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July 25, 2014

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State Board of Medicine  
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Also via e mail: RA-STRegulatoryCounsel@pa.gov

RE: Proposed Rulemaking (Prosthetists, Orthotists, Pedorthists, Orthotic Fitters)

To Whom It May Concern:

I am writing of behalf of the Pennsylvania Orthotic and Prosthetic Society (POPS) to comment on the Proposed Rulemaking.

As you may be aware POPS was instrumental in initiating the licensing effort here in Pennsylvania since 2006. We worked extensively with legislators to promote an understanding of the need for licensure and to help establish language that would ensure quality care to residents of the Commonwealth. The first bill was introduced in 2007 (HB2015), followed by HB255 (2009), HB 48 (2011) and amendment HB2242 (2014). Our comments are based on the history of the new law, its intent and why the statute which pre-existed was inadequate to assure that optimal quality of care would be available to residents of the Commonwealth.

I would first like to express concern that POPS was not listed under *Background and Need for Amendments* as a stakeholder. POPS represents orthotists, prosthetists, pedorthists, orthotic fitters, facilities and suppliers in the Commonwealth. As such should be considered a primary stakeholder. Although discussions were held, I do not believe there was an equitable exchange among true stakeholders. POPS is however, grateful for the opportunity to attend the meetings of the Allied Health Committee.

That being said, the following are the comments of the Pennsylvania Orthotic and Prosthetic Society, most of which reflect inconsistencies in the proposed regulations and the explicit language of Act 90 and Act 104.

**General Provisions**

**18.802. Definitions**

*CAAHEP* - This entity does not appear and is not included in the language of ACT 90 nor any prior bills relating to licensure. It is "one" accreditor of programs as is ABHES -Accrediting Bureau of Health Education Schools (ABHES is the only program accreditor approved by the US Dept of Education and is also recognized by the Council For Higher Education Accreditation)CAAHEP was not created until 1994. The reference to CAAHEP in the Regulations would not be consistent with the language or intent of the statute. It would also restrict individuals certified prior to the CAAHEP creation date of 1994, from qualifying for a license. It would bias educational program accreditors by eliminating others such as ABHES which is also recognized by the Council for Higher Education Accreditation.

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*Custom-designed device*- there is no category such as this recognized by CMS or the orthotics and prosthetics industry. The appropriate definition and term is Custom-fabricated device which is referenced under this section. therefore use of this definition or term is redundant and creates ambiguity.

*ICE*- The Institute for Credentialing Excellence is a developer of standards for both certification programs and it is both a provider of and a clearing house for information on trends in certification, test development and delivery, assessment-based certificate programs, and other information relevant to the credentialing community.

*NCCA*- The National Commission for Certifying Agencies or its successors. The NCCA helps to ensure the health, welfare, and safety of the public through the accreditation of a variety of individual certification programs that assess professional competency

*NCOPE*- This entity does not appear and is not included in the language of Act 90 nor any prior bills . NCOPE was not created until 1999. The reference to NCOPE in the Regulations would not be consistent with the language or intent of the statute. It would also restrict individuals certified prior to the creation date of 1999, from qualifying for a license.

*Orthotic and prosthetic assistant*- This class of provider does not appear and is not included in the language of Act 90, nor any prior bills . CMS does not recognize such class. There is no taxonomy code for this class. The very purpose of the law was to make clear that only licensed individuals are permitted to provide orthotic, prosthetic, pedorthic care . Delegation of patient care should only be to licensed individuals such as orthotists, prosthetists, pedorthists, orthotic fitters, occupational therapists, physical therapists, and athletic trainers (within the scope of their practice)

*Orthotic and prosthetic technician*- This class does not appear and is not included in Act 90. These are not patient care providers. These are assemblers or manufacturing personnel who may or may not work onsite at an orthotic and prosthetic facility. (Individuals not applicable to Act 90, technicians, administrative personnel, shipping receiving, purchasing agents)

*Pedorthic Device*-

(ii)" The term does not include the following " is NOT in Act 90 and contradicts the actual language which specifically states " **AND** non therapeutic accommodative footwear, regardless of method etc..."  
Therefore those non therapeutic accommodative footwear etc are statutorily included  
The insertion of this section is not in accordance with the language or intent of the statute and would modify the description of a pedorthic device as provided in Act 90.

#### **18.812. Clinical Residency**

- (a) A graduate prosthetist shall practice only under a licensed prosthetist in the Commonwealth (A BOC certified or ABC certified prosthetist can not practice unless licensed, so that language should be deleted)
- (b) NCOPE needs to be deleted since it does not appear in Act 90 nor any prior bill relative to licensure.. Rather the language should say.  
"The clinical residency shall be in accordance with BOC or ABC certification guidelines"

#### **18.814. Prosthetist license**

- (a) As set forth in the Act the language should say Requires 4 years education, training and/or work experience consisting of a bachelors degree with a major in prosthetics, or orthotics and prosthetics and 3800 hours of direct patient care experience. There is no requirement within Act 90 or reference to CAAHEP. (see comments above under definitions) Certification program must be accredited by NCCA.

#### **18.815. Alternate pathway for prosthetist license**

- (a) Through March 31, 2015 an individual may apply for a license as a prosthetist without exam by submitting an application for licensure without exam, paying the application fee and providing documentation to the Board that the applicant meets the qualifications pursuant Act 104.

#### **18.816. Demonstration of qualifications**

These were only requirement under the licensing without exam and have been amended through Act 104. Act 90 did not have these requirements under licensing with exam.

#### **18.821. Graduate Permit**

- (2) CAAHEP is not a recognized entity under Act 90 (see above descriptions) This reference should be deleted.

(3) NCOPE is not a recognized entity under Act 90 (see above descriptions) This reference should be deleted and replaced with: Has registered with a clinical residency in accordance with BOC or ABC certification guidelines

**18.822. Clinical residency**

(a) A graduate orthotist shall practice only under a licensed orthotist in the Commonwealth (A BOC certified or ABC certified orthotist can not practice unless licensed, so that language should be deleted)

(b) NCOPE is not a recognized entity under Act 90 (see above descriptions) This reference should be deleted and replaced with: Has registered with a clinical residency in accordance with BOC or ABC certification guidelines

**18.823. Provisional orthotist license**

(2) CAAHEP is not a recognized entity under Act 90 (see above descriptions) This reference should be deleted.

(3) NCOPE is not a recognized entity under Act 90 (see above descriptions) This reference should be deleted and replaced with: Has completed a clinical residency in accordance with BOC or ABC certification guidelines

**18.824. Orthotist license.**

(2) (should say) Requires 4 years education, training and/or work experience consisting of a bachelors degree with a major in orthotics, or orthotics and prosthetics and 3800 hours of direct patient care experience. There is no requirement within Act 90 or reference to CAAHEP. (see comments above under definitions) Certification program must be accredited by NCCA.

**18.825 Alternate pathway for orthotist license.**

(a) Through March 31, 2015 an individual may apply for a license as an orthotist without exam by submitting an application for licensure without exam, paying the application fee and providing documentation to the Board that the applicant meets the qualifications pursuant Act 104.

**18.826. Demonstration of qualifications**

These were only requirement under the licensing without exam and have been amended through Act 104. Act 90 did not have these requirements under licensing with exam.

**18.831. Temporary Practice Permit**

(2) NCOPE needs to be deleted since it does not appear in Act 90 nor any prior bill.

Rather the language should say.

"Has successfully completed a precertification education program in accordance with BOC or ABC (or its successors) certification guidelines"

**18.832. Patient Fitting Experience**

(a) should say "only under the direct supervision of a licensed pedorthist, orthotist or prosthetist."

**18.833. Pedorthist license**

(2) NCOPE needs to be deleted since it does not appear in Act 90 nor any prior bill.

Rather the language should say.

"Has successfully completed a pedorthic education program in accordance with BOC or ABC (or its successors) certification guidelines" Certification program must be accredited by NCCA.

**18.834. Alternate pathway for pedorthist license.**

(a) Through March 31, 2015 an individual may apply for a license as an pedorthist without exam by submitting an application for licensure without exam, paying the application fee and providing documentation to the Board that the applicant meets the qualifications pursuant Act 104.

**18.835. Demonstration of qualifications**

This section should be revised to reflect amendment by Act 104

**18.841. Temporary practice permit**

(2) NCOPE needs to be deleted since it does not appear in Act 90 nor any prior bill.

"Has successfully completed an orthotic fitter education program in accordance with BOC or ABC (or its successors) certification guidelines"

**18.842 Orthotic fitting care experience**

(a) A graduate orthotic fitter shall practice only under a licensed orthotist, pedorthist or orthotic fitter in the Commonwealth  
(A BOC certified or ABC certified orthotist or orthotic fitter cannot practice unless licensed, so that language should be deleted)

**18.843. Orthotic Fitter license**

(2) NCOPE needs to be deleted since it does not appear in Act 90 nor any prior bill.  
Rather the language should say.

"Has successfully completed an orthotic fitter education program in accordance with BOC or ABC (or its successors) certification guidelines" Certification program must be accredited by NCCA

**18.844. Alternate pathway for orthotic fitter license.**

(a) Through March 31, 2015 an individual may apply for a license as an orthotic fitter without exam by submitting an application for licensure without exam, paying the application fee and providing documentation to the Board that the applicant meets the qualifications pursuant Act 104.

**18.845. Demonstration of qualifications**

This section should reflect the amendments made by Act 104.

**18.852 Delegation**

Act 90 clearly prohibits the delegation of patient care to non licensed individuals.

"(j) Any person who is not licensed as a prosthetist, orthotist, pedorthist, or orthotic fitter shall not practice prosthetics, orthotics, pedorthics or orthotic fitting."

The language and intent of the law are clear that only licensed individuals are permitted to provide orthotic, prosthetic, pedorthic care. Delegation of patient care, if at all should only be to licensed individuals such as orthotists, prosthetists, pedorthists, orthotic fitters, occupational therapists, physical therapists, athletic trainers (within the scope of their practice). No prior bills included language that would permit delegation of patient care.

(1)

ABC has established its own individual certification classes for other than orthotists, prosthetists, pedorthists and orthotic fitters, the BOC has not. ABC has established standards of delegation to these classes of providers, however delegating would be unique to ABC certifees only and would not be representative of the entire Orthotic, Prosthetic, Pedorthic Community and should not be deemed as "standards of acceptable practice". CMS does not recognize orthotic, prosthetic, or pedorthic assistants as a class of provider.

The principal purpose of Act 90 was to assure that the residents of the Commonwealth are treated only by qualified individuals. There is no provision in the Act for delegation of clinical responsibilities to any unlicensed person. To allow this will open the door to abuse and contradicts the very reason for the law.

In summary I would like to point out that Act 90 does not require that certification be maintained and POPS does not believe that should be a requirement for license renewal. Additionally, application for licensure appears to extend to anyone in any state. POPS believes the regulations should require the individual be working for a company located within the Commonwealth.

If this letter raises any questions or if you would like further elaboration on the points set forth, please do not hesitate to contact me.

Thank you for your consideration.

Sincerely,

Eileen Levis  
President