

# RULES AND REGULATIONS

## Title 49—PROFESSIONAL AND VOCATIONAL STANDARDS

### STATE BOARD OF MEDICINE

[ 49 PA. CODE CHS. 16 AND 18 ]

#### Prosthetists, Orthotists, Pedorthists and Orthotic Fitters

The State Board of Medicine (Board) 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*

This final-form rulemaking will be effective upon publication 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 on June 30, 2014, published at 44 Pa.B. 4364 (July 12, 2014), 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.

This 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, with a 30-day public comment period. The Board received comments from members of the regulated community and the public, the House Professional Licensure Committee (HPLC) and the Independent Regulatory Review Commission (IRRC). Several commentators 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 withdrawn. As of early May 2016, the Board issued the following licenses:

	<i>Alternate Pathway</i>	<i>Traditional Licensure</i>
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 the POPS comments related 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 asserted that the Board should delete references in the final-form 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 asserted 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 asserted that the Board should list the Accrediting Bureau of Health Education Schools (ABHES) in the regulations. Neither Act 90 nor Act 104 mentions 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 that 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 ABC and BOC. To meet the qualifications for certification by ABC or BOC as a prosthetist or orthotist, an individual shall complete a CAAHEP-accredited education program and an NCOPE-approved residency program. To meet the qualifications for certification by ABC or BOC as a pedorthist, an individual shall complete an NCOPE-approved pedorthic precertification education program. The Board's reference to CAAHEP and NCOPE in the regulations alerts the public that approved education is required for licensure in orthotics and prosthetics in this Commonwealth. All 12 United States institutions that offer prosthetics/orthotics education at the bachelor's degree 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 the regulations correctly reference CAAHEP.

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

POPS objected 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 ABC or BOC) is a prerequisite to licensure; completion of an NCOPE-approved residency program is a prerequisite to certification. Accordingly, the regulations regarding 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, regulations regarding a graduate permit should reference NCOPE. In §§ 18.811(b)(3) and 18.821(b)(3) (relating to graduate permit), the Board requires an applicants for a graduate permit as a prosthetist or orthotist to register with NCOPE for 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 asserted that requiring clinical residencies to be NCOPE-approved would be inconsistent "with the language or intent of the statute" 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 under 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 residency, POPS suggested that the provisions regarding 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 this Commonwealth would need to apply for a graduate permit. That is, 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 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 asserted that the Board's requirement that an applicant has 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. Certification is a requirement for licensure in section 13.5(a)(3) of the act. The licensure qualification of meeting particular educational minimums is in section 13.5(a)(2) of the act. Moreover, CAAHEP is the only National accrediting body for orthotic and prosthetic education programs and is required in all states that license these professionals.

POPS suggested that the Board delete the definition of "custom-designed device" proposed in § 18.802 (relating to definitions) stating that this is not a term recognized by the Center for Medicare & Medicaid Services (CMS) or the industry. The term is used in section 2 of the act (63 P.S. § 422.2) in the definition of "prosthesis." The definition begins 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 suggested that the Board's definition of "pedorthic device" is contrary to the act because subparagraph (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, which specifically excludes "nontherapeutic, accommodative inlays and nontherapeutic accommodative footwear, regardless of 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 that proposed §§ 18.816, 18.826, 18.835 and 18.845 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 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 withdrew these sections from this final-form rulemaking. The Board 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 suggested that the Board should not have separated the educational and experiential qualifications for prosthetist and orthotist licensure in §§ 18.814(b)(2) and (3) and 18.824(b)(2) and (3). The Board finds that the

provisions are separated by “and” in section 13.5(a)(2)(i) and (ii) of the act, and that the list of qualifications is easier to read separated into paragraphs. Therefore, the Board declines to place the two qualifications into a single sentence as recommended by POPS.

Regarding § 18.832 (relating to patient fitting experience) for graduate pedorthists, POPS suggested 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 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 did not require licensees to maintain their ABC or BOC certifications. Nowhere in § 18.861 (relating to biennial renewal of license) is there mention of the maintenance of certification as a condition of renewal. However, the Board strongly recommends that a professional who holds 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 this requirement because it believes the restriction would violate the United States and Pennsylvania Constitutions and would be a barrier to individuals who are considering relocating to this Commonwealth 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 supervision and assistance), 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 health care fields. The Board defines “orthotic and prosthetic assistant” in § 18.802 as an individual who assists with patient care tasks, not an individual who provides that care. In addition, in proposed § 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, and with significant input from the regulated community, the Board 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 shall be subject to direct supervision, defined so 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 certified pedorthist, submitted comments suggesting that the Board adopt a definition for “indirect supervision” as used in Iowa, which would “imply that a licensed certified professional would be liable and responsible for any non-licensed Orthotic Fitters.” According to this commentator, the proposal would also make the licensed professional accountable for training and formal education of nonlicensed individuals. Licensed professionals would not be present during the delivery of care. However, the licensee would be required to sign medical records produced by nonlicensed 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 would be required.

In response, the Board notes that in Iowa Nationally-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 Nationally-certified orthotic fitters. The Board believes that the proposed rulemaking was actually more inclusive of supportive personnel because it allowed 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. This revised final-form 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.

Senator Mike Stack made a similar comment on behalf of his constituents, suggesting the Board permit indirect supervision of nonlicensed 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, Esq., made an identical suggestion.

Ashley Nicoletti, Esq., provided a similar comment, suggesting that a definition of “indirect supervision” similar to the ABC and BOC guidelines be included. The commentator suggested the following language:

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.

This commentator explained that this addition was suggested 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. This 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.

This commentator 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 statute. The Board declines to add this provision.

POPS suggested that the Board delete the definition of "orthotic and prosthetic assistant" in § 18.802 because CMS does not recognize these "classes" and because the purpose of the act 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 suggested 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 that licenses orthotic and prosthetic professionals. Accordingly, the Board declines to delete the definition of "orthotic and prosthetic technician" in § 18.202. However, the Board revised this final-form 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. This final-form 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 BOC*

Claudia Zacharias, President and CEO of BOC, noted that the Board's references to National certification were stated inconsistently throughout the proposed rulemaking, and suggested, as a solution, that the Board amend the definitions of "ABC" and "BOC" to provide that these organizations are National 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, amended the definitions of "ABC" and "BOC" to clarify that they are Board-approved organizations. In addition to amending these definitions, the Board amended the sections noted by BOC as not referring to certification consistently so that the references are internally consistent.

BOC commented that § 18.832(a) 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 amended § 18.832(a) accordingly.

BOC noted that proposed § 18.835(4), regarding demonstration of qualifications, which referred to the experiential component of pedorthic education should state "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 of supervised patient fitting experience." The Board prefers to retain the statutory term. In this final-form rulemaking, the text of proposed § 18.835(4) has been moved to § 18.833(b)(3) (relating to pedorthist license). In response to BOC's comment, the Board 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 were coordinated with the pharmacy, durable medical equipment and mastectomy organizations in this Commonwealth. RJH suggested that the Board add a definition of "facility" to clarify that the licensed individual is a legally operating business within this Commonwealth. The definition would provide that "facility" means the business location where care is provided and has appropriate equipment to provide comprehensive orthotic, prosthetic and pedorthic care; and that licensees shall be available to provide the care or supervise the provision of care by orthotic fitters or nonlicensed 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 regulations; "facility" is not used in the regulations 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 shall 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 suggested that the Board include a definition of "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 “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 made amendments as previously discussed to standardize the terminology used in this final-form 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 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 previously noted, the Board 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 commentator also noted that individuals in fabrication businesses are not supervised by licensees. The commentator suggested that the definition of “orthotic and prosthetic technician” in § 18.202 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 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 also amended § 18.852 to clarify that the prosthetist or orthotist shall provide all of the necessary measurements and instructions to the technician for the fabrication, assembly, modification and servicing of the device.

*Comments from the HPLC*

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 act. The act aims to promote the health and welfare of the citizens of this 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 ABC or BOC a prosthetist or orthotist is required to complete a 1-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 act prohibits the practice of these professions without licensure. Therefore, 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 act.

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 this 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 this Commonwealth. The Board believes that the creation of these permits and provisional licenses was necessary to effectuate the intent of the act.

The HPLC commented that the Board should be more specific pertaining to §§ 18.814(b)(6) and 18.824(b)(6), suggesting that the Board make reference to the act for licensees who need more clarification. Sections 18.814(b)(6) and 18.824(b)(6) provided that an applicant for licensure shall “otherwise satisf[y] the requirements for licensure” and not be barred from licensure. The Board determined that the provision is superfluous and deleted it from this final-form rulemaking.

Finally, the HPLC commented that it understood the Board would be making amendments to the proposed rulemaking to conform to Act 104, and that it looked forward to seeing the advance notice of final rulemaking (ANFR). Because the provisions of Act 104 expired as of March 31, 2015, the Board deleted the sections regarding alternative pathways to licensure.

*Comments from IRRC*

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

For the first public meeting with stakeholders, the Board invited 33 individuals, including: Claudia Zacharias, President, BOC; Stephen Fletcher, Director of Clinical Resources, and Catherine Carter, Executive Director, 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, 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; Brian Lagana, Executive Director, Pedorthic Footcare Association; industry representatives

from Carter Orthopedics and the National Orthotics Manufacturers Association; Anjali Weber, Director of Accreditation, ICE; and Marlene Tremmel and Sharon Engdahl, HPLC staff.

The first public meeting with stakeholders held in September 2012 was attended by 17 individuals, including 4 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 BOC, ABC, the National Orthotics Manufacturers Association, the Pennsylvania Orthopaedic Society, the Pennsylvania 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 2012.

In addition, the Board requested that the stakeholders that it had identified communicate with their colleagues and inform them of the November 2012 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, Hub's Home Oxygen & Medical Supplies/CressCare Medical; Michael J. Gartland, Compliance Analyst, Klingensmith Health Care; Dana Finn, Facility Accreditation Coordinator, BOC; Zack Chait, BOC; Anjali Weber, ICE; Steve Fletcher, ABC; Claudia Zacharias, BOC; Eileen Levis, POPS; Randy Stevens, POPS; and Sofya Tamarkin. In addition to multiple meetings with 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 this final-form rulemaking. The Board 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 this final-form rulemaking. The Board believes this 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 this final-form rulemaking is in the public interest.

IRRC noted that the Board provided fee reports for all of the fees regarding 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 regarding discrete functions performed by Board staff regarding 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 regarding 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. 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.

The most recent fiscal report of the Board was delivered by the Bureau of Finance and Operations at the Board's April 19, 2016, meeting. The following is the Fiscal Year 2015-2016 budget for the Board:

<i>Administrative costs</i>	
Board administration	\$2,445,000
Commissioner's Office	\$51,000
Revenue Office	\$40,000
Departmental services	\$362,000
Board member expenses	\$48,000
<i>Legal costs</i>	
Legal Office	\$2,471,000
Hearing expenses	\$16,000
Professional Compliance Office	\$536,000
Enforcement and investigation	\$1,617,000
Professional Health Monitoring Programs	\$298,000
<i>Total Board Costs</i>	\$8,184,000

Regarding § 18.802, 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 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 of “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 act,” to describe licensees in § 18.802. The Board amended these definitions to make them consistent. IRRC commented on the Board’s definition of “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 amended § 18.802 accordingly.

IRRC asked the Board to consider including provisions regarding the titles that the holders of graduate permits, provisional licenses and temporary permits may use. The Board added provisions regarding 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 added provisions requiring permit holders and provisional licensees to inform patients of the status of their licensure. The Board determined that the appropriate title for a prosthetist or orthotist during the period of the residency is “prosthetist/orthotist resident.” The Board 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 proposed to call pedorthists and orthotic fitters in training “graduate pedorthist/orthotic fitter.” The Board determined that these providers are more commonly known as trainees or “in training.” The Board settled upon “pedorthist/orthotic fitter trainee” because it is shorter and easier for employers to fit on an identification badge.

IRRC noted a misplaced provision in § 18.814(b)(3) 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 proposed § 18.816, regarding demonstration of qualifications, contained the necessary information concerning how to demonstrate the experience requirements. Instead of removing the provision from § 18.814, the Board revised this final-rulemaking to delete the separate sections pertaining to demonstration of qualifications (including § 18.816) and instead 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 commented that proposed § 18.815, regarding alternate pathway for prosthetist license, expired on July 7, 2014, and asked the Board to withdraw this section. Act 104 replaced provisions in Act 90 regarding licensure without examination and provided a new expiration date of March 31, 2015. As that date has also passed, the Board withdrew § 18.815 and §§ 18.825, 18.834 and 18.844, the coordinate sections for the other profession.

Regarding proposed §§ 18.816, 18.826, 18.835 and 18.845, IRRC asked the Board to make amendments to ensure that the requirements are clear for each type of permit or license. The Board withdrew these sections and instead 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) (relating to provisional prosthetist license). The omission in § 18.823 was inadvertent and the Board added “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 did not provide a restriction regarding the provisional prosthetist license or provisional orthotist license, and also determined that the certification exam providers (ABC and BOC) are under no obligation to report failures to the Board. Therefore, the proposed 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 it 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 act 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 1 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 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 deleted “supervised” from § 18.843(b)(3). The Board 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 source for the other licensees under Act 90.

Regarding § 18.851 (relating 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 asked what would be a reasonable period of time and opined 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 amended § 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, 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) of the act (which provides, in pertinent part, that any person who is not licensed as a prosthetist, orthotist, pedorthist or orthotic fitter may not practice prosthetics, orthotics, pedorthics or orthotic fitting) and how this section conforms to the intent of the General Assembly. One segment of the regulated community asserted that Act 90 does not provide for assistants, technicians or support personnel. The opposing segment of the regulated community asserted 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 commentators further asserted 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 health care, there are both licensed and unlicensed individuals providing a range of services to patients. Examples of unlicensed individuals include certified nursing aides, medication aides, medical assis-

tants and laboratory technicians. The Board agrees that the act 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, 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 (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 commentators 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 commentators may no longer have an interest in the level of supervision that shall 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 this Commonwealth might have thought of entering one of these professions, but changed their minds 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 § 18.852(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 (relating to unprofessional and immoral conduct) and those in § 16.61 (relating to unprofessional and immoral conduct). The Board 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 cross-referenced in this 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 in § 18.861 to section 13.5(g)(2) of the act, which provides for continuing education requirements for pedorthists and orthotic fitters. The Board 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 questioned whether it was necessary to

reference the disciplinary section of the act in each section of the regulations 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. IRRC noted some inconsistent wording among parallel sections. The Board revised this final-form rulemaking for consistency.

*Comments following the ANFR*

The Board sent a draft of the final rulemaking to stakeholders and published an ANFR at 45 Pa.B. 5682 (September 19, 2015). The Board received additional comments during the 30-day public comment period and months afterward, as late as February 2016. In late February 2016, a Board representative met with POPS’ counsel to address POPS’ concerns and to ensure that this final-form rulemaking protected the public and was consistent with current practices in the professions. POPS continued to object to the use of “assistant” and preferred “support personnel.” However, as “assistant” is used in 12 of the 13 states which license prosthetists and orthotists, the Board retains the term.

The Board also received identical comments from RJH and the Pennsylvania Pharmacists Association requesting that the Board include definitions of “health care practitioner” and “pharmacist” and add a regulation to repeat the exceptions provision in section 15.5 of the act (63 P.S. § 422.15e). 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 the 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 regarding 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, Pennsylvania Association of Medical Suppliers, asking if a prefabricated orthotic device includes “step in/impression box” or whether it means “prefabricated 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 act 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.”

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 regarding exceptions. As previously discussed, 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 this final-form rulemaking*

The Board amended §§ 16.11 and 16.13 to delete the alternate pathway for licensure which has expired and to make the sections internally consistent.

In § 18.802, the Board amended the definitions of “ABC” and “BOC” to clarify that these organizations are approved by the Board. The Board combined the proposed definitions of “custom-designed device” and “custom-fabricated device” in recognition of the similarity between the two. In the definition of “ICE,” the Board 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 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 revised to the definitions of “orthotic and prosthetic assistant,” “orthotic and prosthetic technician” and “pedorthic support personnel” in response to public comments as previously discussed.

*Amendments regarding qualifications for licensure as a prosthetist*

The Board amended § 18.811 to incorporate the title “prosthetist resident” and to include clarifying language regarding how an applicant can demonstrate each qualification to obtain a graduate permit. The Board also added an example of other applicable law that could result in the denial of an application and has eliminated superfluous language. The Board amended § 18.812 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 amended §§ 18.813 and 18.814 to incorporate the relevant titles and to include clarifying language regarding how an applicant can demonstrate each qualification to obtain a license. These sections are 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 BOC announced its intent to discontinue issuing new certifications for prosthetists after July 2016 and another credentialing organization may choose to fill the void created by BOC’s departure from the field. Although no new certifications will be issued, BOC will continue to renew existing certifications for prosthetists.

Proposed § 18.815 was withdrawn as this pathway to licensure has expired. Additionally, § 18.816 was withdrawn 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 regarding qualifications for licensure as an orthotist*

The Board amended § 18.821 to incorporate the title “orthotist resident” and to include clarifying language regarding how an applicant can demonstrate each qualification to obtain a graduate permit. The Board also added an example of other applicable law that could result in the denial of an application and has eliminated superfluous language. The Board amended § 18.822 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 amended §§ 18.823 and 18.824 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 BOC announced its intent to discontinue issuing new certifications for orthotists after July 2016 and another credentialing organization may choose to fill the void created by BOC’s departure from the field. Although no new certifications will be issued, BOC will continue to renew existing certifications for orthotists.

Proposed § 18.825 was withdrawn as this pathway to licensure has expired. Additionally, § 18.826 was withdrawn 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 regarding qualifications for licensure as a pedorthist*

The Board amended § 18.831 to make stylistic edits, to incorporate the title “pedorthist trainee” and to include clarifying language regarding how an applicant can demonstrate each qualification to obtain a temporary practice permit. The Board also amended this section to clarify that an NCOPE-approved pedorthic education program is required. The Board deleted 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 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 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 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.” BOC announced its intention to discontinue issuing new certifications for pedorthists after July 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. Proposed §§ 18.834 and 18.835 were withdrawn.

*Amendments regarding qualifications for licensure as an orthotic fitter*

Sections 18.841—18.843 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-approved or BOC-approved orthotic fitter precertification education program. NCOPE announced in 2015 that it would no longer approve orthotic fitter education programs. The Board is eliminating the “equivalent” education option because anything other than an ABC-approved or BOC-approved program would not lead to certification. While BOC announced its intent to discontinue issuing certifications for prosthetists, orthotists and pedorthists, it will continue to issue certifications to orthotic fitters. However, the Board 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. Proposed §§ 18.844 and 18.845 were withdrawn as are no longer necessary.

*Amendments regarding the regulation of practice*

The Board amended § 18.851 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, the Board renamed this section “supervision and assistance” and significantly revised it 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 has been amended to cross-reference the more general provisions in § 16.61. Subsection (b)(11) has been revised to refer to supervision and assistance of unlicensed assistive personnel (orthotic and prosthetic assistants and technicians, and pedorthic support personnel). Subsection (b)(13) has been amended for clarity in response to a comment by IRRC.

*Amendments regarding biennial renewal and reactivation*

Section 18.861 has been amended to refer to the term of art “disposition in lieu of trial” which had been edited by the Legislative Reference Bureau according to the *Pennsylvania Code & Bulletin Style Manual*. 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 18 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.

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 also amended subsection (a)(4) to delete the proviso “if licensure occurred within 3 years of completion of the approved educational program.” The Board made this change to be consistent with how all other licensure categories are handled.

Section 18.863 (relating to inactive and expired status of licenses; reactivation of inactive or expired license) 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 ABC, BOC or another credentialing organization whose certification program is recognized by ICE, accredited by NCCA and approved by the Board. In that BOC announced its intention to discontinue the initial examinations for certification as a prosthetist, orthotist and pedorthist after July 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 Board, 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, a sunset date has not been assigned.

*Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on June 30, 2014, the Board submitted a copy of the notice of proposed rulemaking, published at 44 Pa.B. 4364, to IRRC and the Chairpersons of the HPLC and the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC) for review and comment.

Under section 5(c) of the Regulatory Review Act, the Board shall submit to IRRC, the HPLC and the SCP/PLC copies of comments received during the public comment period, as well as other documents when requested. In preparing the final-form rulemaking, the Board considered all comments from IRRC, the HPLC and the public.

Under section 5.1(j.2) of the Regulatory Review Act (71 P.S. § 745.5a(j.2)), on September 14, 2016, the final-form rulemaking was deemed approved by the HPLC and the SCP/PLC. Under section 5.1(e) of the Regulatory Review Act, IRRC met on September 15, 2016, and approved the final-form rulemaking.

*Contact Person*

Interested persons may obtain information regarding the final-form rulemaking by writing to Suzanne Zerbe, Board Administrator, State Board of Medicine, P.O. Box 2649, Harrisburg, PA 17105-2649, 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.

(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.

(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, 49 Pa. Code Chapters 16 and 18, are amended by adding §§ 18.801, 18.802, 18.811—18.814, 18.821—18.824, 18.831—18.833, 18.841—18.843, 18.851—18.853 and 18.861—18.864 and amending §§ 16.11 and 16.13 to read as set forth in Annex A, with ellipses referring to the existing text of the regulations.

(*Editor's Note:* Proposed §§ 18.815, 18.816, 18.825, 18.826, 18.834, 18.835, 18.844 and 18.845 included in the proposed rulemaking have been withdrawn by the Board.)

(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 J. HEINE, MD, FACEP, FACP,  
*Chairperson*

(*Editor's Note:* See 46 Pa.B. 6195 (October 1, 2016) for IRRC's approval order.)

**Fiscal Note:** Fiscal Note 16A-4943 remains valid for the final adoption of the subject regulations.

**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.**

(a) The following medical doctor licenses are issued by the Board:

- (1) License without restriction.
- (2) Institutional license.
- (3) Extraterritorial license.

- (4) Graduate license.
- (5) Temporary license.
- (6) Interim limited license.
- (b) The following nonmedical doctor licenses and certificates are issued by the Board:
  - (1) Nurse-midwife license.
  - (2) Nurse-midwife certificate of prescriptive authority.
  - (3) Physician assistant license.
  - (4) Acupuncturist license.
  - (5) Practitioner of Oriental medicine license.
  - (6) Behavior specialist license.
  - (7) Athletic trainer license.
  - (8) Perfusionist license.
  - (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:
  - (1) Registration as a supervising physician of a physician assistant.
  - (2) Biennial registration of a license without restriction.
  - (3) Biennial registration of an extraterritorial license.
  - (4) Biennial registration of a midwife license.
  - (5) Biennial registration of a physician assistant license.
  - (6) Biennial registration of a drugless therapist license.
  - (7) Biennial registration of a limited license—permanent.
  - (8) Biennial registration of an acupuncturist license.
  - (9) Biennial registration of a practitioner of Oriental medicine license.
  - (10) Biennial registration of a behavior specialist license.
  - (11) Biennial registration of athletic trainer license.
  - (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 registration of a prosthetist license.
  - (16) Biennial registration of an orthotist license.
  - (17) Biennial registration of a pedorthist license.
  - (18) Biennial registration of an orthotic fitter license.

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

\* \* \* \* \*

(m) *Genetic Counselor License:*

Application for genetic counselor license .....	\$50
Application for uncertified genetic counselor license .....	\$100
Biennial renewal of genetic counselor license .....	\$75
Application for reactivation of genetic counselor license .....	\$50
Application for temporary provisional genetic counselor license .....	\$50

(n) *Prosthetists:*

Application for prosthetist license .....	\$50
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) *Orthotists:*

Application for orthotist license .....	\$50
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
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
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**

Sec.	
18.801.	Purpose.
18.802.	Definitions.

**QUALIFICATIONS FOR LICENSURE AS A PROSTHETIST**

18.811.	Graduate permit.
18.812.	Clinical residency.
18.813.	Provisional prosthetist license.
18.814.	Prosthetist license.

**QUALIFICATIONS FOR LICENSURE AS AN ORTHOTIST**

18.821.	Graduate permit.
18.822.	Clinical residency.
18.823.	Provisional orthotist license.
18.824.	Orthotist license.

**QUALIFICATIONS FOR LICENSURE AS A PEDORTHIST**

18.831.	Temporary practice permit.
18.832.	Patient fitting experience.
18.833.	Pedorthist license.

**QUALIFICATIONS FOR LICENSURE AS AN ORTHOTIC FITTER**

18.841.	Temporary practice permit.
18.842.	Orthotic fitting care experience.
18.843.	Orthotic fitter license.

**REGULATION OF PRACTICE**

18.851.	Scope and standards of practice.
18.852.	Supervision and assistance.
18.853.	Unprofessional and immoral conduct.

**BIENNIAL RENEWAL AND REACTIVATION**

18.861.	Biennial renewal of license.
18.862.	Continuing education.
18.863.	Inactive and expired status of licenses; reactivation of inactive or expired license.
18.864.	Professional liability insurance coverage for licensed prosthetist, orthotist, pedorthist or orthotic fitter.

**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., a Board-approved organization with certification programs accredited by 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., a Board-approved organization with certification programs accredited by 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 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*—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 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 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 supervision of the orthotist or prosthetist, assists with patient care tasks assigned by the orthotist or prosthetist.

*Orthotic and prosthetic technician*—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 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 pursuant to a written prescription of a licensed prescribing practitioner.

*Orthotist*—An individual who is licensed by the Board to practice orthotics.

*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 by the Board to practice pedorthics.

*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 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 who is licensed by the Board to practice prosthetics.

*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 practice as a 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.

(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), § 16.61 or § 18.853 (relating to unprofessional and immoral conduct) or other applicable law, such as 18 Pa.C.S. § 9124 (relating to use of records by licensing agencies).

(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 prosthetist resident shall practice only under the direct supervision of a licensed 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 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.

(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), § 16.61 or § 18.853 (relating to unprofessional and immoral conduct) or other applicable law, such as 18 Pa.C.S. § 9124 (relating to use of records by licensing agencies).

(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; and 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. 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) Holds current certification as a prosthetist, 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.

(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), § 16.61 or § 18.853 (relating to unprofessional and immoral conduct) or other applicable law, such as 18 Pa.C.S. § 9124 (relating to use of records by licensing agencies).

(d) An individual holding an active, unsuspended prosthetist license may use the title "prosthetist."

**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 practice as 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.

(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), § 16.61 or § 18.853 (relating to unprofessional and immoral conduct) or other applicable law, such as 18 Pa.C.S. § 9124 (relating to use of records by licensing agencies).

(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) An orthotist resident shall practice only under the direct supervision of a licensed orthotist 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 orthotist 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 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.

(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), § 16.61 or § 18.853 (relating to unprofessional and immoral conduct) or other applicable law, such as 18 Pa.C.S. § 9124 (relating to use of records by licensing agencies).

(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; and 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) 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.

(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), § 16.61 or § 18.853 (relating to unprofessional and immoral conduct) or other applicable law, such as 18 Pa.C.S. § 9124 (relating to use of records by licensing agencies).

(d) An individual holding an active, unsuspended orthotist license may use the title "orthotist."

#### QUALIFICATIONS FOR LICENSURE AS A PEDORTHIST

##### § 18.831. Temporary practice permit.

(a) After completion of an NCOPE-approved pedorthic education program and prior to providing pedorthic patient care in this Commonwealth, an individual shall submit an application for a temporary practice permit authorizing the individual to practice as a 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-approved pedorthic precertification education program. 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.
- (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), § 16.61 or § 18.853 (relating to unprofessional and immoral conduct) or other applicable law, such as 18 Pa.C.S. § 9124 (relating to use of records by licensing agencies).

(d) A temporary practice permit is valid for a maximum of 1 year and is nonrenewable.

(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 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 pedorthist trainee and is responsible for countersigning within 15 days the entries in the patient’s clinical record.

(b) The supervised patient fitting experience shall be obtained subsequent to education and 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-approved pedorthic precertification education program. 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 certification as a pedorthist from ABC, 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.

(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), § 16.61 or § 18.853 (relating to unprofessional and immoral conduct) or other applicable law, such as 18 Pa.C.S. § 9124 (relating to use of records by licensing agencies).

(d) An individual holding an active, unsuspended pedorthist license may use the title “pedorthist.”

**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 practice orthotic fitting as 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 ABC-approved or BOC-approved orthotic fitter precertification education program. An applicant shall demonstrate completion of an ABC-approved or BOC-approved orthotic fitter precertification education program by having the educational institution submit, directly to the Board, verification of completion.

(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), § 16.61 or § 18.853 (relating to unprofessional and immoral conduct) or other applicable law, such as 18 Pa.C.S. § 9124 (relating to use of records by licensing agencies).

(d) A temporary practice permit is valid for a maximum of 1 year and is nonrenewable.

(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) 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. 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 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 shall 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 neces-

sary 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 an ABC-approved or BOC-approved orthotic fitter precertification education program. Unless previously submitted under § 18.841 (relating to temporary practice permit), an applicant shall demonstrate completion of an ABC-approved 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 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 certification as an orthotic fitter from ABC, 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.

(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), § 16.61 or § 18.853 (relating to unprofessional and immoral conduct) or other applicable law, such as 18 Pa.C.S. § 9124 (relating to use of records by licensing agencies).

(d) An individual holding an active, unsuspended orthotic fitter license may use the title "orthotic fitter."

### 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. Supervision and assistance.

(a) 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) Supervising or assigning tasks to assistants, technicians or support personnel contrary to § 18.852 (relating to 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 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) 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 credentialing body since the most recent application for biennial renewal, whether or not licensed to practice in that other jurisdiction.

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

(5) Verify on the application that the licensed prosthetist, orthotist, pedorthist or orthotic fitter has completed the continuing education mandated by section 13.5(g)(1) or (2) of the act (63 P.S. § 422.13e(g)(1) and (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 accord-

ance 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.

(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 examination offered by ABC, BOC or another credentialing organization whose certification program is recognized by ICE, accredited by NCCA and approved by the Board.

**§ 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.

[Pa.B. Doc. No. 16-1807. Filed for public inspection October 21, 2016, 9:00 a.m.]

**STATE BOARD OF PHYSICAL THERAPY  
[ 49 PA. CODE CH. 40 ]  
Continuing Education Enforcement**

The State Board of Physical Therapy (Board) amends §§ 40.67 and 40.192 (relating to continuing education for licensed physical therapist; and continuing education for certified physical therapist assistant) to read as set forth in Annex A.

*Effective Date*

This final-form rulemaking will become effective upon publication in the *Pennsylvania Bulletin*.

*Statutory Authority*

This final-form rulemaking is authorized under section 3(a) of the Physical Therapy Practice Act (act) (63 P.S. § 1303(a)), which provides the Board's general authority to promulgate regulations not inconsistent with law as it may deem necessary for the performance of its duties and the proper administration of the act.

*Description and Need for this Final-Form Rulemaking*

Section 7.2 of the act (63 P.S. § 1307.2) requires each licensed physical therapist to complete at least 30 hours of continuing physical therapy education during each biennial renewal period. Section 9.1(j) of the act (63 P.S. § 1309.1(j)) requires each certified physical therapist assistant to complete at least 30 hours of continuing physical therapy education during each biennial renewal period. The Board has incorporated these requirements

into §§ 40.67(a) and 40.192(a), respectively. Under §§ 40.19(c)(5) and 40.191(c)(5) (relating to renewal of physical therapist license; and renewal of certification), to renew a license or certificate, a licensed physical therapist or certified physical therapist assistant is required to verify that the licensee or certificate holder has completed the required amount of continuing education. Moreover, the Board will not renew the license of a physical therapist or the certificate of a physical therapist assistant if the individual cannot verify that the continuing education required during the immediately preceding biennium has been completed. Although these requirements are conditions for renewal, a licensee or certificate holder may mistakenly verify satisfaction of the continuing education requirement. Upon audit, however, it is discovered that the licensee or certificate holder has not completed the requirements.

Under section 11(a)(6) of the act (63 P.S. § 1311(a)(6)), the Board may suspend or revoke a license or certificate for unprofessional conduct. Under section 12(c) of the act (63 P.S. § 1312(c)), the Board may levy a civil penalty against a licensee or certificate holder who has violated the act. Under § 40.52(11) (relating to unprofessional conduct; physical therapists), unprofessional conduct includes violating a provision of the act or the Board's regulations that establish a standard of conduct. Disciplinary actions for failing to complete the continuing education requirement in a timely manner invariably result in the licensee being required to pay a civil penalty proportionate to the amount of deficiency and to make up the deficiency promptly. Accordingly, the Board determined that it should utilize the more streamlined citation procedures under section 5(a) of the act of July 2, 1993 (P.L. 345, No. 48) (Act 48) (63 P.S. § 2205(a)), which provides that the Commissioner of Professional and Occupational Affairs (Commissioner), after consultation with licensing boards in the Bureau of Professional and Occupational Affairs (Bureau), may promulgate a schedule of civil penalties for violations of the acts or regulations of these licensing boards and agents of the Board may issue citations for violations covered by the schedule of civil penalties. Therefore, the Commissioner separately proposed a rulemaking using the Act 48 citation system to levy the civil penalty. However, the regulatory scheme must assure that, in addition to paying the civil penalty, the licensee has made up the deficient continuing education. This final-form rulemaking sets forth the procedures to address curing the deficiency.

This final-form rulemaking adds § 40.67(f). A licensed physical therapist who is determined through the post-renewal continuing education audit to be deficient will be issued an Act 48 citation for failing to complete the required amount of continuing education and will be required to make up the deficiency and provide proof to the Board within 6 months of the issuance of the citation. If the licensee does not do so, the licensee will be subject to disciplinary action, including the suspension of the license under section 11(a)(6) of the act for committing unprofessional conduct. Because mandatory continuing education is generally considered to be a condition of renewal, § 40.67(f) exempts for this disciplinary proceeding a licensee who permitted the license to expire at the conclusion of a renewal period during which the licensee did not complete the required amount of continuing education and did not practice the profession until reactivating the license under § 40.20(c) (relating to inactive status of physical therapist license) upon a demonstration that the licensee subsequently completed the required deficient continuing education.

Section 40.192(f) is added to provide similar provisions for certified physical therapist assistants. A certified physical therapist assistant who does not make up the deficiency will be subject to disciplinary action under § 40.181(a)(6) (relating to refusal, suspension or revocation of certification) for committing unprofessional conduct, as authorized under section 9.1(f) of the act. A physical therapist assistant who permitted the certificate to expire and did not provide services until reactivating under § 40.191(g) upon a demonstration that the certificate holder subsequently completed the required deficient continuing education would be exempted from this disciplinary process.

While the Commonwealth's prosecuting attorneys may utilize this "citation and make-up" system as one tool in addressing a licensee or certificate holder who has not completed the required continuing education, they retain the discretion to also file formal action under section 11(a)(2) of the act, which provides that the Board may suspend or revoke a license or certificate of an individual who has attempted to or obtained a license or certificate by fraud or misrepresentation, if the licensee/certificate holder, for example, knows that the required continuing education has not been completed, but verifies on the renewal application that the licensee/certificate holder has completed the required amount of continuing education.

*Summary of Comments and Responses to Proposed Rulemaking*

The Board published notice of proposed rulemaking at 44 Pa.B. 7178 (November 15, 2014) with a 30-day public comment period. The Board received no comments from the public. The Board received comments from the House Professional Licensure Committee (HPLC) and the Independent Regulatory Review Commission (IRRC) as part of their review of the proposed rulemaking under the Regulatory Review Act (71 P.S. §§ 745.1—745.14). The Board did not receive comments from the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC).

The HPLC commented to note a typographical error in the proposed rulemaking as delivered. The Legislative Reference Bureau corrected this typographical error prior to publication of the proposed rulemaking in the *Pennsylvania Bulletin*.

IRRC pointed to the requirement of section 7.2 of the act that each licensed physical therapist shall complete the required amount of continuing education and "shall provide the board with evidence of the completion of the continuing education" and the similar requirement of section 9.1(j) of the act that each certified physical therapist assistant shall complete the required amount of continuing education and "shall provide the board with evidence of the completion of the continuing education." Because section 3(a) of the act requires that the Board's regulations be consistent with the act, IRRC asked for the Board's specific statutory authority for allowing a licensee or certificate holder who has not met the continuing education requirement to continue to practice or provide services for 6 more months.

The Board's use of a post-renewal audit process to identify those who have not completed the required continuing education is consistent with the act and comports with constitutional requirements of due process. Under §§ 40.19(c)(5) and 40.191(c)(5), an applicant for renewal is required to "verify that the [licensed physical therapist or certified physical therapist assistant, respec-

tively,] has complied with the continuing education requirements mandated by . . . the act . . . during the biennial period immediately preceding the period for which renewal is sought in accordance with [§§ 40.67 and 40.192, respectively]." This verification is the evidence upon which the Board may grant renewal. The Board simply could not possibly review documentation of continuing education for every licensed physical therapist and every certified physical therapist assistant during the window for renewal. Under §§ 40.19(c)(5) and 40.191(c)(5) "[t]he Board will not renew [a license or certificate] if the [licensed physical therapist or certified physical therapist assistant] has not completed the continuing education required under . . . the act during the biennial period immediately preceding the period for which renewal is sought." After the close of the biennial renewal process, the Board conducts a random audit of licensees and certificate holders to verify compliance with the continuing education requirements. This post-renewal audit system is standard for the boards and commissions under the Bureau. For an individual who have provided the verification, it is not until the audit that the Board would obtain information suggesting that the licensee has not completed all required continuing education. And even then, the Board cannot remove a licensee from practice without due process of law. Because the license has been renewed and the licensee retains a property interest in the license, the Board cannot rescind renewal and provide the licensee with only the opportunity for a post-deprivation hearing without specific authorization from the General Assembly.

By this final-form rulemaking, the Board is not granting licensees who failed to complete required continuing education an additional 6 months to practice. The Board's renewal of the license or certificate based on the certification statement verifying completion of the continuing education authorizes the continued practice for the next biennium. Because there has been no final determination that the licensee failed to complete the required continuing education, the Board cannot yet remove the licensee from practice at the time of audit or any other time prior to a final determination even if through formal disciplinary action rather than an Act 48 citation. Only after a licensee or certificate holder admits the violation or a final adjudication is issued finding a violation of the continuing education requirements after a hearing can the Board take disciplinary action. The Board could have chosen to suspend the license or certificate until the deficient continuing education is remedied, rather than permitting the opportunity to remedy the deficiency. However, the Board's goal in enforcing the continuing education requirements is two-fold—deterrence and compliance. The Board believes the monetary civil penalty is adequate to deter a licensee or certificate holder from future violations, and the threat of additional discipline for failure to cure the deficiency will result in compliance within the required 6 months. It is worth noting again that an applicant for renewal who verifies completion of the required amount of continuing education without a basis to do so is separately subject to disciplinary action, including a suspension of the license.

IRRC noted that the rulemaking would require the licensed physical therapist or certified physical therapy assistant to "make up the deficiency and provide proof of the entire required amount of continuing education in subsection (b)." Because subsection (a) sets the required amount of continuing education and subsection (b) describes the documentation that, in general, a licensee or certificate holder must have to establish completion of a

continuing education course or program, IRRC asked what would constitute the proof that a licensee or certificate holder would be required to submit and inquired if the Board meant to refer to subsection (a). Because this was not clear, the Board revised this sentence to require the licensee or certificate holder to “make up the deficiency and provide proof, in accordance with subsection (b), of completion of the entire amount of continuing education required under subsection (a).”

IRRC also pointed to the existing provisions in §§ 40.67(b)(3) and 40.192(b)(3) that note that the Board will audit licensed physical therapists and certified physical therapist assistants to verify compliance with the continuing education requirements. IRRC expressed concern that the Board will only audit those who have been cited and provided documentation of making up the deficiency rather than fully reviewing each person’s proof. The post-renewal audit process was developed for the licensing board office staff to determine that all licensees generally are in compliance with the continuing education requirements. Bureau statistics from the last 20 audits conducted Bureau-wide indicate that nearly 90% of licensees who are audited are found to be in compliance. The statistics from the Board’s last audit demonstrate that 98% of licensees and certificate holders that are subject to audit are found to be in compliance. Those for whom the audit does not show compliance are referred to the Professional Compliance Office for possible disciplinary action. At this point, and with possible additional investigation, the Department’s prosecuting arm now addresses that subset of licensees who did not establish compliance with the continuing education requirements. Under these regulations, when disciplinary action has begun by means of the issuance of an Act 48 citation (unless the matter is dismissed through appeal), the prosecution division will be expecting the later submission of proof of making up the deficient continuing education. The prosecution division will be expected to file formal action if the licensed physical therapist or certified physical therapist assistant has not provided adequate proof of completion of all required continuing education.

Finally, IRRC questioned how the Board determined that 6 months is a reasonable and feasible amount of time for the regulated community to make up continuing education deficiencies. The Board acknowledges that the General Assembly, in making completion of continuing education a condition precedent for renewal, determined that continuing education is necessary to maintain competence and therefore provides public protection. The Board determined that 6 months is long enough for the licensee to have had an opportunity to challenge a citation before a hearing examiner and possibly appeal to the Board. It is also long enough that the licensee has a reasonable opportunity to find and complete relevant continuing education courses. Additionally, it is short enough to minimize any additional notable deterioration in the licensee’s skills and knowledge. Finally, 6 months is a reasonable period of time for the prosecution division to track and is a relatively simple and straightforward date for licensees and certificate holders to measure and follow.

As the Board was preparing this final-form rulemaking, the Legislative Reference Bureau contacted staff to inform them that the section number for the related schedule of civil penalties being promulgated by the Commissioner would need to change to § 43b.26 because the schedule of civil penalties for the State Board of Optometry would be added as § 43b.25. Therefore, the Board made appropriate revisions to this final-form rule-

making to correct the cross-references to § 43b.26 (relating to schedule of civil penalties—physical therapists and physical therapist assistants).

#### *Fiscal Impact and Paperwork Requirements*

This final-form rulemaking will not have adverse fiscal impact on the Commonwealth or its political subdivisions and will not impose additional paperwork requirements upon the Commonwealth, political subdivisions or the private sector.

#### *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on October 31, 2014, the Board submitted a copy of the notice of proposed rulemaking, published at 44 Pa.B. 7178, to IRRC and the Chairpersons of the HPLC and the SCP/PLC for review and comment.

Under section 5(c) of the Regulatory Review Act, the Board shall submit to IRRC, the HPLC and the SCP/PLC copies of comments received during the public comment period, as well as other documents when requested. In preparing the final-form rulemaking, the Board has considered all comments from IRRC and the HPLC.

Under section 5.1(j.2) of the Regulatory Review Act (71 P.S. § 745.5a(j.2)) on September 14, 2016, the final-form rulemaking was deemed approved by the HPLC and the SCP/PLC. Under section 5.1(e) of the Regulatory Review Act, IRRC met on September 15, 2016, and approved the final-form rulemaking.

#### *Additional Information*

Further information may be obtained by contacting Michelle Roberts, Board Administrator, State Board of Physical Therapy, P.O. Box 2649, Harrisburg, PA 17105-2649, ra-physical@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) and regulations promulgated thereunder, 1 Pa. Code §§ 7.1 and 7.2.
- (2) A public comment period was provided as required by law and all comments were considered.
- (3) The amendments to this final-form rulemaking do not enlarge the scope of proposed rulemaking published at 44 Pa.B. 7178.
- (4) The final-form rulemaking adopted by this order is necessary and appropriate for the administration of the act.

#### *Order*

The Board, acting under its authorizing statute, orders that:

(a) The regulations of the Board, 49 Pa. Code Chapter 40, are amended by amending §§ 40.67 and 40.192 to read as set forth in Annex A, with ellipses referring to the existing text of the regulations.

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

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

(d) The final-form rulemaking shall take effect upon publication in the *Pennsylvania Bulletin*.



NORMAN L. JOHNSON, PT, DPT, DEd,  
*Chairperson*

*(Editor's Note: See 46 Pa.B. 6643 (October 22, 2016) for a final-form rulemaking by the Bureau relating to this final-form rulemaking.)*

*(Editor's Note: See 46 Pa.B. 6195 (October 1, 2016) for IRRC's approval order.)*

**Fiscal Note:** Fiscal Note 16A-6515 remains valid for the final adoption of the subject regulations.

### Annex A

## TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

### PART I. DEPARTMENT OF STATE

#### Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

#### CHAPTER 40. STATE BOARD OF PHYSICAL THERAPY

##### Subchapter A. PHYSICAL THERAPISTS

##### CONTINUING EDUCATION

#### § 40.67. Continuing education for licensed physical therapist.

\* \* \* \* \*

(e) *Authoring publications.* A licensed physical therapist may earn continuing education credit for authoring publications as provided in this subsection.

(1) Prior to the end of the biennial renewal period for which credit is sought, the licensed physical therapist shall apply to the Board on forms provided by the Board and submit the documentation necessary to establish entitlement to credit.

(2) Subject to the limitations of paragraph (3), 1 contact hour of continuing education credit will be awarded for each hour spent in research or writing. Credit will not be awarded if the total research and writing time was less than 1 hour.

(3) Within the subject matter limitations of subsection (c), a licensed physical therapist may earn credit for authoring a publication as follows:

(i) Authoring or editing a book, not to exceed 15 contact hours.

(ii) Authoring or editing a chapter of a book, not to exceed 10 contact hours.

(iii) Authoring or reviewing a published peer-reviewed article, not to exceed 10 contact hours.

(iv) Authoring a non-peer-reviewed article published in a physical therapy publication, not to exceed 5 contact hours.

(4) Credit for authoring a publication will be awarded only for the biennial renewal period in which it was published.

(f) *Disciplinary action authorized.* Unless otherwise excused by the act or this chapter, failure to complete the minimum required amount of continuing education during the applicable renewal period will subject the licensee to discipline under section 12(c) of the act (63 P.S. § 1312(c)) in accordance with the schedule of civil penalties in § 43b.26 (relating to schedule of civil penalties—physical therapists and physical therapist assistants). Within 6 months after the issuance of a citation under § 43b.26 for failure to complete the required amount of continuing education, the licensee shall make up the

deficiency and provide proof, in accordance with subsection (b), of completion of the entire amount of continuing education required under subsection (a). In addition to a civil penalty assessed under this subsection, failure to complete the required amount of continuing education and to provide the Board with proof of completion of the required amount of continuing education within 6 months after the issuance of a citation under § 43b.26 will subject the licensee to disciplinary action under section 11(a)(6) of the act for committing unprofessional conduct as defined in § 40.52(11). This subsection does not apply to a licensee who permitted the licensee's license to expire at the conclusion of a biennial renewal period for which the licensee did not complete the required amount of continuing education and did not practice the profession prior to reactivating that license under § 40.20(c) upon a demonstration that the licensee subsequently completed the required deficient continuing education.

#### Subchapter C. PHYSICAL THERAPIST ASSISTANTS

##### CONTINUING EDUCATION

#### § 40.192. Continuing education for certified physical therapist assistant.

\* \* \* \* \*

(e) *Authoring publications.* A certified physical therapist assistant may earn continuing education credit for authoring publications as provided in this subsection.

(1) Prior to the end of the biennial renewal period for which credit is sought, the certified physical therapist assistant shall apply to the Board on forms provided by the Board and submit the documentation necessary to establish entitlement to credit.

(2) Subject to the limitations of paragraph (3), 1 contact hour of continuing education credit will be awarded for each hour spent in research or writing. Credit will not be awarded if the total research and writing time was less than 1 hour.

(3) Within the subject matter limitations of subsection (c), a certified physical therapist assistant may earn credit for authoring a publication as follows:

(i) Authoring or editing a book, not to exceed 15 contact hours.

(ii) Authoring or editing a chapter of a book, not to exceed 10 contact hours.

(iii) Authoring or reviewing a published peer-reviewed article, not to exceed 10 contact hours.

(iv) Authoring a non-peer-reviewed article published in a physical therapy publication, not to exceed 5 contact hours.

(4) Credit for authoring a publication will be awarded only for the biennial renewal period in which it was published.

(f) *Disciplinary action authorized.* Unless otherwise excused by the act or this chapter, failure to complete the minimum required amount of continuing education during the applicable renewal period will subject the certified physical therapist assistant to discipline under section 12(c) of the act (63 P.S. § 1312(c)) in accordance with the schedule of civil penalties in § 43b.26 (relating to schedule of civil penalties—physical therapists and physical therapist assistants). Within 6 months after the issuance of a citation under § 43b.26 for failure to complete the required amount of continuing education, the physical therapist assistant shall make up the deficiency and

provide proof, in accordance with subsection (b), of completion of the entire amount of continuing education required under subsection (a). In addition to a civil penalty assessed under this subsection, failure to complete the required amount of continuing education and to provide the Board with proof of completion of the required amount of continuing education within 6 months after the issuance of a citation under § 43b.26 will subject the certified physical therapist assistant to disciplinary action under section 9.1(f) of the act for committing unprofessional conduct as provided in § 40.181(a)(6). This subsection does not apply to a certified physical therapist assistant who permitted the physical therapist assistant's certificate to expire at the conclusion of a biennial renewal period for which the physical therapist assistant did not complete the required amount of continuing education and did not provide patient services prior to reactivating that certificate under § 40.191(g) upon a demonstration that the physical therapist assistant subsequently completed the required deficient continuing education.

[Pa.B. Doc. No. 16-1808. Filed for public inspection October 21, 2016, 9:00 a.m.]

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**BUREAU OF PROFESSIONAL AND  
OCCUPATIONAL AFFAIRS**

**[ 49 PA. CODE CH. 43b ]**

**Schedule of Civil Penalties—Physical Therapists  
and Physical Therapist Assistants**

The Commissioner of Professional and Occupational Affairs (Commissioner) adds § 43b.26 (relating to schedule of civil penalties—physical therapists and physical therapist assistants) to read as set forth in Annex A.

*Effective Date*

This final-form rulemaking will become effective upon publication in the *Pennsylvania Bulletin*.

*Statutory Authority*

This final rulemaking is authorized under section 5(a) of the act of July 2, 1993 (P.L. 345, No. 48) (Act 48) (63 P.S. § 2205(a)).

*Background and Need for this Final-Form Rulemaking*

Section 5(a) of Act 48 provides that the Commissioner, after consultation with licensing boards in the Bureau of Professional and Occupational Affairs (Bureau), may promulgate a schedule of civil penalties for violations of the acts or regulations of the licensing boards and agents of the Bureau may issue citations for violations covered by the schedule of civil penalties. Act 48 citations streamline the disciplinary process by eliminating the need for formal orders to show cause, answers, adjudications and orders, and consent agreements. At the same time, a licensee who receives an Act 48 citation retains the due process right of appeal prior to the imposition of discipline. The State Board of Physical Therapy (Board) has not previously had an Act 48 schedule of civil penalties.

As is being done for other licensing boards with continuing education requirements, the Commissioner proposed a civil penalty schedule for violation of the continuing education requirements for licensees of the Board, because the Commissioner and the Board believe the Act 48 citation process will be a much more efficient method of handling these violations, while still ensuring licensees

due process. Payment of the civil penalty will not relieve a licensee of the obligation to complete the required amount of mandatory continuing education. Because the primary objective of the disciplinary process is compliance, under a separate final-form rulemaking promulgated by the Board, a licensee who fails to complete the required amount of mandatory continuing education during the biennial renewal period will also be required to complete the required continuing education during the next 6 months. Failure to complete the required continuing education by that deadline will subject the licensee to formal disciplinary action. The final-form rulemaking is intended to apply to those licensees and certificate holders who mistakenly verified that they satisfied the continuing education requirement and timely renewed, but who later were determined not to have satisfied the requirements. In support of the additional disciplinary objective of deterrence, the Commonwealth's prosecuting attorneys have discretion to file formal action under section 11(a)(2) of the Physical Therapy Practice Act (63 P.S. § 1311(a)(2)) against those licensees and certificate holders who attempt to or obtain licensure or certification by fraud or misrepresentation. As provided in §§ 40.67(b)(3) and 40.192(b)(3) (relating to continuing education for licensed physical therapist; and continuing education for certified physical therapist assistant), the Board will audit physical therapists and physical therapist assistants to verify compliance with the continuing education requirements, and licensees and certificate holders are required to respond to audit notices timely. The Board believes that prompt issuance of a citation and subsequent audit notices will encourage compliance with the continuing education requirements.

The Commissioner, in consultation with the Board, therefore establishes a schedule of civil penalties to be enforced by citation under Act 48. For a first offense violation of failing to complete the required amount of mandatory continuing education during the biennial renewal period under § 40.67(a) or § 40.192(a), a civil penalty of \$25 for each credit hour that the licensee or certificate holder, respectively, is deficient, up to a maximum of \$1,000. For a second offense violation with a deficiency of 20 hours or less the civil penalty is \$50 per hour of deficiency, and for a third offense violation with a deficiency of 10 hours or less the civil penalty is \$100 per hour of deficiency. Offenses beyond these amounts of deficiency and all subsequent offenses will not be subject to an Act 48 citation, but rather will proceed through the formal disciplinary process. Additionally, the Commissioner, in consultation with the Board, establishes for a first offense of failing to respond timely to an audit notice under § 40.67(b)(3) or § 40.192(b)(3) by a licensee or certificate holder, respectively, a civil penalty of \$100, increasing to \$250 for a second offense and \$500 for a third offense, with subsequent offenses resulting in formal disciplinary action. However, a citation could only be issued if the underlying audit notice notified the licensee that failure to respond would result in issuance of a citation.

Additionally, § 40.20(b) (relating to inactive status of physical therapist license) prohibits a licensed physical therapist whose license has lapsed from practicing physical therapy in this Commonwealth, and § 40.191(j) (relating to renewal of certification) prohibits a certified physical therapist assistant whose certificate has lapsed from providing physical therapy services in this Commonwealth. As is being done for other licensing boards, the Commissioner also proposed a civil penalty schedule for practice on a lapsed or expired license or certificate,

because the Commissioner and the Board believe the Act 48 citation process will be a much more efficient method of handling these violations, while still ensuring licensees due process. Because failure to renew a license might be an attempt to avoid the continuing education requirements, use of an Act 48 citation for lapsed license practice will be limited to those first-time offenders who are in compliance with the continuing education requirements. A licensee who practiced on a lapsed license without having complied with the continuing education will instead be subject to formal disciplinary action where the Board has the authority to suspend or revoke a license.

The Commissioner, in consultation with the Board, establishes for practicing on a lapsed or expired license or certificate (while in compliance with continuing education requirements) in violation of § 40.20(b) or § 40.191(j), respectively, a civil penalty of \$50 per month, up to a maximum of \$1,000, for practicing less than one renewal cycle. Violations of practicing for more than one renewal cycle while expired will not be subject to an Act 48 citation, but rather would proceed through the formal disciplinary process.

#### *Summary of Comments and Responses to Proposed Rulemaking*

The Commissioner published the proposed rulemaking at 44 Pa.B. 7173 (November 15, 2014) with a 30-day public comment period. The Commissioner received no comments from the public. The Commissioner received no comments from the House Professional Licensure Committee (HPLC) or the Senate Consumer Protection and Professional Licensure Committee (SCP/PLC) as part of their review of proposed rulemaking under the Regulatory Review Act (71 P.S. §§ 745.1—745.14). The Independent Regulatory Review Commission (IRRC) notified the Commissioner that it had no objections, comments or recommendations and that, if the final-form rulemaking was delivered without revisions and the legislative committees do not take any action, the final-form rulemaking would be deemed approved.

As the Board was preparing this final-form rulemaking, the Legislative Reference Bureau contacted staff to inform the Commissioner and the Board that the section number would need to be changed because the schedule of civil penalties for the State Board of Optometry would be added as § 43b.25. Therefore, proposed § 43b.25 is renumbered and adopted in this final-form rulemaking as § 43b.26, and all cross-references in the Board's companion final-form rulemaking regarding continuing education enforcement have been corrected. No other changes have been made to this final-form rulemaking.

#### *Fiscal Impact and Paperwork Requirements*

This final-form rulemaking will not have adverse fiscal impact on the Commonwealth or its political subdivisions and will not impose additional paperwork requirements upon the Commonwealth, political subdivisions or the private sector.

#### *Regulatory Review*

Under section 5(a) of the Regulatory Review Act (71 P.S. § 745.5(a)), on October 31, 2014, the Board submitted a copy of the notice of proposed rulemaking, published at 44 Pa.B. 7173, to IRRC and the Chairpersons of the HPLC and the SCP/PLC for review and comment.

Under section 5(c) of the Regulatory Review Act, the Board shall submit to IRRC, the HPLC and the SCP/PLC copies of comments received during the public comment period, as well as other documents when requested.

Under section 5.1(j.2) of the Regulatory Review Act (71 P.S. § 745.5a(j.2)), on September 14, 2016, the final-form rulemaking was deemed approved by the HPLC and the SCP/PLC. Under section 5(g) of the Regulatory Review Act, the final-form rulemaking was deemed approved by IRRC effective September 14, 2016.

#### *Additional Information*

Further information may be obtained by contacting Michelle Roberts, Board Administrator, State Board of Physical Therapy, P.O. Box 2649, Harrisburg, PA 17105-2649, ra-physical@pa.gov.

#### *Findings*

The Commissioner 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) and regulations promulgated thereunder, 1 Pa. Code §§ 7.1 and 7.2.

(2) A public comment period was provided as required by law.

(3) This final-form rulemaking does not include any amendments that would enlarge the scope of proposed rulemaking published at 44 Pa.B. 7173.

(4) The final-form rulemaking adopted by this order is necessary and appropriate for the administration of the Physical Therapy Practice Act.

#### *Order*

The Commissioner, acting under the authority of Act 48, orders that:

(a) The regulations of the Commissioner, 49 Pa. Code Chapter 43b, are amended by adding § 43b.26 to read as set forth in Annex A.

*(Editor's Note:* This section was proposed as § 43b.25 and is renumbered in this final-form rulemaking as § 43b.26 due to an intervening final-form rulemaking.)

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

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

(d) The final-form rulemaking shall take effect upon publication in the *Pennsylvania Bulletin*.

IAN J. HARLOW,  
*Commissioner*

*(Editor's Note:* See 46 Pa.B. 6639 (October 22, 2016) for a final-form rulemaking by the Board relating to this final-form rulemaking.)

*(Editor's Note:* See 46 Pa.B. 6195 (October 1, 2016) for IRRC's approval order.)

**Fiscal Note:** Fiscal Note 16A-6516 remains valid for the final adoption of the subject regulation.

Annex A

TITLE 49. PROFESSIONAL AND VOCATIONAL STANDARDS

PART I. DEPARTMENT OF STATE

Subpart A. PROFESSIONAL AND OCCUPATIONAL AFFAIRS

CHAPTER 43b. COMMISSIONER OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS

SCHEDULE OF CIVIL PENALTIES, GUIDELINES FOR IMPOSITION OF CIVIL PENALTIES AND PROCEDURES FOR APPEAL

§ 43b.26. Schedule of civil penalties—physical therapists and physical therapist assistants.

STATE BOARD OF PHYSICAL THERAPY

<i>Violation under 49 Pa. Code</i>	<i>Title/Description</i>	<i>Penalties</i>
Section 40.20(b)	Practicing physical therapy after failing to renew but before reactivation of license (in compliance with continuing education requirements)	One biennial renewal cycle or less— \$50 per month lapsed, not to exceed \$1,000 More than one biennial renewal cycle— formal action
Section 40.67(a)	Failure of licensed physical therapist to complete the required amount of continuing education	1st offense—\$25 per hour of deficiency, not to exceed \$1,000 2nd offense—deficient 20 hours or less— \$50 per hour of deficiency not to exceed \$1,000 2nd offense—deficient more than 20 hours— formal action 3rd offense—deficient 10 hours or less— \$100 per hour of deficiency not to exceed \$1,000 3rd offense—deficient more than 10 hours— formal action Subsequent offenses—formal action
Section 40.67(b)(3)	Failure of licensed physical therapist to respond to continuing education audit request within 30 days, or other time period set forth in audit request that notifies the licensee that failure to respond is subject to discipline	1st offense—\$100 2nd offense—\$250 3rd offense—\$500 Subsequent offenses—formal action
Section 40.191(j)	Providing services as a physical therapist assistant after failing to renew but before reactivation of certification (in compliance with continuing education requirements)	One biennial renewal cycle or less— \$50 per month lapsed, not to exceed \$1,000 More than one biennial renewal cycle—formal action
Section 40.192(a)	Failure of certified physical therapist assistant to complete the required amount of continuing education	1st offense—\$25 per hour of deficiency, not to exceed \$1,000 2nd offense—deficient 20 hours or less—\$50 per hour of deficiency, not to exceed \$1,000 2nd offense—deficient more than 20 hours— formal action 3rd offense—deficient 10 hours or less—\$100 per hour of deficiency, not to exceed \$1,000 3rd offense—deficient more than 10 hours— formal action Subsequent offenses—formal action
Section 40.192(b)(3)	Failure of certified physical therapist assistant to respond to continuing education audit request within 30 days, or other time period set forth in audit request that notifies the physical therapist assistant that failure to respond is subject to discipline	1st offense—\$100 2nd offense—\$250 3rd offense—\$500 Subsequent offenses—formal action

[Pa.B. Doc. No. 16-1809. Filed for public inspection October 21, 2016, 9:00 a.m.]