The Maryland
Acupuncture
Society, Inc.

January 30, 2012

John Baker, Chair
Maryland Board of Physical Therapy Examiners
4201 Patterson Avenue
Baltimore, MD 21215

Re: Draft Regulations Intramuscular Manual Therapy

Dear Mr. Baker:

It has come to the attention of the Maryland Acupuncture Society (MAS) that your Board is conducting an informal comment period, having completed a draft proposal of administrative regulations for inclusion of Intramuscular Manual Therapy (IMT) in the scope of practice for duly licensed physical therapists.

MAS has serious concerns about these regulations in their current draft and feels they are insufficient to assure the safe treatment of patients with this procedure by physical therapists.

As you know, IMT (more commonly referred to as "trigger point dry-needling" or "dry-needling") is identical in procedure and treatment outcomes to the common acupuncture procedure known as "lifting and thrusting of ashi points". The Chinese first described in detail the anatomy and physiology of the muscular system in the Huang Di Nei Jing Ling Shu (a classic oriental medicine text published during the Han Dynasty, 206BC – 220AD, and a foundational textbook used in current accredited acupuncture programs), writing about this procedure as an option to alleviate muscular pain and illness. Of the 255 "trigger points" [i] used by a physical therapist to perform this procedure, 234 (92%) have identical anatomic correspondence with classical, miscellaneous, or new acupuncture points[ii].

Indeed, Dr. C. Chan Gunn, MD, a physician credited by the medical community as one of the founders of dry-needling, wrote numerous journal articles published throughout the 1970s and 1980s identifying an electrical output he could measure and document at the site of an established "tender motor" acupuncture point (locus), and renaming it a "trigger point". He suggested, "that, as a first step towards the understanding and acceptance of acupuncture by the medical profession, the present anachronic systems locus nomenclature be dispensed with in favor of a modern, scientific one using nuero-anatomic descriptions[iii]." Thus the emergence of "dry-needling" as new, more acceptable terminology to describe a long-standing acupuncture procedure.

Lifting and thrusting is one of numerous needling procedures that an acupuncturist is required to learn through their formalized education. In addition to learning to identify acupuncture points associated with "meridians", a student must also learn to diagnose the tender "ashi" points along the muscles of the body. Both a 2003 and 2008 job task analysis conducted by the National Certification Commission of Acupuncture and Oriental Medicine (NCCAOM) found that 82% of acupuncturists report the use of lifting and thrusting of tender ashi points daily in their clinical practice, making this a common treatment that has been long established in the acupuncture field.

For these reasons, MAS maintains that there is no substantive difference between dry-needling and the acupuncture procedure known as "lifting and thrusting". As such, our Society feels it has a vested interest in offering our expertise on this procedure through comments on these proposed regulations. We have great concern regarding the lack of any standards of competency required by these proposed regulations, and should the Physical Therapy Board decide to continue forward with this administrative change to include the invasive procedure of needling within the scope of practice for its licensees, we hope that they will give careful consideration to our comments below.

1) MAS finds the naming of this procedure "Intramuscular Manual Therapy" to be inaccurate, misleading, and a possible source of confusion to the general public, leading potential patients to believe that this procedure is commonly learned and practiced by physical therapists in their formal schooling.

The procedural (CPT) code 91740 – Manual Therapy was created in 1999 by the American Medical Association (AMA) to consolidate several separate CPT codes. The AMA owns the exclusive right to create and define procedural codes, and all other health providers are required to use these codes in billing for the medical procedures they are authorized to perform.

In the July 1999 issue of *CPT Assistant*, the AMA stated: "Manual therapy techniques consist of, but are not limited to, connective tissue massage, joint mobilization and manipulation, manual lymphatic drainage, manual traction, passive range of motion, soft tissue mobilization and manipulation, and therapeutic massage. As the code descriptor states, 'manual,' providers use their hands to administer these techniques. Therefore, code 97140 describes 'hands-on' therapy techniques.[iv]" In other words, the treatment outcomes are achieved solely by the use of the hands directly on the patient's body.

Constant attendance (one-on-one) procedures that introduce a device for the practitioner to use in order to diagnose or achieve therapeutic benefit are properly billed under their own distinct procedural codes, not under manual therapy. For example: 97032 – electrical stimulation (manual); 97035 – ultrasound; 95860 – Needle electromyography; 97810 – acupuncture, 1st set.

Therefore, to describe the insertion of a needle to achieve pain relief as a "manual therapy" is inaccurate and misleading. The U.S. Attorney's Office agrees. While recently investigating a physician who was found to have inappropriately billed Medicare for a procedure he described and documented as "dry-needling", U.S. Attorney Kevin Doyle stated: "The only code for Medicare that would cover something like dry-needling would be an acupuncture code[v]."

Naming this procedure Intramuscular Manual Therapy and calling it a "physical therapy intervention" may lead consumers to mistakenly believe this is a common and standard procedure learned by a physical therapist in his formal schooling. In contrast, accredited physical therapy programs do not include training in medical devices that penetrate into live body tissue. Physical therapy interventions involving the use of mechanical devices that are included in a physical therapist's formalized schooling include only those devices that are used externally and do not break the skin barrier into live muscular and intramuscular tissue.

Aside from acupuncture, the needle electromyography (EMG) procedure referenced above may be the most similar to dry-needling, as it requires placement of thin, solid needles deep into the intramuscular layer of the body in order to diagnose and follow diseases of the peripheral nervous system and muscle. EMG is not a procedure taught in the standard curriculum of physical therapy schooling and is also not considered a "physical therapy intervention".

In their *Model Policy for Needle Electromyography and Nerve Conduction Studies*, the American Association of Neuromuscular and Electrodiagnostic Medicine (AANEM) advises that: "The needle EMG examination must be performed by a physician specially trained in electrodiagnostic medicine. … Non-physician providers, including physical therapists, chiropractors, physician assistants, and others, do not have the appropriate training and knowledge to perform and interpret EMG studies[vi]".

2) These regulations as proposed lack even the basic standards of assuring coursework is completed through a program that has shown competency in both its curriculum and in the instructors hired to train the physical therapists in this procedure.

In the August 17, 2010 opinion regarding creation of dry-needling regulations, the Attorney General of Maryland stated: "Given that the Legislature has placed specific limitations on a physician's use of acupuncture needles in the Medical Practice Act, any rulemaking process adopted by the Physical Therapy Board would presumably need to consider standards and restrictions at least as stringent as those imposed on physicians … who use acupuncture needles for similar therapeutic purposes.[vii]"

It is interesting to note that while these regulations are in no manner equivalent to the standards required of physicians, they do match up almost exactly to the limited curriculum of the most extensive dry-needling course offered to physical therapists in the country. This course is offered by Myopain Seminars in Bethesda, Maryland. Myopain Seminars is owned and directed by Jan Dommerholt, the physical therapist who chaired the task force established by your Board to develop these proposed regulations.

Clearly a financial conflict of interest exists, as Mr. Dommerholt's seminar series would stand to receive a great number of enrollees should these regulations be enacted into law in their current form. MAS has great concern that public safety may have been disregarded in the drafting of these regulations so that the educational and training requirements imposed upon physical therapists would not exceed that which is already available to them through the Myopain seminar.

The proposed regulations fall far short in comparison to the stringent standards to which physicians are held in several areas:

A) **Lack of accreditation**: The Maryland Board of Physicians requires that physicians seeking to use acupuncture needles in order to "prevent or modify the perception of pain or to normalize physiological functions[viii]" must complete their coursework in an "institution accredited or recognized by the ACCME to conduct such courses[ix]." The organization approved to accredit such programs requires the physician to pass an examination demonstrating mastery of needling techniques to assure competency and safety.

In contrast, these regulations give no specification as to where such coursework must be completed other than to state that they may not be completed online. Under these regulations, any person of the general public could establish a live, in-person "course" on dry-needling and offer to "instruct" the physical therapist. After completing said make-shift course, a physical therapist would not have to pass any such exam demonstrating competency as the physician would. MAS recommends that these regulations require all coursework to be from a recognized, accredited institution and that upon completion of all required training, a physical therapist be required to demonstrate competency through examination prior to performing dry-needling on any member of the general public.

B) **Minimal Hours of Coursework**: Though physicians seeking certification in acupuncture needling are only required by the Medical Board to complete 200 hours of coursework, the organization authorized to accredit programs of study requires that these programs contain a minimum of 300 hours of education and an additional two years of clinical experience prior to the physician receiving certification, all of which must be completed *subsequent* to the physician's graduation from medical school[x].

In contrast, these proposed regulations give no such specification as to when the required 200 hours must be completed, nor is any continuing education required to assure needling skills are maintained. Much of the required coursework included in these regulations is included in a physical therapist's formal schooling. Therefore, a physical therapist could claim completion of the majority of the requirements *prior to* graduation from physical therapy school.

In the AANEM's position statement "Who is Qualified to Perform Electrodiagnostic Medicine?", it is noted that the American Board of Physical Therapy Specialties has developed an examination for select physical therapists that perform electrophysiology studies to take after completing <u>2000 hours</u> of direct patient care in which a minimum of 500 EMG examinations are conducted under supervision. However, even with the availability of a 2000 hour training course for physical therapists, the AANEM still maintains that: "… only physicians should conduct any part of the examination which requires needle insertion[xi]." It is stressed by the AANEM that placement of needles in the intramuscular level of the body requires an extensive knowledge of deep anatomic structures, and "additional risk factors that require testing by a physician knowledgeable in the recognition and management of those problems" such as major vessels near the abdomen or lung, the use of anticoagulants, recent history of cardiac surgery for valve replacement or pacemakers, bleeding disorders, and indwelling central venous or arterial lines.

According to a 2006 case study regarding a pneumothorax that occurred as a result of dry-needling, while acupuncture is generally considered a safe procedure with low risk of serious complications, such risks are directly related to the amount of training the practitioner has undergone and decrease with increased hours of required training[xii]. In this study, a physician whom had completed 350 hours of training specific to acupuncture procedures caused the pneumothorax while using the dry-needling technique on trigger points for pain in the rhomboid muscle of the shoulder. It was noted that the trigger points used in this case were <u>not</u> considered to be high-risk for pneumothorax, demonstrating that serious adverse effects from dry-needling can occur even when treatment is administered to seemingly safe areas of the body.

A review of liability claims filed with Guild Insurance Limited, an Australian based company that provides malpractice insurance for physical therapists (referred to as physiotherapy), showed that the rate of pneumothorax reports in a twelve month period of time had increased in conjunction with an increase in the number of physical therapists performing dry-needling during the same period. The Guild wrote: "While there is little doubt acupuncture has significant benefits, the importance of adequate training, knowledge, and experience are critical to the successful defence [sic] of a liability action. … [When investigating a claim] the Registration Board will also look at the extent of training a practitioner has on acupuncture, his or her professional competencies in the context of that training, as well as the extent of continuing education that has been undertaken.[xiii]"

To minimally meet the requirements set forth for physicians, these regulations would need to include 200 hours of coursework *subsequent* to graduation from a formal physical therapy program.

As previously noted, unlike a physician who graduates from medical school with countless hours of training in invasive procedures such as needling, physical therapy schooling includes no such coursework. The "mechanical devices" taught in physical therapy schooling are used either on the surface, and do not penetrate the skin barrier, or are used to remove dead tissue from the surface of the skin.

It is the position of MAS that physical therapists are not equivalent to physicians, and therefore should be held to a considerably greater number of hours of training than those required for physicians before being permitted to perform this procedure.

C) **No standard of competency for dry-needling instructors**: Due to the lack of requirement that coursework be completed in an accredited program, there also is no standard of competency created for the supervising instructor other than it must be a "physical therapist competent in intramuscular manual therapy procedures who has completed the requisite coursework." MAS is unaware of any program in the country taught solely by physical therapists that meets this requirement. Therefore, it is unlikely that any instructor offering to supervise has himself completed the full course of required training to be able to practice, much less teach, this procedure.

For example, MAS is aware of two companies that offer dry-needling classes in Maryland. The first, a Colorado based company known as Kinetacore (also known as Global Education of Manual Therapists) offers to "certify" the physical therapist in dry-needling after only two 27.5 hour courses. Most of the Kinetacore instructors teaching these two short courses have no credentials establishing competency in dry-needling other than their own completion of the 55 hours of coursework, and subsequent clinical implementation of the procedure.

Similarly, the previously mentioned Myopain Seminars (also known as the Travell Series) in Bethesda, Maryland, offers certification in dry-needling after the practitioner has completed five courses for a total of only 137.5 hours of instruction. Furthermore, though several of the Travell Series instructors are physicians, including the medical director, these physicians do not hold an additional license in physical therapy. Therefore, because these proposed regulations

specifically state that training be completed under the supervision of a "physical therapist", all physicians would be ineligible to supervise the required training portion.

Because no 200 hour dry-needling program currently exists in the country, physical therapists whom wish to instruct others can only satisfy the vague competency requirements by claiming the majority of their coursework was completed prior to graduation from a formal physical therapy program. As noted above, this allows physical therapists to instruct dry-needling after completing significantly less post-graduate coursework than is required of a physician performing or teaching the same procedure.

3) Most disturbing to MAS is the fact that these regulations are passive, and therefore the Physical Therapy Board will have no means of monitoring its licensees to determine who is performing this procedure and whether they have adequately completed the required coursework. Rather than requiring the physical therapist to register with the Board or apply for a Board designated certification in dry-needling, as is required by the Board of Medicine of its physicians and the Board of Acupuncture of its animal acupuncturists, these regulations require the licensee to show proof of the required coursework *only upon request* by the Physical Therapy Board. MAS wonders how the Physical Therapy Board will have any way to know when to make such a request of its licensees, if under these regulations it has no way to know that a physical therapist has decided to use dry-needle procedures in his clinical practice.

MAS thanks you for your time and consideration of the serious issues we have commented upon in regards to these proposed regulations. As you can see, the passage of these regulations into administrative law without considerable revisions would constitute a significant safety risk to the health care consumers of Maryland.

Both the National Chiropractic Council (NCC) and the Allied Professionals Insurance Company (APIC), two nationwide risk retention groups that offer malpractice insurance to physical therapists, agree stating that due to the lack of uniform and competent training available, physical therapists who utilize the dry-needling procedure will have their malpractice insurance policies cancelled.

APIC states: "To justify that dry needling is within the scope of physical therapy is not only overreaching but almost irresponsible and dangerous … The dry needling courses currently being offered, including the Travell Series [Myopain Seminars] and the course offered by the Global Education of Manual Therapists [Kinetacore], not only allow physical therapists to use needles on patients without sufficient training, but constitue a public health hazard.[xiv]"

As licensed acupuncturists are already extensively and competently trained and duly licensed to employ the use of this procedure in their daily treatment of patients, MAS holds that there is little to no public need established to justify allowing physical therapists to conduct this invasive procedure with such minimal requirements for competent education, training, and regulatory monitoring as these regulations would allow. For these reason, we strongly suggest that these regulations be withdrawn for consideration until such time as they can be amended to more than meet the minimum standards as recommended by the Attorney General.

Sincerely,

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President, Maryland Acupuncture Society

Cc: Maryland Board of Acupuncture
Maryland Board of Physicians
MedCHI
Maryland Chapter of the American Academy of Medical Acupuncture

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