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Lisa W. Durden, Director
Office of Secretary of State
Professional Licensing Boards Division
Georgia State Board of Physical Therapy
237 Coliseum Drive
Macon, GA 31217

Re: Comments regarding proposed rule amendment 490-9-.05 (Dry Needling Rule)

GAAAM, GKAOMA and CAAGASC Position: Opposed

Dear Board members,

The Georgia Association of Acupuncture & Asian Medicine (GAAAM), Georgia Korean Acupuncture & Oriental Medicine Association (GKAOMA), and the Chinese Acupuncture Association of Georgia Acupuncture Safety Committee (CAAGASC) (hereinafter “the Petitioner”) respectfully request that the Georgia State Board of Physical Therapy (hereinafter “the Board”) refuse to adopt or significantly amend its proposed rule change regarding Rule 490-9-.05 as it has been proposed. We strongly object to the proposed rule on the grounds that it would allow physical therapists to start inserting acupuncture needles as deep as 5” into their patients with as little as 20 hours of training on an interim basis. Proposed Rule 490-9-.05(C)(4). The proposed rule is similarly flawed since it would continue to require only a total of only 50 hours of training within the year for physical therapists to be fully authorized to engage in “dry needling.” Proposed Rule 490-9-.05(C)(3).

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Such minimal levels of training are wholly inadequate to protect public safety and are inconsistent with the Board’s legal obligation to act so as to “safeguard[] the public health, safety, and welfare...” GA Code § 43-33-2. They are exactly the type of inadequate standards being pushed by companies that profit from dry needling training courses. Such cursory standards are why the American Medical Association recently explained in adopting a policy critical of dry needling that, “[I]ax regulation and nonexistent standards surround this invasive practice ... For patients’ safety, practitioners should meet standards required for acupuncturists and physicians.”¹

The grossly inadequate level of training required under both the Board’s 20-hour proposed standard and its current 50-hour training standard are highlighted by the fact that Georgia statute requires that even medical doctors with extensive training and experience in invasive practices and the use of needles should have 300 hours of acupuncture training before they can legally insert acupuncture needles into patients. Ga. Admin Code § 360-6-.09

While Georgia statute has defined physical therapy to include “dry needling”, this does nothing to change the fact that “dry needling” plainly constitutes acupuncture as it has been practiced for over 2,000 years. The origin of the term “acupuncture” literally means “to puncture” “with a needle” and is accurately defined by the National Institute of Health as “a family of procedures involving the stimulation of points on the body using a variety of techniques.”² Of course, even Georgia statute acknowledges that, “[d]ry needling is a technique of the practice of acupuncture.” Ga. Code § 43-34-62.

Attempts to define “dry needling” as something other than acupuncture also does nothing to avoid the inherent and obvious risks related to the insertion of acupuncture needles into patients. As documented by the U.S. Food and Drug Administration (FDA), these risks have been well documented and range from the risks of organ puncture to blood infections. 61 Fed. Reg. 64616 (Dec. 6, 1996). This is why acupuncturists in Georgia are required to complete a Master’s degree in Acupuncture and Chinese Medicine that includes courses in anatomy and physiology, pathology, basic pharmacology, physical assessment and at least 1365 hours of acupuncture-specific training, including 705 hours of acupuncture specific didactic material and 660 hours of supervised clinical training. Furthermore, those who have less than one year post graduate experience applying for an acupuncture license must complete an additional one year of supervised practice under a licensed acupuncturist before being granted their permanent full licensure.

¹ “AMA Adopts New Policies on Final Day of Annual Meeting,” American Medical Association website, June 15, 2016, <http://www.ama-assn.org/ama/pub/news/news/2016/2016-06-15-new-policies-annual-meeting.page>

² National Institute of Health, National Center for Complimentary and Integrative Health, online: <https://nccih.nih.gov/health/acupuncture>

The inadequate training typically associated with “dry needling” led CNA, the largest provider of professional liability coverage to physical therapists, to describe dry needling as “an emerging area of risk.” See CNA Physical Therapy Professional Liability Exposure: 2016 Claim Report Update at pp. 19, 22.³ CNA’s 2016 report identifies a number of significant dry needling related injuries. 19, 22.

The notion that physical therapists should be able to start inserting acupuncture needles up to 5” into their patients (and potentially attaching electrical current to such needles) with 20, or even 50, hours of training is entirely unsupportable from a public safety perspective. Proposed Rule 490-9-.05(C)(4). The Board should be working to significantly strengthen and increase the current training standard of 50 hours, not taking steps to lower a bar that already fails to protect public safety.

While we respect the training physical therapists receive in their traditional areas of practice, a vast majority of physical therapists have not received training prior to graduation or licensure in the safe and effective use of any needles, let alone acupuncture needles used in “dry needling” for deep needle insertion. Georgia is one of a very small number of states that has statutorily allowed physical therapists to insert acupuncture needles. But there is no rational basis to read this statutory provision as a license for the Board to allow physical therapists to engage in dry needling without the level of classroom *and* clinical training that is critical to protecting public health from persons who are practicing acupuncture. The Legislature’s requirement that medical doctors have 300 hours of training highlights the magnitude of the gap between the proposed regulations and any level of training that would be appropriate for the Board to adopt.

1. The proposed regulations are inconsistent with the Board’s legal obligations

The Georgia Physical Therapy Act makes clear that, "this chapter is enacted for the purpose of safeguarding the public health, safety, and welfare by providing for state administrative control, supervision, and regulation of the practice of physical therapy. The practice of physical therapy is declared to be affected with the public interest." GA Code § 43-33-2. Importantly, it also provides that, “this chapter shall be liberally construed so as to accomplish the purpose stated in this Code section." *Id.* Similarly, Georgia law also requires that the Board, "adopt such rules and regulations as shall be reasonably necessary for the enforcement and implementation of the provisions and purposes of this chapter and other laws of this state insofar as they relate to physical therapy." GA Code § 43-33-10. Because the proposed regulations would allow a level of training that is inadequate to protect public safety

³ Physical Therapy Professional Liability Exposure: 2016 Claim Report Update, CNA/HPSO, on-line at: https://www.cna.com/web/wcm/connect/2d3eaa76-aca2-4f6f-bfd8-e7706368cdac/RC_Healt_PT_Claim_Report_Update.pdf?MOD=AJPERES&CACHEID=2d3eaa76-aca2-4f6f-bfd8-e7706368cdac



they are inconsistent with the Board's core obligation to protect "public health, safety and welfare" under GA Code § 43-33-2 and 10.

The Board's own regulations require that, "[d]ry needling must be directly performed by a licensed physical therapist that is specifically trained and competent by virtue of education and training to perform dry needling." Rule § 490-5-.05. The Georgia Physical Therapist Code of Ethics also requires that "any individual who is licensed as a physical therapist shall abide by the following ethical standard: . . . Accept the responsibility to protect the public and the profession from unethical, incompetent, or illegal acts." Rule § 490-9-.02. The proposed regulations would be inconsistent with both of these requirements.

There is no credible medical or factual support that a physical therapist can safely start inserting acupuncture needles, which are an FDA-regulated Class II prescription medical device, with either 20 or 50 hours of training. The lack of any meaningful requirement for supervised clinical training is especially egregious. Again, since dry needling is the practice of acupuncture it is useful to recognize that acupuncturists in Georgia are required to have at least 660 hours of supervised clinical training in addition to 705 hours of classroom training. This supervised clinical training is widely viewed as a critical component of learning to insert acupuncture needles in a manner that is safe not only for a typical patient, but the complex diversity of patients' that health care providers actually see in their practice.

Hands on clinical experience with the oversight of an experienced practitioner is particularly key to safely gaining the experience in treating patients with special considerations or unique health or physical challenges. A typical 50-hour "dry needling" course would include some subset of that time inserting acupuncture needles into other physical therapist classmates that are not presenting any real symptoms or complications. Treatments on fellow classmates are a common starting point for learning to safely insert acupuncture needles, but are certainly no substitute for the training and experience that can only come from treating hundreds of different patients that have real ailments and real personal health and treatment complications.

A person leaving a typical dry needling course, for example, will not likely have any hands on experience using acupuncture needles on elderly patients, juveniles, disabled patients, patients with severe medical conditions, mental illness, or other specific and unique health needs. Treating patients with diverse ages, physical conditions, and health histories can only come from a robust level of supervised clinical training that alone should significantly exceed the current 50-hour training standard. To the extent the Board believes the current 50-hour standard for training is adequate, however, then it is internally inconsistent with the proposal to allow physical therapists to begin inserting acupuncture needles with less than half that level of training.

We believe that the Board should seriously reevaluate and reconsider its perspective on both the minimal 20-hour training level it has both proposed, as well as its current 50-hour

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standard. We are hopeful that the information below about “dry needling” helps inform the Board about why robust training for anyone engaged in inserting acupuncture needles is so important to public safety.

2. Dry needling is the practice of acupuncture.

As the Georgia Legislature has observed, dry needling is the practice of acupuncture. Ga. Code § 43-34-62. This position was recently echoed by the American Medical Association (“AMA”) which explained that “[d]ry needling is indistinguishable from acupuncture” Exhibit 1.⁴ That said, dry needling promoters typically claim that dry needling does not constitute the practice of acupuncture and use rationale to argue they should not be required to meet the extensive safety and training standards that have long been required for practicing acupuncture.

The notion that dry needling is not acupuncture is primarily based on an unfortunate lack of understanding about the practice of acupuncture. Dry needling involves the insertion of FDA-defined and regulated acupuncture needles into reactive (painful) acupuncture points, known as “*ashi* points.” “*Ashi* points,” which dry needlers refer to as “trigger points,” have been used in acupuncture for more than 2,000 years for the same therapeutic purposes as “dry needling.”⁵ Importantly, dry needling also involves the same type of risks, such as organ puncture, nerve damage, and blood infections, that are both obvious and recognized by the FDA. 61 Fed. Reg. 64616 (Dec. 6, 1996) attached as Exhibit 2.

The claim put forward by some dry needling promoters that dry needling is distinct from acupuncture since acupuncture involves the insertion of acupuncture needles into “distal points” located at places of the body different from an area of pain or other dysfunction, and the use of energy “meridians” reflects a basic lack of knowledge about the scope of the practice of acupuncture. The direct needling of “*ashi* points” or “trigger points” has long been and continues to be an important part of the practice of acupuncture.⁶ It is factually wrong to assert that acupuncture is limited or defined by the use of distal points or meridians, it simply is not.

⁴ “Physicians take on timely public health issues,” AMA Wire, American Medical Association, online at: <http://www.ama-assn.org/ama/ama-wire/post/physicians-timely-public-health-issues>

⁵ Yellow Emperor’s Inner Classic (黃帝內經, *Huáng Dì nèi jīng*). China; compiled in the first century BCE. To be clear, trigger points are reactive (painful) acupuncture points that are eliciting a flinch reaction on palpation. The *Yellow Emperor’s Inner Classic* explains: “a point of pain indicates a clinically relevant acupuncture point” (以痛為腧, *yǐ tòng wéi shù*).” See also Sun SM. Essential prescriptions worth 1,000 liang of gold (千金要方, *Qiān jīn yào fāng*). China; 652 CE. Sun Si Miao (581–682 CE), a renowned physician of the Sui (581–618 CE) and Tang (618–907 CE) dynasties, called reactive (painful) acupuncture points that are eliciting this abnormality “ah yes! points” (“阿是穴”), from the words often uttered by the patient when pressure is applied to them.

⁶ Fan, AY *et al.*, Evidence That Dry Needling is the Intent to Bypass Regulation to Practice Acupuncture in the
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The notion that dry needling is meaningfully distinct from acupuncture based on the claim it is a “Western medical” philosophy is similarly without merit. It is akin to a group of people claiming their invention of the wheel was unique because they had a different philosophy or culture from the people who actually first invented the wheel. Inserting an acupuncture needle into trigger points for the purpose of providing therapeutic relief is the practice of acupuncture regardless of whether the persons engaged in such acts intend to practice acupuncture or are even aware they are practicing acupuncture.

In a number of non-regulatory contexts, even promoters of dry needling acknowledge that dry needling is basically a different name to describe the practice of acupuncture. The owner of one of the largest national dry needling training companies, Myopain Seminars, in fact, openly acknowledges that “dry needling falls within the scope of acupuncture” but asserts that physical therapists also possess the right to engage in it. Exhibit 3. The national Federation of State Boards of Physical Therapy (“FSBPT”), which strongly advocates for dry needling similarly admits, “[w]hen performed by acupuncturists, dry needling is acupuncture.”⁷

Exhibit 4 shows photos posted by a dry needling training company that offers classes across the United States that plainly identify acupuncture points marked on the recipient’s skin. Whether a physical therapist engaged in dry needling chooses to ignore or is genuinely unaware that they are practicing what originated as a traditionally “Oriental Medical Theory” does not alter the fact that they are.

It is also telling that the American Physical Therapy Association’s (“APTA”) primary white paper on dry needling repeatedly cites to published studies *specific to acupuncture* as grounds to support the effectiveness and benefits of dry needling.⁸ Exhibit 5 details the APTA’s repeated reliance on published acupuncture studies to support the effectiveness of dry needling. The Spinal Manipulation Institute, which offers dry needling classes for physical therapists and chiropractors, specifically trains students in “the nomenclature and the location of several key traditional acupuncture points,” explaining that “much of the literature that ‘dry needling’ draws

United States, *The Journal of Alternative and Complimentary Medicine*, Vol. 22:8 2016.

⁷ FSBPT Resource Paper Regarding Dry Needling, 5th edition, December 2014, https://c.ymcdn.com/sites/www.nypta.org/resource/resmgr/Committees/DryNeedlingResourcePaper_5th.pdf.

⁸ FSBPT Resource Paper Regarding Dry Needling, 5th edition, December 2014, https://c.ymcdn.com/sites/www.nypta.org/resource/resmgr/Committees/DryNeedlingResourcePaper_5th.pdf; Description of Dry Needling In Clinical Practice: An Educational Resource Paper, American Physical Therapy Association (APTA) Public Policy, Practice, and Professional Affairs Unit, February 2013, <http://www.apta.org/StateIssues/DryNeedling/ClinicalPracticeResourcePaper/>.

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from uses the term ‘acupuncture’ in its title, and many of these studies have used both traditional acupuncture points and myofascial trigger points in their treatment regimes.”⁹

A number of these factors and others demonstrating that dry needling is acupuncture are addressed in a recently published paper titled, “Evidence That Dry Needling is the Intent to Bypass Regulation to Practice Acupuncture in the United States.” See Exhibit 6;¹⁰ See similar study at Exhibit 13, titled Dry Needling is One Type of Acupuncture, which was recently published in the journal Medical Acupuncture. The paper not only accurately describes the long-standing use of “trigger points” in the practice of acupuncture, but also documents a number of the primary promoters of dry needling acknowledging that dry needling is based in acupuncture. For example, the paper quotes Dr. Yun-tao Ma (the founder of the American Dry Needling Institute and Dr. Ma’s Integrative Dry Needling, one of the largest dry needling training companies in the United States): “DN originated in Traditional Chinese methods, and has developed from the ancient empirical approach to become modern, evidence-based practice.”¹¹
¹² Dr. Ma is himself a licensed acupuncturist.

While not all dry needling training classes are explicit in their use of well-known acupuncture points or admit that they are engaged in acupuncture, these acknowledgments highlight why the claim that dry needling was created out of whole cloth as a Western medical intervention distinct from acupuncture is simply inaccurate. Such claims also represent a form of cultural appropriation of a medical treatment that has a long-respected history in Chinese culture.

While understanding that dry needling is the practice of acupuncture highlights the importance of establishing training requirements that are equivalent to those required for acupuncture, it is of course important to recognize that the Georgia Legislature has explicitly found that dry needling falls within the practice of acupuncture. Ga. Code § 43-34-62(4) (“Dry needling is a technique of the practice of acupuncture.”)

3. Dry needling presents a significant public health risk.

When Olympic skier Torin Yater-Wallace suffered a collapsed lung and was hospitalized

⁹ Spinal Manipulation Institute website, last visited on 8/19/2016, online: <http://www.spinalmanipulation.org/seminar.php?id=9>

¹⁰ Fan, AY *et al.*, Evidence That Dry Needling is the Intent to Bypass Regulation to Practice Acupuncture in the United States, *The Journal of Alternative and Complimentary Medicine*, Vol. 22:8 2016.

¹¹ *Id.* at 2 quoting from Ma YT. *Biomedical Acupuncture for Sports and Trauma Rehabilitation: Dry Needling Techniques*. St. Louis, MO: Churchill Livingstone Elsevier, 2011.

¹² Integrative Dry Needling website, last visited 8/9/2016, <https://integrativedryneedling.com/about-us/dr-yun-tao-ma/>

from a dry needling treatment by a physical therapist in Colorado it made national news, Exhibit 7 (Facebook photo of Yater-Wallace in hospital).¹³ This injury, however, was only one of a growing number of injuries caused by physical therapists and others inadequately trained in the safe use of acupuncture needles. There have been a number of other significant injuries from dry needling that are summarized in Exhibit 8 and referenced in the CNA professional liability report.¹⁴ Adverse events from dry needling have been found to be “[a] very common occurrence for trigger point dry needling” with a reported adverse occurrence rate of over 19%, which is twice the level of adverse events resulting from acupuncture. *See* Exhibit 9.

Examples of injuries from dry needling around the U.S. have included:

- Mixed martial artist Mitch Clarke had an acupuncture needle break off during a dry needling session, cutting tissue inside his arm and requiring surgical removal;¹⁵
- School teacher Emily Kuykendall suffered serious nerve damage during a dry needling treatment in Maryland, Exhibit 10;
- Jamie Del Fierro from San Diego had a chiropractor pierce her lung during a dry needling treatment in San Diego, Exhibit 11;¹⁶

These examples are important to consider since a physical therapist can graduate and become licensed in Georgia without having any education or clinical training in the safe use and insertion of acupuncture needles. Ga. Admin. Code § 490-2 (establishing the requirements for physical therapist licensure in Georgia). Even so, Ga. Admin Code 490-9-.05 would only requires physical therapists to complete 50 hours of training to perform unsupervised dry needling on patients and will be reduced down to a mere 20 hours if the proposed amendments are adopted.

Even medical doctors with extensive training in the use of invasive medical devices need to have 300 hours of training in acupuncture (including 100 hours of clinical training) to satisfy the minimal standards for certification from the American Board of Medical Acupuncture

¹³ Axon R. Torin Yater-Wallace bounces back from collapsed lung with top run. USA Today. 2013 Dec 14. <http://www.usatoday.com/story/sports/olympics/sochi/2013/12/13/torin-yater-wallace-dew-tour-ion-mountain-championship-halfpipe-qualifying/4019707/>.

¹⁴ *See* CNA Report at FN 2.

¹⁵ Mixed Martial Artist Junkie, *see video online*: <http://mmajunkie.com/2015/09/ufcs-mitch-clarke-tells-story-of-acupuncture-needle-shaped-like-a-z-stuck-in-his-arm>

¹⁶ “Lawsuit: Illegal acupuncture caused lung collapse, Chiropractor was performing the treatment without a license, woman claims,” Kristina Davis, San Diego Union Tribune, February 2, 2015.

(ABMA).¹⁷ Importantly, Georgia law specifically requires:

Licensed physicians desiring to practice acupuncture in Georgia shall successfully complete a Board-approved 300 hour course and notify the Board in writing of their intent to practice acupuncture no less than thirty (30) days prior to incorporating such therapies into their medical practice. Ga. Admin Code § 360-6-.09.

There is no rationale or medical basis for allowing physical therapists with little to no experience with invasive use of needles begin inserting needles into patients with 20 hours, or even 50 hours of training, when the Georgia Legislature has required physicians have 300 hours of training prior to using acupuncture needles. While we do not agree that the 300 hours that may be appropriate for highly trained medical doctors would be a reasonable training standard for physical therapists, it certainly provides a compelling reference point for the inadequacy of the current standards.

4. FDA’s regulation of acupuncture needles highlights the inherent risks of acupuncture needles when used without substantial training in the practice of acupuncture.

Under federal law, physical therapists cannot generally purchase or possess the acupuncture needles they use for dry needling. It is “undisputed” that physical therapists use FDA-defined “acupuncture needles” for dry needling. While “dry needlers” prefer to call these needles “solid filiform needles,” they are without question what the FDA has plainly defined and regulated as an “acupuncture needle.” FDA regulations define an “acupuncture needle” as:

. . . 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*. 21 CFR § 880.5580(a) (emphasis added).

To circumvent regulations pertaining to the labeling, sale, and possession of acupuncture needles, some manufacturers and sellers of acupuncture needles for “dry needling” purposes attempt to distinguish their needles from acupuncture needles by avoiding the term “acupuncture needles” and stating their intended use as “dry needling.” However, the FDA clarified it was “reclassifying acupuncture needles for the practice of acupuncture and *substantially equivalent devices of this generic type*.” 61 Fed. Reg. 64616 (Dec. 6, 1996). Therefore, the substantially equivalent (and often identical) devices used for “dry needling” constitute “acupuncture needles,” which are Class II prescription medical devices.

¹⁷ American Board of Medical Acupuncture website, last visited July 31, 2016, <http://www.dabma.org/requirements.asp>.



In regulating acupuncture needles, the FDA described the risks of acupuncture needles as including “sepsis [severe blood infection], excessive trauma, and perforation of blood vessels and organs.” 61 Fed. Reg. 64616 (Dec. 6, 1996) attached as Exhibit 2. As a result, FDA regulations provide specific rules controlling the sale, receipt, and possession of acupuncture needles, including application of FDA’s prescription requirements for medical devices that restrict sale of acupuncture needles to “qualified practitioners of acupuncture.” 21 CFR § 880.5580(b)(1); 61 Fed. Reg. 64616 (Dec. 6, 1996). In designating acupuncture needles as a prescription medical device, the FDA has explained that the sale of acupuncture needles “must be clearly restricted to *qualified practitioners of acupuncture* as determined by the States.” 61 Fed. Reg. 64616 (Dec. 6, 1996) (emphasis added). 21 CFR § 880.5580(b)(1); 21 CFR § 801.109. The “FDA believes that information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any hazards, contraindications, side effects and precautions are commonly known to qualified practitioners of acupuncture.” *See* Exhibit 2.

As a result, the FDA requires that acupuncture needles carry a warning label that substantially states, “Caution: Federal law restricts this device to sale by or on the order of *qualified practitioners of acupuncture* as determined by the States,” a warning that can be found in nearly identical text on every box of *legally* sold acupuncture needles in the United States today. *See* Seirin acupuncture needle label at Exhibit 12.

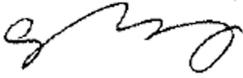
While Georgia law is arguably not explicit as to whether physical therapists would be considered authorized practitioners of acupuncture that can even legally purchase acupuncture needles, FDA’s regulations support requiring a training standard physical therapists wishing to insert acupuncture needles that are equivalent to those required for acupuncturists.

4. Conclusion

For the reasons described above, the Petitioner respectfully requests that the Board rescind its proposed Rule 490-9-.05 and instead initiate a planning process to draft and adopt training standards for physical therapists wishing to insert acupuncture needles that are equivalent to the standard of protection required under Georgia law for acupuncturists. There is simply no medical, scientific or public policy basis that supports providing a weaker and less protective standard for physical therapists engaged in the practice of acupuncture than is required for acupuncturists and medical doctors.

Thank you for considering these comments.

Sincerely,



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