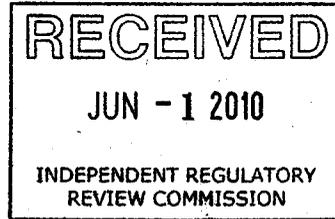


2832

May 19, 2010

Regulatory Unit Counsel
Department of State
P.O. Box 2649
Harrisburg, PA 17105-2649



Re: Regulation 16A-4316 (Assistance by Unlicensed Supportive Personnel)

Dear Counsel:

4646 Smith Street
Harrisburg, PA 17109.1525
717.541.9169
1.800.962.PPTA
717.541.9182 FAX
PAPTASSN@aol.com
www.ppta.org

The Pennsylvania Physical Therapy Association ("PPTA") is hereby filing comments to the above proposed regulations developed by the State Board of Chiropractic (the "Board") and published in the Pennsylvania Bulletin on Saturday, April 24, 2010 (the "Regulations"). While certain aspects of the Regulations are not of concern to the PPTA, a number of the provisions included in the Regulations are of great concern to the PPTA and necessarily should be a concern for the public as well.

officers

Ivan Mulligan, PT, DSc, SCS, ATC
President

Ann D. Dennison, PT, DPT, OCS, ATC
Vice President

Timothy Drevna, PT, DPT, OCS, ATC, CSCS
Treasurer

Tom McNamee, PT
Secretary

Michael P. Johnson, PT, PhD, OCS
Chief Delegate

Initially, it appears clear to the PPTA that the Board is attempting to expand the scope of chiropractic practice through the regulation process by seeking to allow the delegation of certain procedures or acts that themselves are not within the statutory scope of practice of chiropractic. Additionally, the PPTA has significant consumer protection concerns related to both the proposed expanded scope of practice and the proposed delegation of services to unlicensed supportive personnel. The PPTA believes that the effect of the Regulations, if adopted, will potentially increase healthcare costs unnecessarily by opening the door for health care consumers to pay for care that is not provided by appropriately trained health care providers and thus increase the potential for unnecessary additional services. Finally, the PPTA finds it troubling that, to the extent certain procedures set forth in the regulations are within the scope of chiropractic, the Board would allow delegation of such procedures to unlicensed supportive personnel while subsequently requiring that chiropractors pass the National Board of Chiropractic Examiners Exam, which specifically tests in these areas, to be licensed in the Commonwealth.

The statutory authority for delegation by chiropractors to unlicensed supportive personnel is found at 63 P.S. § 625.601 and reads as follows:

Nothing in this Act shall prohibit a licensed chiropractor from utilizing the assistance of unlicensed supportive personnel performing under the direct on-premises supervision of a licensed chiropractor, *provided that a chiropractor may not delegate any activity or duty to such unlicensed individuals which requires formal education or training in the practice of chiropractic or the knowledge and skill of a licensed chiropractor.* (Emphasis added.)

From this definition it is assumed that, regarding the prohibited areas of delegation, a chiropractor himself or herself would have the legal basis to perform such prohibited delegation activities. Conversely, it is assumed that the allowable delegation activities do not require the formal education or training of a chiropractor. As noted with specificity below, the proposed regulations are problematic relating to these concepts and § 625.601 cited above.

In subsection (c) of § 5.54 of the Regulations, it is asserted that "performing the activities or duties identified in this subsection does not require formal education or training in the practice of chiropractic or the knowledge and skill of a licensed chiropractor." With this assertion, the PPTA takes serious issue on at least the following activities:

1. (C)(1)(vi), Instructing and monitoring therapeutic activities in the office, and (C)(1)(xxiv), Performing therapeutic exercises and activities to include the provision of with direct one-on-one contact or constant attendance to achieve the desired therapeutic results of the exercise.

Comment: In this regard, it must be noted that chiropractors, in fact, have no statutory basis to perform therapeutic exercises, a treatment procedure that does require specialized training and education to administer. It is clear that the definition of adjunctive procedures under § 625.102 of the Act does not include therapeutic exercises, which by contrast is an integral part of the practice of physical therapy under 63 P.S. § 1302, Definition of Physical Therapy.¹ Regarding chiropractic practice, in the legislature's enumeration of adjunctive procedures in the Chiropractic Act for the first time in the 1986 Sunset Revisions to the Chiropractic Act, therapeutic exercises were specifically not included. There is no authority in any section of the Act to allow a Chiropractor to administer therapeutic exercise procedures. Therefore, there is no assurance that a Chiropractor is educated and trained to appropriately prescribe therapeutic exercises to patients or to provide appropriate supervision after delegation.

¹ 63 P.S. § 1302 Definitions - Physical Therapy means the following....;

(3) The use of therapeutic exercises and rehabilitation procedures including training in functional activities, with or without the utilization of assistive devices, for the purpose of limiting or preventing disability and alleviating or correcting physical or mental conditions.

Therapeutic exercise is not just a technique that can be casually administered without appropriate training, education and patient follow-up. The patient must be monitored not only to determine whether it is the most appropriate intervention for the musculoskeletal injury or pathology present but also to determine whether the patient is demonstrating the appropriate physiological response to therapeutic exercise.

The instruction of therapeutic exercise is a specific requirement for schools that offer physical therapy by the Commission on Accreditation in Physical Therapy Education (CAPTE), the only nationally recognized entity that accredits physical therapy education programs. This instruction is offered in the professional phase of the physical therapy curriculum, and has several prerequisites including anatomy, physics, biomechanics, and exercise physiology.

Therapeutic exercise, when prescribed appropriately, has been shown to be an effective treatment for neuromusculoskeletal injuries. In order to be prescribed effectively the professional must be involved for several reasons. First, the patient's exercise tolerance must be assessed and co-morbidities must be taken into account when prescribing a therapeutic exercise program. If this is not performed the patient maybe placed at a serious risk for injury or other health problems. For example, a patient with back pain who has been diagnosed with spinal stenosis and is taking beta blockers to control high blood pressure must be closely monitored during the therapeutic exercise program. A beta blocker is a medication that prevents the heart rate from increasing, thus making it necessary to monitor this patient to ensure the program is not too strenuous so as to cause other health related problems. Additionally, with the diagnosis of spinal stenosis there are many exercises and techniques that must be avoided as they will increase pain and limit function. The proposed regulations would enable non-licensed personnel to perform this activity, posing a significant risk to the healthcare consumer.

Accordingly, since there is no basis in the statutory practice of chiropractic to perform therapeutic exercises, it is not in any event a procedure or activity that can be delegated by a licensed chiropractor to an unlicensed supportive person. As stated above, such performance of therapeutic exercises and the delegation of this procedure are simply an attempt to enlarge the chiropractic scope of practice by regulation and are opposed by the PPTA because they would, if adopted, constitute a potential danger to the public without requisite specialized education and training of the provider or their delegee.

2.
 - (x) Assisting in Applying a Cast, Brace, Appliance or Orthotic
 - (xii) Performing Range of Motion Testing
 - (xiii) Performing Muscle Testing
 - (xv) Relaying Instructions for Cast, Brace, Appliance or Orthotic
 - (xviii) Using Rehabilitation Equipment
 - (xxi) Performing extremity measurements
 - (xxii) Performing postural screening

Comment: First, it is questionable that any of the above-enumerated activities are within the defined scope of practice of chiropractic except perhaps for the use of rehabilitation equipment. Assuming for purposes of this comment that these activities are relevant to the scope of chiropractic, performance of these activities requires specialized education or training, without which, again, there are consumer safety issues. How, for example, does an unlicensed supportive person without any formal education or training, even with supervision, appropriately perform a range-of-motion or muscle-testing examination on a patient or prepare and apply an orthotic or brace? All of these measures require knowledge of human anatomy, precise knowledge of the patient's condition and specific training to potentially avoid an adverse outcome on a patient. Range of motion testing and manual muscle testing are specific educational requirements of CAPTE for schools that offer physical therapy. When range of motion and manual muscle testing are instructed in physical therapy curriculum it is after the student has had specifically defined prerequisite coursework including anatomy, biomechanics, surface anatomy and exercise physiology. An individual must have a baseline understanding of how the body moves and the structures required for the movement to occur to accurately assess the range of motion and muscle strength that a patient demonstrates during an examination. When range of motion testing and muscle testing are performed during any patient assessment these tests use standardized techniques that have been taught to demonstrate strong reliability and validity to accurately assess these areas.

When assessing a patient with a musculoskeletal injury range of motion testing is performed to assess the joint in three subsections. First, active range of motion is assessed to determine the amount motion the patient is willing and able to move the area injured. This is followed by passive range of motion in which the physical therapist moves the joint in the available range to determine if there is a restriction of motion. Range of motion testing concludes with assessing the end range of the patient's movement, an assessment which allows the physical therapist to determine whether the patient's movement is considered normal or abnormal. These three components provide the physical therapist with the information needed to not only accurately assess the injured joint and the available movement but also aids in determining how the patient is ultimately treated.

Range of motion testing is also present in the physical therapist assistant educational curriculum. The physical therapist assistant can perform range of motion and manual muscle testing; however, he or she cannot interpret the results of these tests. Range of motion testing and muscle testing are essential components of the physical therapist assistants' education to ensure the reliability and validity of these measurements. The regulations presented by the Board are erroneous by indicating that a non-licensed individual can accurately perform range of motion testing or muscle testing, given the specific patient positioning and proper technique that can only be known through specialized training and education.

Postural screening is a component in the physical therapy curriculum and an essential component in examining a patient. All of the measures in this screening process require knowledge of human anatomy and biomechanics and a precise knowledge of the patient's condition to properly evaluate the patient and make an accurate assessment. Once again, this procedure should not be delegated to non licensed personnel.

The PPTA takes issue that such activities would not require the formal education, training or knowledge of the person delegating the activities to be performed on or in connection with a patient, and for this reason believes that these activities cannot be delegated, even with some level of supervision.

3. Similarly, in (c)(2) of § 5.54 of the Regulation, the PPTA has serious concerns regarding the delegation of the following activities based on the fact, contrary to the assertion in the Regulations, the activities enumerated below require formal education for chiropractic practice and should, therefore, not be delegated, even with supervision, to unlicensed supportive personnel.

- A. (iii) Performing electrical stimulation
- (iv) Performing ultrasound therapy
- (v) Performing mechanical traction
- (vii) Performing other therapeutic modalities classifiable as adjunctive procedures.

Comment: The notion that the above activities or procedures (collectively, the "Modalities") do not require the formal education, training or knowledge of a licensed chiropractor is patently inaccurate. One only has to read the definition of adjunctive procedures in the Act and the definition of chiropractic in § 625.102 of the Act to understand that the Modalities are all forms of adjunctive procedures under the Act and as such require formal education and a special certification for a chiropractor under the law to perform. It is troubling to the PPTA that the Act provides that "the licensee must be certified in accordance with this act to use adjunctive procedures", indicating a higher level of formal education and training, while subsequently proposing regulations that would allow the Modalities to be delegated to unlicensed supportive personnel. Also, § 625.507(b)(15) of the Act, governing continuing chiropractic education, reinforces this fact in that adjunctive procedures are part of the chiropractors' ongoing formal education needed to obtain and maintain their license. Accordingly, it is surprising in the least to assert that the Modalities do not require the formal education, training or knowledge of a licensed chiropractor.

Another point in this regard is how unlicensed supportive personnel, even with some level of supervision, can perform the Modalities, which require formal and specialized education and training for both chiropractors and other health professionals such as physical or occupational therapists or athletic trainers. The Modalities can all cause injury to a patient and should not be employed or utilized unless a person with specific education and training is applying these measures.

In the physical therapy and physical therapist assistant educational curriculum a student must take a modalities class that covers all of the procedures listed in the proposed chiropractic regulations. Prior to this class the student must have taken prerequisite classes in: anatomy, surface anatomy and biomechanics. The physical therapy course work that addresses the Modalities goes into detail specifically identifying the indications and contraindications for the modalities in various patient populations, the proper use of the modality, including proper parameters used for various patient populations, proper setup of the patient to ensure the most advantageous delivery of the modality, and the expected outcome when using the modality.

For example, ultrasound can be used initially when a patient is injured or when a patient has a chronic condition. However, if the ultrasound is set to inappropriate specifications during the treatment it may not facilitate healing as intended, but rather may hinder healing by heating the area too soon and causing a delayed healing response. Another modality listed in the Regulations is mechanical traction. This procedure has been designed to place an outside force on the body to distract joints, typically in the spine. If this force is too great, injury to the muscles and joints in that region may occur. The Modalities are helpful in the rehabilitative process; however, it is essential that those trained in these activities, not unlicensed supportive personnel, administer these modalities to ensure the proper use and setup for the patient to limit the likelihood of injury and maximize the therapeutic benefit. Additionally, if these procedures are used inappropriately it could lead to increased utilization of these modalities or adjunctive procedures causing an increase in visits and further increase in health costs.

4. It should also be noted that under Annex A, § 5.54, Assistance By Unlicensed Supportive Personnel, (G), "a chiropractor may not permit an unlicensed supportive person to perform any activity that the supportive person is not qualified by training, education or experience to perform." This regulation is problematic for two reasons. First, there is no defined threshold for what constitutes "qualified training" for supportive personnel. Second, there is no reference as to what individual or what accreditation facility will identify that supportive personnel have completed the appropriate training and are competent to perform such activities. In other professions, such as physical therapy or occupational therapy, assistants must have structured formal education and are required to take national examinations in order to perform many of the activities discussed in these proposed regulations. Additionally, the supervision of licensed physical or occupational therapists is required based on public safety needs. The Regulations have no such standards or directions concerning the training of the "unlicensed supportive persons" who, under the Regulations would be providing procedures and care that require substantial training and education and have the potential to harm the patient if improperly administered. As noted above, many of the areas identified in the proposed regulations require specialized training by legally qualified healthcare providers who have such specialized training. As such, the delivery of many of the procedures identified in these regulations by such unlicensed supportive personnel constitutes a potential danger to the public safety and welfare.

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For the reasons stated above the PPTA urges that prior to further construction of these proposed regulations that the concerns and objections set forth above be addressed to ensure that the regulations are factually and legally appropriate to most importantly ensure the safety of the consumer patient.

Thank you for the opportunity to provide these comments. I am available to answer any questions you may have regarding the PPTA comments provided here.

Sincerely,

PENNSYLVANIA PHYSICAL THERAPY
ASSOCIATION



Ivan Mulligan, PT, DSC, SCS, ATC, CSCS, President

IM:dms

c: J. Kent Culley, Esquire
Sandra McCuen, PT

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