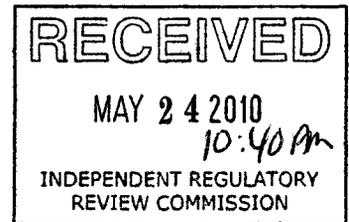


2832

The Insurance Federation of Pennsylvania, Inc.

1600 Market Street
Suite 1520
Philadelphia, PA 17101
Tel: (215) 665-0500 Fax: (215) 665-0540
E-mail: mailbox@ifpenn.org



Samuel R. Marshall
President & CEO

May 24, 2010

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

**Re: No. 16A-4316 proposed regulation on assistance of
unlicensed supportive personnel**

On behalf of the members of the Insurance Federation and our affiliated national trade associations, we offer the following comments in opposition to the State Board of Chiropractic's proposed regulation setting forth a new Section 5.54 concerning the activities and duties that may be performed by unlicensed personnel under the direct supervision of licensed chiropractors. Our members include health, auto and workers compensation insurers who handle claims from chiropractors and other providers.

We appreciate the Board's desire to provide clarity to Section 601 of the Chiropractic Practice Act, which allows a licensed chiropractor to utilize the assistance of unlicensed supportive personnel under the chiropractor's direct on-premises supervision, provided that a chiropractor not delegate to such personnel activities or duties which require the formal education, training, knowledge or skill of a chiropractor. We also appreciate the inclusion of adjunctive procedures. These have been areas of confusion since their enactment, and regulatory clarification is needed.

May 24, 2010

Page two

The proposed regulation, however, fails to provide such clarity and in key areas contradicts the Act's parameters on the use of unlicensed supportive personnel. It goes beyond the Board's authority and the General Assembly's intent in the Act, by allowing unlicensed supportive personnel to perform functions beyond those allowed in the Act and without the supervision required in the Act. In doing so, it presents a danger to the safety of those utilizing chiropractic services and jeopardizes the integrity of the profession, as well as imposing new costs for consumers and insurers paying for these services. Further, many of its provisions are unduly ambiguous.

As such, the proposed regulation fails to meet the criteria for regulatory approval set forth in 71 P.S. 745.5b, and we therefore recommend the Board either withdraw or substantially revise this proposal.

As to the specifics of the proposed regulation and where it falls short of the parameters in the Chiropractic Practice Act and the criteria for regulatory review:

Section 5.54 - Assistance by unlicensed supportive personnel

(a) - Definitions

"Direct supervision": The definition doesn't add clarity: Saying there can't be an intermediate supervisory person presumably (but not clearly) means only that one unlicensed person can't supervise another, and there is no reference to actual supervision.

Subsection (f) attempts to provide a little more clarity (and might be better merged into this definition) by requiring that the supervising chiropractor be "physically present on the premises and able to intervene whenever necessary."

May 24, 2010

Page three

Reading the two subsections in conjunction, however, still offers no practical guidance on what constitutes "direct on-premises supervision." In fact, the regulation proposes a standard that contradicts the Act's requirement that unlicensed supportive personnel be directly supervised: It replaces the Act's requirement of direct supervision with a much different (and lower) standard of being in the same building and able to intervene "whenever necessary."

Under the proposed definition, a chiropractor need not be involved at any stage of a particular visit or treatment episode, or even aware of the visit or treatment episode; that would make any level of supervision, much less direct supervision, impossible. Further, a chiropractor need not be aware of what the unlicensed person is doing at a given time with a given patient, meaning the possibility of intervention would be not in the control of the chiropractor but of the unlicensed person. And if a chiropractor has a high number of unlicensed assistants, the ability to intervene, much less directly supervise, may be theoretical at best.

We recommend the regulation require "direct on-premises supervision of a licensed chiropractor" that entails just that - actually supervising. Absent a requirement of actual supervision - not just being in the same building and able to intervene if summoned - the regulation falls short of Section 601 of the Act: The Act not only expressly refers to supervision, but also refers to unlicensed personnel "assisting" chiropractors. Combined, that means a "direct supervision" definition should include active and ongoing monitoring and a requirement that the chiropractor actively work with unlicensed supportive personnel.

That refinement is particularly important when applied to the more sophisticated functions in subsection (c), as opposed to administrative or clerical functions. The regulation should delineate the degree of active supervision depending on those functions rather than its proposed approach of treating them as one and the same.

May 24, 2010

Page four

Other health care providers are subject to far more exacting standards by their Boards in their use of supportive personnel. The Pennsylvania Physical Therapy Association notes differences between the standards in this proposed regulation and those controlling physical therapists. The same holds true for osteopaths and physicians. Of particular note, physicians are limited to four physician assistants by statute - Section 13(e) of the Medical Practice Act, 63 P.S. Section 422.13(e) - along with much greater detail to ensure proper supervision. The proposed regulation should provide that same clarity and supervision for chiropractic services.

"Unlicensed supportive personnel:" This requires only that such personnel be "regularly employed." We recommend more substance. For instance, what is meant by regularly employed: Does this include part-time employment, and does it extend to being employed by one chiropractor or practice, or can the personnel qualify if moving among practices, which may make verification impossible?

Subsection (b) - Professional responsibility

We recommend greater explanation of what is meant by a chiropractor being "professionally responsible for the actions of unlicensed personnel providing assistance..."

- Does it mean legal liability?
- Does it mean the chiropractor should have professional liability insurance for unlicensed supportive personnel in the same amount the chiropractor has pursuant to Section 508 of the Act?
- Does it mean that errors or malfeasance by unlicensed supportive personnel are attributed to the chiropractor in terms of any reports to appropriate licensing boards or other quality-monitoring entities?

May 24, 2010

Page five

- Does it mean the chiropractor should file with the state the names of all unlicensed supportive personnel, with disclosure of which activities set forth in subsection (c) that personnel is performing? That would allow the state to ascertain whether the number of unlicensed supportive personnel can practically be supervised and are properly qualified.
- Does it mean the chiropractor is to verify or certify that the unlicensed supportive personnel being used have the proper training, education and experience - as set forth in subsection (g) - to perform whatever activities and duties assigned to them?

Subsection (c) - Activities and duties of unlicensed supportive personnel

Subsection (c)(1) lists 24 activities and duties which the regulation proposes do not need the education, training, skill or training of a chiropractor and may be done by unlicensed supportive personnel under the chiropractor's direct on-premises supervision.

These activities and duties cover a broad expanse and emphasize the need for greater clarity on the level of supervision and greater clarity on whether and when the unlicensed supportive personnel can only assist the chiropractor in the performance of an activity or duty, or can perform that activity or duty alone - albeit with the chiropractor "on the premises" and "able to intervene."

The listed activities and duties also emphasize the need for clarity on the level of training, education and experience required of unlicensed supportive personnel performing these functions. While subsection (g) notes these personnel need some level of competency to perform these functions, the regulation fails to provide any guidance on that, presumably leaving this to the discretion of each chiropractor, with no uniformity within the profession and no ability for the Board to monitor, verify, evaluate or enforce this.

May 24, 2010

Page six

As to the listed functions:

Twelve of them seem administrative or clerical - those listed in (i)-(iii), (vii) and (viii), (xi), (xiv)-(xvii) and (xix)-(xx). And two of the functions expressly are limited to assisting the chiropractor - those listed in (ix) and (x), although (ix) refers to "assisting the chiropractor" whereas (x) leaves out reference to the chiropractor, presumably an editing point.

But the remaining ten functions raise concerns, especially given the lack of substance on the required supervision of unlicensed supportive personnel, and the lack of standards on the training, education and experience required:

- (iv) refers to obtaining a patient's vital signs. That's a key part of evaluating a patient and entails training and knowledge of anatomy and physiology. A chiropractor (or somebody else with expertise and training in this area, such as a nurse), should be involved in this as a matter of patient safety.
- (v) refers to developing x-rays, which entails knowledge of Roentgenology or photo darkroom processes. That may not be within a chiropractor's training, but it shouldn't be done by someone without training - poor processing of films can lead to missed findings or more x-rays and therefore needless radiation exposure (and cost).
- (vi) refers to "instructing and monitoring therapeutic exercises in the office," and (xxiv) refers to "performing therapeutic exercises and activities." Providing therapy is part of the active treatment of a patient and requires detailed knowledge of anatomy and physiology. To allow unlicensed supportive personnel to do it without meaningful supervision by the chiropractor is a dangerous expansion of the scope of activities of such personnel, and is in marked contrast to the patient safety standards for similar functions done by physical therapists and their assistants.

May 24, 2010

Page seven

- (xii), (xiii), (xxi) and (xxii) refer to performing tests, measurements and screenings, all of which are integral to the diagnosis and treatment of a patient and generally require expertise in surface anatomy and testing. As such, these items merit greater supervision or limits than in the proposed regulation.
- (xviii) and (xxiv) refer to unlicensed personnel using equipment or performing exercises. Presumably, this means assisting or instructing patients who are using the equipment or performing the exercises, and the regulation should be clearer on that. Assuming that is the goal, these require knowledge and training in muscle physiology and surface anatomy and, like many of the other items, may require decisions that should be left to a licensed chiropractor (or other type of provider). In any event, those also seem functions integral to the treatment of a patient that merit greater supervision.
- (xxiii) refers to rendering first aid, a broad term but again one that may merit more active supervision, if not proper licensure.

Granted, subsection (g) says such unlicensed supportive personnel must be "qualified by training, education or experience to perform" these activities. But that lacks any guidance on what the training, education and experience should be. It could be whatever a given chiropractor decides for a given employee on a given function. That is dangerously subjective and impossible to monitor, as more fully discussed below, and an ineffective protection to ensure that the functions in this subsection are properly delegated and supervised.

Subsection (c)(2) lists seven activities and duties a certified chiropractor may delegate to unlicensed supportive personnel with respect to adjunctive procedures. This is a broad list. In fact, read in conjunction with subsection (d)(2), it suggests the only adjunctive procedure that may not be delegated is the placing of needle electrodes.

May 24, 2010

Page eight

This is far different than the requirements in Section 304 of the Act. Section 304 allows chiropractors to perform adjunctive procedures - defined as "physical measures such as mechanical stimulation, heat, cold, light, air, water, electricity, sound, massage and mobilization" - only if certified by the Board upon passage of an examination and completion of 100 hours of Board-approved study. Further, Section 507 includes adjunctive procedures as part of a chiropractor's continuing education obligation.

Subsection (c)(2) circumvents this by allowing a certified chiropractor to delegate veritably all adjunctive procedures to unlicensed supportive personnel (with the exception of placing needle electrodes). That makes no sense. And the same problems noted in subsection (c)(1) apply here in terms meaningful guidance on the training, education and experience of such personnel, and clarity in direct supervision and assisting versus independently performing these functions.

A review of the seven activities and duties highlights the problem of subsection (c)(2)'s broad delegation authority:

- (i) refers to the applying of hot packs and cryotherapy. This requires expertise in surface anatomy; the danger of burning or otherwise damaging the tissue of a patient highlights the need for meaningful standards in who can perform it.
- (iii)- (vii) refer to the performance of electrical stimulation, ultrasound therapy, mechanical traction, therapeutic laser therapy and other therapeutic modalities. All of these require training and knowledge of anatomy and physiology, and all present real dangers to the patient if improperly done.

Subsection (c)(2)'s broad delegation stands in contrast to the limits of Section 304 of the Act and to Section 601 - which makes no mention a chiropractor's right to delegate adjunctive procedures. Reading those two sections of the Act together suggests that adjunctive procedures are not to be delegated to unlicensed supportive personnel at all, much less under the vague standards proposed here.

May 24, 2010

Page nine

Further, subsection (c)(2) stands in stark contrast to the controls provided, both in legislation and regulation, under the Physical Therapy Practice Act. "Adjunctive procedures," as defined in the Chiropractic Practice Act, mirror physical therapy procedures. Physical therapists, however, are much more limited in their use of unlicensed supportive personnel than proposed here: The activities and duties here can only be performed by properly licensed assistants under the Physical Therapy Practices Act.

It makes no sense - both in construing the various licensing laws together and in assuring patient safety - to allow the same functions that require licensure under the Physical Therapy Practices Act to be performed by unlicensed supportive personnel under the Chiropractor Practices Act. That's especially true given legislative recognition that these procedures require special examination and licensure for a chiropractor to perform them, with no express recognition that any portion of them can be delegated to unlicensed personnel.

Further, subsection (c)(2) runs afoul of the Commonwealth Court's ruling in Kleinberg v. SEPTA, 765 A.2d 405 (2000), affirmed by the Supreme Court, 810 A.2d 635 (2002). The Court determined that "the Physical Therapy Practice Act requires those who are administer physical therapy to be licensed." While it dealt with physicians and physical therapists, not expressly chiropractors, its holding should apply to all health care providers: Those providing physical therapy services need to be licensed.

The Board may believe the adjunctive procedures listed in the Chiropractor Practice Act differ from physical therapy (the 2004 federal court ruling in State Farm v. All-Care Chiropractic suggests that, although without any reference to Kleinberg - and state courts control in construction of state laws). If so, it should spell out how those differ, because the procedures literally match. And if they do match, we recommend that the same safeguards of licensure and supervision that apply under the Physical Therapy Practice Act apply here.

May 24, 2010

Page ten

Subsection (d) - activities and duties to be performed by licensed chiropractors

The activities and duties that may be delegated having been listed in subsection (c), this subsection attempts to list those that may not be delegated.

Granted, the Board says this is not to be an exhaustive list (and makes no reference to diagnosing, just ordering or interpreting diagnostic tests). It therefore leaves unanswered the question of what other activities and duties the Board believes may not be delegated. It is far more limited than the functions listed in the Act's definition of "chiropractic;" and it is far more limited than the areas set forth in Section 507 of the Act regarding the continuing education requirements for chiropractors.

This highlights a confusion that runs through the proposed regulation. Subsections (c) and (g) speak in terms of what may be delegated or performed; subsections (d) and (h) speak in terms of what may not be delegated; and subsection (e) is somewhere in the middle. But they are never integrated - or at least the Board offers no guidance on how they combine to provide a comprehensive list of activities and duties, including adjunctive procedures; how comprehensive that list is; and who and how they can be performed under the Act.

Subsection (e) - other activities and duties

As an editing note, the subsections (b) and (c) referenced here seem misstated - it might mean (c) and (d).

As to substance, this subsection is unclear: It says unlicensed supportive personnel may assist a chiropractor by performing an activity or duty not already listed in the other subsections, and that a chiropractor may delegate such activities and duties not already listed in those subsections, so long as the activity or duty doesn't require the formal education, training, knowledge or skill of a chiropractor.

May 24, 2010

Page eleven

In the regulation's preamble, the Board says those other subsections are not exhaustive, although our experience is that they are. As the purpose should be clarity, this subsection should at least identify the types of activities beyond those already listed it envisions being performed (or not performed) by unlicensed supportive personnel, whether in assisting a chiropractor or having delegated to them by a chiropractor.

Subsection (f) - delegated activities and duties and the requisite supervision

As noted with the proposed regulation's definition of "direct supervision" in subsection (a), this subsection should be merged into that. We also reiterate our concern with the lack of standards in this subsection in defining what constitutes supervision: Being in the same building and able to intervene when necessary is hardly the same as being directly supervised.

Subsection (g) - activities that can't be performed by unlicensed supportive personnel

As an editing note, we assume the regulation is using, here and in subsection (d), the terms "perform" and "delegate" interchangeably. To be consistent with Section 601 of the Act, we recommend staying with the term "delegate" throughout. Further, this subsection refers only to activities, not duties, and "duties" should be added here.

As to substance, the question is how this differs from the activities and duties set forth in subsection (d). Subsection (d) lists seven activities and duties a chiropractor may not delegate to unlicensed supportive personnel, and one with respect to adjunctive procedures. This subsection is more broadly stated, providing that a chiropractor may not allow unlicensed supportive personnel to perform activities such personnel are "not qualified by training, education or experience to perform."

May 24, 2010

Page twelve

What activities, beyond those set forth in subsection (d), might be covered here? We assume, as with subsection (e), that the Board does not mean subsection (d) to be comprehensive - so we again recommend some guidance on what activities and duties the Board envisions being covered here. It may be that all three subsections, along with subsection (h), should be merged with specific activities and duties referenced as "including but not limited to."

Further, this subsection misstates the parameters in Section 601 of the Act. This refers only to the "training, education or experience" of the unlicensed supportive personnel. Section 601, however, refers to "formal education or training in the practice of chiropractic or the knowledge and skill of a licensed chiropractor." As such, the Act sets a significantly higher bar in determining what can or can't be delegated to - or performed by - unlicensed supportive personnel.

This difference is highlighted by the vagueness in this subsection's reference to "qualified by training, education or experience." Who determines the qualifications - how much training is needed - what type of education is required - and how much experience is needed - and who verifies, certifies or monitors any of this? As noted above, those questions must be answered to ensure proper patient safety. Those are the types of a questions a regulation should answer, not raise.

Subsection (h) - activities that can only be performed by a licensed chiropractor

As with subsection (g), this raises the question of what activities, beyond those listed in subsection (d), are covered here. This subsection refers to making the diagnosis and evaluation and specifying the treatment regimen. Those activities and duties should be included in subsection (d), with reconciliation between this subsection's reference to specifying the treatment regimen and subsection (d)'s reference to evaluating or managing a treatment plan.

This subsection also refers to performing "any aspects of the procedures that may not be delegated to unlicensed supportive personnel." That highlights a flaw throughout the proposed regulation: The regulation should address what those aspects are. Subsection (d) at least attempts to do this - although leaving out diagnosis and evaluation and perhaps other activities and duties. This subsection adds nothing and, as with subsection (g), should either be merged with subsection (d) or deleted.

The missing subsection - patient and billing disclosure

The proposed regulation makes no mention of whether and how a chiropractor should disclose to a patient that a particular service is being performed by unlicensed supportive personnel and the level of training, education and experience of such personnel.

Given the breadth of the services the regulation proposes may be done by such unlicensed supportive personnel, the lack of meaningful supervision of them, and the lack of standards on proper training, education and experience, that disclosure is essential for consumers to make informed decisions about their treatment. While this may not be needed for truly administrative or clerical functions, it is crucial for the other functions covered in this regulation.

Further, the regulation gives no guidance on the need for a chiropractor to disclose in any claim for payment whether a service was provided by the chiropractor or unlicensed supportive personnel, or the degree of training, education and experience of such personnel. That is essential to assure proper and informed payment decisions.

Accordingly, we recommend the Board include a subsection on proper disclosures in these areas. We also recommend the Board require these disclosures not only to consumers, but the Board itself. That is essential to monitor and enforce compliance with these provisions.

May 24, 2010
Page fourteen

Fiscal impact

The preamble says the proposed regulation will impose no new paperwork requirements on the private sector. We disagree. Its lack of clarity and its expanded powers of unlicensed supportive personnel will impose new paperwork on those responsible for evaluating claims from chiropractors - including insurers - as we struggle to verify proper delegation and proper training, education and experience.

Notably, the preamble stops short of saying the proposed regulation will have no adverse fiscal impact on the private sector. We believe it will: It will not only make the handling of claims more difficult, but will lead to excess utilization by unlicensed supportive personnel, which will mean increases in premiums for all consumers - including the Commonwealth.

And it will do so without any improvement in the care provided by chiropractors. Just the opposite: By allowing unwarranted use of unlicensed supportive personnel, it will undermine the quality of care provided by that profession.

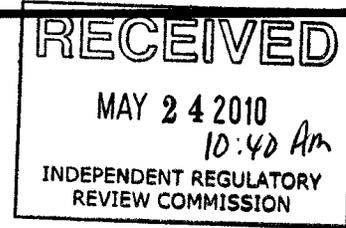
Thank you for the opportunity to comment. We are committed to clear regulation in this area, and we welcome the chance to discuss these concerns further.

Sincerely,

Samuel R. Marshall

2832

From: Samuel R. Marshall [smarshall@ifpenn.org]
Sent: Monday, May 24, 2010 9:53 AM
To: 'st-chiropractic@state.pa.us'
Cc: IRRRC
Subject: Ref. No. 16A-4316
Attachments: chiroregltr.doc



Attached are the comments of the Insurance Federation of Pennsylvania on the above-referenced regulation (assistance by unlicensed supportive personnel). If you have any problems with the transmission, please call at 215-665-0500.

Thanks,

Sam Marshall