

3062



R.J. HEDGES

& ASSOCIATES YOUR COMPLIANCE EXPERTS FOR TODAY AND TOMORROW

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September 5, 2016

Independent Regulatory Review Commission  
333 Market St, 14<sup>th</sup> Floor  
Harrisburg, PA 17101

Subject: IRRC Number 3062

IRRC Members

I am submitting the following comments per the IRRC request for IRRC Number 3062, Regulation # 16A-4943: Prosthetists, Orthotists, Pedorthists and Orthotic Fitters.

I submitted comments to the Bureau of Professional and Occupational Affairs on February 1, 2016, concerning the inclusion of pharmacists in Section 15.5(d) Exceptions. (Attached). On page 18 of the Regulatory Analysis form for PA Code 49 PA Code 16.11, 16.13 and 18.801-18.864, under Comments following Advance Notice of Final Rulemaking, paragraph two, the board concluded: "The Board believes it is highly unlikely that CMS or any other Federal agency would ignore the plain provisions of the act."

I submit that CMS has and will exclude licensed pharmacists from dispensing diabetic shoes to Medicare and Medicaid patients under the state licensing guidelines.

Two states have implemented similar laws for Orthotics and Prosthetics (O&P) where the statute did not recognize pharmacists as license professionals.

- Ohio – The Pennsylvania O&P bill was crafted from the Ohio legislation. On December 31, 2015, the regulation was amended to permit pharmacists to dispense diabetic shoes because CMS and other insurance carriers prohibited pharmacists from practicing within the Scope of Practice.
  - HB 326, effective 10/05/2015:
    - <http://archives.legislature.state.oh.us/bills.cfm?ID=130> HB 326
  - Change to Ohio's code: 4729-5-23, effective 12/31/2015
    - Here's the rule: <http://codes.ohio.gov/oac/4729-5-23>
- Oklahoma – Changed their statute to include pharmacists as a recognized license professional within their statute. Similar to what occurred in Ohio.

Three states had O&P laws which limited or prohibited pharmacists from dispensing diabetic shoes.

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- Illinois – has not changed the state O&P regulations and CMS prohibits pharmacists to dispense diabetic shoes. Access to diabetic shoes in southern Illinois is still an issue. Patients go to Indiana, Kentucky and Missouri to see a supplier of diabetic shoes.
- Alabama and Mississippi had to change the pharmacist scope of practice to specifically state a Licensed Pharmacist may dispense any and all O&P products or devices.

License pharmacists now possess a Doctorate of Pharmacy and work with the patient and their physician's to manage the patient's healthcare. A pharmacist has intimate knowledge of the patient's disease management and specifically manages the patient's diabetic conditions. Other than the patient's Primary Care Physician (PCP), the pharmacist has the next highest access to the patient's health care and the most impact on their medication compliance.

If this regulation goes into effect as written, thousands of Pennsylvania residents will lose access to the only preventative medicine Medicare permits, diabetic shoes. Patient access will be further limited when CMS eliminates the billing codes for Orthotic Fitters to dispense O&P products, which can be as early as January 1, 2017.

The legislature recognized the importance of pharmacists in providing medication and O&P services to Pennsylvania residents and was supported by all pharmacy organizations within the Commonwealth. This bill (HR2242) received unanimous votes in both the House and Senate and was signed into law by then Governor Corbett. I respectfully submit these comments for further review before the final decision.

Sincerely,



R. Jeffrey Hedges, CDME  
President & CEO

Enclosures

Bureau of Professional and Occupational Affairs, Public Comment, dated 08/07/2014

Bureau of Professional and Occupational Affairs, Public Comment, dated 02/01/2016

cc:

Representative Dave Reed  
Representative Tara Tollhill  
Representative Michael Baker  
Senator Don White  
Pennsylvania Pharmacist Association  
Keystone Pharmacy Purchasing Alliance  
Value Drug Company

## Current Regulatory Requirements of DMEPOS Suppliers from a Federal Level

References to the Centers for Medicare and Medicaid Services (CMS) above. CMS sets the standards for Medicare, Medicaid, Tri-Care and insurance companies to follow.

Suppliers of Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) must meet a variety of federally mandated requirements just to open their doors to the public. Requirements include:

- Durable Medical Equipment Suppliers
  - Must follow the Medicare Quality Standards and Suppliers Standards
  - CMS on-site inspection, moving from a tri-annual to annual inspection
  - Accredited with one of the CMS 10 approved accrediting bodies
  - Over 50% of dispensed products are audited
  - Over 80% of diabetic shoes are now being audited
  - PA DME facilities have been decimated by the CMS Competitive Bidding program. Over 50% of PA DME facilities have gone out of business since 2012
- Pharmacies
  - Must meet all the requirements above, plus
  - Meet the state Pharmacy Board of Pharmacy regulations
  - PA Code 24.14(a) "A pharmacy shall maintain a supply of drugs and devices adequate to meet the needs of the health professions and the patients it is intended to serve."
  - Pharmacists are now Doctors of Pharmacy (PharmD), with seven (7) years of college. Pharmacists are now part of the triad of patient care, physicians, pharmacists and patients and are involved with the treatment and medication recommendations.
- Orthotists, Prosthetists, Orthotic Fitters and Pedorthists
  - Must meet all of the requirements for the Durable Medical Equipment Suppliers, plus:
  - Meet strict educational requirements
    - Orthotists & Prosthetists now must have a Master's Degree in O&P
    - There are only three (3) universities accredited for this degree program and enrollment is declining
    - Credentialed by the American Board for Certification in Orthotics, Prosthetics & Pedorthics (ABC) or the Board of Certification / Accreditation Int'l (BOC)
    - Within the next five (5) years there will be a severe national shortage of Orthotists and Prosthetists as retirements far surpass the number of professionals coming into the profession
  - Orthotic Fitters have been targeted by CMS and can only fit prefabricated, Off-The-Shelf orthotic devices in states where there is no licensure requirement
    - CMS is moving most orthotic braces, non-custom, to Off-The-Shelf and is preparing to move these products to the competitive bid program
    - HCPCS codes for Orthotic Fitters are to be removed from approved billing codes, possibly as early as 01/01/2017.
    - This will eliminate the entire profession
  - Almost 100% of O&P products are now being audited
    - 75% of claims are denied by CMS due to errors, most are due to physician's clinical notes
    - O&P facilities are struggling to stay in business, and many have closed across the country



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February 1, 2016

Pennsylvania Department of State  
Teresa Lazo, Assistant Counsel  
Bureau of Professional and Occupational Affairs  
2601 N Third St  
P.O. Box 2649  
Harrisburg, PA 17105-2649

Subject: Public Comment for the Final Regulations PA 16A-4943

Ms. Lazo:

I am reviewing the final regulation for the Orthotic and Prosthetic regulation which has been written following the original Act 90 law enacted on July 6, 2012 and not Act 104 (HB 2242) (signed into law on July 3, 2014).

I have grave concerns about this regulation, how it is written, omissions from the Act that was passed into law, additions that were added which are outside the scope, and intent of the actual law passed on July 3, 2014.

Eileen Levis is submitting comments on behalf of POPS, which specifically relates to the practice of O&P and how this regulation will actual dramatically, reduce the ability for Pennsylvania citizens to access O&P products. I concur with her submission.

My comments are for my clients, independent pharmacies and Durable Medical Equipment facilities here in Pennsylvania and not from any other professional organizations, which I am affiliated.

The bill passed both the House and Senate with unanimous votes. There are key definitions to protect the rights of licensed pharmacist and other licensed disciplines to dispense diabetic shoes. With out these references in the final regulation, CMS will take the Pennsylvania law at face value and will restrict "licensed professionals" who are working within their scope of practice from dispensing diabetic shoes and certain orthotic products. This type of omission has occurred in other states where pharmacies are restricted from dispensing diabetic.

I am requesting the following paragraphs that are in the Act be placed in the regulation.

§ 18.802. Definitions.

"Health care practitioner." [An individual, other than a physician assistant, who is authorized to practice some component of the healing arts by a license, permit, certificate or registration issued by a Commonwealth licensing agency or board.] As defined in section 103 of the act of July 19, 1979 (P.L.130, No.48), known as the Health Care Facilities Act.

\* \* \*

"Pharmacist." As defined in section 2(10) of the act of September 27, 1961 (P.L.1700, No.699), known as the Pharmacy Act.

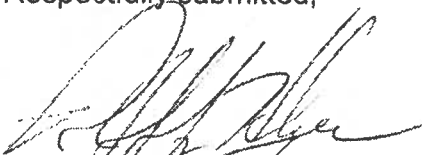
This section is NOT listed in the final regulation:

Section 15.5 (d): Exceptions.

(2) Nothing in this section shall prohibit an individual, INCLUDING, BUT NOT LIMITED TO, A PHARMACIST, PODIATRIST OR PHYSICIAN, from engaging in the practice for which that individual is licensed, registered or certified to practice or to act within the scope of that license, registration or certification held in this Commonwealth.

If you have any questions, please contact me at 724-357-8381 or via email: [Jeff.Hedges@RJHedges.com](mailto:Jeff.Hedges@RJHedges.com).

Respectfully submitted,



R. Jeffrey Hedges, CDME  
President & CEO



**R.J. HEDGES**

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August 7, 2014

Pennsylvania Department of State  
Teresa Lazo, Assistant Counsel  
Bureau of Professional and Occupational Affairs  
2601 N Third St  
P.O. Box 2649  
Harrisburg, PA 17105-2649

Subject: Public Comment for Act 90

Ms. Lazo:

The following comments are for the original Act 90 law enacted on July 6, 2012 and not Act 104 (HB 2242) (signed into law on July 3, 2014). I have coordinated these comments with the Pharmacy, Durable Medical Equipment, and Mastectomy organizations within the Commonwealth. The Board of Certification/Accreditation Int'l (BOC)'s comments are also included within this letter.

I have also communicated with PAMS, but they wish to submit their own comments. POPS has received these comments, but has not responded to my inquiries.

If you have any questions, please contact me at 724-357-8381 or via email: [Jeff@RJHedges.com](mailto:Jeff@RJHedges.com). I look forward working with you, your department as these regulations are constructed, and the additional comment period with Act 104 later in the regulation editing process.

#### **Comments on PA O&P Licensure Regulations**

1. Definitions: (ADD)
  - a. Facility means the business location where orthotic, prosthetic, or pedorthic care is provided and has the appropriate clinical and laboratory space and equipment to provide comprehensive orthotic, prosthetic, or pedorthic care. Licensed orthotists, prosthetists, and pedorthists must be available to either provide care or supervise the provision of care by orthotic fitters or non-licensed staff.

- i. **Reason:** This clarifies that the licensed individual is a legally operating business within the Commonwealth.
  - b. Level of competence means a hierarchical position that an individual occupies within a field or profession relative to other practitioners in the profession.
    - i. **Reason:** Clarifies the profession to the practitioner
2. The type of certification required is stated inconsistently throughout the rules:
- a. 18.815.d, 18.825.d – “...shall demonstrate current National certification from an organization approved by the Board”
  - b. 18.834.b.4, 18.844.b.4 – “...holds current National certification as a [pedorthist, orthotic fitter] from a certification organization recognized by the Board.”
  - c. 18.333.b.4, 18.843.b.4 – “...holds current National certification from the ABC or the BOC.)
  - d. 18.814.8.4, 18.824.b.4 – “...credentialing organization whose certification program is accredited by NCCA.”
  - e. 18.842.a -- “... or orthotic fitter certified by the ABC or the BOC.”
  - f. 18.863.f -- “... by passing the certification examinations offered by either the ABC or the BOC. For prosthetists or orthotists, the applicable examinations are the ABC or BOC examinations required for initial certification. For pedorthists or orthotic fitters, the applicable examinations are the ABC or BOC pedorthist or orthotic fitter examination required for initial certification.”
    - i. **Proposed solution:** In 18.802, the definitions for BOC and ABC could be amended as follows (edited text in bold)
      - 1. ABC— American Board for Certification in Orthotics, Prosthetics & Pedorthics, Inc., **an National certification organization approved and recognized by the Board**, with certification programs accredited by the NCCA. The term includes a successor organization.
      - 2. BOC— Board of Certification/Accreditation International, Inc., a **National certification organization approved and recognized by the Board**, with certification programs accredited by the NCCA. The term includes a successor organization.
3. 18.832.a currently states “...shall practice only under the direct supervision of licensed Pedorthist.” In our opinion, a Pedorthist, Prosthetist, or Orthotist could supervise this individual, as therapeutic footwear is in their scopes of practice.

This would allow the candidate a larger pool of options. A precedent for including supervisors who have different certifications appears in 18.842, where an Orthotist is included as one of two options for supervision for an Orthotic Fitter's "patient fitting experience."

4. The July 7 date needs to be changed throughout.
5. 18.835.4 says that a Pedorthist needs 1,000 hours of "supervised patient fitting experience...." That is not the correct term for the experience needed by a Pedorthist. We would suggest: "supervised experience providing direct patient care in Pedorthics."

Respectfully submitted,



R. Jeffrey Hedges, CDME  
President & CEO