

Comments of the Independent Regulatory Review Commission



State Board of Medicine Regulation #16A-4943 (IRRC #3062)

Prosthetists, Orthotists, Pedorthists and Orthotic Fitters

September 10, 2014

We submit for your consideration the following comments on the proposed rulemaking published in the July 12, 2014 *Pennsylvania Bulletin*. Our comments are based on criteria in Section 5.2 of the Regulatory Review Act (RRA) (71 P.S. § 745.5b). Section 5.1(a) of the RRA (71 P.S. § 745.5a(a)) directs the State Board of Medicine (Board) to respond to all comments received from us or any other source.

1. Conforms to the intention of the General Assembly; Compliance with the RRA.

The Board states in the Preamble and responses to the Regulatory Analysis Form (RAF) that extensive discussions were held with stakeholders regarding the proposed regulation. The Board identifies the stakeholders to include the Independent Regulatory Review Commission (IRRC). IRRC was not a stakeholder, and as such, IRRC did not participate in the drafting of the proposed regulation. We ask the Board to revise the Preamble and RAF of the final-form regulation to ensure that the information provided is accurate.

A commentator, the Pennsylvania Orthotic Prosthetic Society, states that it was not included as a stakeholder, and therefore, there was not an equitable exchange among stakeholders. Section 2 of the RRA, pertaining to legislative intent, provides the following direction: "To the greatest extent possible, this act is intended to encourage the resolution of objections to a regulation and the reaching of a consensus among the commission, the standing committees, interested parties and the agency." 71 P.S. § 745.2(a). We ask the Board to work with the regulated community to resolve as many concerns as possible prior to submitting the final regulation.

2. Comments of the House Professional Licensure Committee.

In a letter dated August 28, 2014, Representative Julie Harhart, Majority Chair of the House Professional Licensure Committee (Committee), and Representative Harry Readshaw, Minority Chair of the Committee, submitted comments on behalf of the Committee pertaining to the Board's statutory authority for graduate permits, clinical residency and provisional licenses for prosthetist and orthotics, and the need for clarification of certain sections. We will review the Board's response as part of our determination of whether the final regulation is in the public interest.

3. Section 16.13. Licensure, certification, examination and registration fees. – Economic or fiscal impact; Reasonableness of requirements; Acceptable data.

The Board provided Fee Report Forms in support of all of the fees proposed to be added to Subsections (n) (relating to prosthetists), (o) (relating to orthotist license), (p) (relating to pedorthists) and (q) (relating to orthotic fitters). However, the Fee Report Form for the biennial renewal fee, which is provided for under each of these subsections, omits the “Fee-Related Activities and Costs” calculation that was provided to support the amount of all of the other proposed fees.

We ask the Board to provide its costs for biennial renewal of these licenses, including the “Fee-Related Activities and Costs,” in support of the amount of the fee in the final regulation.

4. Section 18.802. Definitions. – Conforms with the intention of the General Assembly; Clarity and lack of ambiguity; Need for the regulation; Reasonableness of requirements.

CAAHEP, NCOPE

Act 90 of 2012 (Act 90) provides for the Institute for Credentialing Excellence (ICE) and the National Commission for Certifying Agencies (NCAA) regarding credentialing and certifying entities. The Board, however, also defines the Commission on Accreditation of Allied Health Education Programs (CAAHEP) and the National Commission on Orthotic and Prosthetic Education (NCOPE), and references these entities throughout the regulation in providing requirements for qualification for licensure.

A commentator asserts that requiring credentialing/certification by entities which were not provided for in Act 90 creates restrictions on individuals and educational programs which were not intended by the General Assembly. We ask the Board to explain how designating these additional accreditation and certification programs is necessary and reasonable as relates to qualification for licensure for prosthetists, orthotists, pedorthists and orthotic fitters.

Custom-designed device

Act 90 defines a *custom-fabricated device* and a *custom-fitted device*. In addition to these terms, the proposed regulation defines a *custom-designed device*. A commentator asserts that this category is not recognized in the industry, and, therefore, creates ambiguity. We ask the Board to explain the need for this term and to ensure that use of the term does not create ambiguity for the regulated community.

Licensed prescribing practitioner, Orthotic fitter, Orthotist, Pedorthist, Prosthetist

The Board defines differently the licensure of a *licensed prescribing practitioner* (“licensed by the practitioner’s respective licensing board”), *orthotic fitter* (“licensed by the Board”), *orthotist* (“licensed by the Board”), *pedorthist* (“licensed under the [Medical Practice Act of 1985 (Act)]”)

and *prosthetist* (“licensed under the [Act]”). We ask the Board to review these definitions and make the definitions consistent.

Prefabricated orthotic devices

The devices encompassed by this term in the proposed regulation are defined in Act 90 as *prefabricated orthosis*. Since the proposed regulation includes definitions for the term *orthosis* and *over-the-counter orthoses*, we question why the Board deviated from the term provided for in Act 90? Since “orthotic device” is not defined in the regulation, we recommend that the Board use the Act 90 term to ensure clarity and lack of ambiguity for the regulated community.

- 5. Section 18.811. Graduate permit.**
- Section 18.812. Clinical residency.**
- Section 18.813. Provisional prosthetist license.**
- Section 18.814. Prosthetist license. – Statutory authority; Protection of the public health, safety and welfare; Clarity and lack of ambiguity.**

Under these sections, the Board establishes qualifications for licensure as a graduate prosthetist, a provisionally-licensed prosthetist or a prosthetist. In order to ensure that the public, who would be receiving prosthetic services, can clearly understand the level of qualification of the person providing the service, we ask the Board to consider including provisions related to the titles that the holder of a permit or provisional license may or may not use.

We ask the Board to address these same concerns related to orthotists, pedorthists and orthotic fitters.

- 6. Section 18.814. Prosthetist license. – Clarity and lack of ambiguity; Need for the regulation.**

Paragraph (b)(3) states, “In meeting the requirement of this paragraph, an applicant may present documentation from the applicant’s employer or supervisor and the director of the applicant’s clinical residency in prosthetics or prosthetics/orthotics.” Is this language necessary? We note in the Preamble that the Board states that Section 18.816 (relating to demonstration of qualifications) provides information about the type of documentation that will be required by the Board for an applicant to demonstrate the qualifications in Act 90 and Chapter 18. We also note that parallel provisions related to orthotists, pedorthists and orthotic fitters do not contain this language. We ask the Board to include this language in Section 18.816 or explain why it is needed in this section.

- 7. Section 18.815. Alternate pathway for prosthetist license. – Need for the regulation.**

This section of the regulation expired on July 7, 2014. We ask the Board to remove this section and any other related provisions which are no longer applicable or relevant, or to explain the need for keeping it in the final-form regulation.

This same comment applies to Sections 18.825 (relating to alternate pathway to orthotist license), 18.834 (relating to alternate pathway for pedorthist license) and 18.844 (relating to alternate pathway for orthotic fitter license).

8. Section 18.816. Demonstration of qualifications. – Conforms to the intention of the General Assembly; Clarity and lack of ambiguity; Reasonableness of requirements.

In the Preamble, the Board states that this section provides information about the type of documentation that will be required by the Board for an applicant to demonstrate the qualifications in Act 90 and Chapter 18.

Based on the Board’s description, this section pertains to applicants for a graduate permit, a provisional license or full licensure. However, Paragraph (3) under this section is not applicable for applicants for graduate permits or provisional licenses, and Paragraph (5) could only apply to a limited number of applicants. We ask the Board to amend this section to ensure that the intent and any requirements are clear and reasonable. If the requirement in Paragraph (5) is kept in the final-form regulation, we ask the Board to explain how this requirement conforms to the intent of the General Assembly and is a reasonable requirement.

We ask the Board to address these same concerns related to Sections 18.826 (relating to demonstration of qualifications), 18.835 (relating to demonstration of qualifications) and 18.845 (relating to demonstration of qualifications).

9. Section 18.823. Provisional orthotist license. – Clarity and lack of ambiguity.

Subsection (a) states that a provisional license authorizes the individual to provide direct patient care under “supervision” as defined in Section 18.822(a) (relating to clinical residency). However, Section 18.822(a) defines “*direct* supervision.” [Emphasis added.] Section 18.813 (relating to provisional prosthetist license), which is a parallel provision for prosthetists, states that a provisional license authorizes the individual to provide direct patient care under *direct* supervision. [Emphasis added.] We ask the Board to clarify that a provisional orthotist must practice under “direct supervision.”

10. Section 18.831. Temporary practice permit. – Clarity and lack of ambiguity; Need for the regulation.

Subsection (d) states, “A temporary practice permit automatically expires if the permit holder fails the examination.” What examination does this provision reference? How will this provision be enforced? Can the individual immediately apply for another temporary practice permit? If the permit is valid for a maximum of one year and is nonrenewable, is this provision necessary? We ask the Board to clarify the intent of Subsection (d), and to explain why this specific provision of Subsection (d) is necessary.

These concerns also apply to Section 18.841(d) (relating to temporary practice permit).

11. Section 18.842. Orthotic fitting care experience.

Section 18.843. Orthotic fitter license. – Conforms to the intention of the General Assembly; Clarity and lack of ambiguity; Need for the regulation; Reasonableness of requirements.

Subsection (a) of Section 18.842 states that “a graduate orthotic fitter with a temporary practice permit shall practice only under the *direct supervision* of an orthotist . . .” [Emphasis added.] Paragraph (b)(3) of Section 18.843 requires an applicant to have completed “a minimum of 1,000 hours of *documented supervised* orthotic fitting care experience.” [Emphasis added.] However, Section 13.5(a)(2)(iv) of Act 90 requires orthotic fitters to successfully complete “a minimum of 1,000 hours of *documented patient care*.” 63 P.S. § 422.13e(a)(2)(iv). We ask the Board to explain how these provisions conform to the intent of the General Assembly, and why it is reasonable and necessary for the experience to have been supervised. Additionally, we ask the Board to ensure that explicit requirements are clear in all instances where individuals are required to work under supervision.

12. Section 18.851. Scope and standards of practice. – Clarity and lack of ambiguity; Reasonableness of requirements.

Subsection (d) states that a prosthetist, orthotist, pedorthist or orthotic fitter may not accept a prescription and referral or order when the prosthetist, orthotist, pedorthist or orthotic fitter “knows, or has good cause to believe, that the device cannot be furnished within a *reasonable period of time*.” [Emphasis added.] What is considered to be a reasonable period of time? A regulation has the full force and effect of law; however, this language does not set a binding norm. The Board should revise this subsection to set clear compliance standards.

13. Section 18.852. Delegation. – Statutory authority; Conforms to the intention of the General Assembly; Clarity and lack of ambiguity.

In the Preamble regarding this section, the Board states that the regulated community employs assistants to provide support services and to complete simple tasks that do not require the education and training of a licensee. In this section, the Board provides the conditions under which a prosthetist or orthotist may delegate to an “orthotic and prosthetic assistant” or “orthotic and prosthetic technician,” and a pedorthist may delegate to “pedorthic support personnel.” The Board defines *orthotic and prosthetic assistant*, *orthotic and prosthetic technician*, and *pedorthic support personnel* in Section 18.802 (relating to definitions). We have several concerns related to delegation.

While we recognize the authority of the Board under the Act to adopt regulations as are reasonably necessary to carry out the purposes of the Act, we note that Section 13.5(j) (relating to practice by unregistered persons) of Act 90 states, “Any person who is not licensed as a prosthetist, orthotist, pedorthist or orthotic fitter shall not practice prosthetics, orthotics, pedorthics or orthotic fitting . . .” 63 P.S. § 422.13e(j). We further note that Act 90 does not provide for assistants, technicians or support personnel. Commentators assert that Act 90 clearly prohibits the delegation of patient care to non-licensed individuals. We ask the Board to explain

how Section 18.852 implements Act 90, particularly as relates to Section 13.5(j), and how the regulation conforms to the intent of the General Assembly.

Regarding the conditions for delegation, Paragraph (a)(6) requires that “the practitioner provides direct, onsite supervision of the tasks performed by a delegatee.” Senator Michael Stack and others comment that the regulation should allow for indirect supervision of non-licensed professionals in the area of basic orthotic fittings, particularly diabetic shoes and inserts. These members of the regulated community assert that the proposed requirements are not realistic and would negatively impact employment for those non-licensed professionals who perform these basic tasks. Did the Board consider the economic or fiscal impacts on those in the regulated community who would not desire or qualify for licensure? Did the Board consider the economic or fiscal impacts on entities which would be required to have a licensed prosthetist, orthotist or pedorthist present to provide direct supervision? We ask the Board to explain its consideration of this segment of the regulated community, and to revise its responses to the RAF to address the impact on this segment of the regulated community.

As a point of clarity regarding Paragraph (a)(6), which addresses “the practitioner,” we note that the other paragraphs under Subsection (a) address “the practitioner *delegating the task.*” [Emphasis added.] We ask the Board to clarify that this paragraph also addresses “the practitioner delegating the task.”

14. Section 18.853. Unprofessional and immoral conduct. – Clarity and lack of ambiguity.

Subsection (a) states, “A licensee under this subchapter is subject to refusal of license or permit or disciplinary action under [S]ections 22 and 41 of the [Act] (63 P.S. §§ 422.22 and 422.41).” Subsections (b) and (c) list what is considered unprofessional or immoral conduct. Subsection (a) does not reference unprofessional or immoral conduct, nor does the Board state a direct connection between Subsection (a) and Subsections (b) and (c). We recognize that Section 41(8)(ii) of the Act authorizes the Board to promulgate regulations which define the accepted standard of care related to unprofessional and immoral conduct. We recommend that the Board amend Subsections (b) and (c) to reference Section 41(8) of the Act to ensure that the connection between Subsection (a) and Subsections (b) and (c) is clear for the regulated community.

We recommend that the Board further amend Subsections (b) and (c) to include a reference to the Board’s existing regulation at 49 Pa. Code § 16.61 (relating to unprofessional and immoral conduct). The Board should state that Subsections (b) and (c) are supplemental to Section 16.61, and make clear which provisions take precedence in the event of inconsistencies between Section 16.61 and Subsections (b) and (c).

Finally, Subsection (b)(13) consists of a single sentence that uses the word “or” seven times without any punctuation to provide guidance to the reader. We ask the Board to clarify this provision, particularly with respect to the final phrase: “or those of another practitioner.” What does “those” refer to?

15. Section 18.861. Biennial renewal of license. – Clarity and lack of ambiguity.

Subsection (b)(5) addresses continuing education requirements for prosthetists, orthotists, pedorthists and orthotic fitters. The provision references continuing education mandated by Section 13.5(g)(1) of the Act. However, Section 13.5(g)(1) only provides requirements for a prosthetist and an orthotist. The Board should add a reference to Section 13.5(g)(2), which provides requirements for a pedorthist and an orthotic fitter.

16. Miscellaneous clarity.

Types of certification

The Board of Certification/Accreditation International (BOC) asserts that the regulation inconsistently identifies the type of certification the Board requires. We ask the Board to review the regulation to ensure that all requirements for certification in the final regulation are clear for the regulated community.

References for disciplinary action

As noted in Comment 13, Section 18.853(a) states, “A licensee under this subchapter is subject to refusal of license or permit or disciplinary action under [S]ections 22 and 41 of the [Act] (63 P.S. §§ 422.22 and 422.41).” In Section 18.811(c) and throughout the regulation, the Board states that it may deny an application for disciplinary action in “section 41 of the [Act] (63 P.S. § 422.41) or § 18.853 (relating to unprofessional and immoral conduct).” Since Section 18.853 references Section 41 of the Act, is it necessary to cite the Act in each of the provisions related to disciplinary action?

Consistency of parallel provisions

Various parallel provisions throughout the regulation are inconsistently worded. For example,

- Section 18.811(b) refers to “a graduate permit *to practice as a prosthetist*” and Section 18.821(b) refers to “a graduate permit *to practice as an orthotist*.” [Emphasis added.] However, parallel provisions in Sections 18.831(b) and 18.841(b) refer to “a temporary practice permit” without the “to practice as...” phrase.
- Relating to graduate permits, Section 18.811(c) refers to “an application for a graduate permit” whereas Section 18.821(c) refers to “an application for *licensure as an orthotist*.” [Emphasis added.]
- Section 18.831(c) refers to “an application for a temporary practice permit *as a graduate pedorthist*,” whereas Section 18.841(c) refers to “an application for a temporary practice permit.” [Emphasis added.]

- Section 18.813(c) refers to “an application for a provisional license,” whereas Section 18.823(c) refers to “an application for a provisional license *as an orthotist.*” [Emphasis added.]

We ask the Board to ensure the language is consistent throughout the final regulation.