly advises its licensee to not perform dry needling of trigger points.” The board and Oregon Physical Therapy Association continue to monitor national trends and legislation regarding this issue.

### **Public Participation and Hearing**

The department received the request from the legislature to conduct this sunrise review in March of 2016 and received the applicant report on June 1, 2016. The department posted the proposal and all applicant materials to the sunrise webpage and notified interested parties of a public hearing scheduled for August 2, 2016. Written comments were accepted until the close of the public hearing, with an additional two-week comment period for follow up after the hearing.

The department received over two hundred written comments about the proposal, an online petition with over 1,200 signatures in opposition, a petition with 566 signatures in support, and 27 people testified at the hearing. Here is a brief summary of the comments received in writing and at the public hearing. See Appendix D for all comments.

- The department received comments from many physical therapists, physical therapy students, and physical therapy organizations supporting the proposal and stating that it provides for safe practice of dry needling by physical therapists.
- Many patients of physical therapists who have had dry needling performed for pain wrote in with testimonials in favor of the proposal. They wrote in with success stories, as well as stories of not having insurance coverage for acupuncture as arguments supporting the proposal.
- Physical therapists who teach dry needling courses wrote in support of the proposal, stating that evidence supports dry needling as safe and effective when provided by physical therapists. They wrote that they have practiced and taught dry needling safely without severe adverse events.
- The East Asian Medicine Advisory Committee sent a letter stating that there is no meaningful distinction between dry needling and acupuncture; 54 hours of clinical training is woefully inadequate and does not include supervised clinical hours; and WEAMA and PTWA need to collaborate on this issue.
- The Council of Colleges of Acupuncture and Oriental Medicine submitted comments in opposition to the inclusion of dry needling in the physical therapy scope of practice including:
  - Urging the department to review the council’s position paper and discussion concerning the historical origins of dry needling in the “ashi” point theory of

Chinese medicine. According to its *Position Paper on Dry Needling*, dry needling is an acupuncture technique.

- In 2016, the Federation of Chinese Medicine Societies issued a statement defining the myofascial trigger points as “actually channel points, extra points, and ASHI points” and concluding “dry needling is actually [the] ‘rediscovery’ of acupuncture.
- It further identified what it considered problems with the HumRRO analysis. These included that the basic definition of dry needling adopted by the report is not restricted to trigger point therapy and is overly broad and vague, making it impossible to reliably identify all the needed knowledge and competencies; failure to identify the amount of clinical practice necessary for the insertion of 3-inch needles into the human body; only an estimated 32 percent of licensed physical therapists are trained at the doctoral level upon which the report is based; avoids the issue of a lack of educational standards in the field; and fails to set minimum hours for skills training.
- Many EAMPs and organizations representing EAMPs sent comments opposing the proposal. Many stated that dual licensure is the route physical therapists should take if they wish to do dry needling, which they state is the practice of acupuncture.
- The American Society of Acupuncturists states that dry needling is an acupuncture technique performed regularly by acupuncturists and medical doctors. It states that physical therapists are not appropriately educated on deep anatomic structures and how to safely insert needles into the body, and are not educated on acupuncture theory, needle technique, western or Eastern acupuncture theory, or the full complement of indications and contraindications for needle therapy. It states there is no agreed upon or vetted curriculum, no outside certification, and no independent examination of competency for instructors.
- WEAMA sent a number of comments and reference documents to demonstrate its assertion that dry needling is acupuncture and that the proposal does not meet the sunrise criteria. These included that there are no independently vetted standards for dry needling education, physical therapists should meet the same competency requirements as EAMPs in order to provide dry needling and that adverse event rates are higher than data provided by the applicant report (detailed in the Evidence of Harm section). They stated that the requirement of 54 hours of training is unsubstantiated with no data to quantify this is a sufficient amount of training. The application has not provided cost comparisons to other modalities or mentioned referral to EAMPs for dry needling as an option, in order to demonstrate that the proposal will provide the most cost-effective option to protect the public.
- Other organizations that oppose adding dry needling to the physical therapy scope of practice are: American Medical Association, American Academy of Physical Medicine and Rehabilitation, American Academy of Medical Acupuncture, and American Association of Acupuncture & Oriental Medicine.

## Findings:

- The HumRRO analysis cited in the applicant report as the basis of the 54-hour training requirement (proposed in SB 6374) does not assess dry needling training programs or analyze what adequate training should include.
- There is no standard curriculum for dry needling courses.
- The proposal does not include a supervised experience requirement for dry needling, even though it is an invasive technique.
- The applicant states it has outlined the dry needling post-doctoral continuing education that ensures adequate education, training, and practice experience to perform dry needling. However, there does not appear to be a prerequisite in the dry needling training programs for physical therapists to hold a DPT.
- The applicant over-simplifies the practice of acupuncture in its arguments on why dry needling is not acupuncture, arguing that acupuncture is only based on the ancient rules of channels and meridians and movement of qi (energy flow).
- Some physical therapists contradict the applicant report, stating that there are studies that show using traditional acupuncture points is more accurate than palpation for identifying where to needle trigger points.
- Physical therapists refer to acupuncture needles as tools, just as a stethoscope is a tool. However, acupuncture needles are, and have always been, one of the main tools used by EAMPs.
- EAMP training includes use of needles and needling techniques throughout their curriculum and supervised clinical experience.
- The recommendation by EAMPs and their representative organizations of requiring an EAMP degree as the minimum level of training to perform dry needling does not appear to be the least burdensome alternative to the proposal. Some acupuncture training may be beneficial for performing dry needling, but completing a full EAMP training curriculum and clinical experience would not be necessary to safely perform dry needling in the scope of physical therapy practice.

## Review of Evidence of Efficacy

The legislature also asked the department to review the evidence on the efficacy of dry needling.

***The department is reviewing this request separately from the sunrise process and will add it in the final report***

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## REVIEW OF PROPOSAL USING SUNRISE CRITERIA

The Sunrise Act, in RCW 18.120.010, states that a health care profession should be regulated or the scope of practice expanded only when:

- Unregulated practice can clearly harm or endanger the health, safety, or welfare of the public and the potential for the harm is easily recognizable and not remote or dependent upon tenuous argument;
- The public needs can reasonably be expected to benefit from an assurance of initial and continuing professional ability; and
- The public cannot be effectively protected by other means in a more cost-beneficial manner.

### **First Criterion: Unregulated practice can clearly harm or endanger the health or safety.**

The proposal does not meet this criterion. Physical therapists are currently a thoroughly regulated profession with substantial training in the treatment modalities under their current scope of practice. The proposal adds an invasive procedure with the potential for serious risks of patient injury to the physical therapy scope of practice without providing evidence of adequate training.

Strong arguments were made that needling of trigger points is practiced by acupuncturists in the form of trigger point needling or ashi point needling. Acupuncture is a tightly regulated health profession and EAMPs receive substantial training on needling throughout their programs. Overlaps between scopes of practice are sometimes appropriate; however, not without evidence of adequate training to protect the public, which should include supervised clinical training.

### **Second Criterion: The public needs and can reasonably be expected to benefit from an assurance of initial and continuing professional ability.**

The proposal does not meet this criterion. There are adequate laws and rules in place to assure the public of physical therapists' initial and continued professional ability to practice within their current scope of practice. The proposal does not contain similar assurances.

The applicant has not provided evidence that the proposal provides assurance of initial and continuing professional ability for physical therapists to perform dry needling safely. The HumRRO analysis did not analyze current dry needling training or identify minimum training requirements; there are no consistent standards for the existing training programs; not all Washington state-licensed physical therapists have been trained at the doctorate level; and there is no supervised clinical training included in the proposal.

### **Third Criterion: The public cannot be effectively protected by other, more cost-beneficial means.**

The proposal does not meet this criterion. The current physical therapy scope of practice protects the public. The proposal as written does not offer adequate protections to meet this criterion.

Dry needling is within the acupuncture scope of practice, so EAMPs and acupuncturists can provide this treatment. EAMPs can bill for this treatment as part of overall acupuncture

treatment; however, there is no CPT code for dry needling. Without calling this acupuncture, there is no appropriate code for physical therapists to bill.

Because physical therapists are already treating myofascial pain and trigger points within their current scope of practice, if the applicant group could provide evidence of adequate training that includes a clinical experience component, adding dry needling could be a cost-effective option. If a patient is already receiving physical therapy treatment for myofascial pain, continuing treatment with the physical therapist for dry needling, when indicated, would be more efficient than referring him or her to an acupuncturist or other health care professional for separate treatment.

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## DETAILED RECOMMENDATIONS TO THE LEGISLATURE

The department does not support the applicant's proposal to add dry needling to the physical therapy scope of practice. The proposal as submitted does not meet the sunrise criteria for increasing a profession's scope of practice.

### *Rationale:*

- Dry needling is an invasive procedure with potential serious risks of patient injury.
- The applicant did not demonstrate that 54 hours of training is sufficient to ensure professional ability of physical therapists to perform dry needling. The required training proposed in the bill was not based on the HumRRO analysis cited in the applicant report.
- There is no supervised clinical experience requirement. Physical therapists have vast training, including supervised clinical experience, in anatomy and physiology. However, physical therapist training does not include invasive techniques like needling anatomic structures.
- The applicant report states that the majority of education necessary to perform dry needling is taught in entry-level physical therapy doctoral education. However, not all physical therapists practicing in Washington have completed doctoral level training and a doctorate is not required for licensure.
- During the development of the HumRRO analysis, only physical therapists were consulted. There was no apparent collaboration with other types of health care providers, such as East Asian Medical Practitioners (EAMP) and medical acupuncturists, who have vast training and expertise in needling. The department finds that this type of collaboration would be helpful in identifying minimum training and clinical oversight requirements for safe and effective use of needles.

In addition, there are other challenges to implementing the proposed bill, SB 6374:

- The definition of dry needling is problematic because it states that dry needling does not include the stimulation or treatment of acupuncture points and meridians. Since many trigger points correspond with acupuncture points and meridians (and many argue they are acupuncture ashi points), this is a confusing definition and would be difficult to enforce.
- Section 2 does not limit the dry needling endorsement to physical therapists who have received their DPT, even though the applicant report uses doctoral level training as the basis for its assessment of physical therapists' substantial training in anatomy and physiology. The current physical therapy statute and rules allow full licensure with a baccalaureate physical therapy degree, or a baccalaureate degree plus an advanced physical therapy degree or certificate.

### **Recommendation:**

The department recommends:

- Further study to identify the appropriate level of training needed for physical therapists to safely perform dry needling. Collaboration with needling experts, such as EAMPs and

medical acupuncturists, is strongly encouraged to identify core training and supervised clinical oversight for physical therapists to safely perform this procedure.

- Any future proposed bill to add dry needling to the physical therapy scope of practice should clearly limit the definition to treatment of trigger points within the practice of physical therapy.
- The applicant group should acknowledge the overlap between dry needling and acupuncture. Proposed legislation should clearly include authority for physical therapists to perform acupuncture in the limited practice of dry needling and should clearly authorize them to use acupuncture needles in this limited practice.

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