

No. 2012-90

AN ACT

HB 48

Amending the act of December 20, 1985 (P.L.457, No.112), entitled "An act relating to the right to practice medicine and surgery and the right to practice medically related acts; reestablishing the State Board of Medical Education and Licensure as the State Board of Medicine and providing for its composition, powers and duties; providing for the issuance of licenses and certificates and the suspension and revocation of licenses and certificates; providing penalties; and making repeals," adding definitions; and providing for licensure of prosthetists, orthotists, pedorthists and orthotic fitters.

The General Assembly of the Commonwealth of Pennsylvania hereby enacts as follows:

Section 1. Section 2 of the act of December 20, 1985 (P.L.457, No.112), known as the Medical Practice Act of 1985, is amended by adding definitions to read:

Section 2. Definitions.

The following words and phrases when used in this act shall have the meanings given to them in this section unless the context clearly indicates otherwise:

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

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

"Custom-fitted 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.*

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"ICE." *The Institute for Credentialing Excellence, previously known as the National Organization for Competency Assurance (NOCA).*

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"NCCA." *The National Commission for Certifying Agencies or its successor.*

"Orthosis." *A custom-fabricated or custom-fitted 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 under this act to properly fit, dispense and adjust prefabricated orthotic devices pursuant to*

a written prescription of a physician, podiatrist, certified registered nurse practitioner or physician assistant.

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

"Orthotist." An individual other than a licensed physical therapist, a licensed occupational therapist or an orthotic fitter licensed under this act to practice orthotics pursuant to a written prescription of a physician, podiatrist, certified registered nurse practitioner or physician assistant.

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

"Pedorthic device." Includes therapeutic shoes, shoe modifications made for therapeutic purposes, partial foot prostheses, foot orthoses and below-the-knee pedorthic modalities. The term does not include 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.

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

"Pedorthist." An individual licensed under this act to practice pedorthics pursuant to a written prescription of a physician, podiatrist, certified registered nurse practitioner or physician assistant.

"Podiatrist." An individual licensed under the act of March 2, 1956 (1955 P.L.1206, No.375), known as the Podiatry Practice Act, to practice podiatry.

"Prefabricated orthosis." A brace or support designed to provide for alignment, correction or prevention of neuromuscular or musculoskeletal dysfunction, disease, injury or deformity. The term does not include fabric or elastic support, 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 by a drug store, department store, corset shop or surgical supply facility.

"Prosthesis." 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. The term does not include artificial eyes, ears, fingers or toes, dental appliances, cosmetic devices, such as artificial breasts, eyelashes or wigs, or other devices that do not have a significant impact on the musculoskeletal functions of the body.

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

"Prosthetist." *An individual, other than a licensed physical therapist or occupational therapist, licensed under this act to practice prosthetics pursuant to a written prescription of a physician, podiatrist, certified registered nurse practitioner or physician assistant.*

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Section 2. The act is amended by adding a section to read:

Section 13.5. Prosthetists, orthotists, pedorthists and orthotic fitters.

(a) Licensure qualifications.—*To qualify for licensure to practice prosthetics, orthotics, pedorthics or orthotic fitting, an applicant shall:*

(1) Be of good moral character.

(2) Possess the following education:

(i) For prosthetists, at least four years of education, training and/or work experience, consisting of:

(A) a bachelor's degree with a major in prosthetics or orthotics and prosthetics; and

(B) a minimum of two years (3,800 hours) of experience in providing direct patient care services.

(ii) For orthotists, at least four years of education, training and/or work experience, consisting of:

(A) a bachelor's degree with a major in orthotics or orthotics and prosthetics; and

(B) a minimum of two years (3,800 hours) of experience in providing direct patient care services.

(iii) For pedorthists, a successfully completed board-approved, entry-level pedorthic education program and a minimum of 1,000 hours of supervised patient fitting experience.

(iv) For orthotic fitters, a successfully completed board-approved, entry-level education program specific to orthotic fitting and a minimum of 1,000 hours of documented patient care.

(3) Have fulfilled all educational and training required for certification and received certification by a prosthetic, orthotic, pedorthic and orthotic fitting credentialing organization recognized by ICE, accredited by NCCA and approved by the board.

(4) Pass all examinations that are required for certification by a prosthetic, orthotic, pedorthic or orthotic fitting credentialing organization recognized by ICE, accredited by NCCA and approved by the board.

(5) Submit a board-approved application and any fees as prescribed by the board by regulation.

(6) Keep and make available all patient logs for audit purposes of the experience requirement.

(7) Not be addicted to alcohol, narcotics or other habit-forming drugs.

(8) Not been convicted of a felony under the act of April 14, 1972 (P.L.233, No.64), known as The Controlled Substance, Drug, Device and Cosmetic Act, or of an offense under the laws of another jurisdiction which, if committed in this Commonwealth, would be a

felony under The Controlled Substance, Drug, Device and Cosmetic Act, unless the following apply:

(i) Ten years have elapsed from the date of conviction.

(ii) The applicant satisfactorily demonstrates to the board that the applicant has made significant progress in personal rehabilitation since the conviction and the licensure of the applicant is not expected to create a substantial risk of harm to the health and safety of the applicant's clients or the public or a substantial risk of further criminal violations.

(iii) The applicant otherwise satisfies the qualifications required under this act.

(b) Term of license.—A license issued pursuant to this section shall be valid for two years and may be renewed biennially with the board as provided in subsection (g).

(c) Prosthetic, orthotic, pedorthic and orthotic fitting treatment requirements.—Prior to administering the first prosthetic, orthotic, pedorthic or orthotic fitting, a prosthetist, orthotist, pedorthist or orthotics fitter shall do all of the following:

(1) Ensure the patient has secured a prescription along with clinical notes for treatment by the prescribing authority using prosthetics, orthotics, pedorthics or orthotic fitting from a physician, podiatrist, certified registered nurse practitioner or physician assistant. A prescription under this paragraph shall place conditions and restrictions by the prescribing authority on the course of treatment if required as a matter of sound medical practice.

(2) Ensure the patient has undergone a medical diagnostic examination or has had the results of a recently performed medical diagnostic examination reviewed by a physician, podiatrist, certified registered nurse practitioner or physician assistant.

(3) Retain a copy of the prescription and the results of the medical diagnostic examination in the patient's file.

(d) Exceptions.—

(1) Nothing in this section shall prohibit students enrolled in a prosthetics, orthotics, pedorthics or orthotics fitter educational program from performing prosthetics, orthotics, pedorthics or orthotic fitting in the course of their instruction, provided that a physician or podiatrist is readily available for consultations and that a prosthetist, orthotist, pedorthist or orthotic fitter, respectively, is on site and responsible for the direct supervision of students.

(2) Nothing in this section shall prohibit an individual from engaging in the practice for which that individual is licensed or certified to practice or to act within the scope of that license or certification held in this Commonwealth.

(3) Nothing in this act shall prohibit an individual who is employed by the Federal Government from engaging in the practice of a prosthetist, orthotist, pedorthist or orthotic fitter while in the discharge of the employee's official duties.

(4) Nothing in this section shall prohibit the sale of over-the-counter prostheses, orthoses or pedorthic devices.

(5) *Nothing in this section shall prohibit a representative of a medical device manufacturer registered with the United States Food and Drug Administration from measuring, fitting and adjusting a medical device when the representative pursuant to a written agreement is supervised by the physician performing the procedure.*

(e) *License requirement effective.—Commencing two years after the effective date of this section, individuals shall not practice or hold themselves out as being able to practice prosthetics, orthotics, pedorthics or orthotic fitting in this Commonwealth unless the individuals are licensed in accordance with this section.*

(f) *License without examination.—*

(1) *Within two years after the effective date of this section, an individual may be granted a prosthetic, orthotic, pedorthotic or orthotic fitting license by the board if the individual does all of the following:*

(i) *Complies with subsection (a)(1), (5), (6) and (7).*

(ii) *Meets the following:*

(A) *For prosthetists, a combination of at least four years of education, training and/or work experience, consisting of:*

(I) *a bachelor's degree with a major in prosthetics or orthotics and prosthetics;*

(II) *an associate's degree in prosthetics or orthotics and prosthetics or two or more years of education, training and/or work experience in the field of prosthetics; and*

(III) *a minimum of two years or 3,800 hours of experience in providing direct patient care services.*

(B) *For orthotists, a combination of at least four years of education, training and/or work experience, consisting of:*

(I) *a bachelor's degree with a major in orthotics or orthotics and prosthetics;*

(II) *an associate's degree in orthotics or orthotics and prosthetics or two or more years of education, training and/or work experience in the field of orthotics; and*

(III) *a minimum of two years or 3,800 hours of experience in providing direct patient care services.*

(C) *For pedorthists, a successfully completed board-approved, entry-level pedorthic education program and a minimum of 1,000 hours of supervised patient fitting experience.*

(D) *For orthotic fitters, a successfully completed board-approved, entry-level education program specific to orthotic fitting and a minimum of 1,000 hours of documented patient care.*

(iii) *Complies with the following:*

(A) *holds a valid national certification from an organization approved by the board as a prosthetist, orthotist, pedorthist or orthotic fitter; and*

(B) *has been in active, continuous practice for the three years immediately preceding the effective date of this section.*

(2) This subsection shall expire 730 days from the effective date of this subsection.

(g) Biennial license renewal.—For biennial renewal of a license:

(1) A prosthetist and orthotist must provide certification of successful completion of a minimum of 24 hours of continuing education as approved by the board.

(2) An orthotic fitter and a pedorthist must provide certification of successful completion of a minimum of 13 hours of continuing education as approved by the board.

(3) Certification of continuing education credit hours submitted by the prosthetist, orthotist, pedorthist or orthotic fitter shall be verified as being correct and true by the applicant.

(4) A licensee must file a completed board-approved renewal application.

(5) A licensee must pay any fees established by regulation by the board.

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

(7) The board may waive all or part of the continuing education requirements to a licensee who shows to the satisfaction of the board that the licensee was unable to complete the requirement due to illness, emergency or hardship.

(h) Orthotic fitter scope of practice.—The scope of practice of an orthotic fitter is limited to measuring, fitting, dispensing and adjusting prefabricated devices not requiring more than minor modification of:

(1) Cervical soft foam collars.

(2) Thoraco-lumbo-sacral orthoses.

(3) Lumbo-sacral orthoses.

(4) Knee orthoses.

(5) Ankle foot orthoses.

(6) Foot orthoses.

(7) Elbow orthoses.

(8) Shoulder orthoses.

(9) Abdominal and pelvic:

(i) Trusses.

(ii) Flexible supports.

(iii) Maternity supports.

(10) Compression devices:

(i) Lymphedema garments.

(ii) Compression garments.

(iii) Burn garments.

(11) Breast prosthesis and ancillary supplies.

(i) Liability insurance coverage.—An individual licensed to practice prosthetics, orthotics, pedorthics or orthotic fitting in this Commonwealth shall maintain a level of professional liability insurance coverage in the minimum amount of \$1,000,000 per occurrence or claims made and shall verify to the board the required coverage. Failure to maintain insurance coverage as required shall subject the licensee to disciplinary proceedings. The licensee must provide proof of coverage to the board upon request.

The board shall accept from a licensee as satisfactory evidence of insurance coverage any of the following:

(1) Personally purchased liability insurance.

(2) Professional liability insurance coverage provided by the individual licensee's employer or similar insurance coverage acceptable to the board.

(j) Practice by unregistered persons.—Any person who is not licensed as a prosthetist, orthotist, pedorthist or orthotic fitter shall not practice prosthetics, orthotics, pedorthics or orthotic fitting nor in any written or printed circular or in any business card, letterhead or sign or otherwise assume the title "Prosthetist," "Orthotist," "Pedorthist" or "Orthotic Fitter" nor any other title, abbreviation, name or description implying or calculated to lead to the belief that he is qualified to practice prosthetics, orthotics, pedorthics or orthotic fitting.

Section 3. The board shall promulgate regulations to implement the amendment or addition of sections 2 and 13.5 of the act within 18 months of the effective date of this section. The amendment or addition of sections 2 and 13.5 of the act shall not be enforceable by the State Board of Medicine until the publication of final regulations under this section or 24 months following the effective date of this section, whichever occurs first.

Section 4. This act shall take effect immediately.

APPROVED—The 5th day of July, A.D. 2012

TOM CORBETT