

## 2<sup>nd</sup> AGENDA

### PHYSICAL THERAPY LICENSING BOARD

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**December 17, 2013 – 9:00 a.m.**

**Room 402 – 4th Floor**

Heber M. Wells Building

160 E. 300 S. Salt Lake City, Utah

*This agenda is subject to change up to 24 hours prior to the meeting.*

#### **ADMINISTRATIVE BUSINESS:**

1. Sign Per Diem
2. Call Meeting to Order
3. Review and approve August 27, 2013 minutes
4. Susan Higgs, Compliance report

#### **APPOINTMENTS:**

**Please note: The compliance report and probation interviews may result in a closed meeting in accordance with §52-4-205(1)(a) to discuss the character, professional competence, or physical or mental health of an individual.**

**9:30 a.m.** - Randall Palmer, New Order

**10:00 a.m.** - Craig Bischoff, probation interview

**10:20 a.m.** - Steven Orrock, probation interview

**10:45 a.m.** - Kelly Alvord, discussion regarding suture/staple removal under a physician order.

#### **BOARD BUSINESS/DISCUSSION ITEMS:**

1. Discussion regarding Dry Needling
2. Kim Cohee report on the FSBPT Annual meeting
3. Rule and FSBPT changes
4. Discussion regarding PT and PTA temporary license
5. Environmental Scan
  - Discussion regarding FSBPT new Board member training, will the Division approve and whether Board members would be interested in attending

#### **Next Scheduled Meeting: March 18, 2014**

Meeting scheduled for the next quarter: June 17, 2014; September 16, 2014 and December 16, 2014

**Note:** In compliance with the Americans with Disabilities Act, individuals needing special accommodations (including auxiliary communicative aids and services) during this meeting should notify, Dave Taylor, ADA Coordinator, at least three working days prior to the meeting. Division of Occupational & Professional Licensing, 160 East 300 South, Salt Lake City, Utah 84115, 801-530-6628 or toll-free in Utah only 866-275-3675

# REVISED CHECKLIST FOR PUBLIC MEETINGS

(Fill in the blanks to correspond to each respective board, commission, or committee.)

✓ I am, J. Trent Casper, chairperson of the Physical Therapy Licensing Board.

✓ I would like to call this meeting of the Physical Therapy Licensing Board to order.

✓ It is now (time) \_\_\_\_\_ : \_\_\_\_\_ am on December 17, 2013.

✓ This meeting is being held in room 402 of Heber Wells Building  
in Salt Lake City UT.

✓ Notice of this meeting was provided as required under Utah's Open Meeting laws.

✓ In compliance with Utah's Open Meetings laws, this meeting is being recorded in its entirety. The recording will be posted to the Utah Public Notice Website no later than three business days following the meeting.

✓ In compliance with Utah's Open Meeting laws, written minutes will also be prepared of this meeting. Appropriately marked "*pending approval*" minutes will be available to the public no later than 30 days after the close of the meeting. "*Approved*" minutes will be posted to the Utah Public Notice Website no later than three business days after approval.

✓ The following Board members are in attendance:

	YES	NO
<u>J. Trent Casper</u> , Chairperson	<input type="checkbox"/>	<input type="checkbox"/>
<u>Anne H. Jones</u>	<input type="checkbox"/>	<input type="checkbox"/>
<u>Lindsi Gordon</u>	<input type="checkbox"/>	Excused
<u>Kim Cohee</u>	<input type="checkbox"/>	<input type="checkbox"/>
<u>Kim W. Reid</u>	<input type="checkbox"/>	<input type="checkbox"/>

✓ The following Board members are absent: (Refer to the above list.)

✓ The following individuals representing DOPL and the Department of Commerce are in attendance:

	YES	NO
<u>Mark B. Steinagel</u> , Division Director	<input type="checkbox"/>	<input type="checkbox"/>
<u>Debra Hobbins</u> , Bureau Manager	<input type="checkbox"/>	<input type="checkbox"/>
<u>Shirlene Kimball</u> , Board Secretary	<input type="checkbox"/>	<input type="checkbox"/>
<u>Susan Higgs</u> , Compliance	<input type="checkbox"/>	<input type="checkbox"/>
_____	<input type="checkbox"/>	<input type="checkbox"/>
_____	<input type="checkbox"/>	<input type="checkbox"/>

✓ We welcome any visitors and interested persons at this time. Please be sure to sign the attendance report for the meeting and identify yourself before speaking.

✓ As a courtesy to everyone participating in this meeting, at this time we ask for all cell phones, pagers, and other electronic devices to be turned off or changed to silent mode.

✓ Board motions and votes will be recorded in the minutes.

✓ Let us now proceed with the agenda.

✓ (End of the Meeting) It is now (time) 11:45 (am / pm), and this meeting is adjourned.



**This is the process we will be following to allow PT applicants who have failed the test to sit for the PTA exam:**

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1. After failing the NPTE-PT, the applicant's application for licensure as a Physical Therapist will be denied and the temporary PT license will expire after two failures or after 6 months.
2. The individual will complete the PTA application, submit the fees, but will not need to send in transcripts again.
3. The Division will make the individual eligible to take the NPTE-PTA exam. The applicant will not be issued a temporary license (>3 months since graduation).
4. The applicant will then take and pass the NPTE-PTA and become licensed as a PTA.
5. The PTA will reapply for licensure as a PT when the appropriate time period has passed.
6. The Division will make the individual eligible to take the NPTE-PT exam.
7. The applicant will take and pass the NPTE-PT and become license as a PT.

**R156-24b-305. Temporary Licensure.**

(1) In accordance with Subsection 58-1-303(1), the Division may issue a temporary physical therapist or temporary physical therapist assistant license to a person who meets all qualifications for licensure as a physical therapist or physical therapist assistant except for the passing of the required examination, if the applicant:

(a) submits a complete application for licensure as a physical therapist or physical therapist assistant except the passing of the NPTE examination;

**(b) is a graduate of a CAPTE accredited physical therapy school within three months immediately preceding application for licensure;**

(c) submits evidence of having secured employment conditioned upon issuance of the temporary license, and the employment is under the direct, on-site supervision of a physical therapist with an active, non-temporary license; and

(d) has registered to take the required licensure examination.

(2) A temporary physical therapist or temporary physical therapist assistant license issued under Subsection

(1) expires the earlier of:

(a) six months from the date of issuance;

(b) the date upon which the Division receives notice from the examination agency that the individual has failed the examination twice; or

(c) the date upon which the Division issues the individual full licensure.

(3) A temporary physical therapist or temporary physical therapist assistant license issued in accordance with this section cannot be renewed or extended.




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## Fwd: Of cours, issues...!! PLEASE ANSWER ASAP--employer calling me back.

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Debra Hobbins <dhobbins@utah.gov>  
 To: Shirlene Kimball <skimball@utah.gov>

Wed, Sep 4, 2013 at 7:44 AM

Could you please add PTA temp license to the next PT agenda. Also please add Rule. Thank you.

----- Forwarded message -----

From: **Trent Casper** <jtcasper1@gmail.com>

Date: Tue, Sep 3, 2013 at 5:59 PM

Subject: Re: Of cours, issues...!! PLEASE ANSWER ASAP--employer calling me back.

To: Debra Hobbins <dhobbins@utah.gov>

I agree. I don't think they should have the leeway toward both license applications. I think in this case the 3 month issue would address the current issue but we might want to discuss this further and get a quorum of input next meeting.

Thanks, Trent

On Sep 3, 2013 9:20 AM, "Debra Hobbins" <dhobbins@utah.gov> wrote:

I am sorry you can't read my mind!!

The issue is:

1. Applied for license as PT.
2. Received **temp PT** license till they pass the test.
3. Failed the test, **lost temp PT license**.
4. Took test again, failed. Some up to 9 times!!
5. We said they could apply for PTA license.
6. **Applied for PTA license**.
7. We don't issues temp PTA license because they graduated from the program much longer than 3 months prior to application, many 9-12 months.

My question is, are you in agreement with "no temporary PTA license because the person has graduated from a program > 3 months prior to application for PTA license" or do you think that we should change the Rule?

I think they already had a temporary PT license that they lost when they failed the exam. We are giving them the gift of allowing them to become licensed as PTA and they don't meet the requirements for a temp PTA license.

On Tue, Sep 3, 2013 at 9:09 AM, Trent Casper <jtcasper1@gmail.com> wrote:

Deb, You get to do all the heavy lifting on these issues. I'll give my perspective; please clarify any misunderstandings I have.

To clarify, they are beyond the 3 months since graduation from PT school and I'm assuming took the PT NPTE and didn't pass. Did they apply for the PTA temporary at an earlier time within the 3 months of graduation. I guess I'm not sure how they would have received the PTA temp license if they were beyond the 3 months as I presumed the application process would catch that. So that said if they have qualified for the PTA temp license is there a way to revoke that? Is that what you are proposing. If not I don't see how we can keep them from using a license the department granted until it is revoked according to the rule you listed above, i.e. failing the test twice, passing the test, or 6 months passes.

Thanks, Trent

On Tue, Sep 3, 2013 at 8:39 AM, Debra Hobbins <dhobbins@utah.gov> wrote:

We discussed changing the rule to allow those who fail the PT exam to become PTA. Now we have people who have failed the PT exam who want take the PTA exam AND HAVE A TEMP PTA license. I say that they can't do that, that they are lucky the Board is allowing them to take the PTA test. I feel like they are pushing the limits. In addition, the Rules states:

**R156-24b-305. Temporary Licensure.**

(1) In accordance with Subsection 58-1-303(1), the Division may issue a temporary physical therapist or temporary physical therapist assistant license to a person who meets all qualifications for licensure as a physical therapist or physical therapist assistant except for the passing of the required examination, if the applicant:

(a) submits a complete application for licensure as a physical therapist or physical therapist assistant except the passing of the NPTE examination;

**(b) is a graduate of a CAPTE accredited physical therapy school within three months immediately preceding application for licensure;**

(c) submits evidence of having secured employment conditioned upon issuance of the temporary license, and the employment is under the direct, on-site supervision of a physical therapist with an active, non-temporary license; and

(d) has registered to take the required licensure examination.

(2) A temporary physical therapist or temporary physical therapist assistant license issued under Subsection (1) expires the earlier of:

(a) six months from the date of issuance;

(b) the date upon which the Division receives notice from the examination agency that the individual has failed the examination twice; or

(c) the date upon which the Division issues the individual full licensure.

(3) A temporary physical therapist or temporary physical therapist assistant license issued in accordance with this section cannot be renewed or extended.

All of these folks are way beyond the three months. What is your opinion? Should we change the Rule? I think all of them have had temporary PT licenses.

I must say the person that brought this all about has an employer who thinks that PT grads should not be able to become PTAs. I told my staff to invite him to the next meeting. We can do Rule then when FSBPT has made the testing limits official.

Thanks for everything.

Warmest regards,  
Deb

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Debra F. Hobbins, DNP, APRN, LASUDC  
Bureau Manager--Boards of Nursing, Midwifery, PT, OT, and Vocational Rehab  
PHONE: (801) 530-6789  
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to a CAPTE accredited degree by submitting to the Division a credential evaluation from the Foreign Credentialing Commission on Physical Therapy. ~~Only educational deficiencies in pre-professional subject areas may be corrected by completing college level credits in the deficient areas or by passing the College Level Examination Program (CLEP) demonstrating proficiency in the deficient areas.~~ Pre-professional subject areas include the following:

- (a) humanities;
- (b) social sciences;
- (c) liberal arts;
- (d) physical sciences;
- (e) biological sciences;
- (f) behavioral sciences;
- (g) mathematics; or
- (h) advanced first aid for health care workers.

**R156-24b-302b. Qualifications for Licensure - Examination Requirements.**

(1) In accordance with Subsections 58-24b-302(1)(e), (2)(e) and (3)(e), each applicant for licensure as a physical therapist or physical therapist assistant shall pass the FSBPT's National Physical Therapy Examination with a passing score as established by the FSBPT.

(2) In accordance with Section 58-1-309 and Subsections 58-24b-302(1)(d), (2)(d) and (3)(d), each applicant for licensure as a physical therapist or physical therapist assistant, including endorsement applicants, shall pass all questions on the open book, take home Utah Physical Therapy Law and Rule Examination.

(3) An applicant for licensure as a physical therapist or a physical therapist assistant must have completed the education requirements set forth in Section R156-24b-302, or be enrolled in the final semester of a CAPTE accredited program, in order to be eligible to sit for the examination required for Utah licensure as set forth in Subsection(1) above.

**R156-24b-303a. Renewal Cycle - Procedures.**

(1) In accordance with Subsection 58-1-308(1), the renewal date for the two-year renewal cycle applicable to licensees under Title 58, Chapter 24b is established by rule in Section R156-1-308a.

(2) Renewal procedures shall be in accordance with Section R156-1-308c.

**R156-24b-303b. Continuing Education.**

(1) Required Hours. In accordance with Subsection 58-24b-303(2), during each two year renewal cycle commencing on June 1 of each odd numbered year:

(a) A physical therapist shall be required to complete not fewer than 40 contact hours of continuing education of which a minimum of three contact hours must be completed in ethics/law.

(b) A physical therapist assistant shall be required to complete not fewer than 20 contact hours of continuing education of which a minimum of three contact hours must be completed in ethics/law.

(c) Examples of subjects to be covered in an ethics/law course for physical therapists and physical therapist assistants include one or more of the following:

- (i) patient/physical therapist relationships;
- (ii) confidentiality;
- (iii) documentation;
- (iv) charging and coding;
- (v) compliance with state and/or federal laws that impact the practice of physical therapy; and
- (vi) any subject addressed in the American Physical Therapy Association Code of Ethics or Guide for Professional Conduct.

(d) The required number of contact hours of continuing education for an individual who first becomes licensed during the two year renewal cycle shall be decreased in a pro-rata amount.

(e) The Division may defer or waive the continuing education requirements as provided in Section R156-1-308d.

(2) A continuing education course shall meet the following standards:

(a) Time. Each contact hour of continuing education course credit shall consist of not fewer than 50 minutes of education.

Licensees shall only receive credit for lecturing or instructing the same course up to two times. Licensees shall receive one contact hour of continuing education for every two hours of time spent:

- (i) lecturing or instructing a course;
- (ii) in a post-professional doctorate or transitional doctorate program; or
- (iii) in a post-professional clinical residency or fellowship approved by the American Physical Therapy Association.

(b) Course Content and Type. The course shall be presented in a competent, well organized, and sequential manner consistent with the stated purpose and objective of the course.

(i) The content of the course shall be relevant to the practice of physical therapy and shall be completed in the form of any of the following course types:

- (A) department in-service;

## **Proposed Eligibility Requirements**

(not in effect for at least one year)

**Lifetime limit** – Candidates will be able to take the exam a maximum of 6 times. An individual can take the NPTE for PTs 6 times and also take the NPTE for PTAs 6 times if he or she is otherwise qualified to do so. Candidates will still be allowed up to 3 attempts per year but now will have a 6 time total limit

**Low score limit** – Candidates who receive two very low scores on the exam, currently defined as performing at or close to chance level (scale scores 400 and below), will not be allowed to test again.

Candidates receiving one very low score on the exam will be notified that their performance is so far away from the minimal competence level that they will need to engage in serious remediation, like enrolling in another PT educational program, before attempting the NPTE again and that another score that is very low (400 or below) will result in a lifetime ban.

**English Language Proficiency** – Most foreign-educated physical therapists/assistants will need to pass the TOEFL and meet FSBPT's current score requirements. There will be some exemptions based on country of education. TOEFL scores will be reported directly to FSBPT for purposes of determining eligibility for the NPTE. Candidates will be notified that states may have different requirements for licensure and submitting their scores to the FSBPT does not mean that they have met licensure requirements.

**Substantial Equivalence** – Graduates from non-CAPTE accredited institutions will need to demonstrate their education is equivalent to a CAPTE accredited education by having an authorized agency complete an evaluation using the FSBPT's Coursework Tool (CWT).



**Physical Therapy Law and Rule  
December 2013**

**58-24b-302. Licensure.**

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**(1) An applicant for a license as a physical therapist shall:**

- (a) be of good moral character;**
- (b) complete the application process, including the payment of fees;**
- (c) submit proof of graduation from a professional physical therapist education program that is accredited by a recognized accreditation agency;**
- (d) pass an open-book, take-home Utah Physical Therapy Law and Rule Examination;**
- (e) after complying with Subsection (1)(c), pass a licensing examination;**
- (f) be able to read, write, speak, understand, and be understood in the English language and demonstrate proficiency to the satisfaction of the board if requested by the board; and**
- (g) meet any other requirements established by the division, by rule.**

(2) An applicant for a license as a physical therapist assistant shall:

- (a) be of good moral character;
- (b) complete the application process, including the payment of fees set by the division, in accordance with Section 63J-1-504, to recover the costs of administering the licensing requirements relating to physical therapist assistants;
- (c) submit proof of graduation from a physical therapist assistant education program that is accredited by a recognized accreditation agency;
- (d) pass an open-book, take-home Utah Physical Therapy Law and Rule Examination;
- (e) after complying with Subsection (2)(c), pass a licensing examination;
- (f) be able to read, write, speak, understand, and be understood in the English language and demonstrate proficiency to the satisfaction of the board if requested by the board; and
- (g) meet any other requirements established by the division, by rule.

(3) An applicant for a license as a physical therapist who is educated outside of the United States shall:

- (a) be of good moral character;
- (b) complete the application process, including the payment of fees; and
- (c) (i) provide satisfactory evidence that the applicant graduated from a professional physical therapist education program that is accredited by a recognized accreditation agency; or  
(ii) (A) provide satisfactory evidence that the applicant graduated from a physical therapist education program that prepares the applicant to engage in the practice of physical therapy, without restriction;  
(B) provide satisfactory evidence that the education program described in Subsection (3)(c)(ii)(A) is recognized by the government entity responsible for recognizing a physical therapist education program in the country where the program is located; and  
(C) pass a credential evaluation to ensure that the applicant has satisfied uniform educational requirements;
- (d) pass an open-book, take-home Utah Physical Therapy Law and Rule Examination;
- (e) after complying with Subsection (3)(c), pass a licensing examination;
- (f) be able to read, write, speak, understand, and be understood in the English language and demonstrate proficiency to the satisfaction of the board if requested by the board; and
- (g) meet any other requirements established by the division, by rule.

(4) The division shall issue a license to a person who holds a current unrestricted license to practice physical therapy in a state, district, or territory of the United States of America, other than Utah, if the person:

- (a) is of good moral character;

- (b) completes the application process, including payment of fees;
  - (c) passes an open-book, take-home Utah Physical Therapy Law and Rule Examination; and
  - (d) is able to read, write, speak, understand, and be understood in the English language and demonstrate proficiency to the satisfaction of the board if requested by the board.
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(5) (a) Notwithstanding Subsection 58-1-307(1)(c), an individual may not engage in an internship in physical therapy, unless the person is:

- (i) certified by the division; or
- (ii) exempt from licensure under Section 58-24b-304.

(b) The provisions of Subsection (5)(a) apply, regardless of whether the individual is participating in the supervised clinical training program for the purpose of becoming a physical therapist or a physical therapist assistant.

#### **58-24b-303. Term of license - Renewal - Temporary license for physical therapist assistant.**

(1) A license issued under this chapter shall be issued in accordance with a two-year renewal cycle established by rule. The division may, by rule, extend or shorten a license renewal process by one year in order to stagger the renewal cycles that the division administers.

(2) At the time of license renewal, the licensee shall provide satisfactory evidence that the licensee completed continuing education competency requirements, established by the division, by rule.

(3) If a license renewal cycle is shortened or extended under Subsection (1), the division shall increase or reduce the required continuing education competency requirements accordingly.

(4) A license issued under this chapter expires on the expiration date indicated on the license, unless the license is renewed under this section.

(5) Notwithstanding any other provision of this chapter, the division may, by rule, grant a temporary license, that expires on July 1, 2014, as a physical therapist assistant to an individual who:

- (a) was working as a physical therapist assistant in Utah before July 1, 2009; and
- (b) complies with the requirements described in Subsections 58-24b-302(2)(a), (b), (c), (f), and (g).

#### **R156-24b-305. Temporary Licensure.**

(1) **In accordance with Subsection 58-1-303(1), the Division may issue a temporary physical therapist or temporary physical therapist assistant license to a person who meets all qualifications for licensure as a physical therapist or physical therapist assistant except for the passing of the required examination, if the applicant:**

**(a) submits a complete application for licensure as a physical therapist or physical therapist assistant except the passing of the NPTE examination;**

**(b) is a graduate of a CAPTE accredited physical therapy school within three months immediately preceding application for licensure;**

**(c) submits evidence of having secured employment conditioned upon issuance of the temporary license, and the employment is under the direct, on-site supervision of a physical therapist with an active, non-temporary license; and**

**(d) has registered to take the required licensure examination.**

(2) A temporary physical therapist or temporary physical therapist assistant license issued under Subsection (1) expires the earlier of:

- (a) six months from the date of issuance;
- (b) the date upon which the Division receives notice from the examination agency that the individual has failed the examination twice; or
- (c) the date upon which the Division issues the individual full licensure.

(3) A temporary physical therapist or temporary physical therapist assistant license issued in accordance with this section cannot be renewed or extended.



Physical Therapy Board of California

BUSINESS, CONSUMER SERVICES, AND HOUSING AGENCY - GOVERNOR EDMUND G. BROWN JR.

## Physical Therapy Board of California

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Phone: (916) 561-8200 Fax: (916) 263-2560

Internet: [www.ptbc.ca.gov](http://www.ptbc.ca.gov)



## STAPLE & SUTURE REMOVAL

*Is staple removal within the scope of practice of a physical therapist?*

The subject of staple removal was considered by the Practice Issues Committee of the Physical Therapy Board of California (Board) at their meeting of August 1995. The Practice Issues Committee opined that physical therapists may not perform invasive procedures; specifically in this instance, that of stapling a wound closed.

The removal of staples, on the other hand, is a non-invasive procedure, which would ordinarily come under the heading of nursing services, and is not normally associated with the practice of physical therapy; however, physical therapists may provide any non-invasive physical rehabilitation procedure they have been adequately trained to perform. Should a facility elect to train physical therapists to do staple removal, the facility would need a written protocol to be included in their policies and procedures manual, and to be used in the training of each physical therapist who will perform this procedure.

The training protocol must be sufficient to ensure the facility's patients that the procedure is being done in a safe and efficient manner by personnel who are trained specifically to remove staples. The training should also include procedures for problem situations resulting from staple removal, and for notification of proper medical personnel.

The Board has received multiple inquiries as to whether suture removal would be considered a non-invasive procedure such as staple removal. After consulting with a physical therapist expert consultant, it has been determined that the removal of sutures would fall under the same category as the removal of staples as indicated above.

Note: This document is not a declaratory opinion of the Physical Therapy Board of California.



State of Utah  
Department of Commerce  
Division of Occupational and Professional Licensing

GARY R. HERBERT  
Governor

FRANCINE A. GIANI  
Executive Director

MARK B. STEINAGEL  
Division Director

October 22, 2013

Curtis B. Jolley, PT, MOMT  
UPTA President  
Performance West Physical Therapy  
1551 Renaissance Towne Drive, Suite 350  
Bountiful, Utah 84010

Dear Mr. Jolley:

This letter is written in response to your question about whether a physical therapist in Utah may practice intramuscular manual therapy, or trigger point dry needling. After meeting with Mr. Mark Steinagel, Director, Division of Occupational and Professional Licensing and Mr. Ron Kunzler, Assistant Attorney General, and reviewing the supplemental material you kindly provided, including "Description of Dry Needling in Clinical Practice: An Educational Resource Paper" dated February 2013 and the "FSBPT Dry Needling Resource Paper (Intramuscular Manual Therapy)" 4<sup>th</sup> edition, July 2013, the Division has reached a position. The position of the Division is that the performance of trigger point dry needling seems to be outside of the scope of practice of a physical therapist in the State of Utah. In fact, we feel that the statute is unclear and requires a statutory change to allow a physical therapist to perform dry needling, especially considering the relatively recent addition of "modern research" to the Acupuncture Practice Act, provided in pertinent part below:

**58-72-102. Definitions.**

(4) (a) "Practice of acupuncture" means the insertion of acupuncture needles and application of moxibustion to specific areas of the body based on traditional oriental medical diagnosis and **modern research** as a primary mode of therapy.

(b) Adjunctive therapies within the scope of practice of acupuncture may include:

(i) manual, mechanical, thermal, electrical, light, and electromagnetic treatments based on traditional oriental medical diagnosis and **modern research**;

(ii) the recommendation, administration, or provision of dietary guidelines, herbs, supplements, homeopathics, and therapeutic exercise based on traditional oriental medical diagnosis and **modern research** according to practitioner training;

Trigger point dry needling is a therapeutic intervention used to treat and alleviate myofascial pain that uses a dry needle, without medication, that is inserted into a trigger point with the goal of releasing/inactivating the trigger points and relieving pain. It is used to improve

pain control, reduce muscle tension, normalize biochemical and electrical dysfunction of motor endplates, and to facilitate an accelerated return to active rehabilitation. The needles used for dry needling are the same needles used to perform acupuncture.

The scope of practice for physical therapists in Utah is established in the Physical Therapist Practice Act, Utah Code 58-24b-102 (11). It reads in relevant part as follows:

- (11)(a) "Physical therapy" or "physiotherapy" means:
- (iii) formulating a therapeutic intervention plan for the treatment of a physical impairment, injury, or pain;
  - (iv) assessing the ongoing effects of therapeutic intervention for the treatment of a physical impairment or injury;
  - (v) treating or alleviating a physical impairment by designing, modifying, or implementing a therapeutic intervention;
- (b) "Physical therapy" or "physiotherapy" does not include:
- (i) diagnosing disease;
  - (ii) performing surgery;
  - (iii) performing acupuncture;
  - (iv) taking x-rays; or
  - (v) prescribing or dispensing a drug, as defined in Section 58-37-2.

The term "therapeutic intervention" is defined as follows:

- (14) "Therapeutic intervention" includes:
- (d) manual therapy, including:
    - (i) soft tissue mobilization;
    - (j) mechanical or electrotherapeutic modalities;

Utah Code 58-24b-102 (11)(b) prohibits physical therapists from performing acupuncture. The Division's research regarding the practice of trigger point dry needling confirms that it is the practice of acupuncture. Therefore, the Division finds that it is outside the scope of practice of physical therapists in Utah. Our decision is purely statutory in nature. Our intent is not to restrict the practice of physical therapists, nor is there any question about whether or not a physical therapist could be competent to perform this treatment modality. As defined in statute, it is simply prohibited.

Because trigger point dry needling is a therapeutic intervention that includes the use of manual therapy involving soft tissue mobilization and a mechanical modality, several states have found dry needling to be within the physical therapy scope of practice; however, current Utah law does not allow it to be within the scope of practice of physical therapists in Utah.

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This letter is intended as informal guidance only and does not constitute a declaratory order under the Utah Administrative Procedures Act. If you have any questions please feel free to contact me at (801) 530-6789 or by email: [dhobbins@utah.gov](mailto:dhobbins@utah.gov).

Sincerely,

Debra F. Hobbins, DNP, APRN, LASUDC  
Bureau Manager  
Utah Department of Commerce  
Division of Occupational and Professional Licensing

# FIELD JERGER LLP

PORTLAND OREGON

JOSEPH A. FIELD\*  
R. SCOTT JERGER\* †  
MATTHEW A. ARBAUGH\*  
JONATHAN C. SMALE  
TAKASHI HASHIMOTO\* °

\* ALSO ADMITTED IN WASHINGTON  
† ALSO ADMITTED IN TEXAS  
° OF COUNSEL

**RECEIVED**

NOV 18 2013

November 13, 2013  
DIVISION OF OCCUPATIONAL  
& PROFESSIONAL LICENSING

Re: Dry Needling and Violations of the U.S. Food, Drug, and Cosmetic Act (FDCA) and  
Food and Drug Administration Rules

Dear State Board of Physical Therapy:

I write on behalf of the National Center for Acupuncture Safety and Integrity (NCASI), a nonprofit corporation working to protect the public from the unlicensed practice of acupuncture and the illegal sale and use of acupuncture needles. NCASI is aware that a number of state boards of physical therapy have authorized physical therapists to practice what is referred to as “trigger-point dry needling” (“TPDN”), also known as “dry needling.” Those promoting “TPDN” openly acknowledge that they are using labeled acupuncture needles to practice “TPDN,” but claim that “TPDN” falls outside the statutory and regulatory definitions of practicing acupuncture. While specific state laws vary on the definition of the practice of acupuncture, the federal Food and Drug Administration (“FDA”) strictly regulates the sale of acupuncture needles as Class II prescription medical devices under the U.S. Food, Drug, and Cosmetic Act (FDCA) only to qualified and licensed acupuncture practitioners. Specifically, FDA regulations restrict that the sale of acupuncture needles to anyone but a person *authorized to practice acupuncture and for use in acupuncture*. The sale of acupuncture needles to anyone other than a qualified and licensed acupuncture practitioner is a violation of both the FDCA and the FDA rules described below.

Please be aware that to the extent your board authorizes the use of acupuncture needles by persons who are not explicitly authorized to practice *acupuncture*, your actions are inconsistent with federal law and could expose your state board to liability in the event a person is injured by one of the practitioners your board regulates. There is no dispute that the practice of “TPDN” absolutely depends on the use of FDA-regulated acupuncture needles. Any official sanctioning of “TPDN” by a state professional board signals to potential patients that those practicing “TPDN” are qualified, trained and legally authorized to possess, purchase and use acupuncture needles, a Class II prescription medical device under FDA regulations. As a result, state regulatory and professional boards that endorse the practice of “TPDN” by persons who are not explicitly authorized to practice acupuncture is inconsistent with federal law.

### **FDA’s regulation of acupuncture needles as Class II prescription medical devices**

Acupuncture needles are regulated under the FDCA as Class II prescription medical devices that are subject to FDA’s strict prescription sale requirements. *See* 21 CFR § 880.5580

Letter re Dry Needling

November 13, 2013

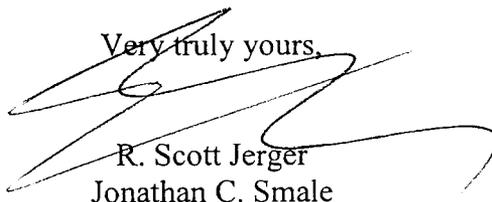
Page 3

With this letter your board and your state have notice that to the extent your board approves or otherwise endorses the use of acupuncture needles for the practice of "TPDN" by persons who are not legally authorized to practice acupuncture you may be exposing your board to liability for endorsing a practice that involves the violation of FDA regulations and the unauthorized use of a Class II medical device.

NCASI encourages your board to carefully review the enclosed regulations and other documents related to the regulation of acupuncture needles. To the extent your board has already endorsed or approved the practice of "TPDN" by persons who are not authorized to practice acupuncture, NCASI encourages your board to reconsider such actions. If your board has yet to address the issue of "TPDN," we encourage you to take a position that is consistent with the FDA's regulation of acupuncture needles as Class II prescription medical devices.

Thank you for your careful consideration of these issues.

Very truly yours,

A handwritten signature in black ink, appearing to be "R. Scott Jerger", written over a horizontal line.

R. Scott Jerger  
Jonathan C. Smale

cc: client  
Enclosures

Code of Federal Regulations]  
[Title 21, Volume 8]  
[Revised as of April 1, 2013]  
[CITE: 21CFR880.5580]

TITLE 21--FOOD AND DRUGS  
CHAPTER I--FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
SUBCHAPTER H--MEDICAL DEVICES

PART 880 -- GENERAL HOSPITAL AND PERSONAL USE DEVICES

Subpart F--General Hospital and Personal Use Therapeutic Devices

Sec. 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,

(2) Device material biocompatibility, and

(3) Device sterility.

[61 FR 64617, Dec. 6, 1996]

acupuncture needles is available in the General Hospital Branch guidance document entitled "Guidance on the Content of Premarket Notification (510(k) Submissions for Hypodermic Single Lumen Needles" (draft), April 1993 (Ref. 4). A copy of this guidance document is available from the Division of Small Manufacturers Assistance (HFZ-220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850-4307, 301-443-6597 or 800-638-2041 and FAX 301-443-8818.

Consistent with the act and the regulations, after thorough review of the clinical data submitted in the petitions, and after FDA's own literature search, on March 29, 1996, FDA sent the Acupuncture Coalition a letter (order) reclassifying acupuncture needles for general acupuncture use, and substantially equivalent devices of this generic type, from class III to class II (special controls). As required by § 860.134(b)(7), FDA is announcing the reclassification of the generic type of device. Additionally, FDA is amending part 880 (21 CFR part 880) to include the classification of acupuncture needles for the practice of acupuncture by adding new § 880.5580.

#### Environmental Impact

The agency has determined that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Under 21 CFR 25.24(e)(2), the reclassification of a device is categorically exempt from environmental assessment and environmental impact statement requirements. Therefore, neither an environmental assessment nor an environmental impact statement is required.

#### Analysis of Impacts

FDA has examined the impacts of the final rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96-354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this final rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the final rule is not a significant regulatory action as defined by the Executive Order and so is not

subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because reclassification of devices from class III to class II will relieve some manufacturers of the cost of complying with the premarket approval requirements of section 515 of the act (21 U.S.C. 360e), and may permit small potential competitors to enter the marketplace by lowering their costs, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

#### Paperwork Reduction Act of 1995

FDA concludes that the labeling requirements in this final rule are not subject to review by the Office of Management and Budget because they do not constitute a "collection of information" under the Paperwork Reduction Act of 1995 (Pub. L. 104-13). Rather, the proposed warning statements are "public disclosure of information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public" (5 CFR 1320.3(c)(2)).

#### References

The following references have been placed on display in the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857 and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. FDA letter (order) to the Acupuncture Coalition dated March 29, 1996.
2. Classification of anesthesiology devices, development of general provisions; 44 FR 63292 at 63299, November 2, 1979.
3. Anesthesiology Devices Advisory Panel's supplemental data sheet, November 30, 1976.
4. Guidance on the Content of Premarket (510(k) Submissions for Hypodermic Single Lumen Needles (draft), April 1993.

#### List of Subjects in 21 CFR Part 880

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 880 is amended as follows:

#### **PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES**

1. The authority citation for 21 CFR part 880 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. New § 880.5580 is added to subpart F to read as follows:

#### **§ 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,

(2) Device material biocompatibility, and

(3) Device sterility.

Dated: November 20, 1996.

D. B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 96-31047 Filed 12-5-96; 8:45 am]

BILLING CODE 4160-01-F

## **DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**

### **24 CFR Part 5**

[Docket No. FR-4154-C-02]

RIN 2501-AC36

### **Revised Restrictions on Assistance to Noncitizens; Correction**

**AGENCY:** Office of the Secretary, HUD.

**ACTION:** Interim rule, correction.

**SUMMARY:** On November 29, 1996 (61 FR 60535), HUD published an interim rule implementing the changes made to Section 214 of the Housing and Community Development Act of 1980 by the Use of Assisted Housing by Aliens Act of 1996. Section 214 prohibits HUD from making certain financial assistance available to persons other than United States citizens, nationals, or certain categories of eligible noncitizens. The November 29, 1996 interim rule incorrectly provided for a public comment due date of November 29, 1996. The public comment due date should have been January 28, 1997, 60 days after publication of the November 29, 1996 interim rule. The purpose of this document is to correct the due date for public comments in the November 29, 1996 rule.

Devices that were in investigational status before the enactment of the Medical Device Amendments of 1976 are not considered to have been in commercial distribution for purposes of section 513 of the Act.

After review of the information submitted in the petitions and its own literature search of safety information, FDA has determined that acupuncture needles intended for use in the practice of acupuncture by qualified practitioners as determined by the States could safely be reclassified from class III to class II with the implementation of special controls.

The special controls are compliance with 1) labeling provisions for single use only and the prescription statement in 21 CFR 801.109 (restriction to use by or on the order of qualified practitioners as determined by the States), 2) device material biocompatibility, and 3) device sterility. 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. Therefore, pursuant to section 801.109(c), such indications do not need to be on the dispensing packaging but sale must be clearly restricted to qualified practitioners of acupuncture. Guidance on the type of information needed to support biocompatibility and sterility can be found in the existing General Hospital Branch Guidance on the Content of Premarket [510(k)] Submissions for Hypodermic Single Lumen Needles, April 1993. A copy of this guidance is enclosed.

FDA's decision is also in keeping with but not dependent upon the recommendation of the Anesthesiology Devices Advisory Panel, published in the Federal Register of November 2, 1979 (44 FR 63299) that acupuncture needles be classified in class II. The supplemental data sheet completed by that panel, dated November 30, 1976, listed sepsis, excessive trauma and perforation of blood vessels and organs as specific risks, and recommended restricting the device to prescription use.

Therefore, FDA, for the reasons set forth in this letter, is ordering the reclassification of the generic type of device identified on page 1, from class III to class II. Further, since the reclassification is based upon scientific evidence demonstrating that general controls and the special controls provide a reasonable assurance of safety and effectiveness, the labeling requirements of the 1973 Federal Register document no longer apply to acupuncture needles intended for use in the practice of acupuncture by qualified practitioners. However, before acupuncture needles can be legally marketed, they must be the subject of a cleared premarket notification [510(k)] submission.

Code of Federal Regulations]  
[Title 21, Volume 8]  
[Revised as of April 1, 2013]  
[CITE: 21CFR801.109]

TITLE 21--FOOD AND DRUGS  
CHAPTER I--FOOD AND DRUG ADMINISTRATION  
DEPARTMENT OF HEALTH AND HUMAN SERVICES  
SUBCHAPTER H--MEDICAL DEVICES

PART 801 -- LABELING

Subpart D--Exemptions From Adequate Directions for Use

Sec. 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; and

(2) The method of its application or use.

(c) Labeling on or within the package from which the device is to be dispensed bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented: *Provided, however*, That such information may be omitted from the dispensing package if, but only if, the article is a device for which directions, hazards, warnings, and other information are commonly known to practitioners licensed by law to use the device. Upon written request, stating reasonable grounds therefor, the Commissioner will offer an opinion on a

In conformance with the requirements for prescription devices set out in 21 Code of Federal Regulations (CFR) 801.109, acupuncture needles are to be sold only to “*qualified practitioners of acupuncture* as determined by the States” (emphasis added). Accordingly, labeling on the package from which acupuncture needles are to be dispensed bears the prescription statement “Caution: Federal law restricts this device to sale by or on the order of *qualified practitioners of acupuncture* as determined by the States” (emphasis added).

#### **SAMPLE LABELS**

##### **(1) AcuMaster-brand acupuncture needles (Manufactured in China)**

The prescription labeling on a dispensing package of AcuMaster-brand acupuncture needles states:

CAUTION FOR U.S. ONLY: Federal law restricts this device to sale by or on the order of *qualified practitioners of acupuncture* as determined by the States.

(Emphasis added.)

##### **(2) Carbo-brand acupuncture needles (Manufactured in China)**

The prescription labeling on a dispensing package of Carbo-brand acupuncture needles states:

Caution: Federal law restricts this device to sale by or on the order of *qualified practitioners of acupuncture* as determined by the States.

(Emphasis added.)

##### **(3) DBC-brand acupuncture needles (Manufactured in Korea)**

The prescription labeling on a dispensing package of DBC-brand acupuncture needles states:

Caution: Federal law restricts this device to sale by or on the order of *qualified practitioners of acupuncture* as determined by the States.

(Emphasis added.)

##### **(4) Dongbang-brand acupuncture needles (Manufactured in Korea)**

The prescription labeling on a dispensing package of Dongbang-brand acupuncture needles states:

Caution: Federal law restricts this device to sale by or on the order of *qualified practitioners of acupuncture* as determined by the States.

(Emphasis added.)

##### **(5) Seirin-brand acupuncture needles (Manufactured in Japan)**

The prescription labeling on a dispensing package of Seirin-brand acupuncture needles states:

Caution: Federal law restricts this device to sale by or on the order of *qualified practitioners of acupuncture* as determined by the States.

(Emphasis added.)



## Dry needling letter

Leslie Adrian <LAdrian@aon.fsbpt.org>

Tue, Dec 3, 2013 at 7:59 AM

To: "cba@fsbpt.org" <cba@fsbpt.org>

To all Administrators,

The Federation has retained a law firm who specializes in FDA issues and are working with them to determine an appropriate course of action. We are also in contact with APTA and trying to coordinate our efforts. The issue is a bit complex, so we expect it will take some time before we have any specific information to share with our member boards. Until then, we would recommend that licensing boards not respond to the letter. We will keep you informed as much as possible along the way. If you would please share this information with your board members, we would appreciate it. Please feel free to contact me if you have any questions.

Thank you,

Leslie

Leslie Adrian, PT, DPT, MS, MPA

Director of Professional Standards

Federation of State Boards of Physical Therapy

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