

<h1 style="margin: 0;">Regulatory Analysis Form</h1> <p style="margin: 0;">(Completed by Promulgating Agency)</p> <p style="margin: 0;">(All Comments submitted on this regulation will appear on IRRC's website)</p>		INDEPENDENT REGULATORY REVIEW COMMISSION	
(1) Agency: Department of State, Bureau of Professional and Occupational Affairs, State Board of Medicine		2014 JUN 30 AM 10: 41	
(2) Agency Number: 16A Identification Number: 4943		IRRC Number: 3062	
(3) PA Code Cite: 49 Pa. Code §§ 16.11, 16.13, 18.801-18.864			
(4) Short Title: Prosthetists, Orthotists, Pedorthists and Orthotic Fitters			
(5) Agency Contacts (List Telephone Number and Email Address): Primary Contact: Teresa Lazo, Board Counsel, State Board of Medicine, Department of State, P.O. Box 2649, Harrisburg, PA 17105-2649 (phone 717-783-7200) (fax 787-0251); tlazo@pa.gov. Secondary Contact: Cynthia K. Montgomery, Regulatory Counsel, State Board of Osteopathic Medicine P.O. Box 2649, Harrisburg, PA 17105-2649 (phone 717-783-7200) (fax 787-0251) cymontgome@pa.gov.			
(6) Type of Rulemaking (check applicable box): <input checked="" type="checkbox"/> Proposed Regulation <input type="checkbox"/> Final Regulation <input type="checkbox"/> Final Omitted Regulation		<input type="checkbox"/> Emergency Certification Regulation; <input type="checkbox"/> Certification by the Governor <input type="checkbox"/> Certification by the Attorney General	
(7) Briefly explain the regulation in clear and nontechnical language. (100 words or less) The act of July 5, 2012 (P.L. 873, No. 90) (Act 90) amended the Medical Practice Act of 1985 (act), to require the Board to issue licenses to prosthetists, orthotists, pedorthists and orthotic fitters, to regulate the practice of these professions and to discipline licensees.			
(8) State the statutory authority for the regulation. Include specific statutory citation. The amendments are authorized under sections 8 and 13.5 (c) of the Medical Practice Act of 1985 (act) (63 P.S. §§ 422.8 and 422.13e(c)).			
(9) Is the regulation mandated by any federal or state law or court order, or federal regulation? Are there any relevant state or federal court decisions? If yes, cite the specific law, case or regulation as well as, any deadlines for action. Yes, the State Board of Medicine (Board) makes these changes to conform the Board's regulations to the amendments made to the act by Act 90.			

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(10) State why the regulation is needed. Explain the compelling public interest that justifies the regulation. Describe who will benefit from the regulation. Quantify the benefits as completely as possible and approximate the number of people who will benefit.

The rulemaking is required to implement Act 90.

(11) Are there any provisions that are more stringent than federal standards? If yes, identify the specific provisions and the compelling Pennsylvania interest that demands stronger regulations.

There are no Federal licensure standards.

(12) How does this regulation compare with those of the other states? How will this affect Pennsylvania's ability to compete with other states?

This rulemaking implements the statutorily-mandated creation of new classes of licensees. Thirteen states in addition to this Commonwealth license these professions, with statutory and regulatory requirements for licensure, continuing education and liability insurance being similar in all of the states.

Professionals in states with licensure are eligible for reimbursement by public and private insurers. Accordingly, the implementation of licensure in this Commonwealth is advantageous to the new licensees.

(13) Will the regulation affect any other regulations of the promulgating agency or other state agencies? If yes, explain and provide specific citations.

The regulation will not affect other regulations of the Board or other state agencies.

(14) Describe the communications with and solicitation of input from the public, any advisory council/group, small businesses and groups representing small businesses in the development and drafting of the regulation. List the specific persons and/or groups who were involved. ("Small business" is defined in Section 3 of the Regulatory Review Act, Act 76 of 2012.)

Following enactment of Act 90 on July 5, 2012, a draft rulemaking was prepared. On August 14, 2012, the Board provided the draft to stakeholders, including members of the regulated community and their association representatives; representatives from the University of Pittsburgh's prosthesis and orthotic educational program; representatives from the Temple University School of Podiatry, which operates a podiatric education program; the Pennsylvania Medical Society and physician specialty organization in orthopedics; representatives from the House Professional Licensure Committee (HPLC) and Independent Regulatory Review Commission (IRRC); the two National credentialing bodies for the profession, the American Board of Certification (ABC) and the Board of Certification (BOC).

A meeting with stakeholders was held on September 10, 2012. After making amendments to the draft based on comments received during and after the September 10, 2012, meeting, the Board provided another draft of the rulemaking to the stakeholders on November 27, 2012.

On December 4, 2012, the Board again met with stakeholders regarding the draft rulemaking. Additional amendments were made based on input from the stakeholders. At its

February 6, 2013, meeting, the Board approved the draft rulemaking for publication as proposed rulemaking.

The entire regulation package was prepared and reviewed internally. A few additional questions arose during the review process, and on November 12, 2013, these questions were posed to stakeholders via email. The stakeholders responded by November 20, 2013, and based on the responses, additional edits were made to the proposed annex. The most significant changes included providing that the graduate permit for prosthetists and orthotists would be valid for up to 90 days after successful completion of the clinical residency or until a provisional license was issued, whichever happened sooner. This change was made so that these individuals would not be required to stop working in the field for a period of several months while the provisional license application was processed. In addition, a new section was added to the annex related to delegation to unlicensed assistive personnel, and definitions were added to further identify the unlicensed assistive personnel.

(15) Identify the types and number of persons, businesses, small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012) and organizations which will be affected by the regulation. How are they affected?

Based on information provided by the two certifying bodies, the ABC and BOC, there are currently approximately 130 prosthetists, 220 orthotists, 150 pedorthists and 150 orthotic fitters working in Pennsylvania, for a total of 650 licensees. According to the Pennsylvania Department of Labor and Industry (L&I) in 2010, the majority (52.3%) of prosthetists and orthotists work in medical equipment and supplies manufacturing, while a minority (7.2%) work for the Federal government. Other prosthetists and orthotists work in health and personal care stores, offices of other health practitioners, general medical and surgical hospitals, offices of physicians, and commercial goods merchant wholesalers. Unfortunately, L&I does not have statistics for pedorthists or orthotic fitters.

For the business entities listed above, small businesses are defined in Section 3 of the Regulatory Review Act, Act 76 of 2012, which provides that a small business is defined by the U.S. Small Business Administration's Small Business Size Regulations under 13 CFR Ch. 1 Part 121. These size standards have been established for types of businesses under the North American Industry Classification System (NAICS). In applying the NAICS standards to the types of businesses where prosthetists and orthotists work, a small business in medical equipment and supplies manufacturing is one with 500 or fewer employees for surgical and medical instrument manufacturing as well as for surgical appliance and supplies manufacturing and for all other miscellaneous manufacturing. There are no small business size standards for Federal government agencies under the NAICS standards. For health and personal care stores, the threshold for a small business is \$7.0 million or less in total income annually. For general medical and surgical hospitals, the NAICS threshold for small businesses is \$35.5 million or less in total annual income while in offices of physicians, the threshold is \$10.0 million or less in total annual income. Although commercial goods merchant wholesalers are not specifically included in the NAICS size standards, a small business is one with 100 employees or less in the following categories: "other commercial equipment merchant wholesalers," "medical, dental, and hospital equipment and supplies merchant wholesalers," and "other professional equipment and supplies merchant wholesalers."

For comparison purposes, the BOC indicated that the majority of individuals they certify work in medical supply stores (as noted above for health and personal care stores) or pharmacies (which have an NAICS threshold of \$25.5 million or less in total income annually). Prosthetists and Orthotists are more likely to work in an institutional setting, or in manufacturing. Thus, it is likely that the vast majority of the prosthetists and orthotists are working in small businesses as defined in the North American Industry Classification System (NAICS).

According to the Small Business Administration (SBA), there are approximately 982,692 businesses in Pennsylvania; of which 978,831 are small businesses; and 3,861 are large businesses. Of the 978,831 small businesses, 236,775 are small employers (those with fewer than 500 employees) and the remaining 772,056 are non-employers. Thus, the vast majority of businesses in Pennsylvania are considered small businesses.

The licensees/small businesses will be affected by the statutory requirements of licensure, liability insurance and continuing education (CE). Individuals practicing in these areas will be required to obtain a license in order to continue practicing. Once the license is obtained, licensees will be required to maintain liability insurance in order to practice. Licensees will be required to renew their licenses biennially, which requires completion of CE. All of these activities have associated costs.

(16) List the persons, groups or entities, including small businesses, that will be required to comply with the regulation. Approximate the number that will be required to comply.

As noted in the response to question (15), all individuals providing the services described in the statute will be required to obtain and maintain licensure and comply with the associated statutory provisions. It is estimated that virtually all of the individual licensees are either small businesses themselves or are employed by small businesses.

(17) Identify the financial, economic and social impact of the regulation on individuals, small businesses, businesses and labor communities and other public and private organizations. Evaluate the benefits expected as a result of the regulation.

Act 90 requires prosthetists, orthotists, pedorthists and orthotic fitters to complete continuing education (CE). Prosthetists and orthotists must complete 24 hours biennially; pedorthists and orthotic fitters must complete 13 hours biennially. Online courses for prosthetists and orthotists cost \$20 - \$50 per credit, or a total of \$480 - \$1200 for 24 credits. Attendance at a National conference, such as that held by the American Academy of Orthotics and Prosthetics would cost more. The Board will use the figure of \$1,000 as an average cost for compliance with the CE requirement, or \$500 per year. Multiplied by the 350 prosthetists and orthotists who must comply with the provision yields an annual cost of \$175,000 for these licensees.

Pedorthists and orthotic fitters can obtain CE for about \$25 per credit through various sources approved by ABC and/or BOC. Compliance with 13 hours of CE is estimated to cost $\$25 \times 13 = \$325 / 2 = \$162.50$ (annual cost) $\times 300$ licensees = \$48,750.

The total cost of CE for all 650 licensees is approximately \$223,750.00 annually.

Act 90 also requires prosthetists, orthotists, pedorthists and orthotic fitters to maintain professional liability insurance. Costs of insurance vary greatly, depending upon the type of licensee, the licensee's practice, the practice setting, the geographic location and whether the licensee works full-time or part-time.

Information was obtained from the American Academy of Orthotics and Prosthetics regarding the cost of liability insurance for the various licensees. The minimum cost of liability insurance is \$2,000 per year, and the potential maximum cost of liability insurance is \$150,000 per year. There is great variation in the cost of liability insurance because of the different roles these licensees might fill, from manufacturer, distributor, retailer to facilities only, retailer to patients generally, retailer to the practitioner's own patients, providing patient care, working only as part of an orthopedic rehabilitation team, etc. It was estimated that a sole proprietor involved only in sales of stock merchandise to individuals for whom the proprietor provided patient care would cost between \$5,000 and \$8,000 for pedorthists and orthotic fitters and between \$8,000 and \$15,000 for orthotists and prosthetists.

Because of the wide variability, it is impossible to estimate with accuracy the aggregate cost of liability insurance for the 650 licensees. Nevertheless, the Board is required to do so. Accordingly, the Board will estimate that the average cost of liability insurance will be approximately \$10,000 per year. For the 650 total licensees, the total cost to the regulated community will be approximately \$6,500,000.

The combined CE and insurance costs for all licensees is approximately \$6,723,750 per year.

Aggregated costs of initial licensure are estimated at \$28,000. For the first year of licensure, the total annual costs will be approximately \$6,751,750. Biennial renewal fee expenses will be \$47,625, so the total costs for the second and fourth years will be \$6,771,375. The costs for the third and fifth years will be only for CE and insurance of \$6,723,750.

Not all of the financial and economic impact of the regulation will be negative due to the CE and insurance requirements. Continuing education providers and insurers will benefit from these new costs.

(18) Explain how the benefits of the regulation outweigh any cost and adverse effects.

The General Assembly determined that the public who receives the services of these four groups of professionals, or new licensees, will benefit from these changes by being assured of a minimum level of competence because licensees must meet certain qualifications for licensure and must complete CE to renew their licenses; and by being assured of the ability to recover for injuries caused by negligent practice due to the professional liability insurance coverage mandate.

(19) Provide a specific estimate of the costs and/or savings to the **regulated community** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

See the answer to question 17 for information on the costs.

(20) Provide a specific estimate of the costs and/or savings to the **local governments** associated with compliance, including any legal, accounting or consulting procedures which may be required. Explain how the dollar estimates were derived.

There are no costs or savings to local governments associated with compliance with the rulemaking.

(21) Provide a specific estimate of the costs and/or savings to the **state government** associated with the implementation of the regulation, including any legal, accounting, or consulting procedures which may be required. Explain how the dollar estimates were derived.

Operations of the Board are supported entirely from fees paid by licensees, so there are no costs to state government from the Board's operations.

(22) For each of the groups and entities identified in items (19)-(21) above, submit a statement of legal, accounting or consulting procedures and additional reporting, recordkeeping or other paperwork, including copies of forms or reports, which will be required for implementation of the regulation and an explanation of measures which have been taken to minimize these requirements.

See the answer to question 17 for information on the costs to the regulated community.

(23) In the table below, provide an estimate of the fiscal savings and costs associated with implementation and compliance for the regulated community, local government, and state government for the current year and five subsequent years.

	Current FY Year	FY +1 Year	FY +2 Year	FY +3 Year	FY +4 Year	FY +5 Year
SAVINGS:	\$	\$	\$	\$	\$	\$
Regulated Community						
Local Government						
State Government						
Total Savings						
COSTS:						
Regulated Community	0	\$6,751,750	\$6,771,375	\$6,723,750	\$6,771,375	\$6,723,750
Local Government						
State Government						
Total Costs	0	\$6,751,750	\$6,771,375	\$6,723,750	\$6,771,375	\$6,723,750
REVENUE LOSSES:						
Regulated Community						
Local Government						
State Government						
Total Revenue Losses						

(23) Provide the past three year expenditure history for programs affected by the regulation.

Program

State Board of Medicine	FY -3 (FY 2010-11)	FY -2 (FY 2011-12)	FY -1 (FY 2012-13)	Current FY (Budgeted)
	\$4,850,758.87	\$5,432,876.38	\$5,863,561	\$6,948,000

(24) For any regulation that may have an adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), provide an economic impact statement that includes the following:

- (a) An identification and estimate of the number of small businesses subject to the regulation.
- (b) The projected reporting, recordkeeping and other administrative costs required for compliance with the proposed regulation, including the type of professional skills necessary for preparation of the report or record.
- (c) A statement of probable effect on impacted small businesses.
- (d) A description of any less intrusive or less costly alternative methods of achieving the purpose of the proposed regulation.

(a) As noted in the answer to question 15, there are currently approximately 130 prosthetists, 220 orthotists, 150 pedorthists and 150 orthotic fitters working Pennsylvania. Virtually all of these licensees either are small businesses or work in small businesses. Thus, 650 small businesses will be subject to the regulation.

(b) As stated in the answer to question 17, aggregated costs of initial licensure are estimated at \$28,000. Biennial renewal fee expenses will be \$47,625. Added to the combined CME and insurance costs of \$6,723,750, the total costs to all licensees will be \$6,799,375.

(c) It is probable that these new costs will impact small businesses. However, the regulation simply effectuates statutory mandates so the Board does not have discretion in amending any of the statutory requirements.

(d) There are no less intrusive or less costly alternative methods of achieving the purpose of the final regulation because the licensure requirements were mandated by the General Assembly.

(25) List any special provisions which have been developed to meet the particular needs of affected groups or persons including, but not limited to, minorities, the elderly, small businesses, and farmers.

Other than small businesses, the Board does not believe there are any affected persons that would have particular needs.

(26) Include a description of any alternative regulatory provisions which have been considered and rejected and a statement that the least burdensome acceptable alternative has been selected.

The Board worked closely with the regulated community to understand the certification process for prosthetists, orthotists, pedorthists and orthotic fitters, and to craft regulations that comport with the National processes. In doing so, the Board had to provide a means by which a graduate could practice after completing the didactic portion of the education and prior to completing the residency or patient care portion of the education. In addition, the Board had to provide a means by which an individual who had completed the residency or patient care portion of the education, but had not yet completed the examination component, could practice.

To this end, the Board will issue Graduate Permits to prosthetists and orthotists who complete the didactic education and Provisional Licenses to individuals who have completed the residency. Full licensure may be obtained following successful completion of the examination sequence.

For pedorthists and orthotic fitters, the Board will issue a temporary practice permit to permit the individuals to complete the patient care/patient fitting experience prior to full licensure.

(27) In conducting a regulatory flexibility analysis, explain whether regulatory methods were considered that will minimize any adverse impact on small businesses (as defined in Section 3 of the Regulatory Review Act, Act 76 of 2012), including:

- a) The establishment of less stringent compliance or reporting requirements for small businesses;
- b) The establishment of less stringent schedules or deadlines for compliance or reporting requirements for small businesses;
- c) The consolidation or simplification of compliance or reporting requirements for small businesses;
- d) The establishment of performing standards for small businesses to replace design or operational standards required in the regulation; and
- e) The exemption of small businesses from all or any part of the requirements contained in the regulation.

There are no particular compliance or reporting requirements for small businesses; all licensees must meet the same qualifications and report the same CE. Small businesses could not be exempt from the regulation because the regulation effectuates statutory mandates.

(28) If data is the basis for this regulation, please provide a description of the data, explain in detail how the data was obtained, and how it meets the acceptability standard for empirical, replicable and testable data that is supported by documentation, statistics, reports, studies or research. Please submit data or supporting materials with the regulatory package. If the material exceeds 50 pages, please provide it in a searchable electronic format or provide a list of citations and internet links that, where possible, can be accessed in a searchable format in lieu of the actual material. If other data was considered but not used, please explain why that data was determined not to be acceptable.

This rulemaking is not based upon any scientific data, studies or references.

(29) Include a schedule for review of the regulation including:

- | | |
|---|-------------------------------|
| A. The date by which the agency must receive public comments: | <u>N/A</u> |
| B. The date or dates on which public meetings or hearings will be held: | <u>N/A</u> |
| C. The expected date of promulgation of the proposed regulation as a final-form regulation: | <u>June 2014</u> |
| D. The expected effective date of the final-form regulation: | <u>June 2014</u> |
| E. The date by which compliance with the final-form regulation will be required: | <u>Upon final publication</u> |
| F. The date by which required permits, licenses or other approvals must be obtained: | <u>Upon final publication</u> |

(30) Describe the plan developed for evaluating the continuing effectiveness of the regulations after its implementation.

The Board continually reviews the efficacy of its regulations, as part of its annual review process under Executive Order 1996-1. The Board reviews its regulatory proposals at regularly scheduled public meetings, which occur 10 months of the year. More information can be found on the Board's website (www.dos.state.pa.us/med).

FEE REPORT FORM

Agency: State - BPOA

Date: February 4, 2013

Contact: Katie True
Commissioner, Bureau of Professional & Occupational Affairs

Phone No. 783-7192

Fee Title, Rate and Estimated Collections:

Application for Pedorthist temporary permit: \$25.00
Estimated temporary permit revenue: \$250.00 (10 applications x \$25.00)

Fee Description:

The fee will be charged to every applicant for reactivation of a Pedorthist temporary permit.

Fee Objective:

The fee should (1) offset the identifiable costs incurred by the State Board of Medicine to process an application and (2) defray a portion of the Board's administrative overhead.

Fee-Related Activities and Costs:

Staff time-process application	(.25 hr)	8.89
Administrative Overhead:		<u>15.88</u>
	Total Estimated Cost:	\$ 24.77
	Proposed Fee:	\$ 25.00

Analysis, Comment, and Recommendation:

It is recommended that a fee of \$25.00 be established for processing an application for a Pedorthist temporary permit.

Board Staff - receives application, reviews for completeness, verifies that supporting documents are attached, contacts applicant to request any missing information and/or documents. Information provided on the application regarding criminal conviction/chemical dependency/etc. may necessitate further research and review. Board staff issues permit through computer when application is complete.

FEE REPORT FORM

Agency: State - BPOA

Date: February 4, 2013

Contact: Katie True
Commissioner, Bureau of Professional & Occupational Affairs

Phone No. 783-7192

Fee Title, Rate and Estimated Collections:

Initial application for Pedorthist license:	\$25.00
Estimated initial application revenue:	\$1875.00 (75 applications x \$25.00)

Fee Description:

The fee will be charged to every applicant for a Pedorthist license.

Fee Objective:

The fee should (1) offset the identifiable costs incurred by the State Board of Medicine to process an application and (2) defray a portion of the Board's administrative overhead.

Fee-Related Activities and Costs:

Staff time-process application	(.25 hr)	8.89
Administrative Overhead:		<u>15.88</u>
	Total Estimated Cost:	\$ 24.77
	Proposed Fee:	\$ 25.00

Analysis, Comment, and Recommendation:

It is recommended that a fee of \$25.00 be established for processing an application for a Pedorthist license.

Board Staff - receives application, reviews for completeness, verifies that supporting documents are attached, contacts applicant to request any missing information and/or documents. Information provided on the application regarding criminal conviction/chemical dependency/etc. may necessitate further research and review. Board staff issues license through computer when application is complete.

FEE REPORT FORM

Agency: State - BPOA

Date: February 4, 2013

Contact: Katie True
Commissioner, Bureau of Professional & Occupational Affairs

Phone No. 783-7192

Fee Title, Rate and Estimated Collections:

Initial application for Pedorthist license without examination:		\$25.00
Estimated initial application revenue:	\$1875.00	(75 applications x \$25.00)

Fee Description:

The fee will be charged to every applicant for a Pedorthist license without examination.

Fee Objective:

The fee should (1) offset the identifiable costs incurred by the State Board of Medicine to process an application and (2) defray a portion of the Board's administrative overhead.

Fee-Related Activities and Costs:

Staff time-process application	(.25 hr)	8.89
Administrative Overhead:		<u>15.88</u>
	Total Estimated Cost:	\$ 24.77
	Proposed Fee:	\$ 25.00

Analysis, Comment, and Recommendation:

It is recommended that a fee of \$25.00 be established for processing an application for a Pedorthist license without examination.

Board Staff - receives application, reviews for completeness, verifies that supporting documents are attached, contacts applicant to request any missing information and/or documents. Information provided on the application regarding criminal conviction/chemical dependency/etc. may necessitate further research and review. Board staff issues license through computer when application is complete.

FEE REPORT FORM

Agency: State - BPOA

Date: February 4, 2013

Contact: Katie True
Commissioner, Bureau of Professional & Occupational Affairs

Phone No. 783-7192

Fee Title, Rate and Estimated Collections:

\$75.00

Biennial Renewal Fee – Pedorthist

Estimated Biennial Revenue: \$11,250.00

(150 applications x \$75.00)

Fee Description:

The fee will be charged biennially to every Pedorthist applicant for license renewal.

Fee Objective:

The fee should defray a portion of the State Board of Medicine's administrative overhead.

Analysis, Comment, and Recommendation:

It is recommended that a renewal fee of \$75.00 be established for Pedorthist licensees, thereby causing those licensees to contribute to the operational costs of the State Board of Medicine.

FEE REPORT FORM

Agency: State - BPOA

Date: February 4, 2013

Contact: Katie True
Commissioner, Bureau of Professional & Occupational Affairs

Phone No. 783-7192

Fee Title, Rate and Estimated Collections:

Application for Reactivation of Pedorthist license:	\$25.00
Estimated reactivation revenue:	\$50.00
	(2 applications x \$25.00)

Fee Description:

The fee will be charged to every applicant for reactivation of a Pedorthist license.

Fee Objective:

The fee should (1) offset the identifiable costs incurred by the State Board of Medicine to process an application and (2) defray a portion of the Board's administrative overhead.

Fee-Related Activities and Costs:

Staff time-process application	(.25 hr)	8.89
Administrative Overhead:		<u>15.88</u>
	Total Estimated Cost:	\$ 24.77
	Proposed Fee:	\$ 25.00

Analysis, Comment, and Recommendation:

It is recommended that a fee of \$25.00 be established for processing an application for a reactivation of a Pedorthist license.

Board Staff - receives application, reviews for completeness, verifies that supporting documents are attached, contacts applicant to request any missing information and/or documents. Information provided on the application regarding criminal conviction/chemical dependency/etc. may necessitate further research and review. Board staff issues license through computer when application is complete.

FEE REPORT FORM

Agency: State - BPOA **Date:** February 04, 2013
Contact: Katie True
Commissioner, Bureau of Professional & Occupational Affairs
Phone No. 783-7192

Fee Title, Rate and Estimated Collections:

Application for Orthotic Fitter temporary permit:	\$25.00
Estimated reactivation revenue: \$500.00	(20 applications x 25.00)

Fee Description:

The fee will be charged to every licensee for an Orthotic Fitter temporary permit.

Fee Objective:

The fee should (1) offset the identifiable costs incurred by the State Board of Medicine to process a reactivation application and (2) defray a portion of the Board's administrative overhead.

Fee-Related Activities and Costs:

Staff time-process reactivation application (.50 hr)	8.89
Administrative Overhead:	<u>15.88</u>
Total Estimated Cost:	\$ 24.77
Proposed Fee:	\$ 25.00

Analysis, Comment, and Recommendation:

It is recommended that a fee of \$50.00 be established for processing an application for an Orthotic Fitter temporary permit.

Board Staff - receives application, reviews for completeness, verifies that supporting documents are attached, contacts applicant to request any missing information and/or documents. Information provided on the application regarding criminal conviction/chemical dependency/etc. may necessitate further research and review. Board staff issues permit through computer when application is complete.

FEE REPORT FORM

Agency: State - BPOA

Date: February 4, 2013

Contact: Katie True
Commissioner, Bureau of Professional & Occupational Affairs

Phone No. 783-7192

Fee Title, Rate and Estimated Collections:

Initial application for Orthotic Fitter license:		\$25.00
Estimated initial application revenue:	\$1250.00	(50 applications x \$25.00)

Fee Description:

The fee will be charged to every applicant for an Orthotic Fitter license.

Fee Objective:

The fee should (1) offset the identifiable costs incurred by the State Board of Medicine to process an application and (2) defray a portion of the Board's administrative overhead.

Fee-Related Activities and Costs:

Staff time-process application	(.25 hr)	8.89
Administrative Overhead:		<u>15.88</u>
	Total Estimated Cost:	\$ 24.77
	Proposed Fee:	\$ 25.00

Analysis, Comment, and Recommendation:

It is recommended that a fee of \$25.00 be established for processing an application for an Orthotic Fitter license.

Board Staff - receives application, reviews for completeness, verifies that supporting documents are attached, contacts applicant to request any missing information and/or documents. Information provided on the application regarding criminal conviction/chemical dependency/etc. may necessitate further research and review. Board staff issues license through computer when application is complete.

FEE REPORT FORM

Agency: State - BPOA

Date: February 4, 2013

Contact: Katie True
Commissioner, Bureau of Professional & Occupational Affairs

Phone No. 783-7192

Fee Title, Rate and Estimated Collections:

Initial application for Orthotic Fitter license without examination:	\$25.00
Estimated initial application revenue:	\$2500.00 (100 applications x \$25.00)

Fee Description:

The fee will be charged to every applicant for an Orthotic Fitter license.

Fee Objective:

The fee should (1) offset the identifiable costs incurred by the State Board of Medicine to process an application and (2) defray a portion of the Board's administrative overhead.

Fee-Related Activities and Costs:

Staff time-process application	(.25 hr)	8.89
Administrative Overhead:		<u>15.88</u>
	Total Estimated Cost:	\$ 24.77
	Proposed Fee:	\$ 25.00

Analysis, Comment, and Recommendation:

It is recommended that a fee of \$25.00 be established for processing an application for an Orthotic Fitter license without examination.

Board Staff - receives application, reviews for completeness, verifies that supporting documents are attached, contacts applicant to request any missing information and/or documents. Information provided on the application regarding criminal conviction/chemical dependency/etc. may necessitate further research and review. Board staff issues license through computer when application is complete.

FEE REPORT FORM

Agency: State - BPOA

Date: February 4, 2013

Contact: Katie True
Commissioner, Bureau of Professional & Occupational Affairs

Phone No. 783-7192

Fee Title, Rate and Estimated Collections: \$75.00

Biennial Renewal Fee – Orthotic Fitter

Estimated Biennial Revenue: \$9750.00

(130 applications x \$75.00)

Fee Description:

The fee will be charged biennially to every Orthotic Fitter applicant for license renewal.

Fee Objective:

The fee should defray a portion of the State Board of Medicine's administrative overhead.

Analysis, Comment, and Recommendation:

It is recommended that a renewal fee of \$75.00 be established for Orthotic Fitter licensees, thereby causing those licensees to contribute to the operational costs of the State Board of Medicine.

FEE REPORT FORM

Agency: State - BPOA

Date: February 4, 2013

Contact: Katie True
Commissioner, Bureau of Professional & Occupational Affairs

Phone No. 783-7192

Fee Title, Rate and Estimated Collections:

Application for Reactivation of Orthotic Fitter license:	\$25.00
Estimated reactivation revenue: \$50.00	(2 applications x 25.00)

Fee Description:

The fee will be charged to every licensee for Reactivation of an Orthotic Fitter license.

Fee Objective:

The fee should (1) offset the identifiable costs incurred by the State Board of Medicine to process a reactivation application and (2) defray a portion of the Board's administrative overhead.

Fee-Related Activities and Costs:

Staff time-process reactivation application (.50 hr)	8.89
Administrative Overhead:	<u>15.88</u>
Total Estimated Cost:	\$ 24.77
Proposed Fee:	\$ 25.00

Analysis, Comment, and Recommendation:

It is recommended that a fee of \$50.00 be established for processing a reactivation application for an Orthotic Fitter license.

Board Staff - receives application, reviews for completeness, verifies that supporting documents are attached, contacts applicant to request any missing information and/or documents. Information provided on the application regarding criminal conviction/chemical dependency/etc. may necessitate further research and review. Board staff issues license through computer when application is complete.

FEE REPORT FORM

Agency: State - BPOA

Date: February 4, 2013

Contact: Katie True
Commissioner, Bureau of Professional & Occupational Affairs

Phone No. 783-7192

Fee Title, Rate and Estimated Collections:

Initial application for Graduate Orthotist permit:	\$50.00
Estimated initial Orthotist permit revenue:	\$1000.00 (20 applications x \$50.00)

Fee Description:

The fee will be charged to every initial application for a Graduate Orthotist permit.

Fee Objective:

The fee should (1) offset the identifiable costs incurred by the State Board of Medicine to process an initial application for Graduate Orthotist permit and (2) defray a portion of the Board's administrative overhead.

Fee-Related Activities and Costs:

Staff time-process initial application (.50 hr)	17.77
Administrative Overhead:	<u>30.02</u>
Total Estimated Cost:	\$ 47.79
Proposed Fee:	\$ 50.00

Analysis, Comment, and Recommendation:

It is recommended that a fee of \$50.00 be established for processing an initial application for a Graduate Orthotist permit.

Board Staff - receives application, reviews for completeness, verifies that supporting documents are attached, contacts applicant to request any missing information and/or documents. Information provided on the application regarding criminal conviction/chemical dependency/etc. may necessitate further research and review. Board staff issues permit through computer when application is complete.

FEE REPORT FORM

Agency: State - BPOA

Date: February 4, 2013

Contact: Katie True
Commissioner, Bureau of Professional & Occupational Affairs

Phone No. 783-7192

Fee Title, Rate and Estimated Collections:

Initial application for Provisional Orthotist license:	\$50.00
Estimated initial Provisional license revenue: \$750.00	(15 applications x \$50.00)

Fee Description:

The fee will be charged to every initial application for a Provisional Orthotist license.

Fee Objective:

The fee should (1) offset the identifiable costs incurred by the State Board of Medicine to process an initial application for Provisional Orthotist license and (2) defray a portion of the Board's administrative overhead.

Fee-Related Activities and Costs:

Staff time-process initial application (.50 hr)	17.77	
Administrative Overhead:		<u>30.02</u>
Total Estimated Cost:		\$ 47.79
Proposed Fee:		\$ 50.00

Analysis, Comment, and Recommendation:

It is recommended that a fee of \$50.00 be established for processing an initial application for a Provisional Orthotist license.

Board Staff - receives application, reviews for completeness, verifies that supporting documents are attached, contacts applicant to request any missing information and/or documents. Information provided on the application regarding criminal conviction/chemical dependency/etc. may necessitate further research and review. Board staff issues license through computer when application is complete.

FEE REPORT FORM

Agency: State - BPOA

Date: February 4, 2013

Contact: Katie True
Commissioner, Bureau of Professional & Occupational Affairs

Phone No. 783-7192

Fee Title, Rate and Estimated Collections:

Initial application for Orthotist license:		\$50.00
Estimated initial application revenue:	\$10,000.00	(200 applications x \$50.00)

Fee Description:

The fee will be charged to every applicant for an Orthotist license.

Fee Objective:

The fee should (1) offset the identifiable costs incurred by the State Board of Medicine to process an application and (2) defray a portion of the Board's administrative overhead.

Fee-Related Activities and Costs:

Staff time-process application	(0.50 hr)	17.77
Administrative Overhead:		<u>30.02</u>
	Total Estimated Cost:	\$ 47.79
	Proposed Fee:	\$ 50.00

Analysis, Comment, and Recommendation:

It is recommended that a fee of \$50.00 be established for processing an application for an Orthotist license.

Board Staff - receives application, reviews for completeness, verifies that supporting documents are attached, contacts applicant to request any missing information and/or documents. Information provided on the application regarding criminal conviction/chemical dependency/etc. may necessitate further research and review. Board staff issues license through computer when application is complete.

FEE REPORT FORM

Agency: State - BPOA

Date: February 4, 2013

Contact: Katie True
Commissioner, Bureau of Professional & Occupational Affairs

Phone No. 783-7192

Fee Title, Rate and Estimated Collections:

Initial application for Orthotist license without examination		\$100.00
Estimated initial application revenue:	\$2500.00	(25 applications x \$100.00)

Fee Description:

The fee will be charged to every applicant for an Orthotist license without examination.

Fee Objective:

The fee should (1) offset the identifiable costs incurred by the State Board of Medicine to process an application and (2) defray a portion of the Board's administrative overhead.

Fee-Related Activities and Costs:

Staff time-process application	(1.5 hr)	53.31
Administrative Overhead:		<u>37.89</u>
	Total Estimated Cost:	\$ 91.20
	Proposed Fee:	\$ 100.00

Analysis, Comment, and Recommendation:

It is recommended that a fee of \$100.00 be established for processing an application for an Orthotist license without examination.

Board Staff - receives application, reviews for completeness, verifies that supporting documents are attached, contacts applicant to request any missing information and/or documents. Information provided on the application regarding criminal conviction/chemical dependency/etc. may necessitate further research and review. Board staff issues license through computer when application is complete.

FEE REPORT FORM

Agency: State - BPOA

Date: February 4, 2013

Contact: Katie True
Commissioner, Bureau of Professional & Occupational Affairs

Phone No. 783-7192

Fee Title, Rate and Estimated Collections:

\$75.00

Biennial Renewal Fee – Orthotist

Estimated Biennial Revenue: \$16,875.00

(225 applications x \$75.00)

Fee Description:

The fee will be charged biennially to every Orthotist applicant for license renewal.

Fee Objective:

The fee should defray a portion of the State Board of Medicine's administrative overhead.

Analysis, Comment, and Recommendation:

It is recommended that a renewal fee of \$75.00 be established for Orthotist licensees, thereby causing those licensees to contribute to the operational costs of the State Board of Medicine.

FEE REPORT FORM

Agency: State - BPOA

Date: February 4, 2013

Contact: Katie True
Commissioner, Bureau of Professional & Occupational Affairs

Phone No. 783-7192

Fee Title, Rate and Estimated Collections:

Application for Reactivation of Orthotist license:	\$50.00
Estimated Reactivation of Orthotist license revenue:	\$100.00 (2 applications x 50.00)

Fee Description:

The fee will be charged to every licensee for Reactivation of an Orthotist license.

Fee Objective:

The fee should (1) offset the identifiable costs incurred by the State Board of Medicine to process a reactivation application and (2) defray a portion of the Board's administrative overhead.

Fee-Related Activities and Costs:

Staff time-process reactivation application (.50 hr)	17.77
Administrative Overhead:	<u>30.02</u>
Total Estimated Cost:	\$ 47.79
Proposed Fee:	\$ 50.00

Analysis, Comment, and Recommendation:

It is recommended that a fee of \$50.00 be established for processing a reactivation application for an Orthotist license.

Board Staff - receives application, reviews for completeness, verifies that supporting documents are attached, contacts applicant to request any missing information and/or documents. Information provided on the application regarding criminal conviction/chemical dependency/etc. may necessitate further research and review. Board staff issues license through computer when application is complete.

FEE REPORT FORM

Agency: State - BPOA

Date: February 4, 2013

Contact: Katie True
Commissioner, Bureau of Professional & Occupational Affairs

Phone No. 783-7192

Fee Title, Rate and Estimated Collections:

Initial application for Graduate Prosthetist permit: \$50.00
Estimated initial Prosthetist permit revenue: \$750.00 (15 applications x \$50.00)

Fee Description:

The fee will be charged to every initial application for a Graduate Prosthetist permit.

Fee Objective:

The fee should (1) offset the identifiable costs incurred by the State Board of Medicine to process an initial application for Graduate Prosthetist permit and (2) defray a portion of the Board's administrative overhead.

Fee-Related Activities and Costs:

Staff time-process initial application (.50 hr)	17.77
Administrative Overhead:	<u>30.02</u>
Total Estimated Cost:	\$ 47.79
Proposed Fee:	\$ 50.00

Analysis, Comment, and Recommendation:

It is recommended that a fee of \$50.00 be established for processing an initial application for a Graduate Prosthetist permit.

Board Staff - receives application, reviews for completeness, verifies that supporting documents are attached, contacts applicant to request any missing information and/or documents. Information provided on the application regarding criminal conviction/chemical dependency/etc. may necessitate further research and review. Board staff issues permit through computer when application is complete.

FEE REPORT FORM

Agency: State - BPOA

Date: February 4, 2013

Contact: Katie True
Commissioner, Bureau of Professional & Occupational Affairs

Phone No. 783-7192

Fee Title, Rate and Estimated Collections:

Initial application for Provisional Prosthetist license: \$50.00
Estimated initial Provisional license revenue: \$750.00 (15 applications x \$50.00)

Fee Description:

The fee will be charged to every initial application for a Provisional Prosthetist license.

Fee Objective:

The fee should (1) offset the identifiable costs incurred by the State Board of Medicine to process an initial application for Provisional Prosthetist license and (2) defray a portion of the Board's administrative overhead.

Fee-Related Activities and Costs:

Staff time-process initial application (.50 hr)	17.77
Administrative Overhead:	<u>30.02</u>
Total Estimated Cost:	\$ 47.79
Proposed Fee:	\$ 50.00

Analysis, Comment, and Recommendation:

It is recommended that a fee of \$50.00 be established for processing an initial application for a Provisional Prosthetist license.

Board Staff - receives application, reviews for completeness, verifies that supporting documents are attached, contacts applicant to request any missing information and/or documents. Information provided on the application regarding criminal conviction/chemical dependency/etc. may necessitate further research and review. Board staff issues license through computer when application is complete.

FEE REPORT FORM

Agency: State - BPOA

Date: February 4, 2013

Contact: Katie True
Commissioner, Bureau of Professional & Occupational Affairs

Phone No. 783-7192

Fee Title, Rate and Estimated Collections:

Initial application for Prosthetist license:		\$50.00
Estimated initial application revenue:	\$5000.00	(100 applications x \$50.00)

Fee Description:

The fee will be charged to every applicant for a Prosthetist license.

Fee Objective:

The fee should (1) offset the identifiable costs incurred by the State Board of Medicine to process an application and (2) defray a portion of the Board's administrative overhead.

Fee-Related Activities and Costs:

Staff time-process application	(0.50 hr)	17.77
Administrative Overhead:		<u>30.02</u>
	Total Estimated Cost:	\$ 47.79
	Proposed Fee:	\$ 50.00

Analysis, Comment, and Recommendation:

It is recommended that a fee of \$50.00 be established for processing an application for a Prosthetist license.

Board Staff - receives application, reviews for completeness, verifies that supporting documents are attached, contacts applicant to request any missing information and/or documents. Information provided on the application regarding criminal conviction/chemical dependency/etc. may necessitate further research and review. Board staff issues license through computer when application is complete.

FEE REPORT FORM

Agency: State - BPOA
Date: February 4, 2013
Contact: Katie True
Commissioner, Bureau of Professional & Occupational Affairs
Phone No.: 783-7192

Fee Title, Rate and Estimated Collections:

Initial application for Prosthetist license without examination: \$100.00
Estimated initial application revenue: \$3000.00 (30 applications X \$100.00)

Fee Description:

The fee will be charged to every applicant for a Prosthetist license without examination.

Fee Objective:

The fee should (1) offset the identifiable costs incurred by the State Board of Medicine to process an application and (2) defray a portion of the Board's administrative overhead.

Fee-Related Activities and Costs:

Staff time-process application	(1.5 hr)	53.31
Administrative Overhead:		<u>37.89</u>
	Total Estimated Cost:	\$ 91.20
	Proposed Fee:	\$ 100.00

Analysis, Comment, and Recommendation:

It is recommended that a fee of \$100.00 be established for processing an application for a Prosthetist license without examination.

Board Staff - receives application, reviews for completeness, verifies that supporting documents are attached, contacts applicant to request any missing information and/or documents. Information provided on the application regarding criminal conviction/chemical dependency/etc. may necessitate further research and review. Board staff issues license through computer when application is complete.

FEE REPORT FORM

Agency: State - BPOA

Date: February 4, 2013

Contact: Katie True
Commissioner, Bureau of Professional & Occupational Affairs

Phone No. 783-7192

Fee Title, Rate and Estimated Collections: **\$75.00**

Biennial Renewal Fee -- Prosthetist

Estimated Biennial Revenue: \$9750.00 (130 applications x \$75.00)

Fee Description:

The fee will be charged biennially to every Prosthetist applicant for license renewal.

Fee Objective:

The fee should defray a portion of the State Board of Medicine's administrative overhead.

Analysis, Comment, and Recommendation:

It is recommended that a renewal fee of \$75.00 be established for Prosthetist licensees, thereby causing those licensees to contribute to the operational costs of the State Board of Medicine.

FEE REPORT FORM

Agency: State - BPOA

Date: February 4, 2013

Contact: Katie True
Commissioner, Bureau of Professional & Occupational Affairs

Phone No. 783-7192

Fee Title, Rate and Estimated Collections:

Application for Reactivation of Prosthetist license: \$50.00
Estimated Reactivation of Prosthetist license revenue: \$100.00 (2 applications x 50.00)

Fee Description:

The fee will be charged to every licensee for Reactivation of a Prosthetist license.

Fee Objective:

The fee should (1) offset the identifiable costs incurred by the State Board of Medicine to process a reactivation application and (2) defray a portion of the Board's administrative overhead.

Fee-Related Activities and Costs:

Staff time-process reactivation application (.50 hr)	17.77
Administrative Overhead:	<u>30.02</u>
Total Estimated Cost:	\$ 47.79
Proposed Fee:	\$ 50.00

Analysis, Comment, and Recommendation:

It is recommended that a fee of \$50.00 be established for processing a reactivation application for a Prosthetist license.

Board Staff - receives application, reviews for completeness, verifies that supporting documents are attached, contacts applicant to request any missing information and/or documents. Information provided on the application regarding criminal conviction/chemical dependency/etc. may necessitate further research and review. Board staff issues license through computer when application is complete.

2014 JUN 30 AM 10: 42

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

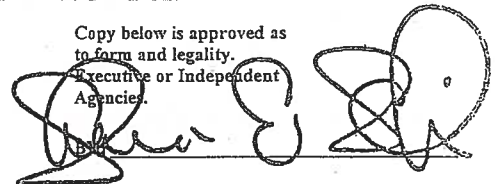
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BY: _____
(DEPUTY ATTORNEY GENERAL)

State Board of Medicine
(AGENCY)

DOCUMENT/FISCAL NOTE NO. 16A-4943

JUN 19 2014

DATE OF APPROVAL

DATE OF ADOPTION: _____

MAY 28 2014

DATE OF APPROVAL

BY: Andrew J. Behnke
Andrew J. Behnke, M.D.

(Executive Deputy General Counsel
Strike inapplicable title)

TITLE: Chairperson
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

Check if applicable
Copy not approved.
Objections attached.

Check if applicable. No
Attorney General approval or
objection within 30 day after
submission.

NOTICE OF PROPOSED RULEMAKING

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF MEDICINE

49 PA. CODE §§ 16.11, 16.13 AND SUBCHAPTER L, §§ 18.801-18.864

PROSTHETISTS, ORTHOTISTS, PEDORTHISTS AND
ORTHOTIC FITTERS

The State Board of Medicine (Board) proposes to amend §§ 16.11 and 16.13 (related to licenses, certificates and registrations; and licensure, certification, examination and registration fees), and to add a new Subchapter L, comprised of §§ 18.801 – 18.864 (related to prosthetists, orthotists, pedorthists and orthotic fitters), to read as set forth in Annex A.

Effective Date

The amendments will be effective upon publication of the final-form rulemaking in the Pennsylvania Bulletin.

Statutory Authority

The act of July 5, 2012 (P.L. 873, No. 90) (Act 90) amended the Medical Practice Act of 1985 (act) (63 P.S. §§ 422.1 – 422.51a), to require the Board to issue licenses to prosthetists, orthotists, pedorthists and orthotic fitters, to regulate the practice of these professions and to discipline licensees. Section 8 of the act (63 P.S. § 422.8) authorizes the Board to adopt regulations as are reasonably necessary to carry out the purposes of the act.

Background and Need for Amendments

Act 90 was introduced to provide licensure for and regulatory oversight of the four named professions. Act 90 became effective immediately, and instructed the Board to promulgate regulations within 18 months of the effective date, or by January 5, 2014. Act 90 further provided that it would become effective upon publication of final rulemaking or 24 months from the effective date, whichever occurred first.

Following enactment of Act 90 on July 5, 2012, a draft rulemaking was prepared. On August 14, 2012, the Board provided the draft to stakeholders, including members of the regulated community and their association representatives; representatives from the University of Pittsburgh's prosthetic and orthotic educational program; representatives from the Temple University School of Podiatry, which operates a pedorthic education program; the Pennsylvania Medical Society and physician specialty organization in orthopedics; representatives from the House Professional Licensure Committee (HPLC) and Independent Regulatory Review Commission (IRRC); and the two National credentialing bodies for the profession, the American Board of Certification (ABC) and the Board of Certification (BOC). The Board also invited these stakeholders and interested parties to a meeting on September 10, 2012, and announced the meeting on the Board's website in order to invite all other interested parties.

Extensive discussions were held with the stakeholders regarding the draft rulemaking at the meeting on September 10, 2012. After making amendments to the draft based on comments received during and after that meeting, the Board provided another draft of the draft rulemaking to the stakeholders on November 27, 2012. On December 4, 2012, the Board again met with stakeholders regarding the draft rulemaking. Additional amendments were made based on input from the stakeholders. At its February 6, 2013, meeting, the Board approved the draft rulemaking for publication as proposed rulemaking.

Description of Proposed Amendments

The proposed rulemaking would update § 16.11 (related to licenses, certificates and registrations) to add prosthetists, orthotists, pedorthists and orthotic fitters to the list of individuals licensed by the Board. In addition, the Board proposes to issue the following permits which apply to individuals who have completed their educational program but have not yet completed all requirements for full licensure (such as, residency, practice requirement or examination): graduate prosthetist permit, provisional prosthetist license, graduate orthotist permit, provisional orthotist license, temporary practice permit – pedorthist and temporary practice permit – orthotic fitter. The proposed rulemaking would also update § 16.13 (related to licensure, certification, examination and registration fees) to provide for fees for the various applications for initial licensure and for biennial renewal of the prosthetists, orthotists, pedorthists and orthotic fitters licenses; as well as for the application for reactivation. The fees are based on estimates of the cost of processing each of the application types, with consideration given to the average salary of the new licensees in each licensing category.

The proposed amendments would create a new Subchapter L in Chapter 18. Section 18.801 (related to purpose) would state the purpose of the subchapter, which is to implement the amendments to the act related to licensure of prosthetists, orthotists, pedorthists and orthotic fitters. Section 18.802 (related to definitions) would set forth definitions of terms used in the subchapter.

Sections 18.811 through 18.815 would address the requirements for licensure of prosthetists. Section 18.811 (related to graduate permit) provides the information necessary for an applicant to apply for a graduate permit to practice as a prosthetist during the individual's clinical residency following graduation from the individual's education program. A graduate permit would be valid for practice during the clinical residency and would remain valid for up to 90 days after successful completion of the clinical residency, or until a temporary license is granted. A graduate permit is nonrenewable. Should an individual fail to complete the clinical residency and later re-enroll in a clinical residency, the individual would be required to obtain a new graduate permit.

Section 18.812 (related to clinical residency) sets forth criteria for a clinical residency, including the nature of supervision that must be provided to a graduate permit holder, that the clinical residency must be accredited by the National Commission on Orthotic and Prosthetic Education (NCOPE), and that the clinical residency must be obtained subsequent to meeting the education requirement and be at all levels of prosthetic care.

Section 18.813 (related to provisional prosthetist license) provides the information necessary for an applicant to apply for a provisional prosthetist license, which is the license that will allow an individual to provide direct patient care after completion of the clinical residency. This license allows the individual to practice while completing the three-step examination process that will qualify the individual for full licensure. A provisional license is valid for a maximum of 2 years and is nonrenewable. Should an individual fail to successfully complete all examinations in a 2-year period, the individual would be required to re-apply for a provisional license in order to continue practicing.

Section 18.814 (related to prosthetist license) provides the information necessary for an applicant to apply for a prosthetist license. The qualifications for licensure are set forth in section 13.5 (a) of the act (63 P.S. § 422.13e(a)(1)). This section of the act provides that applicants must have “two years (3,800 hours) of experience to qualify for licensure. However, section 13.5(f) of the act, pertaining to license without examination, refers instead to “two years or 3,800 hours” of experience. Because the licensure scheme is intended to ensure that only qualified individuals provide services to the public, the Board interprets both of these sections to require applicants to demonstrate a minimum of 3,800 hours of experience over a period of 2 years. To interpret the statute otherwise could result in an absurd result, for example, where an individual who provided 3,800 hours of professional services sporadically over a 20-year period, without ever developing competence in the profession, could qualify for licensure. The Board does not believe this could have been the intent of the General Assembly.

Section 18.815 (related to alternate pathway for prosthetist license) provides the information necessary for an applicant to apply for a prosthetist license without examination. The act allows for a “grandfathering” period ending July 7, 2014, for individuals who have been in practice prior to the requirement that prosthetists be educated at the master’s degree level. This section will expire at 5:00 p.m. on July 7, 2014. The Board will make applications for licensure, including licensure without examination, available at least 6 months prior to that date.

Section 18.816 (related to demonstration of qualifications) would give applicants information about the type of documentation that will be required by the Board for an applicant to demonstrate the qualifications set forth in the act and this chapter.

Section 18.821 through 18.825 would contain provisions relevant to orthotists. Section 18.821 (related to graduate permit) provides the information necessary for an applicant to apply for a graduate permit to practice as an orthotist during the individual’s clinical residency following graduation from the individual’s education program. A graduate permit is valid only for practice during the clinical residency and is non-renewable. Should an individual fail to complete the clinical residency and later re-enroll in a clinical residency, the individual would be required to obtain a new graduate permit.

Section 18.822 (related to clinical residency) sets forth criteria for a clinical residency, including the nature of supervision that must be provided to a graduate permit holder, that the clinical residency must be accredited by NCOPE, and that the clinical residency must be obtained subsequent to education and be at all levels of orthotic care.

Section 18.823 (related to provisional orthotist license) provides the information necessary for an applicant to apply for a provisional orthotist license, which is the license that will allow an individual to provide direct patient care after completion of the clinical residency. This license allows the individual to practice while completing the three-step examination process that will qualify the individual for full licensure. A provisional license is valid for a maximum of 2 years and is non-renewable. Should an individual fail to successfully complete all examinations in a 2-year period, the individual would be required to re-apply for a provisional license in order to continue practicing.

Section 18.824 (related to orthotist license) provides the information necessary for an applicant to apply for an orthotist license. This section includes the statutory requirements for licensure set forth in section 13.5(a) of the act. The Board interprets the experience requirement in the act related to orthotists the same as the experience requirement for prosthetists, as discussed in the description to § 18.814.

Section 18.825 (related to alternate pathway for orthotist license) provides the information necessary for an applicant to apply for a orthotist license without examination. The statute allowed for a “grandfathering” period ending July 7, 2014, for individuals who have been in practice prior to the requirement that orthotists be educated at the master’s degree level. This section will expire at 5:00 p.m. on July 7, 2014. The Board will make applications for licensure, including licensure without examination, available at least 6 months prior to that date.

Section 18.826 (related to demonstration of qualifications) would give applicants information about the type of documentation that will be required by the Board for an applicant to demonstrate the qualifications set forth in the act and this chapter.

Sections 18.831 through 18.834 would contain provisions relevant to pedorthists. Section 18.831 (related to temporary practice permit) provides the information necessary for an applicant to apply for a temporary practice permit to provide pedorthic patient care after completion of the pedorthic education program. The temporary permit allows the individual to obtain the 1,000 hours of supervised patient fitting experience necessary for full licensure.

Section 18.832 (related to patient fitting experience) sets forth the requirements of the patient fitting experience that a pedorthist must complete after completing the pedorthic education program and prior to applying for licensure.

Section 18.833 (related to pedorthist license) provides the information necessary for an applicant to apply for a pedorthist license. This section includes the statutory requirements for licensure.

Section 18.834 (related to alternate pathway for pedorthist license) provides the information necessary for an applicant to apply for a pedorthist license without examination, as provided in the act. This section will expire at 5:00 p.m. on July 7, 2014. The Board will make applications for licensure, including licensure without examination, available at least 6 months prior to that date.

Section 18.835 (related to demonstration of qualifications) would give applicants information about the type of documentation that will be required by the Board for an applicant to demonstrate the qualifications set forth in the act and this chapter.

Sections 18.841 through 18.844 would contain provisions relevant to orthotic fitters. Section 18.841 (related to temporary practice permit) provides the information necessary for an applicant to apply for a temporary practice permit to provide orthotic fitting patient care after

completion of the orthotic fitter education program. The temporary permit allows the individual to obtain the 1,000 hours of patient fitting experience necessary for full licensure.

Section 18.842 (related to orthotic fitting care experience) sets forth the requirements of the patient fitting experience that an orthotic fitter must complete after completing the orthotic fitter education program and prior to applying for licensure.

Section 18.843 (relating to orthotic fitter license) provides the information necessary for an applicant to apply for an orthotic fitter license. This section includes the statutory requirements for licensure.

Section 18.844 (relating to alternate pathway for orthotic fitter license) provides the information necessary for an applicant to apply for an orthotic fitter license without examination, as provided in the act.

Section 18.845 (related to demonstration of qualifications) would give applicants information about the type of documentation that will be required by the Board for an applicant to demonstrate the qualifications set forth in the act and this chapter.

Section 18.851 (related to scope and standards of practice) sets forth scope and standards of practice for prosthetists, orthotists, pedorthists and orthotic fitters. Subsections (a) and (b) echo requirements in the act that licensees review the prescription and referral or order of the prescribing practitioner and understand any restrictions placed on the course of treatment that the licensee will provide and that licensees review the relevant clinical notes provided by the prescribing practitioner. Subsection (c) requires the licensee to retain a copy of the prescription, clinical notes and results of the patient's medical examination. Subsection (d) forbids a licensee from accepting a prescription when the licensee knows that he or she cannot furnish the device within a reasonable period of time. In such a case, subsection (d) requires the licensee to consult with the prescribing practitioner and notify the patient of the problem. Subsection (e) provides the minimum content of the clinical notes of the medical diagnostic examination that a licensee must review before accepting a prescription.

Section 18.852 (related to delegation) provides rules for licensed prosthetists, orthotists and pedorthists related to delegating tasks to unlicensed assistive personnel. According to individuals involved in these professions, assistants are employed to provide support services and to complete simple tasks that do not require the education and training of a licensee. These individuals would need to be under the direct, on-site supervision of the delegating practitioner.

Section 18.853 (related to unprofessional and immoral conduct) provides notice to licensees related to the disciplinary process and defines conduct that is prohibited as unprofessional or immoral.

Next the Board proposes sections related to biennial renewal and reactivation of a license. Section 18.861 (related to biennial renewal of license) provides for the biennial renewal of the four license categories, and effectuates the provisions relating to continuing education and required professional liability insurance. Subsection (b)(5) requires a licensee to verify that the

licensee has completed the continuing education mandated by statute as a condition of biennial renewal and that the licensee is, or will be, covered by the required professional liability insurance.

Section 18.862 (related to continuing education) sets forth the continuing education requirements for active licensees and those requesting reactivation. In addition, provisions related to requesting a waiver of the continuing education requirements, discipline for non-compliance, approved continuing education sources and the documentation of continuing education completion that licensees must maintain will be set forth in this section.

Section 18.863 (related to inactive status and expired status of license; reactivation of inactive or expired license) provides information to licensees about how a license becomes inactive, that a licensee whose license is inactive is not permitted to practice, and how to reactivate an inactive or expired license. Subsection (d) provides that a licensee whose license has been inactive for 2 or more years will be required to demonstrate continued competence to practice by showing current certification by the ABC or BOC. All of the interested parties who provided input to the Board on this rulemaking agreed that the 2-year period was the appropriate period after which the Board should require demonstration of continued competence through current certification. Late fees are addressed in § 18.863(e).

Section 18.864 (related to professional liability insurance coverage for licensed prosthetist, orthotist, pedorthist or orthotic fitter) repeats section 13.5(i) of the act (63 P.S. § 422.13e(i)), which requires liability insurance for all licensees. Subsection (b) will provide licensees with guidance regarding acceptable proof of coverage. Subsection (c) informs licensees that they are prohibited from practicing until proof of insurance has been provided.

Fiscal Impact and Paperwork Requirements

The statutory requirements for licensure, completion of mandatory continuing education and maintenance of professional liability insurance will have a fiscal impact on the regulated community. However, because these are statutory requirements, it is the statute, and not the Board's proposed rulemaking, that will impose a fiscal requirement on licensees. The proposed amendments will also have a fiscal impact on the state government, through impact on the Board, which will incur costs associated with administering and enforcing the law and regulations. No fiscal impact on local governments is anticipated. The proposed amendments will require additional paperwork by the regulated community and by the Board, in issuing licenses, tracking licenses and maintaining proof of compliance with the statutory and regulatory requirements. No fiscal impact on local governments is anticipated.

Estimates of the costs associated with the statutory requirements and this rulemaking are set out in the "Regulatory Analysis Form," which is available upon request.

Sunset Date

The Board continuously monitors its regulations; therefore, no sunset date has been assigned.

Regulatory Review

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on June 30, 2014, the Board submitted a copy of this proposed rulemaking and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC) and to the Chairpersons of the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC), and the House Professional Licensure Committee (HPLC). A copy of this material is available to the public upon request.

Under section 5(g) of the Regulatory Review Act, IRRC may convey any comments, recommendations or objections to the proposed rulemaking within 30 days of the close of the public comment period. The comments, recommendations or objections must specify the regulatory review criteria that have not been met. The Regulatory Review Act specifies detailed procedures for review of comments, recommendations and objections by the Board, the General Assembly, and the Governor, prior to final publication of the rulemaking.

Public Comment

Interested persons are invited to submit written comments, recommendations or objections regarding this proposed rulemaking to Teresa Lazo, Board Counsel, State Board of Medicine, P.O. Box 2649, Harrisburg, Pennsylvania, 17105-2649, RA-STRegulatoryCounsel@pa.gov within 30 days following publication of this proposed rulemaking in the *Pennsylvania Bulletin*.

Andrew J. Behnke, M.D.
Chair, State Board of Medicine

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 16. STATE BOARD OF MEDICINE

* * * * *

Subchapter B. GENERAL LICENSE, CERTIFICATION AND
REGISTRATION PROVISIONS

§ 16.11. Licenses, certificates and registrations.

* * * * *

(b) The following nonmedical doctor licenses and certificates are issued by the Board:

* * * * *

- (9) Prosthetist license.
- (10) Orthotist license.
- (11) Pedorthist license.
- (12) Orthotic fitter license.
- (13) Graduate prosthetist permit.
- (14) Provisional prosthetist license.
- (15) Graduate orthotist permit.
- (16) Provisional orthotist license.
- (17) Temporary practice permit – pedorthist.
- (18) Temporary practice permit – orthotic fitter.

(c) The following registrations are issued by the Board:

* * * * *

- (13) Biennial renewal of a prosthetist.
- (14) Biennial renewal of an orthotist.
- (15) Biennial renewal of a pedorthist.
- (16) Biennial renewal of an orthotic fitter.

* * * * *

§ 16.13. Licensure, certification, examination and registration fees.

* * * * *

(n) Prosthetists.

<u>Application for prosthetist license</u>	<u>\$50</u>
<u>Application for prosthetist license without examination.....</u>	<u>\$100</u>
<u>Biennial renewal of prosthetist license</u>	<u>\$75</u>
<u>Application for reactivation of prosthetist license</u>	<u>\$50</u>
<u>Application for graduate prosthetist permit.....</u>	<u>\$50</u>
<u>Application for provisional prosthetist license.....</u>	<u>\$50</u>

(o) Orthotist license.

<u>Application for orthotist license.....</u>	<u>\$50</u>
<u>Application for orthotist license without examination</u>	<u>\$100</u>
<u>Biennial renewal of orthotist license.....</u>	<u>\$75</u>
<u>Application for reactivation of orthotist license</u>	<u>\$50</u>
<u>Application for graduate orthotist permit.....</u>	<u>\$50</u>
<u>Application for provisional orthotist license.....</u>	<u>\$50</u>

(p) Pedorthists.

<u>Application for pedorthist license</u>	<u>\$25</u>
<u>Application for pedorthist license without examination</u>	<u>\$25</u>
<u>Biennial renewal of pedorthist license</u>	<u>\$75</u>
<u>Application for reactivation of pedorthist license</u>	<u>\$25</u>
<u>Application for pedorthist temporary permit</u>	<u>\$25</u>

(q) Orthotic fitters.

<u>Application for orthotic fitter license</u>	<u>\$25</u>
<u>Application for orthotic fitter license without examination</u>	<u>\$25</u>
<u>Biennial renewal of orthotic fitter license</u>	<u>\$75</u>
<u>Application for reactivation of orthotic fitter license</u>	<u>\$25</u>
<u>Application for orthotic fitter temporary permit</u>	<u>\$25</u>

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CHAPTER 18. STATE BOARD OF MEDICINE—PRACTITIONERS

OTHER THAN MEDICAL DOCTORS

* * * * *

Subchapter L. PROSTHETISTS, ORTHOTISTS, PEDORTHISTS AND

ORTHOTIC FITTERS

GENERAL PROVISIONS

§ 18.801. Purpose.

This subchapter implements section 13.5 of the act (63 P.S. § 422.13e) pertaining to prosthetists, orthotists, pedorthists and orthotic fitters, which was added by the act of July 5, 2012 (P.L. 873, No. 90), effective July 5, 2012.

§ 18.802. Definitions.

The following words and terms, when used in this subchapter, have the following meanings, unless the context clearly indicates otherwise:

ABC – American Board for Certification in Orthotics, Prosthetics and Pedorthics, Inc., an organization with certification programs accredited by the NCCA. This term shall include a successor organization.

Accommodative – Designed with a primary goal of conforming to an individual's anatomy.

BOC – Board of Certification/Accreditation International, Inc., an organization with certification programs accredited by the NCCA. This term shall include a successor organization.

CAAHEP – Commission on Accreditation of Allied Health Education Programs, recognized by the Council for Higher Education Accreditation to accredit prosthetic and orthotic education programs.

NCCA – The National Commission for Certifying Agencies or its successor.

Custom-designed device – A prosthesis, orthosis or pedorthic device that is designed to comprehensive measurements or a mold for use by a patient in accordance with a prescription and which requires substantial clinical and technical judgment in its design.

Custom-fabricated device – A prosthesis, orthosis or pedorthic device that is fabricated to comprehensive measurements or a patient model or mold for use by a patient in accordance with a prescription and which requires substantial clinical and technical judgment in its design, fabrication and fitting.

Custom-fitted or custom-modified device – A prefabricated prosthesis, orthosis or

pedorthic device to accommodate the patient's measurement that is sized or modified for use by the patient in accordance with a prescription and which requires substantial clinical judgment and substantive alteration in its design for appropriate use.

Hour of continuing education – At least 50 minutes of instruction (including relevant question and answer sessions) in an approved course of continuing education or an equivalent time that an on-line or correspondence course would be presented live.

ICE – The Institute for Credentialing Excellence, previously known as the National Organization for Competency Assurance.

Licensed prescribing practitioner – A physician, podiatrist, certified registered nurse practitioner or physician assistant, licensed by the practitioner's respective licensing board, who may issue orders and prescriptions to a prosthetist, orthotist, pedorthist or orthotic fitter.

NCOPE – National Commission on Orthotic and Prosthetic Education, an organization that approves pre-certification education courses for pedorthists and orthotic fitters and accredits residency programs for prosthetists and orthotists.

Orthosis – A custom-designed, custom-fabricated, custom-fitted or custom-modified device designed to externally provide support, alignment or prevention to the body or a limb for the purposes of correcting or alleviating a neuromuscular or musculoskeletal disease, injury or deformity.

Orthotic and prosthetic assistant – An unlicensed individual who, under the direct, on-site supervision of the orthotist or prosthetist, assists an orthotist or prosthetist with patient care and who may fabricate, repair and maintain devices to provide maximum fit and function.

Orthotic and prosthetic technician – An unlicensed individual who, under the direct on-site supervision of an orthotist or prosthetist, provides technical support to an orthotist or prosthetist and who may fabricate, repair and maintain devices.

Orthotic fitter – An individual who is licensed by the Board to practice orthotic fitting.

Orthotic fitting – The fitting, dispensing and adjusting pursuant to a written prescription of a licensed prescribing practitioner, of prefabricated orthotic devices.

Orthotics – The practice of evaluating, measuring, designing, fabricating, assembling, fitting, adjusting or servicing an orthosis for the correction or alleviation of neuromuscular or musculoskeletal dysfunction, disease, injury or deformity, as provided in the act.

Orthotist – An individual who is licensed by the Board to practice orthotics pursuant to a written prescription of a licensed prescribing practitioner.

Over-the-counter orthoses and pedorthic devices – Prefabricated, mass-produced items that are prepackaged and require no professional advice or judgment in either size selection or use, including fabric or elastic supports, corsets, generic arch supports and elastic hose.

Pedorthic device –

(i) Includes therapeutic shoes, shoe modifications made for therapeutic purposes, partial foot prostheses, foot orthoses and below-the-knee pedorthic modalities.

(ii) The term does not include any of the following:

(A) Nontherapeutic, accommodative inlays and nontherapeutic accommodative footwear, regardless of method of manufacture.

(B) Unmodified, nontherapeutic over-the-counter shoes.

(C) Prefabricated, unmodified or unmodifiable foot care and footwear products.

Pedorthic support personnel – An unlicensed individual who, under the direct on-site supervision of a pedorthist, assists a pedorthist in the provision of pedorthic care. Pedorthic support personnel may not practice prosthetics, orthotics, pedorthics or orthotic fitting.

Pedorthics – The practice of evaluating, measuring, designing, fabricating, assembling, fitting, adjusting or servicing necessary to accomplish the application of a pedorthic device for the prevention or amelioration of painful or disabling conditions related to the lower extremities.

Pedorthist – An individual licensed under the act to practice pedorthics pursuant to a written prescription of a licensed prescribing practitioner.

Podiatrist – An individual licensed under the Podiatry Practice Act (63 P.S. §§ 42.1 – 42.21c) to practice podiatry.

Prefabricated orthotic devices –

(i) A brace or support designed to provide for alignment, correction or prevention of neuromuscular or musculoskeletal dysfunction, disease, injury or deformity.

(ii) The term does not include fabric or elastic supports, corsets, arch supports, low-temperature plastic splints, trusses, elastic hose, canes, crutches, soft cervical collars, dental appliances or other similar devices carried in stock and sold as over-the-counter items.

Prosthesis –

(i) A custom-designed, custom-fabricated, custom-fitted or custom-modified device to replace an absent external limb for purposes of restoring physiological function that is not surgically implanted.

(ii) The term does not include artificial eyes, ears, fingers or toes; dental appliances; cosmetic devices such as breast prostheses, eyelashes or wigs; or other devices that do not have a significant impact on the musculoskeletal functions of the body.

Prosthetics – The practice of evaluating, measuring, designing, fabricating, assembling, fitting, adjusting or servicing a prosthesis.

Prosthetist – An individual, other than a licensed physical therapist or occupational therapist, licensed under the act to practice prosthetics pursuant to a written prescription of a licensed prescribing practitioner.

QUALIFICATIONS FOR LICENSURE AS A PROSTHETIST

§ 18.811. Graduate permit.

(a) Prior to providing direct patient care during a clinical residency, an individual shall submit an application, on forms made available by the Board, for a graduate permit that authorizes the individual to work as a graduate prosthetist. The Board may grant a graduate permit to an individual who submits a completed application including any necessary supporting documents, pays the application fee set forth in § 16.13(n) (relating to licensure, certification, examination and registration fees), and meets the qualifications set forth in subsection (b).

(b) The Board may issue a graduate permit to practice as a prosthetist to an applicant who:

- (1) Is of good moral character.
- (2) Has earned a bachelor's degree, post-baccalaureate certificate or higher degree from a CAAHEP-accredited education program with a major in prosthetics or prosthetics/orthotics.
- (3) Has registered with NCOPE as a prosthetist or prosthetist/orthotist resident.
- (4) Has complied with § 18.864 (relating to professional liability insurance for licensed prosthetist, orthotist, pedorthist and orthotic fitter.)
- (5) Otherwise satisfies all requirements for a graduate permit and is not barred from

licensure.

(c) The Board may deny an application for a graduate permit upon any of the grounds for disciplinary action set forth in section 41 of the act (63 P.S. § 422.41) or § 18.852 (relating to unprofessional and immoral conduct).

(d) A graduate permit is valid during the clinical residency and for up to 90 days after successful completion of the clinical residency or until a provisional license is issued, whichever occurs first. A graduate permit is nonrenewable.

§ 18.812. Clinical residency.

(a) A graduate prosthetist shall practice only under the direct supervision of a licensed prosthetist, ABC-certified prosthetist or BOC-certified prosthetist within the clinical residency. For purposes of this section, “direct supervision” means the supervisor is available for consultation throughout the patient care process and is able to visually assess the care being provided. The supervisor shall review the results of care and the documentation of the services rendered by the supervised individual and is responsible for countersigning within 15 days all entries in the patient’s clinical record.

(b) The clinical residency must be accredited by NCOPE.

(c) The clinical residency must be obtained subsequent to education and be at all levels of prosthetic care.

§ 18.813. Provisional prosthetist license.

(a) An individual shall submit an application, on forms made available by the Board, for a provisional license which will authorize the individual to provide direct patient care, under direct supervision as defined in § 18.812(a) (relating to clinical residency), as a provisionally-licensed prosthetist following completion of a clinical residency. The Board may grant a provisional

license to an individual who submits a completed application including any necessary supporting documents, pays the application fee set forth in § 16.13(n) (relating to licensure, certification, examination and registration fees), and meets the qualifications in subsection (b).

(b) The Board may grant a provisional license to an individual who:

(1) Is of good moral character.

(2) Has earned a bachelor's degree, post-baccalaureate certificate or higher degree from a CAAHEP-accredited education program with a major in prosthetics or prosthetics/orthotics.

(3) Has completed an NCOPE-accredited clinical residency in prosthetics or prosthetics/orthotics.

(4) Has complied with § 18.864 (relating to professional liability insurance for licensed prosthetist, orthotist, pedorthist or orthotic fitter.)

(5) Otherwise satisfies all requirements for a provisional license is not barred from licensure.

(c) The Board may deny an application for a provisional license upon any of the grounds for disciplinary action set forth in section 41 of the act (63 P.S. § 422.41) or § 18.852 (relating to unprofessional and immoral conduct).

(d) A provisional license is valid for a maximum of 2 years and is nonrenewable.

§ 18.814. Prosthetist license.

(a) An applicant for a license to practice as a prosthetist shall submit, on forms made available by the Board, a completed application for licensure, including all necessary supporting documents, and pay the application fee set forth in § 16.13(n) (relating to licensure, certification, examination and registration fees).

(b) The Board may issue a license to practice as a prosthetist to an applicant who:

(1) Is of good moral character.

(2) Has earned a bachelor's degree, post-baccalaureate certificate or higher degree from a CAAHEP-accredited education program with a major in prosthetics or prosthetics/orthotics.

(3) Has completed a minimum of 3,800 hours of experience in providing direct patient care services in prosthetics or in prosthetics and orthotics over a period of 2 years. 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.

(4) Has met the qualifications for certification and has received certification from a prosthetic credentialing organization whose certification program is accredited by NCCA.

(5) Has complied with § 18.864 (relating to professional liability insurance coverage for licensed prosthetis, orthotist, pedorthist or orthotic fitter.).

(6) Otherwise satisfies all requirements for licensure and is not barred from licensure.

(c) The Board may deny an application for licensure as a prosthetist or upon any of the grounds for disciplinary action set forth in section 41 of the act (63 P.S. § 422.41) or § 18.852 (relating to unprofessional and immoral conduct).

§ 18.815. Alternate pathway for prosthetist license.

(a) Through July 7, 2014, an individual may apply for licensure as a prosthetist without examination by submitting an application for licensure without examination, paying the application fee in § 16.13(h) (relating to licensure certification, examination and registration fees), and providing documentation acceptable to the Board to demonstrate that the applicant

meets the qualifications of section 13.5(a)(8), (f) and (i) of the act (63 P.S. § 422.13e(a)(8), (f) and (i)), as set forth in this section.

(b) The Board may issue a license under this section to an applicant for prosthetist licensure who complies with this section; demonstrates the qualifications in sections 13.5(a)(1), (5), (6), (7) and (8) of the act, pertaining to good moral character , application and fees, patient logs, alcohol or drug addiction and criminal history, and the qualifications in section 13.5(f) of the act (63 P.S. § 422.13e(f) (relating to licensure without examination).

(c) To meet the qualifications for licensure in section 13.5(f) of the act, an applicant shall have a combination of at least 4 years of education, training and work experience, consisting of one of the following:

(1) A bachelor's degree with a major in prosthetics or prosthetics/orthotics and, if the bachelor's degree was completed in less than 4 academic years, additional training or work experience in providing direct patient care to total 4 years.

(2) An associate's degree in prosthetics or prosthetics/orthotics and a minimum of 3,800 hours of experience in providing direct patient services in prosthetics or in prosthetics and orthotics over a period of 2 years, to total at least 4 years of education, training and work experience.

(3) At least 2 or more years of education, training or work experience in the field of prosthetics and a minimum of 3,800 hours of experience in providing direct patient care services in prosthetics or in prosthetics and orthotics over a period of 2 years, to total at least 4 years of education, training and work experience.

(d) To meet the qualifications for licensure in section 13.5(f) of the act, an applicant shall demonstrate current National certification from an organization approved by the Board as a

prosthetist or prosthetist and orthotist.

(e) To meet the qualifications for licensure in section 13.5(f) of the act, an applicant shall demonstrate that the applicant has been in active, continuous practice for the 3-year period between July 5, 2009, and July 5, 2012.

(f) The Board may deny an application for licensure as a prosthetist without examination upon any of the grounds for disciplinary action set forth in section 41 of the act (63 P.S. § 422.41) or § 18.852 (relating to unprofessional and immoral conduct).

(g) This section expires at 5:00 p.m. on July 7, 2014. An application for licensure without examination received after July 7, 2014 will be returned to applicant.

§ 18.816. Demonstration of qualifications.

An applicant for prosthetist licensure shall:

(1) Demonstrate the degree or other education and training by having the educational institution submit, directly to the Board, verification of the degree and official transcript or certificates of attendance at other training.

(2) Demonstrate direct patient care by having the applicant's supervisor, employer or a referral source file an attestation on a form provided by the Board. If attestation is from a referral source, it shall include a copy of the applicant's Federal EIN and evidence of the date the applicant received the EIN.

(3) Demonstrate National certification by having the National certification body send verification of National certification directly to the Board.

(4) Demonstrate compliance with § 18.864 (relating to professional liability insurance coverage for licensed prosthetist, orthotist, pedorthist or orthotic fitter) by verification and, if requested, a copy of an insurance binder, certificate, policy, declarations page or

other documentation acceptable to the Board.

(5) Demonstrate that the applicant has been in active, continuous practice for the 3-year period between July 5, 2009, and July 5, 2012, by attestation and one of the following:

(i) Applicant's Federal tax returns from 2009 - 2012 listing the applicant's occupation as prosthetist or orthotist, as appropriate.

(ii) Attestation from the applicant's employer or health care referral source, including the Federal EIN information set forth in paragraph (4) demonstrating that the applicant has been in active, continuous practice.

QUALIFICATIONS FOR LICENSURE AS AN ORTHOTIST

§ 18.821. Graduate permit.

(a) Prior to providing direct patient care during a clinical residency, an individual shall submit an application, on forms made available by the Board, for a graduate permit that authorizes the individual to work as a graduate orthotist. The Board may grant a graduate permit to an individual who submits a completed application including any necessary supporting documents, pays the application fee set forth in § 16.13(o) (relating to licensure, certification, examination and registration fees), and meets the qualifications set forth in subsection (b).

(b) The Board may issue a graduate permit to practice as an orthotist to an applicant who:

(1) Is of good moral character.

(2) Has earned a bachelor's degree, post-baccalaureate certificate or higher degree from a CAAHEP-accredited education program with a major in orthotics or prosthetics/orthotics.

- (3) Has registered with NCOPE as an orthotist or prosthetist/orthotist resident.
 - (4) Has complied with § 18.864 (relating to professional liability insurance coverage for licensed prosthetist, orthotist, pedorthist or orthotic fitter.)
 - (5) Otherwise satisfies all requirements for a graduate permit is not barred from licensure.
- (c) The Board may deny an application for licensure as an orthotist upon the any of grounds for disciplinary action set forth in section 41 of the act (63 P.S. § 422.41) or § 18.852 (relating to unprofessional and immoral conduct).
- (d) A graduate permit is valid during the clinical residency and for up to 90 days after successful completion of the clinical residency or until a provisional license is issued, whichever occurs first. A graduate permit is nonrenewable.

§ 18.822. Clinical residency.

- (a) A graduate orthotist shall practice only under the direct supervision of a licensed orthotist, ABC-certified orthotist or BOC-certified orthotist within the clinical residency. For purposes of this section, “direct supervision” means the supervising licensed individual is available for consultation throughout the patient care process and is able to visually assess the care being provided. The supervisor shall review the results of care and the documentation of the services rendered by the supervised individual and is responsible for countersigning within 15 days all entries in the patient’s clinical record.
- (b) A clinical residency must be accredited by NCOPE.
- (c) A clinical residency must be obtained subsequent to education and be at all levels of orthotic care.

§ 18.823. Provisional orthotist license.

(a) Following completion of the clinical residency, an individual may submit an application, on forms made available by the Board, for a provisional license which will authorize the individual to provide direct patient care under supervision as defined in § 18.822(a), (relating to clinical residency). The Board may grant a provisional license to an individual who submits a completed application including any necessary supporting documents, pays the application fee set forth in § 16.13(o) (relating to licensure, certification, examination, and registration fees) and meets the qualifications in subsection (b).

(b) The Board may grant a provisional license to an individual who:

(1) Is of good moral character.

(2) Has earned a bachelor's degree, post-baccalaureate certificate or higher degree from a CAAHEP-accredited education program with a major in orthotics or prosthetics/orthotics.

(3) Has completed an NCOPE-accredited clinical residency in orthotics or prosthetics/orthotics.

(4) Has complied with § 18.864 (relating to professional liability insurance coverage for licensed prosthetist, orthotist, pedorthist or orthotic fitter.)

(5) Otherwise satisfies all requirements for a provisional license and is not barred from licensure.

(c) The Board may deny an application for a provisional license as an orthotist upon any of the grounds for disciplinary action set forth in section 41 of the act (63 P.S. § 422.41) or § 18.852 (relating to unprofessional and immoral conduct).

(d) A provisional license is valid for a maximum of 2 years and is nonrenewable.

§ 18.824. Orthotist license.

(a) An applicant for a license to practice as an orthotist shall submit, on forms made available by the Board, a completed application for licensure, including all necessary supporting documents, and pay the application fee set forth in § 16.13(o) (relating to licensure, certification, examination and registration fees).

(b) The Board may issue a license to practice as an orthotist to an applicant who:

(1) Is of good moral character.

(2) Has earned a bachelor's degree, post-baccalaureate certificate or higher degree from a CAAHEP-accredited education program with a major in orthotics or prosthetics/orthotics.

(3) Has completed a minimum of 3,800 hours of experience in providing direct patient care services in orthotics or in prosthetics and orthotics over a period of 2 years.

(4) Has met the qualifications for certification and has received certification from an orthotic credentialing organization whose certification program is accredited by NCCA.

(5) Has complied with § 18.864 (relating to professional liability insurance coverage for licensed prosthetist, orthotist, pedorthotist or orthotic fitter.)

(6) Otherwise satisfies all requirements for licensure and is not barred from licensure.

(c) The Board may deny an application for licensure as an orthotist upon any of the grounds for disciplinary action set forth in section 41 of the act (63 P.S. § 422.41) or § 18.852 (relating to unprofessional and immoral conduct).

§ 18.825. Alternate pathway for orthotist license.

(a) Through July 7, 2014, an individual may apply for licensure as an orthotist without examination by submitting an application for licensure without examination, paying the application fee in § 16.13(o) (relating to licensure certification, examination and registration

fees, and providing documentation acceptable to the Board to demonstrate that the applicant meets the qualifications of section 13.5(a)(8), (f) and (i) of the act (63 P.S. § 422.13e(a)(8), (f) and (i)), as set forth in this section.

(b) The Board may issue a license under this section to an applicant for orthotist licensure who complies with this section; demonstrates the qualifications in sections 13.5(a)(1), (5), (6), (7) and (8) of the act pertaining to good moral character , application and fees, patient logs, alcohol or drug addiction and criminal history, and the qualifications in section 13.5(f) of the act (63 P.S. § 422.13e(f)).

(c) To meet the qualifications for licensure in section 13.5(f) of the act, an applicant must have a combination of at least 4 years of education, training and/or work experience, consisting of one of the following:

(1) A Bachelor's degree with a major in orthotics or prosthetics/orthotics and, if the Bachelor's degree was completed in less than 4 academic years, additional training or work experience in providing direct patient care to total 4 years.

(2) An Associate's degree in orthotics or prosthetics/orthotics and a minimum of 3,800 hours of experience in providing direct patient care in orthotics or in prosthetics and orthotics over a period of 2 years, to total at least 4 years of education, training and work experience.

(3) At least 2 or more years of education, training or work experience in the field of orthotics and a minimum of 3,800 hours of experience in providing direct patient care in orthotics or in prosthetics and orthotics over a period of 2 years, to total at least 4 years of education, training and work experience.

(c) To meet the qualifications for licensure in section 13.5(f) of the act, an applicant shall

demonstrate current National certification from an organization approved by the Board as a orthotist or prosthetist and orthotist.

(d) To meet the qualifications for licensure in section 13.5(f) of the act, an applicant shall demonstrate that the applicant has been in active, continuous practice for the 3-year period between July 5, 2009, and July 5, 2012.

(e) The Board may deny an application for licensure as an orthotist without examination upon any of the grounds for disciplinary action set forth in section 41 of the act (63 P.S. § 422.41) or § 18.852 (relating to unprofessional and immoral conduct).

(f) This section expires at 5:00 p.m. on July 7, 2014. An application for licensure without examination received after July 7, 2014 will be returned to applicant.

§ 18.826. Demonstration of qualifications.

An applicant for orthotist licensure shall:

- (1) Demonstrate the degree or other education and training by having the educational institution submit, directly to the Board, verification of the degree and official transcript or certificates of attendance at other training.
- (2) Demonstrate direct patient care by having the applicant's supervisor, employer or a referral source file an attestation on a form provided by the Board. If attestation is from a referral source, it shall include a copy of the applicant's Federal EIN and evidence of the date the applicant received the EIN.
- (3) Demonstrate National certification by having the National certification body send verification of National certification directly to the Board.
- (4) Demonstrate compliance with § 18.864 (relating to professional liability insurance coverage for licensed prosthetist, orthotist, pedorthist or orthotic fitter) by verification

and, if requested, a copy of an insurance binder, certificate, policy, declarations page or other documentation acceptable to the Board.

(5) Demonstrate that the applicant has been in active, continuous practice for the 3-year period between July 5, 2009, and July 5, 2012, by attestation and one of the following:

- (i) Applicant's Federal tax returns from 2009 – 2012 listing the applicant's occupation as prosthetist or orthotist, as appropriate.
- (ii) Attestation from the applicant's employer or health care referral source, including the Federal EIN information set forth in paragraph (4) demonstrating that the applicant has been in active, continuous practice.

QUALIFICATIONS FOR LICENSURE AS A PEDORTHIST

§ 18.831. Temporary practice permit.

(a) Prior to providing pedorthic patient care and after completion of an approved pedorthic education program, an individual shall submit an application for a temporary practice permit authorizing the individual to work as a graduate pedorthist, on forms made available by the Board. The Board may grant a temporary practice permit to an applicant who submits a completed application including any necessary supporting documents, pays the application fee set forth in § 16.13(p) (relating to licensure, certification, examination and registration fees) and meets the qualifications set forth in subsection (b).

(b) The Board may issue a temporary practice permit to an applicant who:

- (1) Is of good moral character.
- (2) Has successfully completed an NCOPE-accredited pre-certification education

program or its equivalent as determined by the Board.

(3) Otherwise satisfies all requirements for a temporary practice permit and is not barred from licensure.

(c) The Board may deny an application for a temporary practice permit as a graduate pedorthist upon the grounds for disciplinary action set forth in section 41 of the act (63 P.S. § 422.41) or § 18.852 (relating to unprofessional and immoral conduct).

(d) A temporary practice permit is valid for a maximum of 1 year and is nonrenewable; however, a temporary practice permit automatically expires if the permit holder fails the examination.

§ 18.832. Patient fitting experience.

(a) A graduate pedorthist with a temporary practice permit shall practice only under the direct supervision of a licensed pedorthist within the work experience. For purposes of this section, “direct supervision” means the supervisor is available for consultation throughout the patient care process and is able to visually assess the care being provided. The supervisor shall review the results of care and the documentation of the services rendered by the supervised individual and is responsible for countersigning within 15 days all entries in the patient’s clinical record.

(b) The supervised patient fitting experience must be obtained subsequent to education and must encompass all aspects of pedorthic care.

§ 18.833. Pedorthist license.

(a) An applicant for a license to practice as a pedorthist shall submit, on forms made available by the Board, a completed application for licensure, including all necessary supporting documents, and pay the application fee set forth in § 16.13(p) (relating to licensure, certification,

examination and registration fees).

(b) The Board may issue a license to practice as a pedorthist to an applicant who:

(1) Is of good moral character.

(2) Has successfully completed an NCOPE-accredited pedorthic education program or its equivalent as determined by the Board.

(3) Has completed a minimum of 1,000 hours of supervised patient fitting experience.

(4) Holds current National certification from the ABC or BOC.

(5) Has complied with § 18.864 (relating to professional liability insurance coverage for prosthetist, orthotist, pedorthists and orthotic fitters).

(6) Otherwise satisfies all requirements for licensure and is not barred from licensure.

(c) The Board may deny an application for licensure as a pedorthist upon the grounds for disciplinary action set forth in section 41 of the act (63 P.S. § 422.41) or § 18.852 (relating to unprofessional and immoral conduct.)

§ 18.834. Alternate pathway for pedorthist license.

(a) Through July 7, 2014, an individual may apply for licensure as a pedorthist without examination by submitting an application for licensure without examination, paying the application fee in § 16.13(p) (relating to licensure, certification and registration fees), and providing documentation acceptable to the Board to demonstrate that the applicant meets the qualifications of sections 13.5(a)(8), (f), (i) of the act (63 P.S. §§ 422.13e(a)(8), (f) and (i)).

(b) The Board may issue a license under this section to an applicant for pedorthist licensure without examination who complies with this section and:

(1) Meets the qualifications of sections 13.5(a)(1), (5), (6), (7) and (8) of the act.

(2) Has successfully completed an NCOPE-accredited pedorthic education program.

or its equivalent as determined by the Board.

- (3) Has completed a minimum of 1,000 hours of supervised patient fitting experience.
- (4) Holds current National certification as a pedorthist from a certification organization recognized by the Board.
- (5) Has been in active continuous practice for the 3-year period between July 5, 2009, and July 5, 2012.
- (6) Has complied with § 18.864 (relating to professional liability insurance coverage for prosthetist, orthotist, pedorthist and orthotic fitter).
- (c) The Board may deny an application for licensure as a pedorthist without examination upon any of the grounds for disciplinary action set forth in section 41 of the act (63 P.S. § 422.41) or § 18.852 (relating to unprofessional and immoral conduct).
- (d) This section expires at 5:00 p.m. on July 7, 2014. An application for licensure without examination received after July 7, 2014, will be returned to the applicant.

§ 18.835. Demonstration of qualifications.

An applicant for pedorthist licensure shall:

- (1) Demonstrate compliance with § 18.864 (relating to professional liability insurance coverage for licensed prosthetist, orthotist, pedorthist or orthotic fitter) by verification and, if requested, a copy of an insurance binder, certificate, policy, declarations page or other documentation acceptable to the Board.
- (2) Demonstrate National certification by having the National certification body send verification of National certification directly to the Board.
- (3) Demonstrate completion of an NCOPE accredited pedorthic education program by having the educational institution submit, directly to the Board, verification of

completion or demonstrate completion of an equivalent educational program by submitting an official transcript, course syllabi, or other information to demonstrate equivalence as requested by the Board.

(4) Demonstrate 1,000 hours of supervised patient fitting experience by having the applicant's supervisor, employer or a referral source file an attestation on a form provided by the Board. If attestation is from a referral source, it shall include a copy of the applicant's Federal EIN and evidence of the date the applicant received the EIN.

(5) Demonstrate that the applicant has been in active, continuous practice for the 3-year period between July 5, 2009, and July 5, 2012, by attestation and one of the following:

(i) Applicant's Federal tax returns from 2009 – 2012 listing the applicant's occupation as pedorthist.

(ii) Attestation from the applicant's employer or health care referral source, including the Federal EIN information set forth in paragraph (4) demonstrating that the applicant has been in active, continuous practice.

QUALIFICATIONS FOR LICENSURE AS AN ORTHOTIC FITTER

§ 18.841. Temporary practice permit.

(a) Prior to providing any orthotic fitting care, an individual must obtain a temporary practice permit authorizing the individual to work as a graduate orthotic fitter. An individual shall submit an application for a temporary practice permit, on forms made available by the Board. The Board may grant a temporary practice permit to an individual who submits a completed application including any necessary supporting documents, pays the application fee set forth in §

16.13(p) (relating to licensure, certification, examination and registration fees) and meets the qualifications set forth in subsection (b).

(b) The Board may grant a temporary practice permit to an individual who:

(1) Is of good moral character.

(2) Has successfully completed an NCOPE-approved orthotic fitter education program or its equivalent as determined by the Board.

(3) Otherwise satisfies all requirements for a temporary practice permit and is not barred from licensure.

(c) The Board may deny an application for a temporary practice permit upon the grounds for disciplinary action set forth in section 41 of the act (63 P.S. § 422.41) or § 18.852 (relating to unprofessional and immoral conduct).

(d) A temporary practice permit is valid for a maximum of 1 year and is nonrenewable; however, a temporary practice permit automatically expires if the permit holder fails the examination.

§ 18.842. Orthotic fitting care experience.

(a) A graduate orthotic fitter with a temporary practice permit shall practice only under the direct supervision of an orthotist or orthotic fitter licensed by the Board or an orthotist or orthotic fitter certified by ABC or BOC. For purposes of this section, “direct supervision” means the supervising licensed individual is available for consultation throughout the patient care process and is able to visually assess the care being provided. The supervisor shall review the results of care and the documentation of the services rendered by the supervised individual and is responsible for countersigning within 15 days all entries in the patient’s clinical record.

(b) The orthotic fitting care experience must be obtained subsequent to education.

§ 18.843. Orthotic fitter license.

(a) An applicant for a license to practice as an orthotic fitter shall submit, on forms made available by the Board, a completed application for licensure, including all necessary supporting documents, and pay the application fee set forth in § 16.13(q) (relating to licensure, certification, examination and registration fees).

(b) The Board may issue a license to practice as an orthotic fitter to an applicant who:

(1) Is of good moral character.

(2) Has successfully completed a BOC- or NCOPE-approved orthotic fitter education program or its equivalent as determined by the Board.

(3) Has completed a minimum of 1,000 hours of documented supervised orthotic fitting care experience.

(4) Holds current National certification from ABC or BOC.

(5) Has complied with § 18.864 (relating to liability professional insurance coverage for prosthetist, orthotist, pedorthist and orthotic fitter).

(6) Otherwise satisfies all requirements for licensure and is not barred from licensure.

(c) The Board may deny an application for licensure as an orthotic fitter upon the grounds for disciplinary action set forth in section 41 of the act or § 18.852 (relating unprofessional and immoral conduct).

§ 18.844. Alternate pathway for orthotic fitter license.

(a) Through July 7, 2014, an individual may apply for licensure as an orthotic fitter without examination by submitting an application for licensure without examination, paying the application fee in § 16.13(q) (relating to licensure, certification and registration fees), and providing documentation acceptable to the Board to demonstrate that the applicant meets the

qualifications of sections 13.5(a)(8), (f) and (i) of the act (63 P.S. §§ 422.13e(a)(8), (f) and (i)).

(b) The Board may issue a license under this section to an applicant for orthotic fitter licensure without examination who complies with this section and:

- (1) Meets the qualifications of sections 13.5(a)(1), (5), (6), (7) and (8) of the act.
- (2) Has successfully completed a Board-approved entry level orthotic fitter education program.
- (3) Has completed a minimum of 1,000 hours of supervised orthotic fitting care experience.
- (4) Holds current National certification as an orthotic fitter from a certification organization recognized by the Board.
- (5) Has been in active continuous practice for the 3-year period between July 5, 2009, and July 5, 2012.
- (6) Has complied with § 18.864 (relating to liability professional insurance coverage for prosthetist, orthotist, pedorthist and orthotic fitter).

(c) The Board may deny an application for licensure as an orthotic fitter without examination upon any of the grounds for disciplinary action set forth in section 41 of the act (63 P.S. § 422.41) or § 18.852 (relating to unprofessional and immoral conduct).

(d) This section expires at 5:00 p.m. on July 7, 2014. An application for licensure without examination received after July 7, 2014 will not be accepted and will be returned to the applicant.

§ 18.845. Demonstration of qualifications.

An applicant for orthotic fitter licensure shall:

- (1) Demonstrate compliance with § 18.864 (relating to professional liability insurance

coverage for licensed prosthetist, orthotist, pedorthist or orthotic fitter) by verification and, if requested, a copy of an insurance binder, certificate, policy, declarations page or other documentation acceptable to the Board.

(2) Demonstrate National certification by having the National certification body send verification of National certification directly to the Board.

(3) Demonstrate completion of a Board-approved entry level orthotic fitter education program by having the educational institution submit, directly to the Board, verification of completion.

(4) Demonstrate 1,000 hours of supervised orthotic fitting care experience by having the applicant's supervisor, employer or a referral source file an attestation on a form provided by the Board. If attestation is from a referral source, it shall include a copy of the applicant's Federal EIN and evidence of the date the applicant received the EIN.

(5) Demonstrate that the applicant has been in active, continuous practice for the 3-year period between July 5, 2009, and July 5, 2012, by attestation and one of the following:

(i) Applicant's Federal tax returns from 2009 – 2012 listing the applicant's occupation as pedorthist.

(ii) Attestation from the applicant's employer or health care referral source, including the Federal EIN information set forth in paragraph (4) demonstrating that the applicant has been in active, continuous practice.

REGULATION OF PRACTICE

§ 18.851. Scope and standards of practice.

- (a) Prior to providing services to a patient, a prosthetist, orthotist, pedorthist or orthotic fitter shall review the prescription and referral or valid order of the licensed prescribing practitioner and shall understand any conditions or restrictions placed on the course of treatment by the licensed prescribing practitioner.
- (b) Prior to providing services to a patient, a prosthetist, orthotist, pedorthist or orthotic fitter shall ensure the patient has undergone a medical diagnostic examination or has had the results of a recently performed medical diagnostic examination reviewed by a licensed prescribing practitioner by obtaining a copy of the prescription and relevant clinical notes.
- (c) A prosthetist, orthotist, pedorthist or orthotic fitter must retain a copy of the prescription and referral or valid order, clinical notes and results of the relevant medical diagnostic examination in the patient's file.
- (d) A prosthetist, orthotist, pedorthist or orthotic fitter may not accept any 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. In such instances, the prosthetist, orthotist, pedorthist or orthotic fitter shall consult with the licensed prescribing practitioner who wrote the prescription and referral or order and shall disclose the issue to the patient.
- (e) For purposes of this section, the results of the medical diagnostic examination must include, at a minimum, diagnosis, prognosis, medical necessity and duration of need relevant to the practice of the prosthetist, orthotist, pedorthist or orthotic fitter.

§ 18.852. Delegation.

- (a) 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

performance of tasks if the following conditions are met:

(1) The delegation is consistent with the standards of acceptable prosthetic, orthotic and pedorthic practice embraced by the prosthetic, orthotic and pedorthic community in this Commonwealth.

(2) The practitioner delegating the task has knowledge that the delegatee has education, training, experience and competency to safely perform the task being delegated.

(3) The practitioner delegating the task has determined, by reviewing the case, that the delegation to the delegatee does not create an undue risk to the particular patient.

(4) The nature of the task and the delegation of the task has been explained to the patient by the practitioner delegating the task, and the patient does not object to the performance by the delegatee.

(5) The practitioner delegating the task assumes the responsibility for the delegated task, including the performance of the task, and is available to the delegatee for additional direction or assistance.

(6) The practitioner provides direct, on-site supervision of the tasks performed by a delegatee.

(7) The practitioner delegating the task assumes the responsibility for ensuring that the delegatee does not state or in any way imply, including through the use of titles, that the delegatee is licensed to practice orthotics, prosthetics, pedorthics or orthotic fitting.

(b) A prosthetist, orthotist or pedorthist may not delegate a task if the performance of the task is restricted by law to performance by a prosthetist, orthotist, pedorthist or orthotic fitter, or if the performance of the task requires knowledge and skill not ordinarily possessed by assistive personnel, including knowledge of complications and risks associated with the delegated task.

(c) A prosthetist, orthotist or pedorthist is responsible for the delegated task and may be disciplined for improperly delegating a task, for improperly supervising a delegatee and for the improper performance of a delegated task performed by the delegatee.

§ 18.853. Unprofessional and immoral conduct.

(a) A licensee under this subchapter is subject to refusal of license or permit or disciplinary action under sections 22 and 41 of the act (63 P.S. §§ 422.22 and 422.41). Following a final determination subject to the right of notice, hearing and adjudication and the right of appeal therefrom in accordance with the Administrative Agency Law (2 Pa.C.S. §§ 501-508 and 701-704), this chapter, and the General Rules of Administrative Practice and Procedure (1 Pa. Code §§ 31.1 – 35.251), the Board may refuse licensure or impose any of the corrective actions of section 42 of the act (63 P.S. § 422.42).

(b) Unprofessional conduct includes:

- (1) Engaging in any conduct prohibited under § 16.110 (relating to sexual misconduct).
- (2) Performing an act in a healthcare profession in a fraudulent, incompetent or negligent manner.
- (3) Violating a provision of the act or this chapter setting a standard of professional conduct.
- (4) Engaging in healthcare practice beyond the licensee's authority to practice.
- (5) Representing oneself to be a physician or other healthcare practitioner whose profession the licensee is not licensed to practice.
- (6) Practicing while the licensee's ability to do so is impaired by alcohol, drugs, physical disability or mental instability.

- (7) Revealing personally identifiable facts obtained as the result of a practitioner-patient relationship without the prior consent of the patient, except as authorized or required by statute or regulation.
- (8) Misconduct in the practice of the licensee's profession or performing tasks fraudulently, incompetently, or negligently or by use of methods of treatment which are not in accordance with treatment processes accepted by a reasonable segment of the profession.
- (9) The promotion of the sale of services and devices in such manner as to exploit the patient or client for the financial gain of the practitioner or a third party.
- (10) Directly or indirectly offering, giving, soliciting or receiving, or agreeing to receive any fee or other consideration to or from a third party for the referral of a patient or client.
- (11) Delegating professional services contrary to § 18.852 (relating to delegation).
- (12) Over-utilizing services by providing excessive evaluation or treatment procedures not warranted by the condition of the patient or by continuing treatment beyond the point of possible benefit.
- (13) Making gross or deliberate misrepresentations or misleading claims as to professional qualifications or of the efficacy or value of the treatments or remedies given or recommended or those of another practitioner.
- (14) Overcharging for professional services, including filing false statements for collection of fees for which services are not rendered.
- (15) Failing to maintain a record for each patient that accurately reflects the evaluation and treatment of the patient.

- (16) Advertising or soliciting for patronage in a manner that is fraudulent or misleading. Examples of advertising or soliciting which is considered fraudulent or misleading includes:
- (i) Advertising by means of testimonials; anecdotal reports of orthotics, prosthetics or pedorthics practice successes; or claims of superior quality of care to entice the public.
 - (ii) Advertising which contains false, fraudulent, deceptive or misleading materials, warranties or guarantees of success, statements which play upon vanities or fears of the public, or statements which promote or produce unfair competition.
- (c) Immoral conduct includes:
- (1) Misrepresenting or concealing a material fact in obtaining a license issued by the Board or renewal, reactivation or reinstatement thereof.
 - (2) Being convicted of a crime involving moral turpitude, dishonesty or corruption in the courts of this Commonwealth, the United States, or another state, the District of Columbia, a territory of the United States, or another country.
 - (3) Committing an act involving moral turpitude, dishonesty or corruption.

BIENNIAL RENEWAL AND REACTIVATION

§ 18.861. Biennial renewal of license.

- (a) The license of a prosthetist, orthotist, pedorthist or orthotic fitter will expire biennially on December 31 of each even-numbered year, in accordance with § 16.15 (relating to biennial registration; inactive status and unregistered status). A prosthetist, orthotist, pedorthist or orthotic fitter may not practice after December 31 of an even-numbered year unless the

prosthetist, orthotist, pedorthist or orthotic fitter has completed the biennial renewal process and the Board has issued a current license.

(b) As a condition of biennial registration, a prosthetist, orthotist, pedorthist or orthotic fitter shall:

(1) Submit a completed application, including payment of the biennial renewal fee set forth in § 16.13 (relating to licensure, certification, examination and registration fees) for application for biennial renewal of prosthetist, orthotist, pedorthist or orthotic fitter license.

(2) Disclose on the application any license to practice as a prosthetist, orthotist, pedorthist or orthotic fitter in another state, territory, possession, or country.

(3) Disclose on the application any disciplinary action pending before or taken by an appropriate healthcare licensing authority in any other jurisdiction or the licensee's National credentialing body since the most recent application for biennial renewal, whether or not licensed to practice in that other jurisdiction.

(4) Disclose on the application any pending criminal charges and any finding or verdict of guilt, admission of guilt, plea of *nolo contendere*, probation without verdict, disposition in lieu of trial or accelerated rehabilitative disposition in any criminal matter since the most recent application for biennial renewal.

(5) Verify on the application that the licensed prosthetist, orthotist, pedorthist or orthotic fitter has completed the continuing education mandated by section 13.5(g)(1) of the act (63 P.S. § 422.13e(g)(1)) during the biennial period immediately preceding the period for which renewal is sought in accordance with § 18.862 (relating to continuing education).

(6) Verify on the application that the licensee maintains professional liability insurance coverage in accordance with section 13.5(i) of the act and § 18.864 (relating to professional liability insurance for licensed prosthetist, orthotist, pedorthist or orthotic fitter.

§ 18.862. Continuing education.

(a) Credit hour requirements. A licensed prosthetist, orthotist, pedorthist or orthotic fitter shall satisfy the following continuing education credit hour requirements:

(1) As a condition for biennial renewal, a prosthetist shall complete at least 24 hours of ABC- or BOC-approved continuing education applicable to the practice of prosthetics and an orthotist shall complete at least 24 hours of continuing education applicable to the practice of orthotics.

(2) As a condition for biennial renewal, a pedorthist shall complete at least 13 hours of continuing education applicable to the practice of pedorthics and an orthotic fitter shall complete at least 13 hours of continuing education applicable to the practice of orthotic fitting.

(3) No credit for continuing education will be given for courses in office management or practice building.

(4) A licensee is not required to complete continuing education during the biennium in which the licensee was first licensed if licensure occurred within 3 years of completion of the approved educational program.

(5) Except when reactivating an inactive license, when the Board has granted a waiver, or when ordered by the Board, continuing education credits may be used to satisfy the continuing education credit hour requirements only for the biennial period in

which the credits were earned. No hour of continuing education may be used to satisfy the requirement of paragraphs (1) or (2) for more than one biennium.

(6) A licensee may request a waiver of the continuing education credit hour requirements because of serious illness, emergency, military service or other demonstrated hardship by submitting a request for waiver with all supporting documentation to the Board at least 90 days prior to the end of the biennial renewal period for which the waiver is sought. The Board may grant the waiver request in whole or in part and may extend the deadline by which the credit hour requirements must be met.

(b) *Disciplinary action.* A licensee may be subject to disciplinary action if the licensee submits false information to the Board regarding completion of the continuing education credit hour requirements in order to complete biennial renewal or fails to complete the continuing education hour requirements and practices as a prosthetist, orthotist, pedorthist or orthotic fitter after the end of the biennial period.

(c) *Documentation of continuing education.* Licensees shall maintain documentation of completion of continuing education by maintaining the certificate of attendance or completion issued by the course provider. Licensees shall maintain the certificates for at least 5 years after the end of the biennial renewal period in which the continuing education was completed. Certificates shall include the name of the course provider, the name and date of the course, the name of the licensee, the number of credit hours based on a 50-minute hour, and the category of continuing education, if applicable.

§ 18.863. Inactive and expired status of licenses; reactivation of inactive or expired license.

(a) A prosthetist, orthotist, pedorthist or orthotic fitter license will become inactive if the licensee requests in writing that the Board place the license on inactive status. The Board will provide written confirmation of inactive status to the licensee at the licensee's last known address on file with the Board.

(b) A prosthetist, orthotist, pedorthist or orthotic fitter license will be classified as expired if the licensee fails to renew the license by the expiration of the biennial renewal period on December 31 of each even-numbered year. The Board will provide written notice to a licensee who fails to make biennial renewal by sending a notice to the licensee's last known address on file with the Board.

(c) A prosthetist, orthotist, pedorthist or orthotic fitter whose license has become inactive or expired may not practice in this Commonwealth until the license has been reactivated.

(d) To reactivate an inactive or expired license, the licensee shall apply on forms made available by the Board and fully answer the questions. The licensee shall:

(1) Include the documentation required under § 18.862(c) (relating to continuing education for license prosthetist, orthotist, pedorthist or orthotic fitter) for the immediately preceding biennium. Unless waived by the Board under section 13.5(i)(3) of the act (63 P.S. § 422.13e(i)(3)), the Board will not reactivate any license until the required continuing education for the preceding biennium has been successfully completed.

(2) Pay the current biennial renewal fee and the reactivation fee in § 16.13 (relating to licensure, certification, examination and registration fees).

- (3) Verify that the licensee did not practice as a prosthetist, orthotist, pedorthist or orthotic fitter in this Commonwealth while the license was inactive or expired except as provided in subsection (e).
- (e) A licensee who has practiced with an inactive or expired license and who cannot make the verification required under subsection (d)(3) shall also pay the fees required under section 225 of the Bureau of Professional and Occupational Affairs Fee Act (63 P.S. § 1401-225), as described in this subsection. Payment of a late fee does not preclude the Board from taking disciplinary action for practicing as a prosthetist, orthotist, pedorthist or orthotic fitter without a currently renewed license.
- (1) A licensee whose license was active at the end of the immediately preceding biennial renewal period and who practiced after the license became inactive or expired shall pay a late fee of \$5 for each month or part of a month from the beginning of the current biennium until the date the reactivation application is filed.
- (2) A licensee whose license has been inactive or expired since before the beginning of the current biennium shall pay the biennial renewal fee for each biennial renewal period during which the licensee practiced and shall pay a late fee of \$5 for each month or part of a month from the first date the licensee practiced as a prosthetist, orthotist, pedorthist or orthotic fitter in this Commonwealth after the license became inactive or expired until the date the reactivation application is filed.
- (f) A licensee whose license has been inactive for more than 2 years and who has not been engaged in practice in another jurisdiction, shall demonstrate continued competence by passing the certification examinations offered by either the BOC or ABC. For prosthetists or orthotists, the applicable examinations are the BOC or ABC examinations required for initial certification;

for pedorthists or orthotic fitters, the applicable examinations are the BOC or ABC pedorthist or orthotic fitter examination required for initial certification.

§ 18.864. Professional liability insurance coverage for licensed prosthetist, orthotist, pedorthist or orthotic fitter.

(a) A licensed prosthetist, orthotist, pedorthist or orthotic fitter shall maintain a level of professional liability insurance coverage in the minimum amount of \$1,000,000 per occurrence or claims made as required by section 13.5(i) of the act (63 P.S. § 422.13e(i)), and shall provide proof of coverage upon request.

(b) Proof of professional liability insurance coverage may include:

(1) A certificate of insurance or copy of the declaration page from the insurance policy setting forth the effective date, expiration date, and dollar amounts of coverage.

(2) Evidence of a plan of self-insurance approved by the insurance commissioner of the Commonwealth under regulations of the Department of Insurance at 31 Pa. Code §§ 243.1 – 243.11 (relating to medical malpractice and health-related self-insurance plans).

(c) A licensee who does not have professional liability insurance coverage as required by section 13.5(i) of the act may not practice as a prosthetist, orthotist, pedorthist or orthotic fitter in this Commonwealth.



COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
STATE BOARD OF MEDICINE

Post Office Box 2649
Harrisburg, Pennsylvania 17105-2649
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June 30, 2014

The Honorable John F. Mizner, Esq., Chairman
INDEPENDENT REGULATORY REVIEW COMMISSION
14th Floor, Harristown 2, 333 Market Street
Harrisburg, Pennsylvania 17101

Re: Proposed Regulation
State Board of Medicine
16A-4943: Prosthetists, Orthotists, Pedorthists and Orthotic Fitters

Dear Chairman Mizner:

Enclosed is a copy of a proposed rulemaking package of the State Board of Medicine pertaining to Prosthetists, Orthotists, Pedorthists and Orthotic Fitters.

The Board will be pleased to provide whatever information the Commission may require during the course of its review of the rulemaking.

Sincerely,

A handwritten signature in black ink, appearing to read "Andrew J. Behrke".

Andrew J. Behrke, M.D., Chairperson
State Board of Medicine

AJB/TL:ld

Enclosure

cc: Travis N. Gery, Esq., Commissioner
Professional and Occupational Affairs
Patricia Allan, Director of Policy, Department of State
Kevin Schmidt, Chief Counsel
Department of State
Cynthia Montgomery, Regulatory Counsel
Department of State
Teresa Lazo, Counsel
State Board of Medicine
Wesley Rish, Counsel
State Board of Medicine
State Board of Medicine

**TRANSMITTAL SHEET FOR REGULATIONS SUBJECT TO THE
REGULATORY REVIEW ACT**

I.D. NUMBER: 16A-4943
SUBJECT: Prosthetists, Orthotists, Pedorthists and Orthotic Fitters
AGENCY: DEPARTMENT OF STATE
 BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS
 STATE BOARD OF MEDICINE

TYPE OF REGULATION

- X Proposed Regulation
- Final Regulation
- Final Regulation with Notice of Proposed Rulemaking Omitted
- 120-day Emergency Certification of the Attorney General
- 120-day Emergency Certification of the Governor
- Delivery of Tolled Regulation
 - a. With Revisions
 - b. Without Revisions

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<u>DATE</u>	<u>SIGNATURE</u>	<u>DESIGNATION</u>
		<i>HOUSE COMMITTEE ON PROFESSIONAL LICENSURE</i>
6/30/14	<i>Michele Warren</i>	MAJORITY CHAIR <u>Julie Harhart</u>
		MINORITY CHAIR _____
		<i>SENATE COMMITTEE ON CONSUMER PROTECTION & PROFESSIONAL LICENSURE</i>
6/30/14	<i>Mary Walmer</i>	MAJORITY CHAIR <u>Robt. M. Tomlinson</u>
		MINORITY CHAIR _____
		<i>INDEPENDENT REGULATORY REVIEW COMMISSION</i>
6/30/14	<i>K Cooper</i>	ATTORNEY GENERAL (for Final Omitted only)
6/30/14	<i>Courne Inant</i>	LEGISLATIVE REFERENCE BUREAU (for Proposed only)