CDL-1

FACE SHEET
FOR FILING DOCUMENTS
WITH THE LEGISLATIVE REFERENCE BUREAU

(Pursuant to Commonwealth Documents Law)

DO NOT WRITE IN THIS SPACE

Copy below is hereby approved as to form and legality. Attorney General

BY: _____
(DEPUTY ATTORNEY GENERAL)

_____
DATE OF APPROVAL

Copy below is hereby certified to be a true and correct copy of a document issued, prescribed or promulgated by:

State Board of Medicine
(AGENCY)

DOCUMENT/FISCAL NOTE NO. 16A-4943

DATE OF ADOPTION: _____

BY: Marilyn L. Heine M.D.
Marilyn Heine, M.D.

TITLE: Chairperson
(EXECUTIVE OFFICER, CHAIRMAN OR SECRETARY)

Copy below is approved as to form and legality. Executive or Independent Agencies.

BY: Marisa H. Z. Lehr

JUL 29 2016
DATE OF APPROVAL

(Executive Deputy General Counsel
Strike inapplicable title)

| | Check if applicable
Copy not approved.
Objections attached.

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

FINAL 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) hereby amends §§ 16.11 and 16.13 (relating to licenses, certificates and registrations; and licensure, certification, examination and registration fees), and adds Chapter 18, Subchapter L (relating 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. Following the delivery of proposed rulemaking, the General Assembly amended Act 90 by way of the act of July 2, 2014 (P.L. 941, No. 104) (Act 104). The Act 104 amendments altered the qualifications for licensure without examination and extended the date for individuals to obtain licensure without examination to March 31, 2015. The final-form rulemaking is authorized under section 3 of Act 90 and under section 2 of Act 104, as well as under section 8 of the act (63 P.S. § 422.8), which authorizes the Board to adopt regulations as are reasonably necessary to carry out the purposes of the act.

Summary of Comments and Responses to Proposed Rulemaking

Notice of the proposed rulemaking was published at 44 Pa.B. 4364 (July 12, 2014), inviting public comment. The Board received comments from members of the regulated community/public, the House Professional Licensure Committee (HPLC) and the Independent Regulatory Review Commission (IRRC). Several commenters submitted comments stating that some of the provisions of the proposed rulemaking were not consistent with Act 104. Because the Board's adoption of the proposed rulemaking predated the passage of Act 104, the Board was aware that, at the time of publication, some of the provisions conflicted with Act 104. The provisions of Act 104 which related to the alternate pathway for licensure expired on March 31, 2015. Accordingly, those sections of the proposed rulemaking related to the alternate pathway have been deleted. As of early May 2016, the Board has issued the following licenses:

	Alternate Pathway	Traditional Licensure
Prosthetist	168	52
Orthotist	256	58
Pedorthist	79	38
Orthotic Fitter	120	70

Comments from the Pennsylvania Orthotic and Prosthetic Society

Eileen Levis, President of The Pennsylvania Orthotic and Prosthetic Society (POPS) submitted comments on behalf of POPS on July 25, 2014. Several of POPS comments relate to the Board's references to the Commission on Accreditation of Allied Health Education Programs (CAAHEP), the National Commission for Certifying Agencies (NCCA), and the National Commission on Orthotic and Prosthetic Education (NCOPE). POPS asserts that the Board should delete references in the rulemaking to CAAHEP and NCOPE because these organizations are not listed in Act 90. Act 90 includes a definition for only two organizations - the Institute for Credentialing Excellence (ICE) and NCCA. Conversely, POPS asserts that the Board should reference the Board of Certification/Accreditation International, Inc. (BOC) and the American Board for Certification in Orthotics, Prosthetics and Pedorthics, Inc. (ABC) and further asserts that the Board should list the Accrediting Bureau of Health Education Schools (ABHES) in the regulations. Neither Act 90 nor Act 104 mentions the BOC, ABC or ABHES, just as neither mentions CAAHEP or NCOPE.

The Board believes it is important to refer to both CAAHEP and NCOPE. Section 13.5 of the act (63 P.S. § 422.13e) requires all applicants for licensure as a prosthetist, orthotist, pedorthist or orthotic fitter have received certification by a prosthetic, orthotic, pedorthic or orthotic fitter credentialing organization accredited by NCCA. The two NCCA-accredited organizations that currently certify individuals in orthotics, prosthetics and pedorthics are the ABC and the BOC. To meet the qualifications for certification by the ABC or the BOC as a prosthetist or orthotist, an individual must complete a CAAHEP-accredited education program and an NCOPE-approved residency program. To meet the qualifications for certification by the ABC or the BOC as a pedorthist, an individual must complete an NCOPE-approved pedorthic precertification education program. The Board's reference to CAAHEP and NCOPE in the regulation alerts the public that approved education is required for licensure in orthotics and prosthetics in this Commonwealth. All 12 United States institutions which offer prosthetics/orthotics education at the bachelor's or higher degree level are accredited by CAAHEP. (The accredited programs are at Alabama State University, California State University, Loma Linda University, University of Hartford, St. Petersburg College, Georgia Institute of Technology, Northwestern University, Eastern Michigan University, Century College, University of Pittsburgh, University of Texas Southwest Medical Center and the University of Washington.) Moreover, 10 of the other 13 States that license orthotists and prosthetists specifically reference CAAHEP as the accrediting body for orthotic and prosthetic education. (CAAHEP does not accredit pedorthic or orthotic fitter education programs.) Accordingly, the Board believes its proposed regulations correctly reference CAAHEP.

POPS suggests that the Board should instead refer to ABHES in its regulation. ABHES accredits diploma technology programs and some associate degree programs. ABHES does not currently accredit any prosthetic, orthotic, pedorthic or orthotic fitter education programs. Because ABHES does not accredit any programs in the professions addressed by Acts 90 and 104, the Board declines to specifically reference it in the regulations.

POPS next objects to the Board's references to NCOPE in §§ 18.802, 18.811, 18.812, 18.822, 18.823, 18.831, 18.833, 18.841 and 18.843. In response, the Board notes that certification

(by the ABC or the BOC) is a prerequisite to licensure; completion of an NCOPE-approved residency program is a prerequisite to certification. Accordingly, regulatory sections related to licensure should reference NCOPE so that everyone reading the regulations has notice that an NCOPE-approved residency is required for licensure. Moreover, every other State which licenses orthotists and prosthetists explicitly requires completion of an NCOPE-approved residency program as a qualification for licensure.

Similarly, regulatory sections related to a graduate permit should reference NCOPE. In §§ 18.811(b)(3) and 18.821(b)(3) (relating to graduate permit), the Board requires applicants for a graduate permit as a prosthetist or orthotist to have registered with NCOPE for their residency. The graduate permit authorizes the holder to practice the profession only within the approved residency program, where appropriate clinical education and supervision/monitoring of the new graduate's skills may occur. POPS asserts that requiring clinical residencies to be NCOPE-approved would be inconsistent "with the language or intent of the statue" and "would also restrict individuals certified prior to the creation date of 1999, from qualifying for a license." However, no one who was certified prior to 1999 would now be applying to the Board for a graduate permit to participate in a clinical residency program. Individuals that were certified prior to 1999 would have already qualified for licensure pursuant to the alternate pathway for existing practitioners.

If POPS is suggesting that the Board should issue graduate permits to authorize individuals to practice the profession in some way other than within an NCOPE-approved residency prior to meeting the qualifications for licensure, the Board disagrees. The Board is charged with regulating the professions in the interest of public health and safety; in its regulation of all the professions that it licenses, the Board requires individuals seeking licensure to be enrolled in or to have completed an education or experiential learning program that the Board finds to be of sufficiently high quality to ensure public health and safety. Moreover, the requirement that individuals complete an NCOPE-accredited residency is consistent with the requirements for certification by both ABC and BOC, and with the requirements for licensure in other states. Permitting graduates to practice without the educational structure and supervision of an approved residency program would endanger the public health and safety and would be a disservice to the graduates who would not be able to meet qualifications for certification or licensure through a work experience that is not an NCOPE-approved residency. Accordingly, the Board declines to delete its references to NCOPE.

Also related to the residency, POPS suggested that the provisions related to the clinical residency for prosthetists and orthotists in §§ 18.812 and 18.822 (relating to clinical residency) should permit graduate permit holders to practice only under the supervision of a licensee of the Board. Upon review, the Board agrees that only individuals who plan to complete a clinical residency within the Commonwealth would need to apply for a graduate permit. Conversely, individuals completing a clinical residency in another state would not need to apply for or obtain a graduate permit from the Board. Therefore, the Board has amended these provisions to require that the supervisor be a licensee of the Board as suggested by POPS.

Regarding §§18.814 and 18.824 (relating to prosthetist license; and orthotist license), POPS asserts that the Board's requirement that applicants have earned a bachelor's degree, post-baccalaureate certificate or higher degree from a CAAHEP-accredited education program is

inconsistent with the act and that the Board should only require that an applicant be certified by a certification program accredited by NCCA. The Board disagrees that certification by a certification program accredited by NCCA is the only requirement for licensure. The licensure qualification of meeting particular educational minimums is set forth in section 13.5(a)(2) of the act. Certification is a requirement for licensure set forth in section 13.5(a)(3) of the act (63 P.S. § 422.13e(a)(3)). However, one condition of obtaining certification by ABC or BOC is the completion of a CAAHEP-accredited education program. If the Board were to require something other than a CAAHEP-accredited education, applicants who met the Board's education requirement would be unable to meet the education requirement for certification, and thus, would be ineligible for licensure. Finally, CAAHEP is the only National accrediting body for orthotic and prosthetic education programs and is required in all states which license these professionals. If the Board were to require something other than CAAHEP-accredited education, licensees of the Board may find it difficult to obtain reciprocal licensure as a prosthetist or orthotist in another state should the need arise. For all of these reasons, the Board has retained the requirement that the education program required by section 13.5(a)(2) of the act be CAAHEP-accredited.

POPS suggests that the Board delete the definition for "custom-designed device" stating that this is not a term recognized by CMS or the industry. The term is used in section 2 of the act, in the definition of "prosthesis." The definition commences with "a custom-designed, custom-fabricated, custom-fitted or custom-modified device." However, the act further defines only two of the terms: "custom-fabricated device" and "custom-fitted device." Accordingly, the Board defined the other two terms used in the act: custom-designed device and custom-modified device, basing the definitions on input from industry stakeholders.

POPS suggests that the Board's definition of "pedorthic device" is contrary to the act because subsection (ii) is not, according to POPS, in the act. The Board respectfully disagrees. The definition of "pedorthic device" included in § 18.802 is virtually identical to that in section 2 of the act (63 P.S. § 422.2), which specifically excludes "nontherapeutic, accommodative inlays and nontherapeutic accommodative footwear, regardless of the method of manufacture; unmodified, nontherapeutic over-the-counter shoes; or prefabricated unmodified or unmodifiable foot care and footwear products." The only difference is in the formatting.

POPS commented with regard to proposed §§ 18.816, 18.826, 18.835 and 18.845 (relating to demonstration of qualifications) that these requirements only pertain to licensure under the alternate pathway and should be deleted or amended to conform to Act 104. These sections were intended to provide guidance to all applicants with regard to how to demonstrate that they meet the various requirements for licensure, whether by the traditional pathway or by the alternate pathway. Now that the alternate pathway to licensure is no longer available, the Board has deleted these sections. The Board has revised all other relevant sections to clarify the documentation necessary to demonstrate the qualifications required for licensure as a prosthetist, orthotist, pedorthist or orthotic fitter.

POPS suggests that the Board should not have separated the educational and experiential qualifications for prosthetist and orthotist licensure into subsections in §§ 18.814(b)(2) and (3) and 18.824(b)(2) and (3). The Board finds that the provisions are separated by the word "and" in section 13.5(a)(2)(i) and (ii) of the act (63 P.S. § 422.13e(a)(2)(i) and (ii)), and that the list of

qualifications is easier to read separated into subsections. Therefore, the Board declines to place the two qualifications into a single sentence as recommended by POPS.

Regarding § 18.832 (related to patient fitting experience) for graduate pedorthists, POPS suggests that a graduate pedorthist should be permitted to obtain the patient fitting experience under the direct supervision of a prosthetist or orthotist as well as a pedorthist. The Board was not aware that prosthetists' work was sufficiently similar to pedorthists' work, but defers to POPS' knowledge in this area and has made the change.

Regarding maintenance of certification, POPS commented that Act 90 does not require licensees to maintain their certification and POPS does not believe that it should be a requirement for license renewal. The proposed rulemaking also does not require licensees to maintain their ABC or BOC certification. Nowhere in § 18.861 (relating to biennial renewal of license) is there any mention of the maintenance of certification as a condition of renewal. However, the Board strongly recommends that professionals who hold a certification from ABC or BOC maintain that certification, which may be needed should the licensee seek to relocate to another state. In addition, certification provides a professional community to licensees and a source for keeping up to date on practice issues. Finally, certification may be required by employers as a condition of employment or by insurers as a condition of payment.

Finally, POPS stated that "application for licensure appears to extend to anyone in any state. POPS believes the regulations should require the individual to be working for a company located within the Commonwealth." The Board declines to adopt such a requirement because it believes such a restriction would violate the United States and Pennsylvania constitutions and would be a barrier to individuals who are considering relocating to Pennsylvania to practice their profession but who wish to secure licensure before finalizing a decision to relocate to this Commonwealth.

Comments related to practice by unlicensed individuals

Regarding proposed § 18.852 (relating to delegation), POPS commented that Act 90 "clearly prohibits the delegation of patient care to non-licensed individuals." While the Board agrees that prosthetics, orthotics, pedorthics or orthotic fitting as defined in the act may be exclusively performed by licensed individuals, several stakeholders indicated to the Board that orthotic and prosthetic assistants and orthotic and prosthetic technicians were standard types of employees in the industry, as is the case in many other healthcare fields. The Board defined orthotic and prosthetic assistant as an individual who assists with patient care tasks, not an individual who provides that care. In addition, in § 18.852(b), the Board specifically provided that a task may not be delegated to an unlicensed assistant "if the performance of the task is restricted by law to performance by" a licensed individual, or if the performance of the task requires knowledge or skill not ordinarily possessed by assistive personnel. However, upon review of this comment by the Board, and with significant input from the regulated community, the Board has revised and renamed § 18.852 as pertaining to "supervision and assistance" by unlicensed assistive personnel. As revised, orthotic and prosthetic assistants and pedorthic support personnel must be subject to direct supervision, defined such that the prosthetist, orthotist or pedorthist is on the premises, periodically observes and is continuously available to provide guidance to the assistant.

Sofya Tamarkin, a licensed pedorthist, submitted comments, suggesting that the Board adopt a definition for "indirect supervision" such as that used in Iowa, which would "imply that a licensed certified professional would be liable and responsible for any non-licensed Orthotic Fitters." According to Ms. Tamarkin, her proposal would also make the licensed professional accountable for all training and formal education of non-licensed individuals. Licensed professionals would not be present during the delivery of care, however, the licensee would be required to sign all medical records produced by non-licensed professionals. In addition, the licensee would be required to be available for direct consultation within 15 minutes during the patient's visit in case direct supervision is required.

In response, the Board notes that in Iowa certified orthotic fitters are not licensed and the definition of "indirect supervision" refers to delegation of orthotic fitting tasks to these individuals. The Iowa provision does not permit delegation to noncertified orthotic fitters. In this Commonwealth, the act does provide for licensure of certified orthotic fitters. The Board believes that the proposed regulation is actually more inclusive of supportive personnel, because it allows assignment of tasks to these individuals so long as assignment of the task is consistent with the standards of acceptable practice embraced by the prosthetic, orthotic or pedorthic community in this Commonwealth. The revised rulemaking also provides that only a prosthetist, orthotist or pedorthist may perform an initial patient evaluation and the final provision of a prosthetic, orthotic or pedorthic device to a patient, and that the licensee assigning and supervising the tasks shall bear ultimate responsibility for the completed tasks.

State Senator Mike Stack made a similar comment on behalf of his constituents, suggesting the Board permit indirect supervision of non-licensed orthotic fitters. He suggested the following language: "Indirect supervision – non-licensed Orthotic Fitters are qualified to provide patient care independent of a licensee; however, the licensed supervisor must review and countersign all entries in the patient's clinical record within 15 working days following the delivery of care. The supervisor must be physically available for consultation within 60 minutes during the delivery of care." Irina Rabovetski, Esquire, made an identical suggestion. Ashley Nicoletti, Esquire, provided a similar comment, suggesting that a definition of "indirect supervision" similar to the ABC and BOC guidelines be included. Ms. Nicoletti's suggested language was as follows: "Indirect Supervision does not require the supervising credentialed individual to be on-site however they must be available for consultation throughout the patient care process. The supervisor must 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." Ms. Nicolleti explained that she proposed this addition because the regulation "does not allow for individuals who have been working for less than 2 years to occupy the role of Orthotic Fitter without passing a required board exam. That means that individuals wanting to work in this field have to pass an extremely difficult test that requires intricate medical knowledge. This makes it difficult for existing businesses to hire new employees due to the on-site supervision requirement currently required for new employees." Ms. Nicolleti opined that access to care would be diminished if the Board did not adopt indirect supervision for unlicensed individuals.

The Board believes that the intent of the General Assembly was to ensure public protection by requiring licensure for orthotic and prosthetic, pedorthic and orthotic fitting caregivers. To adopt a regulation that permits unlicensed individuals to provide orthotic and prosthetic, pedorthic and orthotic fitting care to patients would be inconsistent with the statute. The Board declines to add such a provision.

POPS suggests that the Board delete the definition for "orthotic and prosthetic assistant" in § 18.802 because the Center for Medicare/Medicaid Services (CMS) does not recognize these "classes" and because the purpose of the law was to clarify that only licensed individuals are permitted to provide orthotic, prosthetic and pedorthic care. First, the Board notes that CMS rules relate to insurance reimbursement, not to the practice of the professions. The act provides that only licensed individuals may practice prosthetics, orthotics, pedorthics or orthotic fitting within the scope of practice of their license; it does not prohibit unlicensed assistants from providing assistance to licensees so long as the assistant is not practicing the licensed profession. Assistants are common in all health care fields; there are nurse aides, medication aides, medical assistants and medical technicians, for example. POPS suggests that licensees should only be permitted to be assisted by orthotic fitters, occupational therapists, physical therapists and athletic trainers. Nothing in the act suggests that occupational therapists, physical therapists or athletic trainers may take orders from orthotic and prosthetic professionals. Indeed, the practice acts which regulate the practice of occupational therapists, physical therapists and athletic trainers do not authorize these licensees to take orders from orthotists, prosthetists or pedorthists. Moreover, both assistants and technicians are recognized in all but one of the other states which license the prosthetic, orthotic and pedorthic professions.

Regarding orthotic and prosthetic technicians, the Board shares POPS' understanding that these are individual engaged in manufacturing and repairing devices and are not directly involved in patient care. The Board believes that these individuals should be recognized so that, for example, a licensed prosthetist would not be required to perform every discrete task in the manufacture of a prosthetic device, such as painting details on an artificial hand. Technicians appear to be recognized in the industry, as well as being recognized in every other state which licenses orthotic and prosthetic professionals. Accordingly, the Board declines to delete the definition of an orthotic and prosthetic technician. However, the Board has revised the final rulemaking to provide that a prosthetist or orthotist may assign tasks related to the fabrication, assembly, modification and servicing of prosthetic and orthotic devices to technicians working to the specifications provided by the prosthetist or orthotist. The final rulemaking also makes it clear that the prosthetist, orthotist or pedorthist bears the ultimate responsibility for the tasks performed by assistants and technicians.

Comments from the Board of Certification

Claudia Zacharias, President and CEO of the BOC noted that the Board's references to certification were stated inconsistently throughout the proposed regulations, and suggested, as a solution, that the Board amend the definitions for BOC and ABC to provide that these organizations are certification organizations "approved and recognized by the Board." The Board agrees that the act requires applicants to "have received certification by a prosthetic, orthotic, pedorthic and orthotic fitting credentialing organization...approved by the board" and, as such, has amended the definition to clarify that the BOC and the ABC are board-approved organizations.

In addition to amending the definitions for ABC and BOC, the Board has amended the sections noted by BOC as not referring to certification consistently so that the references are internally consistent.

BOC next commented that § 18.832(a) (relating to patient fitting experience) authorizes a graduate pedorthist with a temporary practice permit to practice only under the direct supervision of a pedorthist, and suggested that a graduate pedorthist should be permitted to practice under the direct supervision of a licensed orthotist or prosthetist as well. The Board has amended § 18.832(a) accordingly.

Finally, BOC noted that § 18.835(4) (relating to demonstration of qualifications) which refers to the experiential component of pedorthic education should utilize the language "direct patient care in pedorthics" rather than "patient fitting experience." In response, the Board notes that section 13.5(a)(2)(iii) of act requires pedorthists to complete "a minimum of 1,000 hours in supervised patient fitting experience." The Board prefers to retain the statutory term. In the final-form rulemaking, the content of proposed § 18.835(4) has been moved to § 18.833(b)(3) (relating to pedorthist license). In response to the BOC's comment, the Board has added qualifying language to clarify that the patient fitting experience consists of providing direct patient care in pedorthics.

Comments from R.J. Hedges & Associates

R.J. Hedges & Associates ("RJH") stated that its comments had been coordinated with the "Pharmacy, Durable Medical Equipment and Mastectomy organizations" in the Commonwealth. RJH suggested that the Board add a definition for "facility" to clarify that the licensed individual is a legally operating business within the Commonwealth. The definition would provide that "facility" means the business location where care is provided and that has appropriate equipment to provide comprehensive orthotic, prosthetic and pedorthic care; and that licensees must be available to provide the care or supervise the provision of care by orthotic fitters or non-licensed staff. The Board notes first that the act does not require orthotic fitters to practice under the supervision of orthotists, prosthetists or pedorthists. In addition, definitions are added for terms used in the body of the regulation; the term "facility" is not used in the regulation and the Board does not see a need to define the term. Finally, it is the Board's understanding that practice may take place in a variety of settings, including a hospital, rehabilitation center, or private office. The Board is not aware that all care must take place in a facility that has the equipment to provide comprehensive care; some follow-up care, for example, may take place in an office that is separate from the comprehensive care facility.

RJH next suggested that the Board include a definition for "level of competence" which would be defined as "a hierarchical position that an individual occupies within a field or profession relative to other practitioners in the profession." Because neither the act nor the regulations use the term "level of competence," there is no need to define the term.

Like the BOC comment, RJH commented regarding the different terms used by the Board when discussing the type of certification required. The Board has made amendments as discussed above to standardize the terminology used in the rulemaking. Similarly, RJH noted that a pedorthist trainee should be able to practice under the supervision of a prosthetist or orthotist as

well as a pedorthist. The Board has amended § 18.832(a) accordingly. Finally, RJH commented that the term for the experience obtained by a pedorthist should properly be called "direct patient care" rather than "patient fitting." As noted above, the Board has addressed this comment by qualifying the statutory term "supervised patient fitting experience" as providing direct patient care in pedorthics.

Comments from C-Fab 1, Inc.

C-Fab 1, Inc. submitted comments on May 25, 2015. The comments were written by a self-identified "prosthetic and orthotic technician" practicing for 35 years, who owns a fabrication lab and provides devices to orthotists, prosthetists and pedorthists in this Commonwealth. The comment pointed out that technicians are not support personnel; rather, technicians fabricate and assemble devices based on a work order and specific instructions and measurements from a licensed professional. Once manufactured, the device is returned to the licensee for final fitting. The commenter also noted that individuals in fabrication businesses are not supervised by licensees. The commenter suggested that the definition of technicians should state that technicians manufacture, fabricate, modify, adjust, repair or maintain devices using a mold or specifications provided to them by a licensed orthotist, prosthetist or pedorthist. The Board has adopted a substantially similar definition, eliminating "adjust" as it believes an adjustment would be made in the patient care process. The definition has also been amended to eliminate the requirement of direct supervision. The Board has also amended § 18.852 (relating to delegation) to clarify that the prosthetist or orthotist must provide all of the necessary measurements and instructions to the technician for the fabrication, assembly, modification and servicing of the device.

Comments from the House Professional Licensure Committee

The HPLC submitted comments on August 28, 2014, asking the Board to explain its statutory authority pertaining to Graduate Permits, Clinical Residency and Provisional Licensure for prosthetists and orthotists. The Board has broad authority to promulgate regulations to effectuate the law. The law aims to promote the health and welfare of the citizens of the Commonwealth by ensuring they have access to properly trained orthotic and prosthetic professionals. The training of prosthetists and orthotists needed for licensure includes both didactic education and clinical education/experience. That is, to obtain certification by the ABC or BOC, a prosthetist or orthotist is required to complete a one year clinical residency, and the act provides the requirement of a minimum of 2 years (3,800 hours) of experience in providing direct patient care services. At the same time, the law prohibits the practice of these professions without licensure. As such, neither of these licensee classes could obtain the required clinical education or experience without actually practicing the profession as defined in the act. Accordingly, the Board had to develop some system which would allow these professionals to complete their clinical education and experience requirements without otherwise violating the law.

Without the graduate permits and provisional licenses devised by the Board, graduates of a prosthetist and orthotist education program would be required to complete the clinical residency and supervised experience required for full licensure in another state. Similarly, graduates of a pedorthist and orthotic fitter education program would be required to leave the Commonwealth to complete the 1,000 hours of experience required for full licensure, which is why the Board created

a temporary practice permit for those license classes. The Board believes that it cannot effectuate the statutory intent of ensuring access to quality orthotic and prosthetic professional services without allowing completion of the clinical portion of professional education (clinical residency) and the experience required by the act to take place within the Commonwealth. The Board believes that the creation of these permits and provisional licenses was necessary to effectuate the intent of the act.

HPLC next commented that the Board should be more specific pertaining to §§ 18.814(b)(6) and 18.824(b)(6) (relating to prosthetist license; and orthotist license), suggesting that the Board make reference to the act for licensees who need more clarification. Paragraph (6) provided that an applicant for licensure shall "otherwise satisfy[y] the requirements for licensure" and not be barred from licensure. The Board has determined that the provision is superfluous and has stricken it.

Finally, HPLC commented that it understood the Board would be making amendments to the proposed rulemaking to conform to Act 104 of 2014, and that it looked forward to seeing the advanced notice of final rulemaking. Because the provisions of Act 104 have now expired as of March 31, 2015, the Board has deleted the sections related to alternative pathways to licensure.

Comments from the Independent Regulatory Review Commission

IRRC submitted comments on September 10, 2014. IRRC noted that "A commentator, the Pennsylvania Orthotic Prosthetic Society (POPS) states in its comments that it was not included as a stakeholder, and therefore, there was not an equitable exchange among stakeholders." Upon passage of Act 90, the Board was contacted by only one stakeholder, the ABC, offering assistance with drafting of the rulemaking. The Board attempted to identify stakeholders by finding the prosthetist, orthotist and pedorthist educational programs in the Commonwealth; by researching certification and identifying the relevant certification bodies; by identifying the state professional association; and by speaking with individuals on the legislative staff regarding who might be an interested party.

For the first public meeting with stakeholders, the Board invited 33 individuals, including the president of the Board of Certification (BOC), Claudia Zacharias; Stephen Fletcher, Director of Clinical Resources and Catherine Carter, Executive Director of American Board for Certification (ABC); the Pennsylvania Orthopedic Society, the Amputee Coalition of America, the Pennsylvania Occupational Therapy Association, the Pennsylvania Orthopedic Society, the Pennsylvania Physical Therapy Association and the Pennsylvania Medical Society; Randy Stevens and Eileen Levis from the Pennsylvania Orthotic & Prosthetic Society (POPS); representatives from the University of Pittsburgh's graduate program in orthotics and prosthetics; representatives from the Temple University School of Podiatry, which had run a pedorthics educational program; the Pedorthic Footcare Association's Executive Director Brian Lagana; industry representatives from Carter Orthopedics and the National Orthotics Manufacturers Association; and Anjali Weber, Director of Accreditation for the Institute for Credentialing Excellence.

The first public meeting with stakeholders, held in September of 2012, was attended by 17 individuals, including four who identified themselves to the Board as being from POPS: Randy

Stevens, Kristen Ortiz, Eileen Levis and Joe Carter. In attendance also were representatives from both the BOC and the ABC; the National Orthotics Manufacturers Association; the PA Orthopedic Society and PA Medical Society; the University of Pittsburgh; the Occupational Therapy Association; ICE and several other individuals representing licensees of the Board. The representatives from POPS also attended the Board's second public meeting with stakeholders in November of 2012.

In addition, the Board requested that the stakeholders that it had identified communicate with their colleagues and inform them of the November public meeting should anyone else wish to attend. During the drafting of the proposed rulemaking, the Board also received and considered comments from individuals who wrote to the Board, including Caryn Plessinger, President of Hub's Home Oxygen & Medical Supplies/CressCare Medical; Michael J. Gartland, Compliance Analyst at Klingensmith Health Care; Dana Finn, Facility Accreditation Coordinator from BOC; Zack Chait from BOC; Anjali Weber from ICE; Steve Fletcher from ABC; Claudia Zacharias from BOC; Eileen Levis from POPS; Randy Stevens from POPS; and Sofya Tamarkin. In addition to multiple meetings with all stakeholders, the Board's Allied Health Committee met with Sofya Tamarkin to discuss her concerns. Finally, the Board met with stakeholders and legislative staff to discuss the Act 104 amendments.

IRRC asked the Board to work with the regulated community to resolve as many concerns as possible prior to submitting the final regulation. The Board has worked with the regulated community since passage of Acts 90 and 104 and has continued to do so. The Board is not aware of any particular concern from the regulated community that was not addressed by the amendatory act or that has not been addressed by the amendments to the final-form rulemaking. The Board believes the final-form rulemaking has brought consensus among the stakeholders to the greatest extent possible.

IRRC acknowledged the HPLC comments regarding the Board's statutory authority for graduate permits, clinical residency and provisional licenses for prosthetist and orthotist and the need for clarification of certain sections. IRRC stated that it would review the Board's response as part of its determination of whether the final regulation is in the public interest.

IRRC noted that the Board provided fee reports for all of the fees related to specific license applications but did not provide a breakdown of "Fee-related Activities and Costs" in the fee report form for the biennial renewal fee. Fee report forms for application fees set forth very specific activities related to discrete functions performed by Board staff related to the processing of each application. These "Fee-related Activities and Costs" are applicable only to the fees associated with processing applications of various types. The cost of processing applications, which is offset by the application fee, is based on the amount of time a staff member will need to perform the tasks related to processing and issuing a particular license type, and the salary level of the classification of the staff member that will be required to perform the tasks. Some tasks are performed by lower or higher employee classifications, depending on the complexity of the task. Fees for discrete services provided to an individual, such as processing an application, are set by having the Bureau's revenue office prepare a fee report form after meeting with the Board's administrative staff to determine the tasks related to providing that service. See section 6(d) of the act (63 P.S. § 422.6(d)), which provides that the "board may charge a reasonable fee ... for all

examinations, registrations, certificates, licensures or applications permitted by this act or the regulations thereunder."

Biennial renewal fees, on the other hand, are not based on specific tasks or services performed for individual licensees/applicants. Biennial renewal fees are required to be set to meet the overall operating expenses of the Board, as set forth in section 6(a) of the act (63 P.S. § 422.6(a)). Revenues raised by fees, fines and civil penalties must be sufficient to meet expenditures over a 2-year period. The Board must increase fees by regulation so that projected revenues will meet or exceed projected expenditures. In other words, the biennial renewal fees are designed to cover all the operating expenses of the Board that are not covered by any other fee, including building-related costs, personnel costs, hearing officer costs, investigations based on public complaints, attorney costs and administrative officer costs. The biennial renewal fee is not based on an estimate of particular tasks performed by each type of employee and the classification of the employee, so the fee report form for biennial renewal fees does not include this type of calculation. The types of work for which the revenue generated from biennial fees is allocated includes the intake and processing of complaints filed with the Bureau relevant to the licensees of the Board, the investigation of complaints by the Bureau of Enforcement and Investigation, review of complaints by legal assistants/paralegals, payment for experts to review information and to provide written reports and testimony, costs of prosecution, costs to hold hearings and pay for transcripts and witness fees, cost for legal support to the Board, cost for regulatory support for the Board, cost for administrative support/staff of the Board, and overhead costs including building and power, books, subscriptions, memberships, and the like. Biennial renewal fees are not calculated in the way that application fees are and a fee report form cannot capture information relevant to reviewing a biennial fee. In determining biennial renewal fees, the Board reviews its financial reports and recommendations prepared by the Bureau of Finance and Operations (BFO).

The most recent fiscal report of the Board was delivered by the BFO at the Board's April 19, 2016, meeting. The following is the FY 2015-2016 budget for the Board:

Administrative Costs	
Board Administration	$ 2,445,000
Commissioner's Office	$ 51,000
Revenue Office	$ 40,000
Departmental Services	$ 362,000
Board Member Expenses	$ 48,000

Legal Costs	
Legal Office	$ 2,471,000
Hearing Expenses	$ 316,000
Professional Compliance Office	$ 536,000
Enforcement and Investigation	$ 1,617,000
PHMP	$ 298,000
Total Board Costs	**$ 8,184,000**

Regarding § 18.802 (related to definitions), IRRC asked the Board to explain how designating CAAHEP and NCOPE as "additional accreditation and certification programs is necessary and reasonable as relates to qualification for licensure." As more fully discussed in response to comments from POPS, referencing CAAHEP and NCOPE does not impose any additional qualification for licensure. The act requires certification by an organization that is recognized by ICE and accredited by NCCA. Both ICE-recognized, NCCA accredited organizations that offer certification as a prosthetist or orthotist require completion of a CAAHEP-approved educational program and an NCOPE-approved residency program. IRRC also questioned the need for a definition of "custom-designed device." The Board also discussed its rationale for including a definition for "custom-designed device" in its response to comments from POPS. The Board believes that providing a definition of the term, which is used in the definition of "prosthesis" will aid clarity, as opposed to creating ambiguity.

IRRC pointed out that the Board used several phrases, including "licensed by the Board" and "licensed under the Medical Practice Act" to describe licensees in § 18.802. The Board has amended these definitions to make them consistent. IRRC next commented on the Board's definition for "prefabricated orthotic devices" and asked why the Board deviated from the term provided for in Act 90, which was "prefabricated orthosis." The deviation was unintentional and the Board has amended § 18.802.

IRRC next asked the Board to consider including provisions related to the titles that the holders of graduate permits, provisional licenses and temporary permits may use. The Board has added provisions related to the titles that may be used in §§ 18.811(e), 18.813(e), 18.821(e), 18.823(e), 18.831(e) and 18.841(e) as well as defining the titles in § 18.802. In addition, the Board has added provisions requiring permit holders and provisional licensees to inform patients of the status of their licensure. The Board has determined that the appropriate title for a prosthetist or orthotist during the period of the residency is "prosthetist/orthotist resident." The Board has determined that the appropriate title for a prosthetist or orthotist during the period after the residency is completed but before all examinations have been completed and full licensure granted is "provisionally-licensed prosthetist/orthotist." The Board had proposed to call pedorthists and orthotic fitters in training "graduate pedorthist/orthotic fitter." The Board has now determined that these providers are more commonly known as trainees or "in training." The Board settled upon the title "pedorthist/orthotic fitter trainee" because it is shorter and easier for employers to fit on an identification badge.

IRRC next noted a misplaced provision in § 18.814(b)(3) (relating to prosthetist license) pertaining to the method to demonstrate completion of 3,800 hours of experience in providing direct patient care. IRRC questioned whether this provision was necessary in that § 18.816 (relating to demonstration of qualifications) contained the necessary information regarding how to demonstrate the experience requirements. Instead of removing the provision from § 18.814, the Board revised the final-rulemaking to delete the separate sections pertaining to demonstration of qualifications (including § 18.816) and instead has amended the final-form rulemaking to include in each relevant section information relating to how an applicant may demonstrate meeting each qualification. In this way, an applicant has only one section to review to obtain the information necessary to apply for a specific credential.

IRRC next commented that § 18.815 (related to alternate pathway for prosthetist license) expired on July 7, 2014, and asked the Board to remove the section. Act 104 replaced provisions in Act 90 related to "licensure without examination" and provided a new expiration date of March 31, 2015. As that date has also passed, the Board has deleted the content of § 18.815, as well as coordinate sections for the other professions, §§ 18.825, 18.834 and 18.844 (relating to alternate pathway for orthotist license; alternate pathway for pedorthist license; and alternate pathway for orthotic fitter license).

Regarding proposed §§ 18.816, 18.826, 18.835 and 18.845 (related to demonstration of qualifications), IRRC asked the Board to make amendments to ensure that the requirements are clear for each type of permit or license. The Board has deleted these sections and, instead, has revised each of the relevant licensure sections to clarify the documentation necessary to demonstrate the qualifications corresponding to each type of credential. In addition, the Board has stricken those provisions which have now expired as a result of the elimination of the alternate pathways to licensure.

Regarding § 18.823 (relating to provisional orthotist license), IRRC questioned whether the "supervision" referenced should be called "direct supervision" as it is in § 18.813(a) (related to provisional prosthetist license." The omission in § 18.823 was inadvertent and the Board has added the word "direct" to § 18.823(a).

Regarding proposed §§ 18.831 and 18.841 (relating to temporary practice permit), which provide that a temporary practice permit will expire immediately if the permit holder fails the examination, IRRC questioned what examination was being referenced and how the provision would be enforced. Upon review, the Board notes that it provided no such restriction relating to the provisional prosthetist license or provisional orthotist license, and has also determined that the certification exam providers (the ABC and the BOC) are under no obligation to report failures to the Board, therefore, the final sentence of these sections has been deleted. IRRC also inquired as to whether an individual could apply for another temporary practice permit, and whether the provision was necessary given that the permit is valid for only 1 year and nonrenewable. Finally, IRRC asked the Board to clarify the intent of subsection (d) and explain why the subsection is necessary. Regarding whether subsection (d) is necessary, the remaining provision (a temporary practice permit is valid for a maximum of 1 year and is nonrenewable) is necessary because without the subsection the graduate of a pedorthic or orthotic fitter education program could practice forever without ever taking the certification examination. The statute contemplates that licensure is required to provide services to the public; accordingly, the Board cannot create a permit that would allow individuals to indefinitely circumvent the licensure requirement. The Board's intent is that an individual may obtain one temporary practice permit which is valid for a maximum period of a year.

Regarding §§ 18.842 and 18.843 (relating to orthotic fitting care experience and orthotic fitter license), IRRC asked the Board to explain why it required that the orthotic fitting care experience of an applicant for licensure have been completed "under direct supervision" whereas Act 90 required that the orthotic fitting care experience of an applicant be "documented." IRRC asked the Board to explain how its regulatory provisions conform to the intent of the General Assembly and why it is reasonable and necessary for the experience to have been supervised. First,

§ 18.842 pertains to an individual with a temporary practice permit who is authorized to practice only under direct supervision as an exception to the general requirement that a person be fully licensed to provide patient care as an orthotic fitter. The Board has determined that to protect the public health and safety, direct supervision should be required. However, as § 18.843 pertains to the qualifications necessary for full licensure, the Board acknowledges that some applicants may apply to the Board with experience gained in other states, many of which do not require licensure. Others may apply based on education and experience that was obtained prior to the passage of Act 90. Therefore, the Board has deleted the word "supervised" from § 18.843(b)(3). The Board has clarified that the requirement that the orthotic fitting experience be "documented" requires more than the applicant's assertion that the applicant completed 1,000 hours of fitting experience. Verification of the 1,000 hour requirement by an applicant's employer, supervisor or referral source is consistent with the verification sources for the other licensees under Act 90.

Regarding § 18.851 (related to scope and standards of practice), IRRC questioned the clarity and reasonableness of the requirement that a licensee may not accept a prescription or referral for care when the licensee "knows, or has good cause to believe, that the device cannot be furnished within a reasonable period of time." IRRC asks what would be a reasonable period of time and opines that the Board's language does not set a binding norm. IRRC suggested that the Board revise the subsection to set clear compliance standards.

Health care professions refer to accepted standards of care or practice because it is impossible to precisely define a set numerical standard for all circumstances and situations due to the variability of a patient's condition. Thus, no time certain can be provided. Despite the inability of the Board to set a time certain that would apply for all patients in all circumstances and situations, the Board believes its regulation sets a binding norm just as does the statutory language that provides that a practitioner can be disciplined for providing a service at a level beneath the standard of care for a practitioner which would be normally exercised by the average professional in this Commonwealth. See section 41(8)(ii) of the act (63 P.S. § 422.41(8)(ii)). The Board has amended the language in § 18.851 by adding language similar to that in section 41(8) of the act, specifically, by adding "as would be consistent with the standard of care of the average professional providing the service in this Commonwealth."

Regarding § 18.852 (related to delegation), IRRC correctly noted that the regulated community is divided on this section. IRRC asked the Board to explain how § 18.852 implements Act 90, particularly as it relates to section 13.5(j) (which provides, in pertinent part, that any person who is not licensed as a prosthetist, orthotist, pedorthist or orthotic fitter shall not practice prosthetics, orthotics, pedorthics or orthotic fitting) and how the regulation conforms to the intent of the General Assembly. One segment of the regulated community asserts that Act 90 does not provide for assistants, technicians or support personnel. The opposing segment of the regulated community asserts not only that Act 90 allows licensees to delegate "simple" tasks within their scope of practice, including "basic orthotic fittings, diabetic shoes and diabetic inserts." These commenters further assert that the licensees should be allowed to provide only indirect supervision to unlicensed persons performing these tasks.

The Board believes that neither side in the debate is entirely correct. In healthcare, there are both licensed and unlicensed individuals providing a range of services to patients. Examples

of unlicensed individuals would include nursing aides, medication aides, medical assistants and laboratory technicians. The Board agrees that the statute prohibits the unlicensed practice of prosthetics, orthotics, pedorthics or orthotic fitting. However, members of the regulated community informed the Board that there are two types of unlicensed assistive personnel that have routinely been used in the orthotic and prosthetic profession. For this reason, the Board named and defined these types of unlicensed individuals.

The first type is the orthotic and prosthetic assistant, which is an unlicensed individual who, under direct supervision, assists an orthotist or prosthetist with patient care tasks. These assistants may not engage in unsupervised patient care; rather, they assist the orthotist or prosthetist by performing tasks assigned by the orthotist or prosthetist. An example of a task that might be performed by an orthotic assistant would be performing a follow-up check to see if there is any dermal disturbance at the site of an orthosis. The second type is the orthotic and prosthetic technician, which is an unlicensed individual who provides technical support to an orthotist or prosthetist and who may fabricate, assemble, modify and service devices to the specifications of the orthotist or prosthetist. These individuals do not provide patient care; rather, they provide technical support. An example of a task that might be performed by a prosthetic technician would be painting an artificial hand to match the patient's skin or pouring plastic into a mold provided by the orthotist or prosthetist. Because both of these types of unlicensed assistive personnel are commonplace in the orthotic and prosthetic profession (indeed, the ABC provides certification programs for "O&P assistants" and "O&P technicians") and are recognized in nearly every other state that licenses orthotists and prosthetists, and because their duties are not so expansive as to constitute the practice of orthotics and prosthetics, the Board determined that the regulation should address these individuals.

In its regulation, the Board also recognizes pedorthic support personnel, who are unlicensed individuals who, under the direct supervision of a pedorthist, assist a pedorthist in the provision of pedorthic care. The Board includes these individuals at the request of members of the regulated community who indicated that they utilized support personnel in their pedorthic practices, but who understood that these individuals could not perform the tasks of any licensee, including an orthotic fitter. Just as orthotic and prosthetic assistants and technicians cannot practice prosthetics or orthotics, pedorthic support personnel may not practice prosthetics, orthotics, pedorthics or orthotic fitting. Pedorthics is defined in the act to include measuring patients for a pedorthic device and also to include fitting and adjusting a pedorthic device. Because the use of a "crush box" is for the purpose of measuring patients for a pedorthic device, only a pedorthist may perform this task. Pedorthic support personnel could be involved in teaching patients how to maintain pedorthic devices, cleaning pedorthic devices for patients, and the like.

As to the commenters who suggested that unlicensed individuals should be permitted to do orthotic fittings including diabetic shoes and inserts, the amendment in Act 104 conclusively established that fitting all therapeutic shoes requires, at a minimum, licensure as an orthotic fitter. The amendment added "therapeutic shoes" to the list of devices within the scope of practice of an orthotic fitter. Because even simple diabetic shoes and inserts are therapeutic and are pedorthic devices that are fitted or adjusted for the individual patient, pedorthic support personnel would be prohibited from fitting or adjusting diabetic shoes. Accordingly, unlicensed individuals may not fit diabetic shoes and inserts, no matter how "simple" they appear. Because pedorthic support

personnel cannot perform orthotic fittings, including diabetic shoes and inserts, the Board believes that the second group of commenters may no longer have an interest in the level of supervision that must be provided to these individuals. The Board believes that direct supervision is the most appropriate level of supervision for assistants and pedorthic support personnel.

IRRC asked if the Board considered the economic or fiscal impacts on those in the regulated community who would not desire or qualify for licensure. If IRRC is asking whether individuals who might have been interested in practicing one of the newly-regulated professions would be deterred by the costs of licensure, the Board finds the inquiry too speculative as the Board would have no way to determine how many individuals in the Commonwealth might have thought of entering one of these professions, but changed their mind because of the costs associated with licensure. The Board believes that the General Assembly would have considered this generalized cost of licensure before determining that it was in the public interest to require licensure.

IRRC also asked if the Board had considered the economic or fiscal impacts on entities which would be required to have a licensed prosthetist, orthotist or pedorthist present to provide direct supervision, and asked the Board to address these costs in the Regulatory Analysis Form. Because only a licensee may actually practice these professions, and because the work done by an orthotic and prosthetic assistant, orthotic and prosthetic technician and pedorthic support personnel is solely in a supporting role to a licensee, there would be no additional cost to supervising support personnel. On the contrary, to the extent that support personnel free up the time of licensees to provide direct patient care, there would be an economic benefit to support personnel, not a deficit.

IRRC questioned whether references to "the practitioner" in paragraph (a)(6) were references to the same individual called "the practitioner delegating the task." That was the Board's intent, however, this section has been completely rewritten to address supervision and assistance by the various types of unlicensed assistive personnel, rather than delegation to clarify the Board's understanding of the role of assistants, technicians and support personnel.

IRRC asked the Board to clarify the relationship between the misconduct provisions in § 18.853 and those in § 16.61 (relating to unprofessional and immoral conduct). The Board has addressed this by amendments made to § 18.853(b)(1) and (c). Section 16.61 is a general section applying to all board-regulated practitioners and is now cross-referenced in the final-form rulemaking. Section 18.853 is intended to apply specifically to prosthetists, orthotists, pedorthists and orthotic fitters. IRRC was also concerned that § 18.853(b)(13) was confusing as written. The Board has rewritten the paragraph to aid clarity.

IRRC asked the Board to add a reference to section 13.5(g)(2) of the act, which provides for continuing education requirements for pedorthists and orthotic fitters to § 18.861 (relating to biennial renewal of license). The Board has added the reference. IRRC asked the Board to review the regulation for consistency in how it addressed licensees' certification. The Board did so and more fully discusses this in its response to BOC's comments. IRRC next questioned whether it was necessary to reference the disciplinary section of the act in each section of the regulation explaining each license or permit type. While technically not necessary, the Board wanted to clearly provide notice to applicants of the grounds for denial of a license. Therefore, the Board determined that it should maintain the reference in each section. Finally, IRRC noted some

inconsistent wording between parallel sections. The Board has revised the final-form rulemaking for consistency.

Comments following Advance Notice of Final Rulemaking

The Board sent its draft of the final rulemaking to stakeholders and published Advance Notice of Final Rulemaking in the Pennsylvania Bulletin on September 19, 2015 (45 Pa. B. 5682). The Board received additional comments both during the 30 day public comment period and as well as months afterward, as late as February 2016. In late February, a Board representative met with POPS' counsel to address POPS' concerns and to ensure that the rulemaking both protected the public and was consistent with current practices in the professions. POPS continues to object to the use of the term "assistant" and prefers the term "support personnel;" however, since the term assistant is used in 12 of the 13 states which license prosthetists and orthotists, the Board has retained the term.

The Board also received identical comments from RJ Hedges & Associates and the Pennsylvania Pharmacists Association, requesting that the Board include in the regulations definitions for "health care practitioner" and "pharmacist" and adding a new section to the regulations to repeat the exceptions provision in section 15.5 of the act. According to these groups, CMS "may take this regulation at face value and restrict pharmacists ... from dispensing diabetic shoes and certain orthotic products." The Board declines to include the statutory exceptions in its regulations. First, the Board believes it is highly unlikely that CMS or any other Federal agency would ignore the plain provisions of the act. Second, regulations add clarification to procedures and policies related to professions; regulations are not a substitute to the act and it would be improper for CMS to determine that issues not addressed in regulations are unregulated in light of clear statutory language. Finally, the Board regulates approximately a dozen health-related professions, has not included any statutory exceptions in the regulations of those professions, and finds no compelling reason to deviate in this instance.

The Board received comments from Tom Sedlak, Executive Director of the Pennsylvania Association of Medical Suppliers, asking if a prefabricated orthotic device includes "step in/impression box" or whether it means "pre-fabricated heat molded" devices. Act 104 amended the orthotic fitter scope of practice to specifically provide that orthotic fitting includes measuring, fitting, dispensing and adjusting prefabricated devices including therapeutic shoes. The statute defines custom-fabricated and custom-fitted devices, and limits to only prosthetists, orthotists and pedorthists the provision of these devices. Custom-fabricated, by statutory definition, includes devices "fabricated to comprehensive measurements or a mold."

Finally, the BOC submitted additional comments on February 1, 2016, noting that §§ 18.814 and 18.824 needed minor adjustment to be parallel; the Board made the adjustment. BOC also noted that the Board had not copied all provisions of the act related to exceptions. As discussed above, statutory exception provisions do not appear in any of the Board's regulations of health-related professionals and the Board declines to include them in these regulations. The statutory provisions are fully enforceable.

Description of Amendments to the Final-Form Rulemaking

The Board has amended §§ 16.11 and 16.13 (relating to licenses, certificates and registrations; and licensure, certification, examination and registration fees) to eliminate the alternate pathway for licensure which has expired and to make the sections internally consistent.

In § 18.802 (relating to definitions) the Board has amended the definitions of ABC and BOC to clarify that these organizations are approved by the Board. The Board has combined the definitions of custom-designed device and custom-fabricated device, in recognition of the similarity of the proposed definitions. In the definition of "ICE," the Board has clarified that the term includes a successor organization.

As IRRC requested the Board regulate the titles that may be used by individuals with a graduate permit, provisional license or temporary permit, the Board has added definitions for "orthotic fitter trainee," "orthotist resident," "pedorthist trainee," "prosthetist resident," "provisionally-licensed orthotist" and "provisionally-licensed prosthetist." The Board has also moved the qualifying language "pursuant to a written prescription of a licensed prescribing practitioner" from the definitions of "orthotist," "pedorthist" and "prosthetist" to the definitions of "orthotics," "pedorthics" and "prosthetics" as the phrase more properly defines the practice and not the individual licensee.

Additionally, the Board has made amendments to the definitions of "orthotic and prosthetic assistant," "orthotic and prosthetic technician" and "pedorthic support personnel" in response to public comments as discussed above.

Amendments Relating to Qualifications for Licensure as a Prosthetist

The Board has amended § 18.811 (relating to graduate permit) to incorporate the title "prosthetist resident" and to include clarifying language relating to how an applicant can demonstrate each qualification to obtain a graduate permit. The Board has also added an example of other applicable law that could result in the denial of an application and has eliminated superfluous language. The Board has amended § 18.812 (relating to clinical residency) to clarify that a prosthetist resident completing a clinical residency in this Commonwealth shall practice under the direct supervision of a licensed prosthetist.

The Board has amended §§ 18.813 and 18.814 (relating to provisional prosthetist license; and prosthetist license) to incorporate the relevant titles and to include clarifying language relating to how an applicant can demonstrate each qualification to obtain a license. These sections were also amended to add an example of other applicable law that could result in the denial of an application and to eliminate superfluous language. Section 18.814(b)(4) was also amended to add "another prosthetic credentialing organization whose certification program is recognized by ICE, accredited by NCCA and approved by the Board" to the list of possible certifications. This amendment was made because the Board is aware that the BOC has announced its intent to discontinue issuing new certifications for prosthetists after July of 2016, and another credentialing organization may choose to fill the void created by the BOC's departure from the field. Although

no new certifications will be issued, the BOC will continue to renew existing certifications for prosthetists.

The final-form rulemaking was amended to delete § 18.815 (relating to alternate pathway for prosthetist license) as this pathway to licensure has expired. Additionally, § 18.816 (relating to demonstration of qualifications) has been deleted and its provisions moved to more clearly define the documentation needed to demonstrate the qualifications for a graduate permit, a provisional prosthetist license or a prosthetist license.

Amendments Relating to Qualifications for Licensure as an Orthotist

The Board has amended § 18.821 (relating to graduate permit) to incorporate the title "orthotist resident" and to include clarifying language relating to how an applicant can demonstrate each qualification to obtain a graduate permit. The Board has also added an example of other applicable law that could result in the denial of an application and has eliminated superfluous language. The Board has amended § 18.822 (relating to clinical residency) to clarify that an orthotist resident completing a clinical residency in this Commonwealth shall practice under the direct supervision of a licensed orthotist.

The Board has amended §§ 18.823 and 18.824 (relating to provisional orthotist license; and orthotist license) to incorporate the relevant titles and to include clarifying language relating to how an applicant can demonstrate each qualification to obtain a license. These sections were also amended to add an example of other applicable law that could result in the denial of an application and to eliminate superfluous language. Section 18.824(b)(4) was amended to allow for certification by another orthotic credentialing organization approved by the Board. This amendment was made because the BOC has announced its intent to discontinue issuing new certifications for orthotists after July of 2016 and another credentialing organization may choose to fill the void created by the BOC's departure from the field. Although no new certifications will be issued, the BOC will continue to renew existing certifications for orthotists.

The final-form rulemaking was amended to delete § 18.825 (relating to alternate pathway for orthotist license) as this pathway to licensure has expired. Additionally, § 18.826 (relating to demonstration of qualifications) has been deleted and its provisions moved to more clearly define the documentation needed to demonstrate the qualifications for a graduate permit, a provisional orthotist license or an orthotist license.

Amendments Relating to Qualifications for Licensure as a Pedorthist

The Board has amended § 18.831 (relating to temporary practice permit) to make stylistic edits, to incorporate the title "pedorthist trainee" and to include clarifying language relating to how an applicant can demonstrate each qualification to obtain a temporary practice permit. The Board has also amended this section to clarify that an NCOPE approved pedorthic education program is required. The Board has eliminated the concept of "equivalence" because any equivalent training would not qualify an applicant for certification, which is a separate requirement for licensure. The Board believes it would be a disservice to applicants to accept other "equivalent" training for purposes of granting a temporary practice permit, knowing that the applicant would have to

complete an NCOPE approved education program to achieve certification and qualify for a license. The Board has also added an example of other applicable law that could result in the denial of an application and has eliminated superfluous language.

Section 18.832 (relating to patient fitting experience) has been amended to incorporate the title "pedorthist trainee" and to provide for direct supervision by a licensed prosthetist, orthotist or pedorthist in response to public comments. Section 18.833 (relating to pedorthist license) has been amended consistent with § 18.831 to eliminate the concept of "equivalent" education in recognition of the fact that completion of an NCOPE approved pedorthic precertification education program is required to obtain certification, and certification is required to obtain licensure. It has also been amended to include clarifying language about how an applicant can demonstrate each qualification for licensure. Section 18.833(b)(4) has also been amended to include "another pedorthic credentialing organization whose program is recognized by ICE, accredited by NCCA and approved by the Board." Once again, the BOC has announced its intention to discontinue issuing new certifications for pedorthists after July of 2016, and the Board wants to provide for the possibility of another organization entering the field. In addition, § 18.833 has been amended to add an example of other applicable law that could result in the denial of a license and to eliminate superfluous language. Finally, §§ 18.834 and 18.835 (relating to alternate pathway for pedorthist license; and demonstration of qualifications) have been deleted.

Amendments relating to Qualifications for Licensure as an Orthotic Fitter

Sections 18.841, 18.842 and 18.843 (relating to temporary practice permit; orthotic fitting care experience; and orthotic fitter license) have been amended to incorporate the title "orthotic fitter trainee" and to add clarifying language about how an applicant can demonstrate each qualification. Sections 18.841(b)(2) and 18.843(b)(2) have been amended to clarify that to qualify for a temporary permit or orthotic fitter license, an applicant shall have completed an ABC or BOC approved orthotic fitter precertification education program. NCOPE announced in 2015 that it would no longer approve orthotic fitter education programs. Again, the Board is eliminating the "equivalent" education option because anything other than an ABC or BOC approved program would not lead to certification. While the BOC has announced its intent to discontinue issuing certifications for prosthetists, orthotists and pedorthists, it will continue to issue certifications to orthotic fitters. However, the Board has amended § 18.843(b)(4) to allow certification from another orthotic fitter credentialing organization whose program is recognized by ICE, accredited by NCCA and approved by the Board, to be internally consistent with the prior sections. Finally, the Board has deleted §§ 18.844 and 18.845 (relating to alternative pathway for orthotic fitter license; and demonstration of qualifications) as these sections are no longer necessary.

Amendments relating to the Regulation of Practice

The Board has amended § 18.851 (relating to scope and standards of practice) to clarify that the standard for the provision of prosthetic, orthotic or pedorthic devices would be "within a reasonable period of time as would be consistent with the standard of care of the average professional providing the service in this Commonwealth" in response to IRRC's comment about establishing a binding norm. With regard to § 18.852 (relating to delegation), the Board has renamed the section "Supervision and assistance" and has significantly revised the section in

response to stakeholder comments. It now provides standards for assigning tasks to orthotic and prosthetic assistants, orthotic and prosthetic technicians and pedorthic support personnel, while the licensee remains ultimately responsible for the completed tasks.

Section 18.853 (relating to unprofessional and immoral conduct) has been amended to cross reference the more general provisions in § 16.61 (relating to unprofessional and immoral conduct), to revise subsection (b)(11) to refer to supervision and assistance of unlicensed assistive personnel (orthotic and prosthetic assistants and technicians, and pedorthic support personnel), and to redraft subsection (b)(13) for clarity in response to a comment by IRRC.

Amendments relating to Biennial Renewal and Reactivation

Section 18.861 (relating to biennial renewal of license) has been amended to refer to the term of art "disposition in lieu of trial" which had been edited by the Legislative Reference Bureau. This is a legal term of art used in criminal law that refers to a specific type of disposition of a criminal matter. See, for example, section 118 of the Controlled Substance, Drug, Device and Cosmetic Act (35 P.S. § 780-118). In addition, as requested by IRRC, subsection (b)(5) has been amended to include a cross reference to section 13.5(g)(2) of the act (63 P.S. § 422.13e(g)(2)).

Section 18.862 (relating to continuing education) has been amended to clarify that continuing education courses must be approved by ABC or BOC. The Board has also amended subsection (a)(4) to delete the proviso "if licensure occurred within 3 years of completion of the approved education program." The Board has made this change to be consistent with how the Board handles all other licensure categories.

Section 18.863 (relating to inactive and expired status of licenses; reactivation of inactive or expired licenses) has been amended to clarify that 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 initial certification examination offered by the ABC, the BOC or another credentialing organization whose certification program is recognized by ICE, accredited by NCCA and approved by the Board. In that the BOC has announced its intention to discontinue the initial examinations for certification as a prosthetist, orthotist and pedorthist after July of 2016, the Board wanted to provide for the possibility of another certification organization entering the field.

Fiscal Impact and Paperwork Requirements

The statutory requirements that prosthetists, orthotists, pedorthists and orthotic fitters obtain and renew licenses to practice, obtain and maintain professional liability insurance and complete continuing education biennially will have a fiscal impact and impose paperwork requirements on the regulated community.

The new requirements will also have a fiscal impact and will impose additional paperwork requirements on the Commonwealth, specifically the State Board of Medicine, which is charged with administering the act. However, the costs to the Board will be recouped through application fees and biennial renewal fees.

Sunset Date

The Board continuously monitors the effectiveness of 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)), the Board submitted a copy of the proposed rulemaking, published at 44 Pa.B. 4364 (July 12, 2014), and a copy of a Regulatory Analysis Form to the Independent Regulatory Review Commission (IRRC), and the Chairpersons of the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC) and the House Professional Licensure Committee (HPLC) for review and comment.

Under section 5(c) of the Regulatory Review Act (71 P.S. § 745.5(c)), IRRC, the SCP/PLC and the HPLC were provided copies of all comments received by the Board. In preparing for the final-form rulemaking, the Board has considered all comments received.

Under section 5.1(j.2) of the Regulatory Review Act (71 P.S. § 745.5a(j.2), on _____, 2016, the final-form rulemaking was deemed approved by the HPLC. The SCP/PLC deemed it approved as of _____, 2016. Under section 5.1(e) of the Regulatory Review Act, IRRC met on _____, 2016 and approved the final-form rulemaking.

Contact Person

Interested persons may obtain information regarding the final-form rulemaking by writing to the Suzanne Zerbe, Board Administrator, State Board of Medicine, P.O. Box 2649, Harrisburg, PA 17105-2649, or by e-mail at ST-MEDICINE@pa.gov.

Findings

The Board finds that:

(1) Public notice of proposed rulemaking was given under sections 201 and 202 of the act of July 31, 1968 (P.L. 769, No. 240) (45 P.S. §§1201 and 1202) and the regulations promulgated thereunder, 1 Pa. Code §§7.1 and 7.2 (relating to notice of proposed rulemaking required; and adoption of regulations).

(2) A public comment period was provided as required by law and all comments were considered.

(3) The amendments to the final-form rulemaking do not enlarge the purpose of the proposed rulemaking published at 44 Pa. B. 4364 (July 12, 2014).

(4) This final-form rulemaking is necessary and appropriate for administration and enforcement of the authorizing acts identified in this Preamble.

Order

The Board orders that:

(a) The Regulations of the Board are amended by amending §§ 16.11 and 16.13 (relating to licenses, certificates and registrations; and licensure, certification, examination and registration fees) and by adding Chapter 18, Subchapter L (relating to prosthetists, orthotists, pedorthists and orthotic fitters) to read as set forth in Annex A.

(b) The Board shall submit this order and Annex A to the Office of General Counsel and to the Office of Attorney General as required by law.

(c) The Board shall submit this order and Annex A to IRRC, the HPLC and the SCP/PLC as required by law.

(d) The Board shall certify this order and Annex A and deposit them with the Legislative Reference Bureau as required by law.

(e) This order shall take effect on publication in the *Pennsylvania Bulletin*.

Marilyn Heine, 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—GENERAL PROVISIONS

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) Respiratory therapist license.

(10) Genetic counselor license.

(11) Prosthetist license.

(12) Orthotist license.

(13) Pedorthist license.

(14) Orthotic fitter license.

(15) Graduate prosthetist permit.

(16) Provisional prosthetist license.

(17) Graduate orthotist permit.

(18) Provisional orthotist license.

(19) Temporary practice permit—pedorthist.

(20) Temporary practice permit—orthotic fitter.

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

* * * * *

(12) Biennial registration of a perfusionist license.

(13) Biennial registration of a respiratory therapy license.

(14) Biennial registration of a genetic counselor license.

(15) Biennial ~~renewal~~ REGISTRATION of a prosthetist LICENSE.

(16) Biennial ~~renewal~~ REGISTRATION of an orthotist LICENSE.

(17) Biennial ~~renewal~~ REGISTRATION of a pedorthist LICENSE.

(18) Biennial ~~renewal~~ REGISTRATION of an orthotic fitter LICENSE.

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

* * * * *

(n) *Prosthetists.*

Application for prosthetist license $50

~~Application for prosthetist license without examination .....$100~~

Biennial renewal of prosthetist license.....$75

Application for reactivation of prosthetist license.....$50

Application for graduate prosthetist permit.....$50

Application for provisional prosthetist license.....$50

(o) ~~*Orthotist License*~~ *ORTHOTISTS.*

Application for orthotist license.....$50

~~Application for orthotist license without examination.....$100~~

Biennial renewal of orthotist license.....$75

Application for reactivation of orthotist license.....$50

Application for graduate orthotist permit.....$50

Application for provisional orthotist license.....$50

(p) *Pedorthists.*

Application for pedorthist license.....$25

~~Application for pedorthist license without examination.....$25~~

Biennial renewal of pedorthist license.....$75

Application for reactivation of pedorthist license.....$25

Application for pedorthist temporary permit.....$25

(q) *Orthotic Fitters.*

Application for orthotic fitter license.....$25

~~Application for orthotic fitter license without examination.....$25~~

Biennial renewal of orthotic fitter license.....$75

Application for reactivation of orthotic fitter license.....$25

Application for orthotic fitter temporary permit.....$25

* * * * *

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), regarding prosthetists, orthotists, pedorthists and orthotic fitters.

§ 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 & Pedorthics, Inc., ~~an~~ A BOARD-APPROVED organization with certification programs accredited by the NCCA. The term includes a successor organization.

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

BOC—Board of Certification/Accreditation International, Inc., ~~an~~ A BOARD-APPROVED organization with certification programs accredited by the NCCA. The term includes 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.

~~*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-DESIGNED OR CUSTOM-fabricated device—A prosthesis, orthosis or pedorthic device that is DESIGNED OR 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 online or correspondence course would be presented live.

ICE—The Institute for Credentialing Excellence, previously known as the National Organization for Competency Assurance. THE TERM INCLUDES A SUCCESSOR ORGANIZATION.

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.

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

NCOPE—National Commission on Orthotic and Prosthetic Education, an organization that approves precertification 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 fitter—An individual who is licensed by the Board to practice orthotic fitting.

ORTHOTIC FITTER TRAINEE–AN INDIVIDUAL WHO HOLDS AN ORTHOTIC FITTER TEMPORARY PRACTICE PERMIT ISSUED BY THE BOARD AND WHO IS AUTHORIZED TO PRACTICE IN ACCORDANCE WITH § 18.842 (RELATING TO ORTHOTIC FITTING CARE EXPERIENCE).

Orthotic fitting—The fitting, dispensing and adjusting ~~pursuant to a written prescription of a licensed prescribing practitioner~~ of prefabricated orthotic devices PURSUANT TO A WRITTEN PRESCRIPTION OF A LICENSED PRESCRIBING PRACTITIONER.

Orthotic and prosthetic assistant—An unlicensed individual who, under the direct, ~~onsite~~ supervision of the orthotist or prosthetist, assists ~~an orthotist or prosthetist~~ with patient care ~~and who may fabricate, repair and maintain devices~~ TASKS ASSIGNED BY THE ORTHOTIST OR PROSTHETIST.

Orthotic and prosthetic technician—An unlicensed individual who, ~~under the direct onsite supervision of an orthotist or prosthetist,~~ provides technical support to an orthotist or prosthetist and who may fabricate, ~~repair and maintain~~ ASSEMBLE, MODIFY AND SERVICE devices TO THE SPECIFICATIONS OF A LICENSED ORTHOTIST OR PROSTHETIST.

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~~ PURSUANT TO A WRITTEN PRESCRIPTION OF A LICENSED PRESCRIBING PRACTITIONER.

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

ORTHOTIST RESIDENT–AN INDIVIDUAL WHO HOLDS A GRADUATE PERMIT ISSUED BY THE BOARD AND WHO IS AUTHORIZED TO PRACTICE IN ACCORDANCE WITH §§ 18.821 AND 18.822 (RELATING TO GRADUATE PERMIT; AND CLINICAL RESIDENCY).

Over-the-counter orthoses and pedorthic devices—Prefabricated, mass-produced items that are prepackaged and do not require 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) 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 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 onsite supervision of a pedorthist, assists a pedorthist in the provision of pedorthic care, OR WHO PROVIDES TECHNICAL SUPPORT TO A PEDORTHIST, INCLUDING FABRICATING, ASSEMBLING, MODIFYING AND SERVICING PEDORTHIC DEVICES IN ACCORDANCE WITH THE PEDORTHIST'S SPECIFICATIONS. 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 PURSUANT TO A WRITTEN PRESCRIPTION OF A LICENSED PRESCRIBING PRACTITIONER.

Pedorthist—An individual WHO IS licensed ~~under the act~~ BY THE BOARD to practice pedorthics ~~pursuant to a written prescription of a licensed prescribing practitioner~~.

PEDORTHIST TRAINEE–AN INDIVIDUAL WHO HOLDS A TEMPORARY PRACTICE PERMIT ISSUED BY THE BOARD AND WHO IS AUTHORIZED TO PRACTICE IN ACCORDANCE WITH §§ 18.831 AND 18.832 (RELATING TO TEMPORARY PRACTICE PERMIT; AND PATIENT FITTING EXPERIENCE).

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

Prefabricated ~~orthotic devices~~ ORTHOSIS—

(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 the following:

(A) Artificial eyes, ears, fingers or toes.

(B) Dental appliances.

(C) Cosmetic devices such as breast prostheses, eyelashes or wigs.

(D) 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 PURSUANT TO A WRITTEN PRESCRIPTION OF A LICENSED PRESCRIBING PRACTITIONER.

Prosthetist—An individual~~, other than a licensed physical therapist or occupational therapist,~~ WHO IS licensed ~~under the act~~ BY THE BOARD to practice prosthetics ~~pursuant to a written prescription of a licensed prescribing practitioner~~.

PROSTHETIST RESIDENT–AN INDIVIDUAL WHO HOLDS A GRADUATE PERMIT ISSUED BY THE BOARD AND WHO IS AUTHORIZED TO PRACTICE IN ACCORDANCE WITH §§ 18.811 AND 18.812 (RELATING TO GRADUATE PERMIT; AND CLINICAL RESIDENCY).

PROVISIONALLY-LICENSED ORTHOTIST—AN INDIVIDUAL WHO HOLDS A PROVISIONAL LICENSE ISSUED BY THE BOARD AND WHO IS AUTHORIZED TO PRACTICE IN ACCORDANCE WITH § 18.823 (RELATING TO PROVISIONAL ORTHOTIST LICENSE).

PROVISIONALLY-LICENSED PROSTHETIST—AN INDIVIDUAL WHO HOLDS A PROVISIONAL LICENSE ISSUED BY THE BOARD AND WHO IS AUTHORIZED TO PRACTICE IN ACCORDANCE WITH § 18.813 (RELATING TO PROVISIONAL PROSTHETIST LICENSE).

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~~ PRACTICE as a ~~graduate~~ prosthetist RESIDENT. The Board may grant a graduate permit to an individual who submits a completed application including the necessary supporting documents, pays the application fee in § 16.13(n) (relating to licensure, certification, examination and registration fees) and meets the qualifications in subsection (b).

(b) The Board may issue a graduate permit to practice as a prosthetist RESIDENT 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. AN APPLICANT SHALL DEMONSTRATE THIS REQUIREMENT BY HAVING THE CAAHEP-ACCREDITED EDUCATIONAL INSTITUTION SUBMIT, DIRECTLY TO THE BOARD, VERIFICATION OF COMPLETION OF A BACHELOR'S DEGREE, POST-BACCALAUREATE CERTIFICATE OR HIGHER DEGREE IN PROSTHETICS OR PROSTHETICS/ORTHOTICS, ALONG WITH AN OFFICIAL COPY OF THE APPLICANT'S TRANSCRIPT.

(3) Has registered with NCOPE as a prosthetist or prosthetist/orthotist resident. AN APPLICANT SHALL DEMONSTRATE THIS REQUIREMENT BY HAVING NCOPE SUBMIT, DIRECTLY TO THE BOARD, PROOF THAT THE APPLICANT HAS

REGISTERED FOR AN NCOPE-ACCREDITED PROSTHETIC OR PROSTHETIC/ORTHOTIC RESIDENCY PROGRAM.

(4) Has complied with § 18.864 (relating to professional liability insurance coverage for licensed prosthetist, orthotist, pedorthist or orthotic fitter). AN APPLICANT SHALL DEMONSTRATE THIS REQUIREMENT BY SUBMITTING PROOF OF PROFESSIONAL LIABILITY INSURANCE COVERAGE THROUGH SELF-INSURANCE, A PERSONALLY PURCHASED INSURANCE POLICY OR INSURANCE PROVIDED BY THE APPLICANT'S EMPLOYER IN ACCORDANCE WITH § 18.864.

~~(5) Otherwise satisfies the requirements for a graduate permit and is not barred from licensure.~~

(c) The Board may deny an application for a graduate permit upon the grounds for disciplinary action in section 41 of the act (63 P.S. § 422.41), ~~or~~ §§ 16.61 OR 18.853 (relating to unprofessional and immoral conduct) OR OTHER APPLICABLE LAW, SUCH AS SECTION 9124 OF THE CRIMINAL HISTORY RECORD INFORMATION ACT (18 PA.C.S.A. § 9124).

(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.

(E) AN INDIVIDUAL HOLDING A GRADUATE PERMIT MAY USE THE TITLE "PROSTHETIST RESIDENT" AND SHALL INFORM PATIENTS THAT THE INDIVIDUAL IS COMPLETING A RESIDENCY TRAINING PROGRAM AND IS NOT FULLY LICENSED.

§ 18.812. Clinical residency.

(a) A ~~graduate~~ prosthetist RESIDENT 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~~ PROSTHETIST RESIDENT and is responsible for countersigning within 15 days the entries in the patient's clinical record.

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

(c) The clinical residency shall 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 the necessary supporting documents, pays the application fee 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. UNLESS PREVIOUSLY SUBMITTED UNDER § 18.811(b)(2)

(RELATING TO GRADUATE PERMIT), AN APPLICANT SHALL DEMONSTRATE THIS REQUIREMENT BY HAVING THE CAAHEP-ACCREDITED EDUCATIONAL INSTITUTION SUBMIT, DIRECTLY TO THE BOARD, VERIFICATION OF COMPLETION OF A BACHELOR'S DEGREE, POST-BACCALAUREATE CERTIFICATE OR HIGHER DEGREE IN PROSTHETICS OR PROSTHETICS/ORTHOTICS, ALONG WITH AN OFFICIAL COPY OF THE APPLICANT'S TRANSCRIPT.

(3) Has completed an NCOPE-accredited clinical residency in prosthetics or prosthetics/orthotics. AN APPLICANT SHALL DEMONSTRATE THIS REQUIREMENT BY HAVING THE PROGRAM DIRECTOR OF THE CLINICAL RESIDENCY PROGRAM SUBMIT, DIRECTLY TO THE BOARD, VERIFICATION THAT THE APPLICANT COMPLETED AN NCOPE-ACCREDITED CLINICAL RESIDENCY IN PROSTHETICS OR PROSTHETICS/ORTHOTICS.

(4) Has complied with § 18.864 (relating to professional liability insurance coverage for licensed prosthetist, orthotist, pedorthist or orthotic fitter). AN APPLICANT SHALL DEMONSTRATE THIS REQUIREMENT BY SUBMITTING PROOF OF PROFESSIONAL LIABILITY INSURANCE COVERAGE THROUGH SELF-INSURANCE, A PERSONALLY PURCHASED INSURANCE POLICY OR INSURANCE PROVIDED BY THE APPLICANT'S EMPLOYER IN ACCORDANCE WITH § 18.864.

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

(c) The Board may deny an application for a provisional license upon the grounds for disciplinary action in section 41 of the act (63 P. S. § 422.41), ~~or~~ §§ 16.61 OR 18.853 (relating to unprofessional and immoral conduct) OR OTHER APPLICABLE LAW, SUCH AS SECTION 9124 OF THE CRIMINAL HISTORY RECORD INFORMATION ACT (18 PA.C.S.A. § 9124).

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

(E) AN INDIVIDUAL HOLDING A PROVISIONAL PROSTHETIST LICENSE MAY USE THE TITLE "PROVISIONALLY-LICENSED PROSTHETIST" AND SHALL INFORM PATIENTS THAT THE INDIVIDUAL IS NOT FULLY LICENSED.

§ 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 the necessary supporting documents and pay the application fee 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. UNLESS PREVIOUSLY SUBMITTED UNDER §§ 18.811(b)(2) OR 18.813(b)(2) (RELATING TO GRADUATE PERMIT; OR PROVISIONAL PROSTHETIST LICENSE), AN APPLICANT SHALL DEMONSTRATE THIS REQUIREMENT BY HAVING THE CAAHEP-ACCREDITED EDUCATIONAL INSTITUTION SUBMIT, DIRECTLY TO THE BOARD, VERIFICATION OF COMPLETION OF A BACHELOR'S DEGREE, POST-BACCALAUREATE

CERTIFICATE OR HIGHER DEGREE IN PROSTHETICS OR PROSTHETICS/ORTHOTICS, ALONG WITH AN OFFICIAL COPY OF THE APPLICANT'S TRANSCRIPT.

(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 2-year period. ~~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.~~ AN APPLICANT SHALL DEMONSTRATE THIS REQUIREMENT BY HAVING THE APPLICANT'S EMPLOYER OR SUPERVISOR, THE DIRECTOR OF THE APPLICANT'S CLINICAL RESIDENCY PROGRAM, OR A REFERRAL SOURCE, FILE A VERIFICATION ON A FORM PROVIDED BY THE BOARD. IF VERIFICATION IS MADE BY A REFERRAL SOURCE, IT MUST INCLUDE A COPY OF THE APPLICANT'S FEDERAL EIN AND EVIDENCE OF THE DATE THE APPLICANT RECEIVED THE EIN.

(4) ~~Has met the qualifications for certification and received certification from a~~ HOLDS CURRENT CERTIFICATION AS A PROSTHETHIST, OR AS A PROSTHETIST AND ORTHOTIST, FROM ABC, BOC OR ANOTHER prosthetic credentialing organization whose certification program is RECOGNIZED BY ICE, accredited by NCCA AND APPROVED BY THE BOARD. AN APPLICANT SHALL DEMONSTRATE THIS REQUIREMENT BY HAVING THE ORGANIZATION SEND VERIFICATION OF CERTIFICATION DIRECTLY TO THE BOARD.

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

DEMONSTRATE THIS REQUIREMENT BY SUBMITTING PROOF OF PROFESSIONAL LIABILITY INSURANCE COVERAGE THROUGH SELF-INSURANCE, A PERSONALLY PURCHASED INSURANCE POLICY OR INSURANCE PROVIDED BY THE APPLICANT'S EMPLOYER IN ACCORDANCE WITH § 18.864.

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

(c) The Board may deny an application for licensure as a prosthetist or upon the grounds for disciplinary action in section 41 of the act (63 P. S. § 422.41), ~~or~~ §§ 16.61 OR 18.853 (relating to unprofessional and immoral conduct) OR OTHER APPLICABLE LAW, SUCH AS SECTION 9124 OF THE CRIMINAL HISTORY RECORD INFORMATION ACT (18 PA.C.S.A. § 9124).

(D) AN INDIVIDUAL HOLDING AN ACTIVE, UNSUSPENDED PROSTHETIST LICENSE MAY USE THE TITLE "PROSTHETIST."

~~**§ 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(n) (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 and demonstrates the qualifications in section 13.5(a)(1) and (5)—(8) and (f) of the act.~~

~~(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 2-year period, to total at least 4 years of education, training and work experience.~~

~~(3) At least 2 years or more 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 2-year period, 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 the grounds for disciplinary action in section 41 of the act (63 P. S. § 422.41) or § 18.853 (relating to unprofessional and immoral conduct).~~

~~(g) This section expires at 5 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 demonstrate:~~

~~(1) 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) 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 must include a copy of the applicant's Federal EIN and evidence of the date the applicant received the EIN.~~

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

~~(4) 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) 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) The 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 in paragraph (2) 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~~ PRACTICE as ~~a graduate~~ AN orthotist RESIDENT. The Board may grant a graduate permit to an individual who submits a completed application including the necessary supporting documents, pays the application fee in § 16.13(o) (relating to licensure, certification, examination and registration fees) and meets the qualifications 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. AN APPLICANT SHALL DEMONSTRATE THIS REQUIREMENT BY HAVING THE CAAHEP-ACCREDITED EDUCATIONAL INSTITUTION SUBMIT, DIRECTLY TO THE BOARD, VERIFICATION OF COMPLETION OF A BACHELOR'S DEGREE, POST-BACCALAUREATE CERTIFICATE OR HIGHER DEGREE IN ORTHOTICS OR PROSTHETICS/ORTHOTICS, ALONG WITH AN OFFICIAL COPY OF THE APPLICANT'S TRANSCRIPT.

(3) Has registered with NCOPE as an orthotist or prosthetist/orthotist resident. AN APPLICANT SHALL DEMONSTRATE THIS REQUIREMENT BY HAVING NCOPE SUBMIT, DIRECTLY TO THE BOARD, PROOF THAT THE APPLICANT HAS REGISTERED FOR AN NCOPE-ACCREDITED ORTHOTIC OR PROSTHETIC/ORTHOTIC RESIDENCY PROGRAM.

(4) Has complied with § 18.864 (relating to professional liability insurance coverage for licensed prosthetist, orthotist, pedorthist or orthotic fitter). AN APPLICANT SHALL DEMONSTRATE THIS REQUIREMENT BY SUBMITTING PROOF OF PROFESSIONAL LIABILITY INSURANCE COVERAGE THROUGH SELF-INSURANCE, A PERSONALLY PURCHASED INSURANCE POLICY OR INSURANCE PROVIDED BY THE APPLICANT'S EMPLOYER IN ACCORDANCE WITH § 18.864.

~~(5) Otherwise satisfies the requirements for a graduate permit and is not barred from licensure.~~

(c) The Board may deny an application for ~~licensure as an orthotist~~ A GRADUATE PERMIT upon the grounds for disciplinary action in section 41 of the act (63 P. S. § 422.41), ~~or~~ §§ 16.61 OR 18.853 (relating to unprofessional and immoral conduct) OR OTHER APPLICABLE LAW, SUCH AS SECTION 9124 OF THE CRIMINAL HISTORY RECORD INFORMATION ACT (18 PA.C.S.A. § 9124).

(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.

(E) AN INDIVIDUAL HOLDING A GRADUATE PERMIT MAY USE THE TITLE "ORTHOTIST RESIDENT" AND SHALL INFORM PATIENTS THAT THE INDIVIDUAL IS COMPLETING A RESIDENCY TRAINING PROGRAM AND IS NOT FULLY LICENSED.

§ 18.822. Clinical residency.

(a) ~~A graduate~~ AN orthotist RESIDENT 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~~ 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~~ ORTHOTIST RESIDENT and is responsible for countersigning within 15 days the entries in the patient's clinical record.

(b) ~~A~~ THE clinical residency shall be accredited by NCOPE.

(c) ~~A~~ THE clinical residency shall 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 DIRECT 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 the necessary supporting documents, pays the application fee 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. UNLESS PREVIOUSLY SUBMITTED UNDER § 18.821(b)(2) (RELATING TO GRADUATE PERMIT), AN APPLICANT SHALL DEMONSTRATE THIS REQUIREMENT BY HAVING THE CAAHEP-ACCREDITED EDUCATIONAL INSTITUTION SUBMIT, DIRECTLY TO THE BOARD, VERIFICATION OF COMPLETION OF A BACHELOR'S DEGREE, POST-BACCALAUREATE CERTIFICATE OR HIGHER DEGREE IN ORTHOTICS OR PROSTHETICS/ORTHOTICS, ALONG WITH AN OFFICIAL COPY OF THE APPLICANT'S TRANSCRIPT.

(3) Has completed an NCOPE-accredited clinical residency in orthotics or prosthetics/orthotics. AN APPLICANT SHALL DEMONSTRATE THIS REQUIREMENT BY HAVING THE PROGRAM DIRECTOR OF THE CLINICAL RESIDENCY PROGRAM SUBMIT, DIRECTLY TO THE BOARD, VERIFICATION THAT THE APPLICANT 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). AN APPLICANT SHALL DEMONSTRATE THIS REQUIREMENT BY SUBMITTING PROOF OF PROFESSIONAL LIABILITY INSURANCE COVERAGE THROUGH SELF-INSURANCE, A PERSONALLY PURCHASED INSURANCE POLICY OR

INSURANCE PROVIDED BY THE APPLICANT'S EMPLOYER IN ACCORDANCE WITH § 18.864.

~~(5) Otherwise satisfies the 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 the grounds for disciplinary action in section 41 of the act (63 P. S. § 422.41), ~~or~~ §§ 16.61 OR 18.853 (relating to unprofessional and immoral conduct) OR OTHER APPLICABLE LAW, SUCH AS SECTION 9124 OF THE CRIMINAL HISTORY RECORD INFORMATION ACT (18 PA.C.S.A. § 9124).

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

(E) AN INDIVIDUAL HOLDING A PROVISIONAL ORTHOTIST LICENSE MAY USE THE TITLE "PROVISIONALLY-LICENSED ORTHOTIST" AND SHALL INFORM PATIENTS THAT THE INDIVIDUAL IS NOT FULLY LICENSED.

§ 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 the necessary supporting documents, and pay the application fee 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. UNLESS PREVIOUSLY SUBMITTED UNDER §§ 18.821(b)(2)

OR 18.823(b)(2) (RELATING TO GRADUATE PERMIT; OR PROVISIONAL ORTHOTIST LICENSE), AN APPLICANT SHALL DEMONSTRATE THIS REQUIREMENT BY HAVING THE CAAHEP-ACCREDITED EDUCATIONAL INSTITUTION SUBMIT, DIRECTLY TO THE BOARD, VERIFICATION OF COMPLETION OF A BACHELOR'S DEGREE, POST-BACCALAUREATE CERTIFICATE OR HIGHER DEGREE IN ORTHOTICS OR PROSTHETICS/ORTHOTICS, ALONG WITH AN OFFICIAL COPY OF THE APPLICANT'S TRANSCRIPT.

(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 2-year period. AN APPLICANT SHALL DEMONSTRATE THIS REQUIREMENT BY HAVING THE APPLICANT'S EMPLOYER OR SUPERVISOR, THE DIRECTOR OF THE APPLICANT'S CLINICAL RESIDENCY PROGRAM, OR A REFERRAL SOURCE, FILE A VERIFICATION ON A FORM PROVIDED BY THE BOARD. IF VERIFICATION IS MADE BY A REFERRAL SOURCE, IT MUST INCLUDE A COPY OF THE APPLICANT'S FEDERAL EIN AND EVIDENCE OF THE DATE THE APPLICANT RECEIVED THE EIN.

(4) ~~Has met the qualifications for certification and received certification from an~~ HOLDS CURRENT CERTIFICATION AS AN ORTHOTIST, OR AS A PROSTHETIST AND ORTHOTIST, FROM ABC, BOC OR ANOTHER orthotic credentialing organization whose certification program is RECOGNIZED BY ICE, accredited by NCCA AND APPROVED BY THE BOARD. AN APPLICANT SHALL DEMONSTRATE

THIS REQUIREMENT BY HAVING THE ORGANIZATION SEND VERIFICATION OF CERTIFICATION DIRECTLY TO THE BOARD.

(5) Has complied with § 18.864 (relating to professional liability insurance coverage for licensed prosthetist, orthotist, pedorthotist or orthotic fitter). AN APPLICANT SHALL DEMONSTRATE THIS REQUIREMENT BY SUBMITTING PROOF OF PROFESSIONAL LIABILITY INSURANCE COVERAGE THROUGH SELF-INSURANCE, A PERSONALLY PURCHASED INSURANCE POLICY OR INSURANCE PROVIDED BY THE APPLICANT'S EMPLOYER IN ACCORDANCE WITH § 18.864.

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

(c) The Board may deny an application for licensure as an orthotist upon the grounds for disciplinary action in section 41 of the act (63 P. S. § 422.41), ~~or~~ §§ 16.61 OR 18.853 (relating to unprofessional and immoral conduct) OR OTHER APPLICABLE LAW, SUCH AS SECTION 9124 OF THE CRIMINAL HISTORY RECORD INFORMATION ACT (18 PA.C.S.A. § 9124).

(D) AN INDIVIDUAL HOLDING AN ACTIVE, UNSUSPENDED ORTHOTIST LICENSE MAY USE THE TITLE "ORTHOTIST."

~~**§ 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(e) (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 and demonstrates the qualifications in section 13.5(a)(1) and (5)—(8) and (f) of the act.~~

~~(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 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 2-year period, to total at least 4 years of education, training and work experience.~~

~~(3) At least 2 years or more 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 2-year period, 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 orthotist 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 an orthotist without examination upon the grounds for disciplinary action in section 41 of the act (63 P. S. § 422.41) or § 18.853 (relating to unprofessional and immoral conduct).~~

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

~~§ 18.826. Demonstration of qualifications.~~

~~An applicant for orthotist licensure shall demonstrate:~~

~~(1) 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) 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 must include a copy of the applicant's Federal EIN and evidence of the date the applicant received the EIN.~~

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

~~(4) 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) 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) The 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 in paragraph (2) demonstrating that the applicant has been in active, continuous practice.~~

QUALIFICATIONS FOR LICENSURE AS A PEDORTHIST

§ 18.831. Temporary practice permit.

(a) ~~Prior~~ AFTER COMPLETION OF AN NCOPE APPROVED PEDORTHIC EDUCATION PROGRAM AND PRIOR to providing pedorthic patient care IN THIS COMMONWEALTH ~~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~~ PRACTICE as a ~~graduate~~ pedorthist TRAINEE on forms made available by the Board. The Board may grant a temporary practice permit to an applicant who submits a completed application including the necessary supporting documents, pays the application fee in § 16.13(p) (relating to licensure, certification, examination and registration fees) and meets the qualifications 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~~ APPROVED PEDORTHIC precertification education program ~~or its equivalent as determined by the Board~~. AN APPLICANT SHALL DEMONSTRATE COMPLETION OF AN NCOPE APPROVED PEDORTHIC PRECERTIFICATION EDUCATION PROGRAM BY HAVING THE EDUCATIONAL INSTITUTION SUBMIT, DIRECTLY TO THE BOARD, VERIFICATION OF COMPLETION.

~~(3) Otherwise satisfies the 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 in section 41 of the act (63 P. S. § 422.41), ~~or~~ §§ 16.61 OR 18.853 (relating to unprofessional and immoral conduct) OR OTHER APPLICABLE LAW, SUCH AS SECTION 9124 OF THE CRIMINAL HISTORY RECORD INFORMATION ACT (18 PA.C.S.A. § 9124).

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

(E) AN INDIVIDUAL HOLDING A TEMPORARY PRACTICE PERMIT MAY USE THE TITLE "PEDORTHIST TRAINEE" AND SHALL INFORM PATIENTS THAT THE INDIVIDUAL IS COMPLETING A TRAINING PROGRAM AND IS NOT FULLY LICENSED.

§ 18.832. Patient fitting experience.

(a) A ~~graduate~~ pedorthist TRAINEE with a temporary practice permit shall practice only under the direct supervision of a licensed PROSTHETIST, ORTHOTIST OR 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~~ PEDORTHIST TRAINEE and is responsible for countersigning within 15 days the 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 the necessary supporting documents, and pay the application fee 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~~ APPROVED pedorthic PRECERTIFICATION education program ~~or its equivalent as determined by the Board.~~ UNLESS PREVIOUSLY SUBMITTED UNDER § 18.831 (RELATING TO TEMPORARY PRACTICE PERMIT), AN APPLICANT SHALL DEMONSTRATE COMPLETION OF AN NCOPE APPROVED PEDORTHIC PRECERTIFICATION EDUCATION PROGRAM BY HAVING THE EDUCATIONAL INSTITUTION SUBMIT, DIRECTLY TO THE BOARD, VERIFICATION OF COMPLETION.

(3) Has completed a minimum of 1,000 hours of supervised patient fitting experience PROVIDING DIRECT PATIENT CARE IN PEDORTHICS. AN APPLICANT SHALL DEMONSTRATE THIS REQUIREMENT BY HAVING THE APPLICANT'S EMPLOYER, SUPERVISOR OR A REFERRAL SOURCE FILE A VERIFICATION ON A FORM PROVIDED BY THE BOARD. IF VERIFICATION IS MADE BY A REFERRAL SOURCE, IT MUST INCLUDE A COPY OF THE APPLICANT'S FEDERAL EIN AND EVIDENCE OF THE DATE THE APPLICANT RECEIVED THE EIN.

(4) Holds current ~~National~~ certification AS A PEDORTHIST from the ABC, ~~or~~ the BOC OR ANOTHER PEDORTHIC CREDENTIALING ORGANIZATION WHOSE PROGRAM IS RECOGNIZED BY ICE, ACCREDITED BY NCCA AND APPROVED BY THE BOARD. AN APPLICANT SHALL DEMONSTRATE THIS REQUIREMENT BY HAVING THE ORGANIZATION SEND VERIFICATION OF CERTIFICATION DIRECTLY TO THE BOARD.

(5) Has complied with § 18.864 (relating to professional liability insurance coverage for licensed prosthetist, orthotist, pedorthist or orthotic fitter). AN APPLICANT SHALL DEMONSTRATE THIS REQUIREMENT BY SUBMITTING PROOF OF PROFESSIONAL LIABILITY INSURANCE COVERAGE THROUGH SELF-INSURANCE, A PERSONALLY PURCHASED INSURANCE POLICY OR INSURANCE PROVIDED BY THE APPLICANT'S EMPLOYER IN ACCORDANCE WITH § 18.864.

~~(6) Otherwise satisfies the 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 in section 41 of the act (63 P. S. § 422.41), ~~or~~ §§ 16.61 OR 18.853 (relating to unprofessional and immoral conduct) OR OTHER APPLICABLE LAW, SUCH AS SECTION 9124 OF THE CRIMINAL HISTORY RECORD INFORMATION ACT (18 PA.C.S.A. § 9124).

(D) AN INDIVIDUAL HOLDING AN ACTIVE, UNSUSPENDED PEDORTHIST LICENSE MAY USE THE TITLE "PEDORTHIST."

~~**§ 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, 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), (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 section 13.5(a)(1) and (5)—(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 licensed prosthetist, orthotist, pedorthist or orthotic fitter).~~

~~(c) The Board may deny an application for licensure as a pedorthist without examination upon the grounds for disciplinary action in section 41 of the act (63 P. S. § 422.41) or § 18.853 (relating to unprofessional and immoral conduct).~~

~~(d) This section expires at 5 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 must 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) The 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 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 orthotic fitting care, an individual shall obtain a temporary practice permit authorizing the individual to ~~work~~ PRACTICE ORTHOTIC FITTING as ~~a graduate~~ AN orthotic fitter TRAINEE. 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 the necessary supporting documents, pays the application fee in § 16.13(q) (relating to licensure, certification, examination and registration fees) and meets the qualifications 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~~ ABC OR BOC approved orthotic fitter PRECERTIFICATION education program ~~or its equivalent as determined by the Board.~~ AN APPLICANT SHALL DEMONSTRATE COMPLETION OF AN ABC OR BOC APPROVED ORTHOTIC FITTER PRECERTIFICATION EDUCATION PROGRAM BY HAVING THE EDUCATIONAL INSTITUTION SUBMIT, DIRECTLY TO THE BOARD, VERIFICATION OF COMPLETION.

~~(3) Otherwise satisfies the 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 in section 41 of the act (63 P. S. § 422.41), ~~or~~ §§ 16.61 OR 18.853 (relating to unprofessional and immoral conduct) OR OTHER APPLICABLE LAW, SUCH AS SECTION 9124 OF THE CRIMINAL HISTORY RECORD INFORMATION ACT (18 PA.C.S.A. § 9124).

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

(E) AN INDIVIDUAL HOLDING A TEMPORARY PRACTICE PERMIT MAY USE THE TITLE "ORTHOTIC FITTER TRAINEE" AND SHALL INFORM PATIENTS THAT THE INDIVIDUAL IS COMPLETING A TRAINING PROGRAM AND IS NOT FULLY LICENSED.

§ 18.842. Orthotic fitting care experience.

(a) ~~A graduate~~ AN orthotic fitter TRAINEE 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 the ABC or the BOC~~. For purposes of this section, "direct supervision" means the ~~supervising licensed individual~~ 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~~ ORTHOTIC FITTER TRAINEE and is responsible for countersigning within 15 days the 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 the necessary supporting documents, and pay the application fee 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-approved or NCOPE-approved~~ AN ABC OR BOC APPROVED orthotic fitter PRECERTIFICATION education program ~~or its equivalent as determined by the Board.~~ UNLESS PREVIOUSLY SUBMITTED UNDER § 18.841 (RELATING TO TEMPORARY PRACTICE PERMIT), AN APPLICANT SHALL DEMONSTRATE COMPLETION OF AN ABC OR BOC APPROVED ORTHOTIC FITTER PRECERTIFICATION EDUCATION PROGRAM BY HAVING THE EDUCATIONAL INSTITUTION SUBMIT, DIRECTLY TO THE BOARD, VERIFICATION OF COMPLETION.

(3) Has completed a minimum of 1,000 hours of documented ~~supervised~~ orthotic fitting care experience. AN APPLICANT SHALL DEMONSTRATE THIS REQUIREMENT BY HAVING THE APPLICANT'S EMPLOYER, SUPERVISOR OR A REFERRAL SOURCE FILE A VERIFICATION ON A FORM PROVIDED BY THE BOARD. IF VERIFICATION IS MADE BY A REFERRAL SOURCE, IT MUST INCLUDE A COPY OF THE APPLICANT'S FEDERAL EIN AND EVIDENCE OF THE DATE THE APPLICANT RECEIVED THE EIN.

(4) Holds current ~~National~~ certification AS AN ORTHOTIC FITTER from the ABC, ~~or~~ the BOC OR ANOTHER ORTHOTIC FITTER CREDENTIALING ORGANIZATION WHOSE PROGRAM IS RECOGNIZED BY ICE, ACCREDITED BY NCCA AND APPROVED BY THE BOARD. AN APPLICANT SHALL DEMONSTRATE THIS REQUIREMENT BY HAVING THE ORGANIZATION SEND VERIFICATION OF CERTIFICATION DIRECTLY TO THE BOARD.

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

DEMONSTRATE THIS REQUIREMENT BY SUBMITTING PROOF OF PROFESSIONAL LIABILITY INSURANCE COVERAGE THROUGH SELF-INSURANCE, A PERSONALLY PURCHASED INSURANCE POLICY OR INSURANCE PROVIDED BY THE APPLICANT'S EMPLOYER IN ACCORDANCE WITH § 18.864.

~~(6) Otherwise satisfies the 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 in section 41 of the act (63 P. S. § 422.41), ~~or~~ §§ 16.61 OR 18.853 (relating to unprofessional and immoral conduct) OR OTHER APPLICABLE LAW, SUCH AS SECTION 9124 OF THE CRIMINAL HISTORY RECORD INFORMATION ACT (18 PA.C.S.A. § 9124).

(D) AN INDIVIDUAL HOLDING AN ACTIVE, UNSUSPENDED ORTHOTIC FITTER LICENSE MAY USE THE TITLE "ORTHOTIC FITTER."

~~**§ 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, 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)).~~

~~(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 section 13.5(a)(1), (5) (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 professional liability insurance coverage for licensed prosthetist, orthotist, pedorthist or orthotic fitter).~~

~~(c) The Board may deny an application for licensure as an orthotic fitter without examination upon the grounds for disciplinary action in section 41 of the act (63 P.S. § 422.41) or § 18.853 (relating to unprofessional and immoral conduct).~~

~~(d) This section expires at 5 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 ABC OR BOC 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 must 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) The 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 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 understand 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 shall 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 a prescription and referral or order when the prosthetist, orthotist, pedorthist or orthotic fitter knows, or has good cause to believe, that the device cannot be furnished within a reasonable period of time AS WOULD BE CONSISTENT WITH THE STANDARD OF CARE OF THE AVERAGE PROFESSIONAL PROVIDING THE SERVICE IN THIS COMMONWEALTH. In these instances, the prosthetist, orthotist, pedorthist or orthotic fitter shall consult with the licensed prescribing practitioner who wrote the prescription and referral or order and 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~~ SUPERVISION AND ASSISTANCE.

~~(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, 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, onsite supervision of the tasks performed by a delegate.~~

~~(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.~~

A PROSTHETIST OR ORTHOTIST MAY ASSIGN TASKS RELATED TO THE PRACTICE OF PROSTHETICS OR ORTHOTICS TO AN ORTHOTIC AND PROSTHETIC ASSISTANT WORKING UNDER THE PROSTHETIST'S OR ORTHOTIST'S DIRECT SUPERVISION PROVIDED THAT ASSIGNMENT OF THE TASKS IS CONSISTENT WITH THE STANDARDS OF ACCEPTABLE PROSTHETIC AND ORTHOTIC PRACTICE EMBRACED BY THE PROSTHETIC AND ORTHOTIC COMMUNITY IN THIS COMMONWEALTH.

(B) A PROSTHETIST OR ORTHOTIST MAY ASSIGN TASKS RELATED TO THE FABRICATION, ASSEMBLY, MODIFICATION AND SERVICING OF PROSTHETIC AND ORTHOTIC DEVICES TO AN ORTHOTIC AND PROSTHETIC TECHNICIAN WORKING TO THE SPECIFICATIONS PROVIDED BY THE PROSTHETIST OR ORTHOTIST.

(C) A PEDORTHIST MAY ASSIGN TO PEDORTHIC SUPPORT PERSONNEL TASKS RELATED TO PEDORTHIC CARE WHEN DIRECT SUPERVISION IS PROVIDED, AND MAY ASSIGN TECHNICAL TASKS TO BE COMPLETED TO THE SPECIFICATIONS PROVIDED BY THE PEDORTHIST IF ASSIGNMENT OF THE TASKS IS CONSISTENT WITH THE STANDARDS OF ACCEPTABLE PEDORTHIC PRACTICE EMBRACED BY THE PEDORTHIC COMMUNITY IN THIS COMMONWEALTH.

(D) FOR PURPOSES OF THIS SECTION, "DIRECT SUPERVISION" MEANS THAT THE PROSTHETIST, ORTHOTIST OR PEDORTHIST IS ON THE PREMISES, PERIODICALLY OBSERVES AND IS CONTINUOUSLY AVAILABLE TO PROVIDE GUIDANCE TO THE ASSISTANT OR PEDORTHIC SUPPORT PERSONNEL. FOR PURPOSES OF THIS SECTION "TO THE SPECIFICATIONS PROVIDED" MEANS THAT THE PROSTHETIST, ORTHOTIST OR PEDORTHIST HAS PROVIDED ALL NECESSARY MEASUREMENTS

AND INSTRUCTIONS TO THE TECHNICIAN FOR THE FABRICATION, ASSEMBLY, MODIFICATION AND SERVICING OF THE DEVICE.

(E) ONLY A PROSTHETIST, ORTHOTIST OR PEDORTHIST MAY PERFORM AN INITIAL PATIENT EVALUATION AND THE FINAL PROVISION OF A PROSTHETIC, ORTHOTIC OR PEDORTHIC DEVICE TO DETERMINE THE APPROPRIATENESS OF THE DEVICE DELIVERED TO A PATIENT.

(F) THE PROSTHETIST, ORTHOTIST OR PEDORTHIST ASSIGNING AND SUPERVISING TASKS SHALL BEAR ULTIMATE RESPONSIBILITY FOR THE COMPLETED TASKS.

§ 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 2 Pa.C.S. §§ 501—508 and 701—704 (relating to Administrative Agency Law), this chapter and 1 Pa. Code Part II (relating to General Rules of Administrative Practice and Procedure), the Board may refuse licensure or impose any of the corrective actions in section 42 of the act (63 P. S. § 422.42).

(b) Unprofessional conduct includes:

(1) Engaging in conduct prohibited under §§ 16.61(a) OR 16.110 (relating to UNPROFESSIONAL AND IMMORAL CONDUCT; AND sexual misconduct).

(2) Performing an act in a health care 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 health care practice beyond the licensee's authority to practice.

(5) Representing oneself to be a physician or other health care 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 under 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 a 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 a fee or other consideration to or from a third party for the referral of a patient or client.

(11) ~~Delegating professional services~~ SUPERVISING OR ASSIGNING TASKS TO ASSISTANTS, TECHNICIANS OR SUPPORT PERSONNEL contrary to § 18.852 (relating to ~~delegation~~ SUPERVISION AND ASSISTANCE).

(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.~~ MAKING GROSS MISREPRESENTATIONS, DELIBERATE MISREPRESENTATIONS OR MISLEADING CLAIMS AS TO:

(i) THE LICENSEE'S PROFESSIONAL QUALIFICATIONS.

(ii) THE EFFICACY OR VALUE OF:

(A) THE TREATMENTS OR REMEDIES GIVEN TO A PATIENT BY THE LICENSEE.

(B) THE TREATMENTS OR REMEDIES RECOMMENDED TO A PATIENT BY THE LICENSEE.

(C) THE TREATMENTS GIVEN TO A PATIENT BY ANOTHER PRACTITIONER.

(D) THE RECOMMENDATIONS MADE TO A PATIENT BY 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 include:

(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~~ IN ADDITION TO THE CONDUCT LISTED IN § 16.61(b) or 16.110, 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 the Commonwealth, the United States, 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 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 a license to practice as a prosthetist, orthotist, pedorthist or orthotic fitter in another state, territory, possession or country.

(3) Disclose on the application disciplinary action pending before or taken by an appropriate health care licensing authority in another 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 ~~instead~~ 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) OR (2) of the act (63 P. S. § 422.13e(g)(1) OR (2)) 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 coverage 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-approved or BOC-approved continuing education applicable to the practice of prosthetics and an orthotist shall complete at least 24 hours of ABC-APPROVED OR BOC-APPROVED continuing education applicable to the practice of orthotics.

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

(3) Credit for continuing education will not 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. An hour of continuing education may not be used to satisfy the requirements of paragraph (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 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 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.* A licensee shall maintain documentation of completion of continuing education by maintaining the certificate of attendance or completion issued by the course provider. A licensee shall maintain the certificates for at least 5 years after the end of the biennial renewal period in which the continuing education was completed. A certificate must 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 the immediately preceding biennium. Unless waived by the Board under section 13.5(g)(7) of the act (63 P. S. § 422.13e(g)(7)), the Board will not reactivate a 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 INITIAL certification ~~examinations~~ EXAMINATION offered by ~~either~~ the ABC, ~~or~~ the BOC OR ANOTHER CREDENTIALING ORGANIZATION WHOSE CERTIFICATION PROGRAM IS RECOGNIZED BY ICE, ACCREDITED BY NCCA AND APPROVED BY THE BOARD. ~~For prosthetists or orthotists, the applicable examinations are the ABC or BOC examinations required for initial certification. For pedorthists or orthotic fitters, the applicable examinations are the ABC or BOC pedorthist or orthotic fitter examination required for initial certification.~~

§ 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 million per occurrence or claims made as required under section 13.5(i) of the act (63 P. S. § 422.13e(i)) and provide proof of coverage upon request.

(b) Proof of professional liability insurance coverage includes:

(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 Insurance Department in 31 Pa. Code Chapter 243 (relating to medical malpractice and health-related self-insurance plans).

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

Regulatory Analysis Form

(Completed by Promulgating Agency)

(All Comments submitted on this regulation will appear on IRRC's website)

INDEPENDENT REGULATORY REVIEW COMMISSION

(1) Agency:
Department of State, Bureau of Professional and Occupational Affairs, State Board of Medicine

(2) Agency Number: **16A**

Identification Number: **4943**

IRRC Number: **3062**

(3) PA Code Cite: 49 Pa. Code §§ 16.11, 16.13 and 18.801-18.864

(4) Short Title: Prosthetists, Orthotists, Pedorthists and Orthotic Fitters

(5) Agency Contacts (List Telephone Number and Email Address):

Primary Contact: **Cynthia K. Montgomery, Regulatory Counsel, Department of State, P.O. Box 69523, Harrisburg, PA 17106-5923 (phone 717-783-7200) (fax 787-0251) cymontgome@pa.gov.**
Secondary Contact: **Peter Kovach, Board Counsel, State Board of Medicine, Department of State, P.O. Box 69523, Harrisburg, PA 17106-5923 (phone 717-783-7200) (fax 787-0251); pkovach@pa.gov.**

(6) Type of Rulemaking (check applicable box):

Proposed Regulation
X **FINAL REGULATION**
Final Omitted Regulation

☐ Emergency Certification Regulation;
☐ Certification by the Governor
☐ 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. The act of July 2, 2014 P.L. 941, No. 104) (Act 104) amended Act 90.

(8) State the statutory authority for the regulation. Include specific statutory citation.

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. Following the delivery of proposed rulemaking, the General Assembly amended Act 90 by way of the act of July 2, 2014 (P.L. 941, No. 104) (Act 104). The Act 104 amendments altered the qualifications for licensure without examination and extended the date for individuals to obtain licensure without examination to March 31, 2015. The final-form rulemaking is authorized under section 3 of Act 90 and under section 2 of Act 104, as well as under section 8 of the act (63 P.S. § 422.8), which authorizes the Board to adopt regulations as are reasonably necessary to carry out the purposes of the act.

(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) is required to makes these changes to conform the Board's regulations to the amendments made to the act by Act 90 and by Act 104.

(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 and Act 104, and will benefit the regulated community of prosthetists, orthotists, pedorthists and orthotic fitters by providing clear regulations. The public will benefit by having qualified professionals provide these health-care services.

(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 for prosthetists, orthotists, pedorthists or orthotic fitters.

(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 regulate these professions (Alabama, Arkansas, Florida, Illinois, Iowa, Kentucky, New Jersey, North Dakota, Ohio, Oklahoma, Tennessee, Texas and Washington) with statutory and/or regulatory requirements for licensure, continuing education and liability insurance being similar in all of the states.

(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.)

Upon passage of Act 90, the Board was contacted by only one stakeholder, the ABC, offering assistance with drafting of the rulemaking. The Board attempted to identify stakeholders by finding the prosthetist, orthotist and pedorthist educational programs in the Commonwealth; by researching certification and identifying the certification bodies; by identifying the state professional association; and by speaking with individuals on the legislative staff regarding who might be an interested party.

For the first public meeting with stakeholders, the Board invited 33 individuals, including the president of the Board of Certification (BOC), Claudia Zacharias; Stephen Fletcher, Director of Clinical Resources and Catherine Carter, Executive Director of American Board for Certification (ABC); the Pennsylvania Orthopedic Society, the Amputee Coalition of America, the Pennsylvania Occupational Therapy Association, the Pennsylvania Orthopedic Society, the Pennsylvania Physical Therapy Association and the Pennsylvania Medical Society; Randy Stevens and Eileen Levis from the Pennsylvania Orthotic & Prosthetic Society (POPS); representatives from the University of Pittsburgh's graduate program in orthotics and prosthetics; representatives from the Temple University School of Podiatry, which had run a pedorthics educational program; the Pedorthic Footcare Association's Executive Director Brian Lagana; industry representatives from Carter Orthopedics and the National Orthotics Manufacturers Association; Anjali Weber, Director of Accreditation for the Institute for Credentialing Excellence; and Marlene Tremmel and Sharon Engdahl, staff with the House Professional Licensure Committee.

The first public meeting with stakeholders, held in September of 2012, was attended by 17 individuals, including four who identified themselves to the Board as being from POPS: Randy Stevens, Kristen Ortiz, Eileen Levis and Joe Carter. In attendance also were representatives from both the BOC and the ABC; the National Orthotics Manufacturers Association; the PA Orthopedic Society and PA Medical Society; the University of Pittsburgh; the Occupational Therapy Association; ICE and several other individuals representing licensees of the Board. The representatives from POPS also attended the Board's second public meeting with stakeholders in November of 2012.

In addition, the Board requested that the stakeholders that it had identified communicate with their colleagues and inform them of the November public meeting should anyone else wish to attend. During the drafting of the proposed rulemaking, the Board also received and considered comments from individuals who wrote to the Board, including Caryn Plessinger, President of Hub's Home Oxygen & Medical Supplies/CressCare Medical; Michael J. Gartland, Compliance Analyst at Klingensmith Health Care; Dana Finn, Facility Accreditation Coordinator from BOC; Zack Chait from BOC; Anjali Weber from ICE; Steve Fletcher from ABC; Claudia Zacharias from BOC; Eileen Levis from POPS; Randy Stevens from POPS; and Sofya Tamarkin. In addition to multiple meetings with all stakeholders, the Board's Allied Health Committee met with Sofya Tamarkin to discuss her concerns.

Finally, the Board met with stakeholders and legislative staff to discuss the Act 104 amendments. As a result of those discussions, the Board agreed to publish an Advance Notice of Final Rulemaking and solicit additional comments. The Board continued to receive comments on the final rulemaking through February of 2016. The Board believes that the final rulemaking represents the culmination of extensive outreach and involvement of stakeholders.

(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?

As of early May 2016, the Board has licensed 220 prosthetists, 314 orthotists, 117 pedorthists and 190 orthotic fitters. 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. 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 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. Of the 978,831 small businesses, 236,775 are small employers (fewer than 500 employees) and the remaining 772,056 are non-employers. The 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 practicing prosthetics, orthotics, pedorthics and orthotic fitting as described in the act 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. There are currently 841 licensed prosthetists, orthotists, pedorthists and orthotic fitters practicing in the Commonwealth.

(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.

The act 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 534 prosthetists and orthotists who must comply with the provision yields an annual cost of $267,000 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 x 13 = $325 / 2 = $162.50 (annual cost) x 307 licensees = $49,887.50.

The total cost of CE for all 841 licensees is approximately $316,887.50 annually.

The act also requires prosthetists, orthotists, pedorthists and orthotic fitters to maintain professional liability insurance. Costs of insurance varies 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 licensees. Nevertheless, the Board is required to do so. Accordingly, the Board will estimate that the average cost of liability insurance will be approximately $6,000 for pedorthists and orthotic fitters and approximately $10,000 per year for prosthetists and orthotists For the 841 total licensees, the total cost to the regulated community will be approximately $7,182,000.

The combined CE and insurance costs for all licensees is approximately $7,498,887.50 per year.

Biennial renewal fee expenses will be $63,075. The 841 current licensees will renew in December of even-numbered years (2016, 2018, 2020, etc.)

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 regulations.

(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 15-16	FY +1 16-17	FY +2 17-18	FY +3 18-19	FY +4 19-20	FY +5 20-21
SAVINGS:	$	$	$	$	$	$
Regulated Community						
Local Government						
State Government						
Total Savings						
COSTS:						
Regulated Community	$7,498,887	$7,561,962	$7,498,887	$7,561,962	$7,498,887	$7,561,962
Local Government						
State Government						
Total Costs	$7,498,887	$7,561,962	$7,498,887	$7,561,962	$7,498,887	$7,561,962
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 12-13 (Actual)	FY -2 FY 13-14 (Actual)	FY -1 FY 14-15 (Actual)	Current FY FY 15-16 (Budgeted)
	$6,259,933.04	**$6,871,300.63**	**$7,295,078.33**	**$8,184,000.00**

(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 841 licensed prosthetists, orthotists, pedorthists and orthotic fitters working Pennsylvania. Virtually all of these licensees either are small businesses or work in small businesses. Thus, as many as 841 small businesses will be subject to the regulation.

(b) The reporting, recordkeeping and administrative costs of compliance would be minimal. These would include completing the paperwork required for biennial renewal and for maintaining records of completion of continuing education. Costs associated with liability insurance would be likely be incurred regardless of licensure as any prudent business would have insurance.

(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. The Board has endeavored to keep direct costs to a minimum.

(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.

The Board does not believe there are any affected persons that would have particular needs requiring special provisions.

(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 certification 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 under supervision. 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. The Board believes it has selected the least burdensome acceptable alternative.

(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:	**August 11, 2014**
B. The date or dates on which public meetings or hearings will be held:	**At regularly scheduled Board meetings (see item #30 below)**
C. The expected date of promulgation of the proposed regulation as a final-form regulation:	**Summer 2016**
D. The expected effective date of the final-form regulation:	**Summer 2016**
E. The date by which compliance with the final-form regulation will be required:	**Upon final publication**
F. The date by which required permits, licenses or other approvals must be obtained:	**Upon final publication**

(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. The remaining meeting dates for 2016 are: September 7, October 18 and December 6, 2016. The meeting dates for 2017 are: February 7, March 21, April 19, May 16, June 20, July 25, September 6, October 31, and December 19, 2017. More information can be found on the Board's website (www.dos.state.pa.us/med).

Commentator's List
Reg. 16A-4943

Eileen Levis, President
PA Orthotic Prosthetic Society
3535 High Point Blvd. Suite 20
Bethlehem, PA 18017

R. Jeffrey Hedges, CDME
R.J. Hedges & Assoc.
978 Pumphouse Road
PO Box H
New Florence, PA 15944
Jeff.hedges@RJHedges.com

Sofya Tamarkin
Foot Comfort Center
9808 Bustleton Ave.
Philadelphia, PA 19115
tamarkincontact@hotmail.com

Thomas Morrissey
President & CEO
BostonBrace/NOPCO
20 Ledin Drive
Avon, MA 02322
Tmorrissey@BostonBrace.com

Patricia A. Epple, CAE
Don L. Smith
PA Pharmacists Assoc.
508 N. Third St.
Harrisburg, PA 17101
pepple@papharmacists.com
dsmith@papharmacists.com

Irina Volk Rabovetsky, Esq.
irina.volk@gmail.com

Claudia Zacharias, President & CEO
BOC
10451 Mill Run Circle, Suite 200
Owings Mills, MD 21117

Ashley Nicoletti, Esq.
ashleynicoletti@yahoo.com

Gregory Michalowski
C-Fab 1 Inc.
2820 Old Lincoln Highway
Unit #1
Trevose, PA 19053

Steven Chu
Valley Prosthetics & Orthotics, Inc.
steven@valleypo.com