

BEFORE THE BOARD OF PHYSICAL THERAPY EXAMINERS
DEPARTMENT OF LABOR AND INDUSTRY
STATE OF MONTANA

In the matter of the amendment of) NOTICE OF AMENDMENT AND
ARM 24.177.2105 continuing) ADOPTION
education and the adoption of NEW)
RULE I dry needling)

TO: All Concerned Persons

1. On April 8, 2016, the Board of Physical Therapy Examiners (board) published MAR Notice No. 24-177-33 regarding the public hearing on the proposed amendment and adoption of the above-stated rules, at page 576 of the 2016 Montana Administrative Register, Issue No. 7.

2. On May 5, 2016, a public hearing was held on the proposed amendment and adoption of the above-stated rules in Helena. Numerous comments were received by the May 12, 2016, deadline.

3. The board has thoroughly considered the comments received. A summary of the comments and the board's responses are as follows:

NEW RULE I DRY NEEDLING

OPPONENTS:

COMMENT 1: Several commenters opposed the proposed new rule, claiming it would illegally expand the scope of practice for physical therapists. The commenters asserted that the physical therapist practice act does not "clearly and specifically" authorize physical therapists to perform any invasive procedure, as required by 2-4-305(3), MCA, particularly regarding the insertion of needles. The commenters argued that only the legislature can authorize such an expansion of an occupation's scope of practice.

RESPONSE 1: The board concluded that statutory authority already exists for the board to adopt NEW RULE I as proposed. Section 2-4-305(3), MCA, requires the board to clearly and specifically list the "subject matter of the rule," rather than each procedure for every profession. Section 37-11-201(1), MCA, authorizes the board to adopt rules to implement the physical therapist practice act. Section 37-11-104(2), MCA, describes physical therapy treatment to employ, "for therapeutic effects, physical measures, activities and devices, for preventative and therapeutic purposes, exercise, rehabilitative procedures, massage, mobilization, and physical agents including but not limited to mechanical devices, heat, cold, air, light, water, electricity, and sound."

NEW RULE I (1) clearly and specifically provides "Dry needling is a manual therapy technique that uses a filiform needle as a mechanical device to treat

conditions within the scope of physical therapy practice." And importantly, 37-13-104(2), MCA (acupuncturist practice act), specifically requires that ". . . and with particular regard to the insertion of solid needles used to perform acupuncture, this chapter is not intended to limit, interfere with, or prevent a licensed health professional from practicing within the scope of the health professional's license."

In addition to the statutory foundation, there is also precedent. The board notes that physical therapists have been performing dry needling all over the world for 25 years, including Montana. Physical therapists have also been performing needle Nerve Conduction Studies (NCS) and Electromyography (EMG) since the 1960s. And in 1982, the American Physical Therapy Association (APTA) House of Delegates approved board certification in clinical electrophysiology, which includes needles. Additionally, physical therapists perform various forms of debridement, some of which utilize medical tools and are invasive.

COMMENT 2: One commenter likewise opposed the rule because of procedure and timing, suggesting physical therapists are capable of performing dry needling, but the board should seek specific statutory authority from the legislature before adopting a new rule, like it did for topical medications.

RESPONSE 2: Similar to RESPONSE 1, the board determined that additional legislation is not necessary to recognize that dry needling is within the scope of practice for physical therapists. The new rule is necessary simply to guide the practice to ensure the protection of public health and safety.

COMMENT 3: Several commenters opposed defining dry needling as a "manual therapy," because no accepted medical definition of that term includes penetration of the skin and insertion of needles into underlying tissue and muscle. The commenters believe that only physicians, nurses, phlebotomists, and acupuncturists are specifically authorized to use needles to penetrate the skin.

RESPONSE 3: In the spirit of compromise, the board agrees with the suggestion and is amending the rule to remove the words "manual therapy" from the proposed definition of dry needling.

COMMENT 4: One commenter opposed the new rule, because the original rule proposal referred to the procedure as "trigger point dry needling," while the current proposal refers to it only as "dry needling." The commenter suggested that removing the words "trigger point" is even a further expansion of a physical therapist's scope of practice.

RESPONSE 4: Because the board intends for the updated language to not only standardize regulation nationwide, but also utilize a definition that protects the public as medical technology progresses, the board is not amending per the comment.

COMMENT 5: Several commenters suggested the board should require licensees who perform dry needling to submit proof of passing a clean needle technique exam before performing dry needling.

RESPONSE 5: Because (3) currently contains provisions to ensure clean needle techniques, the board is not further amending per the comment. Additionally, dry needling courses include training in clean needle techniques. Importantly, physicians, physician assistants, and nurses do not have to pass such an exam. The board concluded there is no reason to hold physical therapists to a higher standard and the proposed language suffices to protect public health and safety.

COMMENT 6: Numerous commenters opposed the lack of standards for teaching dry needling and asserted that, while the new rule requires practitioners to obtain the necessary educational foundation, it does not establish standards for teaching dry needling. Several commenters reported that physical therapists appeared to be performing dry needling on patients Monday morning, after receiving only one weekend "crash course," of ten to thirty hours in length. The commenters claimed public safety is at risk because there are no established independent minimum exams to prove competency in either teaching or practicing dry needling.

RESPONSE 6: The board does not believe that completely untrained individuals are taking one crash course in dry needling, and notes that physical therapists are licensed health care providers with seven years of higher education in anatomy, physiology, biomechanics, pharmacology, and more. Increasingly, physical therapy schools are including dry needling patient selection, indications, contraindications, and how to handle adverse reactions in their curricula. For those already graduated, national companies like Kinetacore and others provide continuing education from instructors who have at least four years of experience (two years as an assistant instructor after practicing dry needling for two years).

It is beyond the scope of this board to accredit providers of continuing education. However, (3) requires that licensed physical therapists who perform dry needling are able to demonstrate they have completed training in dry needling that must meet the American Physical Therapy Association (APTA) guidelines or the Federation of State Boards of Physical Therapy (FSBPT) standards. Both documents include standards and qualifications for continuing education providers.

COMMENT 7: Numerous commenters opposed the new rule claiming dry needling and acupuncture are the same thing, and asserted there is a 90+ percent correspondence between dry needling points and acupuncture points. The commenters stated that if physical therapists want to use filiform needles, they should have to get acupuncture licenses.

RESPONSE 7: The board concluded that dry needling and acupuncture are different procedures in terms of historical, philosophical, indicative, and practical context. Acupuncture is based on preserving the ancient theories, principles, and tenets of traditional Chinese medicine, whereas physical therapy is based on theories, principles, and tenets of current, Western medicine. Contemporary physical therapy curriculum does not include traditional Chinese medicine philosophies, nor do physical therapists use traditional acupuncture theories or terminology in daily practice.

The board notes that physical therapists are not attempting to perform acupuncture, nor are they leading clients to believe dry needling is the same as acupuncture. Rather than alter the flow of a person's energy, as in acupuncture, physical therapists use dry needling to stimulate musculoskeletal tissue with the goal of decreasing tissue tone to improve mobility and/or decrease pain, to penetrate the skin, and target specific anatomical structures.

COMMENT 8: Several commenters opposed the rule claiming physical therapists performing dry needling threaten public safety, because they are more likely than acupuncturists to cause potentially harmful side effects – such as pneumothorax, puncturing another large organ (heart, kidney, liver, bladder), or a major blood vessel – because acupuncturists have been practicing for thousands of years, while physical therapists have only been practicing for twenty or so.

RESPONSE 8: The board notes that, although physical therapists have been performing dry needling for more than twenty years, no data, documentation, or articles were submitted to justify the claim that it represents an unreasonable threat to public safety. The board specifically acknowledges the "Brady" study, which included 39 physiotherapists in Ireland and reported 1,463 mild adverse events (AE) in 7,629 treatments with trigger point dry needling (19.18 percent). Common mild AEs included bruising (7.55 percent), bleeding (4.65 percent), pain during treatment (3.01 percent), and pain after treatment (2.19 percent). Uncommon mild AEs were aggravation of symptoms (0.88 percent), drowsiness (0.26 percent), headache (0.14 percent), and nausea (0.13 percent). Rare, mild AEs included fatigue (0.04 percent), altered emotions (0.04 percent), shaking, itching, claustrophobia, and numbness, all 0.01 percent. Critically, zero significant AEs were reported, meaning the estimated upper risk rate for significant AEs was less than or equal to 0.04 percent. The board notes the contrast between that risk (0.04 percent), and the risk associated with taking aspirin (18.7 percent), Ibuprofen (13.7 percent), and Paracetamol (Acetaminophen) (14.5 percent).

COMMENT 9: Several commenters opposed the rule stating they have no confidence physical therapists can address even the mild adverse events possibly caused by dry needling, let alone potential serious adverse events. Examples of serious adverse events include punctured lungs, organs and arteries; bruising, infection and fainting; nausea, dizziness, and blindness; sharp pain, lameness and leaking lumbar spinal fluid; paralysis, and death.

RESPONSE 9: The board notes that, similar to RESPONSE 8, dry needling is not a documented, unreasonable threat to public health and safety. Physical therapists are educated and trained to first and foremost, avoid serious adverse events related to dry needling. Additionally, their education and training also enable them to address both the very rare significant, adverse events, as well as the more common but still rare, mild adverse events associated with dry needling.

COMMENT 10: One commenter suggested NEW RULE I is unnecessary, because physical therapists can release trigger points without having to use needles.

RESPONSE 10: Although true in many cases, the board notes that the intent of the new rule is not to judge the efficacy or adequacy of dry needling. Whether a particular procedure is appropriate and will lead to a successful outcome is for the patient and provider to decide. The board's primary interest is to ensure that qualified physical therapists who provide dry needling, do so in a manner that does not present an unreasonable risk.

COMMENT 11: Several commenters opposed NEW RULE I because of what they anticipate to be negative economic impacts on their small businesses. The commenters stated that the new rule will benefit physical therapists at the expense of acupuncturists who invested resources to learn this procedure, and now the board is authorizing competition.

RESPONSE 11: The board's primary concern is to protect public safety. Further, the board may not restrict trade merely to shield a particular profession from competition. The board's purpose in adopting the new rule is to ensure that physical therapists who provide dry needling treatments on Montana patients are competent, and do not pose an unreasonable risk. The board has no economic interest in this proposal.

PROPOSERS:

COMMENT 12: One commenter, as someone involved in this rulemaking process since before the joint meetings with the Board of Medical Examiners in 2011, supported the proposed new rule, stated the board has done its due diligence to make sure the rule was appropriate, followed administrative procedures, and appropriately considered public feedback. The commenter opined that there is no evidence to show physical therapists performing dry needling represent an unreasonable threat to public safety, and therefore, no legitimate reason to delay the adoption of NEW RULE I.

RESPONSE 12: The board agrees with the comments.

COMMENT 13: One commenter supported the new rule, and opposed specific continuing education and certification for dry needling, saying the board would be unreasonable to expect practitioners to obtain a new license every time they learn a new procedure, or gain a new skill within their trade. Physical therapists are educated professionals adding a skill, not seeing a patient for the first time. As an educator, the commenter knows how painstakingly instructors create curriculums, specifically to avoid injury and death.

RESPONSE 13: The board agrees with the comments.

COMMENT 14: Numerous commenters supported the proposed new rule after learning about opponents who suggest physical therapists are insufficiently trained to perform dry needling. Some were personally offended, saying that understanding

human anatomy is essential to patient safety. Physical therapists are not just random people off the street with one weekend crash course and then sticking needles in people on Monday morning. They receive seven years of undergraduate, graduate, and doctoral level education, and their training includes thousands of hours in human anatomy, physiology, and pathology; biology, biomechanics, and kinesiology; neuroscience, pharmacology, and the origin, insertion, action and innervation of each muscle.

RESPONSE 14: The board agrees with the comments.

COMMENT 15: Several commenters supported the rule because, in addition to physical therapy schools around the nation – including the University of Montana – beginning to incorporate dry needling into their curriculums, physical therapists are receiving training through continuing education by private companies, including Kinetacore, Myopain Seminars, and American Academy of Manipulative Therapy; Intramuscular Stimulation (IMS), and Evidence in Motion (EIM). Kinetacore, for example, includes hands-on training, written and practical examinations in indications for dry needling success, contraindications, potential risks, proper hygiene, proper use of and disposal of needles, appropriate selection of patients, and more.

RESPONSE 15: The board agrees with the comments.

COMMENT 16: Numerous commenters supported the rule proposal because, as practitioners, they have achieved good results using dry needling on patients in Montana, as have their colleagues around the world. They particularly support the rule because although the procedure is minimally invasive, ensuring physical therapists follow certain minimum standards is appropriate to ensure public health and safety.

RESPONSE 16: The board agrees with the comments.

COMMENT 17: Numerous commenters supported the rule proposal because, as patients, physical therapists have performed dry needling on them to successfully:

- Treat low back and shoulder spasms, including those related to Multiple Sclerosis (MS);
- Decrease neck, back, arm, upper leg and knee pain;
- Decrease chronic pain; chronic pain caused by fibromyalgia and fatigue;
- Increase functioning and decrease pain for an above-the-leg amputee;
- Prevent pain of a mixed martial arts fighter;
- Treat rock climbing injuries;
- Release muscle tension;
- Increase range of motion;
- Treat plantar fasciitis;
- Reduce the pain of migraine headaches;

- Treat radiculo-neuropathic myofascial pain (RMNP)(pain stemming from nerve roots);
- Decrease dependence on prescription pain killers; decrease myofascial restrictions (friction within the fascia/"wax paper" effect); and treat
- Neurovascular impairments;
- Overuse injuries;
- TMJ pain;
- Neuropathies (nerve damage);
- Adducer and hip flexor muscle;
- Scar tissue; and
- Balance affected by a big toe injury.

RESPONSE 17: The board agrees with the comments.

COMMENT 18: Numerous commenters supported the rule proposal because, as patients, they recognize dry needling and acupuncture are different. At no time did their physical therapists represent that dry needling treatment was acupuncture.

RESPONSE 18: The board agrees with the comments.

COMMENT 19: Several commenters supported the rule proposal because, as Montana doctors, they and most of their colleagues are comfortable referring patients to physical therapists for dry needling, although hands-on training and an oral exam demonstrating technical proficiency should be part of the rule.

RESPONSE 19: The board agrees with the comments.

COMMENT 20: One commenter supported the proposal because, statistically, the percentage of significant adverse effects from trigger point dry needling is .04 percent, which is less than the adverse effects from taking aspirin or ibuprofen.

RESPONSE 20: The board agrees with the comments.

COMMENT 21: Several comments conveyed that all Kinetacore lead instructors have a minimum of two years of functional dry needling assistant teaching and a minimum of two years practicing dry needling before becoming an assistant instructor.

RESPONSE 21: The board agrees with the comments.

COMMENT 22: Several commenters supported the rules, saying acupuncturists do not own the exclusive right to use a needle to provide health care any more than a carpenter owns the exclusive right to use a hammer or wrench to provide home care. Physical therapists treat muscles not meridians or energy flows.

RESPONSE 22: The board agrees with the comments.

COMMENT 23: A commenter from a small Montana community supported the proposed new rule because if patients cannot access dry needling in Montana, they will travel to Idaho or Washington.

RESPONSE 23: The board agrees with the comments.

COMMENT 24: Numerous commenters supported the proposed new rule because regulating dry needling will expand access to healthcare, by expanding license portability. Specifically, more and more states (31 to date) are regulating dry needling. Licensees don't want to get left behind and believe the proposed new rule will allow Montana to attract higher-qualified providers.

RESPONSE 24: The board agrees with the comments.

COMMENT 25: Several commenters supported the rule proposal, saying that regulators cannot just bury their heads in the sand and act like physical therapists are not already performing dry needling. Physical therapists are currently performing dry needling, because they are being trained to perform it in physical therapy schools and by continuing education providers. Because physical therapists are qualified to perform dry needling, the commenters opined that it is likely illegal for the board to prohibit the procedure. Additionally, because the procedure is minimally invasive, the board would be irresponsible to ignore the practice.

RESPONSE 25: While taking no position on the legal interpretations, the board is only making one minor amendment to the proposed rule, as the board otherwise agrees with the commenters.

COMMENT 26: Multiple health care providers supported the proposed new rule because the healthcare community should seek alternative forms of pain control, including dry needling, instead of defaulting to opioid pain medications.

RESPONSE 26: The board agrees with the comments.

COMMENT 27: One commenter supported the new rule, and suggested the board add language making it unprofessional conduct when a licensee does not comply with the educational requirements.

RESPONSE 27: The suggested amendment exceeds what can be accomplished in a final notice. The board may consider the change in a future rules project.

4. The board has amended ARM 24.177.2105 exactly as proposed.

5. The board has adopted NEW RULE I (ARM 24.177.413) with the following changes, stricken matter interlined, new matter underlined:

NEW RULE I DRY NEEDLING (1) Dry needling is a skilled manual therapy technique performed by a physical therapist using a mechanical device, filiform needles, to penetrate the skin and/or underlying tissues to affect change in body structures and functions for the evaluation and management of neuromusculoskeletal conditions, pain, movement impairments, and disability. (2) through (6) remain as proposed.

AUTH: 37-1-131, 37-11-201, MCA
IMP: 37-1-131, 37-11-101, 37-11-104, MCA

BOARD OF PHYSICAL THERAPY
EXAMINERS
BRIAN MILLER, PRESIDING OFFICER

/s/ DARCEE L. MOE
Darcee L. Moe
Rule Reviewer

/s/ PAM BUCY
Pam Bucy, Commissioner
DEPARTMENT OF LABOR AND INDUSTRY

Certified to the Secretary of State September 12, 2016